Übersetzung durch den Sprachendienst des Bundesministeriums für Gesundheit.
Translation provided by the Language Service of the Federal Ministry of Health.
Stand: Die Übersetzung berücksichtigt die Änderung(en) des Gesetzes durch Artikel 1 des Gesetzes vom 19. Juli 2023 (BGBl. 2023 I Nr. 197)
Version information: The translation includes the amendment(s) to the Act by Article 1 of the Act of 19 July 2023 (Federal Law Gazette 2023 I no. 197)

Medicinal Products Act

(Arzneimittelgesetz – AMG)

Medicinal Products Act in the version published on 12 December 2005 (Federal Law Gazette [BGBl.]) Part I p. 3394, last amended by Article 1 of the Act of 19 July 2023 (Federal Law Gazette 2023 I no. 197)

This version incorporates:

1. the version of the Act promulgated on 12 December 2005 (Federal Law Gazette I p. 3394),
2. Article 12 of the Act of 14 August 2006, which entered into force on 18 August 2006 (Federal Law Gazette I, p. 1869),
3. Article 5 of the Act of 21 December 2006, which entered into force on 28 December 2006 (Federal Law Gazette I p. 3294),
4. Article 2 of the Law of 21 December 2006, which entered into force on 29 December 2006 (Federal Law Gazette I p. 3367),
5. Article 30 of the Act of 26 March 2007, which partially entered into force on 1 April 2007 and partially on 1 January 2009 (Federal Law Gazette I p. 378),
6. Article 2 of the Act of 14 June 2007, which entered into force on 30 June 2007 (Federal Law Gazette I p. 1066),
7. Article 2 of the Act of 20 July 2007, which entered into force on 1 August 2007 (Federal Law Gazette I p. 1574),
8. Article 2 of the Act of 24 October 2007, which entered into force on 1 November 2007 (Federal Law Gazette I p. 2510),
9. Article 9 (1) of the Law of 23 November 2007, which entered into force on 1 January 2008 (Federal Law Gazette I p. 2614),
10. Article 2 of the Act of 15 July 2009, which entered into force on 21 July 2009 (Federal Law Gazette I p. 1801),

11. Article 1 of the Act of 17 July 2009, which entered into force on 23 July 2009 (Federal Law Gazette I, p. 1990, p. 3578),

12. Article 1 of the Ordinance of 28 September 2009, which entered into force on 3 October 2009 (Federal Law Gazette I p. 3172),

13. Article 1 of the Ordinance of 29 November 2010, which entered into force on 9 December 2010 (Federal Law Gazette I p. 1752),

14. Article 7 of the Act of 22 December 2010, which entered into force on 1 January 2011 (Federal Law Gazette I p. 2262),

15. Article 1 of the Act of 25 May 2011, which entered into force on 31 May 2011 (Federal Law Gazette I, p. 946),

16. Article 1 of the Ordinance of 19 July 2011, which entered into force on 26 July 2011 (Federal Law Gazette I p. 1398),

17. Article 13 of the Law of 22 December 2011 which entered into force on 29 December 2011 (Federal Law Gazette I p. 2983),

18. Article 1 of the Ordinance of 16 July 2012, which entered into force on 24 July 2012 (Federal Law Gazette I p. 1534),

19. Articles 1 and 2 of the Act of 19 October 2012, which entered into force on 26 October 2012 (Federal Law Gazette I p. 2192),

20. Article 4 of the Act of 21 March 2013, which entered into force on 29 March 2013 (Federal Law Gazette I p. 566),

21. Article 1 of the Ordinance of 25 March 2013, which entered into force on 9 April 2013 (Federal Law Gazette I p. 627),

22. Article 5 (1) of the Act of 20 April 2013, which entered into force on 25 April 2013 (Federal Law Gazette I p. 868),

23. Article 1 of the Ordinance of 24 June 2013, which entered into force on 29 June 2013 (Federal Law Gazette I p. 1687),

24. Article 2 of the Act of 15 July 2013, which entered into force on 1 August 2013 (Federal Law Gazette I p. 2420),

25. Article 1 of the Ordinance of 12 July 2013, which entered into force on 19 July 2013 (Federal Law Gazette I p. 2439),

26. Article 2 of the Act of 23 July 2013, which entered into force on 1 September 2013 (Federal Law Gazette I p. 2565),

27. Article 1 of the Act of 7 August 2013, which entered into force on 13 August 2013 (Federal Law Gazette I, p. 3108),

28. Article 2 (24) and Article 4 (11) of the Act of 7 August 2013 which entered into force on 15 August 2013 (Federal Law Gazette I p. 3154),

29. Article 1 of the Act of 10 October 2013, which entered into force on 1 April 2014 (Federal Law Gazette I, p. 3813),

30. Article 2a of the Act of 27 March 2014, which entered into force on 1 April 2014 (Federal Law Gazette I p. 261),

31. Article 3 of the Act of 17 December 2014, which entered into force on 24 December 2014 (Federal Law Gazette I p. 2222),

32. Article 52 of the Ordinance of 31 August 2015, which entered into force on 8 September 2015 (Federal Law Gazette I p. 1474),

33. Article 1 of the Ordinance of 2 September 2015, which entered into force on 26 September 2015 (Federal Law Gazette I p. 1571),

34. Articles 2 and 3 of the Act of 10 December 2015, which entered into force on 18 December 2015 (Federal Law Gazette I p. 2210),

35. Article 3 of the Act of 4 April 2016, which entered into force on 20 May 2016 (Federal Law Gazette I p. 569),

36. Article 4 (11) of the Act of 18 July 2016, which enters into force on 1 October 2021 (Federal Law Gazette I p. 1666),

37. Article 1 of the Act of 21 November 2016, which entered into force on 26 November 2016 (Federal Law Gazette I, p. 2623),

38. Article 6b of the Act of 19 December 2016, which entered into force on 1 January 2017 (Federal Law Gazette I p. 2986),

39. Article 1, which entered into force on 24 December 2016, as well as Article 2, which entered into force on 27 January 2022 of the Act of 20 December 2016 (Federal Law Gazette I p. 3048),

40. Article 1 of the Ordinance of 10 March 2017, which entered into force on 16 March 2017 (Federal Law Gazette I p. 456),

41. Article 45 of the Act of 29 March 2017, which entered into force on 5 April 2017 (Federal Law Gazette I p. 626),

42. Article 6 (9) of the Act of 13 April 2017, which entered into force on 1 July 2017 (Federal Law Gazette I p. 872),

43. Article 5 of the Act of 4 May 2017, which entered into force on 13 May 2017 (Federal Law Gazette I, p. 1050),

44. Article 2 of the Act of 17 July 2017, which entered into force on 22 July 2017 (Federal Law Gazette I p. 2421),

45. Article 1 of the Act of 18 July 2017, which entered into force on 29 July 2017 (Federal Law Gazette I, p. 2757),

46. Article 1 of the Ordinance of 17 April 2019, which entered into force on 4 May 2019 (Federal Law Gazette I p. 537),

47. Article 11 of the Act of 6 May 2019, which entered into force on 11 May 2019 (Federal Law Gazette I p. 646),

48. Articles 1 and 2 of the Act of 9 August 2019, which entered into force on 16 August 2019 (Federal Law Gazette I p. 1202),

49. Article 18 of the Act of 20 November 2019, which entered into force on 26 November 2019 (Federal Law Gazette I p. 1626),

50. Article 3c of the Act of 10 February 2020, which entered into force on 1 March 2020 (Federal Law Gazette I p. 148),

51. Article 0 of the Act of 22 March 2020, which entered into force on 1 April 2020 (Federal Law Gazette I p. 604),

52. Article 7 of the Act of 28 April 2020, which entered into force on 23 May 2020 and Article 16a (3) of the Act of 28 April 2020, which entered into force on 23 and 26 May 2020 (Federal Law Gazette I p. 960), as well as Article 8 of the Act of 28 April 2020, which entered into force on 26 May 2022 (Federal Law Gazette I p. 960),

53. Article 94 of the Ordinance of 19 June 2020, which entered into force on 27 June 2020 (Federal Law Gazette I p. 1328),

54. Article 2 (1) of the Act of 25 June 2020, which entered into force on 30 June 2020 (Federal Law Gazette I p. 1474),

55. Article 2b of the Act of 18 November 2020, which entered into force on 19 November 2020 (Federal Law Gazette I p. 2397),

56. Article 5 of the Law of 9 December 2020, which entered into force on 15 December 2020 (Federal Law Gazette I p. 2870),

57. Article 7 of the Act of 21 May 2021, which entered into force on 26 May 2021 (Federal Law Gazette I, p. 1087), as well as Article 8 of the Act of 12 May 2021, which entered into force on 26 May 2022 (Federal Law Gazette I p. 1087),

58. Article 1 of the Ordinance of 19 May 2021, which entered into force on 28 May 2021 (Federal Law Gazette I p. 1164),

59. Article 9 of the Act of 3 June 2021, which entered into force on 9 June 2021 (Federal Law Gazette I p. 1309),

60. Article 10 (4) of the Act of 27 July 2021, which entered into force on 10 August 2021 (Federal Law Gazette I p. 3274),

61. Article 10 of the Act of 10 August 2021, which entered into force on 1 January 2024 (Federal Law Gazette I p. 3436),

62. Article 1 of the Act of 10 August 2021, which entered into force on 1 November 2021 (Federal Law Gazette I, p. 3519),

63. Articles 2 and 3 of the Act of 27 September 2021, which entered into force on 27 and 28 January 2022 respectively (Federal Law Gazette I p. 4530),

64. Article 14 of the Act of 24 June 2022, which entered into force on 1 January 2023 (Federal Law Gazette I p. 959),

65. Article 1a of the Act of 7 November 2022, which entered into force on 12 November 2022 (Federal Law Gazette I p. 1990),

66. Article 2 (2) of the Act of 20 December 2022, which entered into force on 1 January 2023 (Federal Law Gazette I p. 2752),

67. Article 8c of the Act of 20 December 2022, which entered into force on 29 December 2022 (Federal Law Gazette I p. 2793),

68. Article 1 of the Act of 19 July 2023, which entered into force on 27 July 2023 (Federal Law Gazette 2023 I no. 197).

Division 1
Purpose of the Act and definition of terms, scope

Section 1
Purpose of the Act

It is the purpose of this Act to guarantee safety in respect of the trade in medicinal products, ensuring in particular the quality, efficacy and safety of medicinal products in accordance with the following provisions, in the interest of furnishing the population with a proper supply of medicinal products.

Section 2
The term ‘medicinal product’

(1) Medicinal products within the meaning of this Act are medicinal products that are intended for administration to human beings. These comprise substances or preparations made from substances that:

1. are intended for use in or on the human body and are intended for use as remedies with properties for the curing, alleviating or preventing of human diseases or disease symptoms, or

2. can be used in or on the human body or can be administered to a human being, either:

   a) to restore, correct or influence the physiological functions through a pharmacological, immunological or metabolic effect, or

   b) to make a medical diagnosis.

(2) Medicinal products comprise objects that contain a medicinal product pursuant to subsection (1) or to the surface of which a medicinal product specified in subsection (1) is applied and that are intended to come into either temporary or permanent contact with the human body.
(3) Medicinal products within the meaning of this Act are not:

1. veterinary medicinal products within the meaning of Article 4 no. 1 of Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43; L 163, 20.6.2019, p. 112; L 326, 8.10.2020, p. 15; L 241, 8.7.2021, p. 17) in the latest applicable version, as well as veterinary medicinal products pursuant to section 3 of the Veterinary Medicinal Products Act (*Tierarzneimittelgesetz*),

2. foods within the meaning of Article 2 of Regulation (EC) No. 178/2002 of the European Parliament and the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ. L 31 of 1.2.2002, p. 1), last amended by Regulation (EU) 2019/1381 (OJ L 231 of 6.9.2019, p. 1),

3. cosmetic products within the meaning of Article 2 (1) point (a) also in conjunction with paragraph 2 of Regulation (EC) No. 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products (OJ L 342 of 22.12.2009, p. 59,L 318 of 15.11.2012, p. 74; L 72 of 15.3.2013, p. 16; L 142 of 29.5.2013, p.10; L 254 of 28.8.2014, p. 39; L 17 of 21.1.2017, p. 52; L 326 of 9.12.2017, p. 55; L 183 of 19.7.2018, p.27; L 324 of 13.12.2019, p.80; L 76 of 12.3.2020, p. 36), last amended by Regulation (EU) 2019/1966 (OJ L 307 of 28.11.2019, p. 15),

4. products as defined in section 2 (1) of the Tobacco Products Act (*Tabakerzeugnisgesetz*),

5. biocidal products according to Article 3 (1) point (a) of Regulation (EU) No. 528/2012 of 22 May 2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1;

OJ L 303, 20.11.2015, p. 109; L 305, 21.11.2015, p. 55; L 280 of 28.10.2017, p .57), last amended by Commission Delegated Regulation (EU) 2021/407 (OJ L 81 of 9.3.2021, p. 15),

6. (repealed)

7. medical devices and accessories for medical devices within the meaning of Article 2 nos. 1 and 2 of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p.1, L 117 of 3.5.2019, p. 9; L 334 of 27.12.2019, p. 165), amended by Regulation (EU) 2020/561 (OJ L 130 of 24.4.2020, p. 18), in the version in force in each case and within the meaning of Article 2 nos. 2 and 4 of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in-vitro diagnostics and repealing Council Directive 98/79/EG and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p.176; OJ L 117, 3.5.2019, p. 11, L 334 of 27.12. 2019, p. 167) in the latest applicable version, unless they are medicinal products within the meaning of subsection (1) no. 2 letter b,

8. organs within the meaning of section 1a no. 1 of the Transplantation Act (*Transplantationsgesetz*) if they are intended for transplanting to human beings.

(3a) Medicinal products are also products that are, or contain, substances or preparations made from substances that, when all of the product's properties are taken into account, fall under the definition contained in subsection (1) and, at the same time, can fall under the definition of a 'product' pursuant to subsection (3).
(4) As long as a product is authorised or registered as a medicinal product pursuant to this Act, or is exempted from the need for authorisation or registration by ordinance, such product is considered to be a medicinal product. A product is not considered a medicinal product if its authorisation or registration has been rejected by the competent higher federal authority on the grounds that it is not a medicinal product.

Section 3
The term 'substance'

For the purpose of this Act, substances are:

1. chemical elements and chemical compounds as well as their naturally occurring mixtures and solutions,

2. plants, parts of plants and plant constituents, algae, fungi and lichen, whether in their processed or crude state,

3. the bodies of animals, including those of living animals, as well as body parts, body constituents and metabolic products of human beings or animals, whether in their processed or crude state,

4. micro-organisms, including viruses, as well as their constituents or metabolic products.

Section 4
Definition of additional terms

(1) Finished medicinal products are medicinal products that are manufactured beforehand and placed on the market in packaging intended for distribution to the consumer, or other medicinal products intended for distribution to the consumer in the preparation of which any form of industrial process is used, or medicinal products that are produced commercially, except in pharmacies. Finished medicinal products are not intermediate products intended for further processing by a manufacturer.

(2) Blood preparations are medicinal products that are or contain, as active substances, stored blood, plasma or serum obtained from blood, blood components or preparations made from blood components.
(3) Sera are medicinal products within the meaning of section 2 (1) that contain antibodies, fragments of antibodies or fusion proteins with a functional antibody component as their active substance and are used because of this active substance. Sera are not considered blood preparations as defined in subsection (2) or as tissue preparations as defined in subsection (30).
(4) Vaccines are medicinal products within the meaning of section 2 (1) that contain antigens or recombinant nucleic acids and are intended for human use to produce specific antitoxins and protective agents and, insofar as they contain recombinant nucleic acids, are intended exclusively to prevent or treat infectious diseases.
(5) Allergens are medicinal products within the meaning of section 2 (1) that contain antigens or haptens and are intended for human use to diagnose specific antitoxins or protective agents (test allergens), or contain substances that are used to achieve an antigen-specific reduction of a specific immunological over-sensitivity (therapeutic allergens).
(6) (repealed)
(7) (repealed)
(8) Radiopharmaceuticals are medicinal products that are or contain radioactive substances and spontaneously emit ionising radiation and are intended to be used on account of these properties; radionuclides (precursors) that are manufactured for the radio labelling of other substances prior to administration, as well as systems incorporating a fixed mother radionuclide that produces a daughter radionuclide (generator) intended for use in the manufacture of radiopharmaceuticals, are also regarded as radiopharmaceuticals.
(9) Advanced therapy medicinal products are gene therapy medicinal products, somatic cell therapy medicinal products or tissue engineered products pursuant to Article 2, paragraph 1, point (a) of Regulation (EC) No. 1394/2007 of the European Parliament and the Council of 13th November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No. 726/2004 (OJ L 324 of 10.12.2007, p. 121); L 87 of 31.3.2009, p. 174), last amended by Regulation (EU) 2019/1243 (OJ L 198 of 25.07.2019, p. 241).
(10) (repealed)
(11) (repealed)
(12) (repealed)
(13) Adverse reactions are noxious and unintended reactions to the medicinal product. Serious adverse reactions are adverse reactions that are fatal or life-threatening, require hospitalisation or the prolongation of existing hospitalisation, or lead to persistent or significant disability, incapacity, congenital anomalies or birth defects. Unexpected adverse reactions are adverse reactions the type, severity or consequences of which differ from the medicinal product’s expert information.
(14) Manufacturing is the producing, preparing, formulating, treating or processing, filling as well as decanting, packaging, labelling and release of medicinal products; manufacturing is not the mixing of finished medicinal products with feeding stuffs by the animal keeper for immediate feeding to the animals kept by him/her.
(15) Quality is the nature of a medicinal product, determined by identity, content, purity and other chemical, physical and biological properties or by the manufacturing procedure.
(16) A batch is the quantity of a medicinal product produced from the same amount of starting material in a standard manufacturing process or, in the case of a continuous manufacturing procedure, within a specific period of time.
(17) Placing on the market is the keeping in stock for sale or for other forms of supply, the exhibiting and offering for sale and the distribution to others.
(18) In the case of medicinal products requiring a marketing authorisation or registration, the pharmaceutical entrepreneur is the holder of the marketing authorisation or registration. The pharmaceutical entrepreneur is also any person who places medicinal products by parallel

distribution or otherwise on the market under his/her own name, with the exception of the cases provided for in section 9 (1), sentence 2.
(19) Active substances are substances that are intended for use as medically active constituents in the manufacture of medicinal products or which, through their use in the manufacture of medicinal products, are intended to become medically active constituents.
(20) An excipient is any component of a medicinal product, with the exception of the active substance and the packaging material.
(21) Xenogenic medicinal products are medicinal products that are or contain living animal tissues or cells and are intended for use in or on humans.
(22) Wholesaling of medicinal products is any professional or commercial activity for trading purposes that consists of procuring, storing, selling or exporting medicinal products, with the exception of the sale of medicinal products to customers other than doctors, dentists, veterinarians or hospitals.
(22a) Brokering of medicinal products is any professional or commercial activity by persons who, without conducting wholesale distribution, independently and on behalf of another, trade in medicinal products without obtaining actual power of disposal over the medicinal products.
(23) A clinical trial is a trial within the meaning of Article 2 (2) (2) of Regulation (EU) No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158 of 27.5.2014, p. 1, L 311 of 17.11.2016, p. 25). A non-interventional study within the meaning of Article 2 (2) (4) of Regulation (EU) No. 536/2014 is not a clinical trial.
(24) A sponsor is a person, undertaking, institution or organisation within the meaning of Article 2 (2) (14) of Regulation (EU) No. 536/2014.
(25) An investigator is a person within the meaning of Article 2 (2) (15) of Regulation (EU) No. 536/2014. A principal investigator is a person within the meaning of Article 2 (2) (16) of Regulation (EU) No. 536/2014.
(26) A homeopathic medicinal product is any medicinal product prepared in accordance with a homeopathic manufacturing procedure described in the European Pharmacopoeia or, in absence thereof, in the pharmacopoeias currently used officially in the EU Member States. A homeopathic medicinal product can also contain several active substances.
(27) A risk linked to the use of a medicinal product is:

a) any risk to patient or public health linked to the quality, safety or efficacy of the medicinal product,

b) any risk of adverse effects on the environment.

(29) Herbal medicinal products are medicinal products that exclusively contain, as active substances, either one or more herbal substances, one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.
(30) Tissue preparations are medicinal products that are tissues within the meaning of section 1a no. 4 of the Transplantation Act or are manufactured from such tissues. Human sperm and egg cells (germ cells), as well as impregnated egg cells and embryos are neither medicinal products nor tissue preparations.
(30a) The ‘Single European Code’ or ‘SEC’ is the unique identifier for all tissues and tissue preparations that are distributed within the European Union, as specified in Annex VII of Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L 294 of 25.10.2006, p. 32), last amended by (EU) Directive 2015/565 (OJ L 93 of 9.4.2015, p. 43).
(30b) The EU tissue establishment code is the unique identifier for tissue establishments in the European Union. Within the purview of this Act, it applies to all facilities that conduct

activities that require a permit, involving tissues, tissue preparations, haematopoietic stem cells, or stem cell preparations derived from peripheral blood or from umbilical cord blood. Pursuant to Annex VII of Directive 2006/86/EC, the EU tissue establishment code consists of an ISO country code and the tissue establishment number set out in the EU Tissue Establishment Compendium.
(30c) The EU Compendium of Tissue Establishments is the register of all tissue establishments that are approved, licensed, designated or authorised by the Member States' competent authorities and which contains the information on these tissue establishments pursuant to Annex VIII of Directive 2006/86/EC in the latest applicable version. Within the purview of this Act, the register applies to all facilities that conduct activities requiring a permit involving tissues, tissue preparations or haematopoietic stem cells, or stem cell preparations derived from peripheral blood or from umbilical cord blood.
(30d) The EU Tissue and Cell Product Compendium is the register of all the types of tissue, tissue preparations or haematopoietic stem cells, or stem cell preparations derived from peripheral blood or umbilical cord blood, circulating in the European Union, with the corresponding product code.
(31) Reconstitution of a finished medicinal product is the conversion of the medicinal product into its usable form immediately prior to its use according to the specifications contained in the package leaflet or, within the framework of the clinical trial, in accordance with the trial protocol.
(32) Introduction is any type of shipment into, through or from the purview of this Act. Import is the conveyance of products that fall under the Medicinal Products Act from third countries that are not States Party to the Agreement on the European Economic Area for free circulation. Products pursuant to sentence 2 are considered to be imported if they have been brought into the economic system in contravention of customs regulations. Export is any introduction into third countries that are not States Party to the Agreement on the European Economic Area.
(33) An anthroposophic medicinal product is a medicinal product that has been developed according to the anthroposophic understanding of human beings and nature, according to a European Pharmacopoeia or, in the absence thereof, in accordance with a homeopathic manufacturing practice described in the pharmacopoeias currently used officially in the EU Member States, or according to a special anthroposophic manufacturing procedure, and which is intended for use according to the principles of the anthroposophic understanding of human beings and nature.
(34) A post-authorisation safety study is any study of an authorised medicinal product that is conducted to identify, characterise or quantify a safety risk, to confirm a medicinal product's safety profile or to measure the effectiveness of risk management measures.
(35) (repealed)
(36) The risk management system comprises activities in the field of pharmacovigilance and measures that are intended to identify, characterise, avoid or minimise risks associated with a medicinal product; this includes the assessment of the effectiveness of such activities and measures.
(37) The risk management plan is a detailed description of the risk management system.
(38) The pharmacovigilance system is a system used by the marketing authorisation holder and the competent higher federal authority to fulfil especially the tasks and obligations listed in Division 10 and which serves the purpose of post-marketing surveillance and the detection of any changes in the risk-benefit profile.
(39) The pharmacovigilance master file is a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products.
(40) A falsified medicinal product is any medicinal product with a false representation of:

1. its identity, including its packaging and labelling, its name or its composition as regards one or several of its constituents including excipients and the strength of those ingredients;

2. its source, including its manufacturer, its country of manufacture, its country of origin or its marketing authorisation holder; or

3. distribution channels described in the related records and documents.

(41) A falsified active substance is an active substance for which the labelling on the container does not correspond to the actual content or the accompanying documents fail to reflect all of the manufacturers involved or the real channels of distribution.
(42) The EU portal is the portal for the submission of data and information relating to clinical trials that is set up and maintained at EU level in accordance with Article 80 of Regulation (EU) No. 536/2014.

Section 4a
Exceptions to the scope of this Act

This Act does not apply to tissues that are removed from a person in order to reinsert them without changing their material structure into the same person in one and the same treatment procedure.

Section 4b
Special provisions governing advanced therapy medicinal products

(1) In the case of advanced therapy medicinal products that are:

1. prescribed by a doctor as an individual preparation for an individual patient,

2. prepared on a non-routine basis according to specific quality standards, and

3. used in a specialised facility for health care under the professional responsibility of a doctor,

within the purview of this Act, Division 4 with the exception of section 33 and Division 7 of this Act do not apply. The remaining provisions of the Act, as well as Article 14 (1) and Article 15 (1) to (6) of Regulation (EC) No. 1394/2007, apply accordingly with the proviso that the official tasks and powers laid down therein are assumed by the competent authority or the competent higher federal authority in keeping with the tasks entrusted to them by this Act and the holder of the authorisation pursuant to subsection (3) sentence 1 takes the place of the marketing authorisation holder pursuant to this Act or the marketing authorisation holder pursuant to Regulation (EC) No. 1394/2007.
(2) Prepared on a non-routine basis pursuant to subsection (1) sentence 1 no. 2 are, in particular, medicinal products:

1. that are manufactured and used in such small quantities that it is not to be expected that sufficient clinical experience can be collected for a comprehensive evaluation of the medicinal product, or

2. that have not yet been manufactured and used in sufficient quantities so that it has not yet been possible to obtain the necessary data to enable a comprehensive assessment.

(3) Medicinal products pursuant to subsection (1) sentence 1 may only be supplied to others if they have been approved by the competent higher federal authority. Section 21a (2) sentence 1, subsections (3) to (6) and (8) apply accordingly. In addition to the information and documents pursuant to section 21a (2) sentence 1, the application for approval are to be accompanied by the following information and documents:

1. information on the specialised healthcare facility in which the medicinal product is to be used,

2. the number of planned administrations or patients per year,

3. information on dosage,

4. information on the risk management plan containing a description of the risk management system, which the applicant will introduce for the medicinal product in question, together with a summary of the risk management plan and the risk management system, and

5. in the case of advanced therapy medicinal products consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, also the technical documents pursuant to Annexes III A, III B and IV of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106 of 17.4.2001, p. 1), last amended by Regulation (EU) 2019/1381 (OJ L 231 of 6.9.2019, p. 1), as well as information obtained from an environmental impact assessment conducted according to Annex II of Directive 2001/18/EC, pursuant to Annex II point (D) of Directive 2001/18/EC.

Section 22 (2) sentence 1 no. 5, subsections (4) and (7) sentence 1 apply accordingly.
(4) In the case of advanced therapy medicinal products consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, the competent higher federal authority decides on the application for approval in consultation with the Federal Agency for Consumer Protection and Food Safety. The approval by the competent higher federal authority for the dispensing of medicinal products to other persons pursuant to sentence 1 also includes the authorisation for placing on the market the genetically modified organisms from which the medicinal product pursuant to sentence 1 is manufactured or that contain it. Approval may only be granted if:

1. an environmental impact assessment was conducted according to the basic principles contained in Annex II of Directive 2001/18/EC and based on the information according to Annexes III and IV of Directive 2001/18/EC, and

2. according to the latest standards prevailing in science, unjustifiable harmful effects on the health of third parties and the environment are not to be expected.

(5) If the necessary information and documents pursuant to section 21a (2) sentence 1 no. 8 cannot be submitted, the applicant can submit information and documents regarding the mode of action, the anticipated effect and possible risks.
(6) Approval can be issued for a limited period of time.
(7) The holder of the approval must inform the competent higher federal authority, at specific intervals stipulated by the latter by means of an ordinance, about the scale of manufacture and about the data for the comprehensive assessment of the medicinal product. The approval is to be withdrawn if it subsequently becomes known that one of the prerequisites pursuant to subsection (1) sentence 1 had not existed. The approval is to be revoked if one of the prerequisites pursuant to subsection (1) sentence 1 no longer exists.
(8) The applicant must notify the competent higher federal authority forthwith, enclosing the corresponding documents, in the event of any changes in the information or documents that were enclosed with the application for approval. Subsequent to the approval, sentence 1 applies accordingly to the holder of the approval. The latter is required to inform the competent higher federal authority of new or changed risks or of changes in the medicinal product’s risk-benefit balance. In the case of advanced therapy medicinal products consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, the applicant must notify the competent higher federal authority forthwith, enclosing the corresponding documents, if he/she becomes aware of new information on risks to the health of non-affected persons or the environment.

Following approval, sentence 4 applies accordingly to the holder of the approval. Section 29 (1a), (1d) and (2) apply accordingly.
(9) The following changes may be made only if the competent higher federal authority has granted its approval:

1. a change in the information on the dosage, the type or the duration of the administration, or on the therapeutic indications if it does not concern an addition or modification of an indication that is to be classified under another area of therapy,

2. a limitation of the contra-indications, adverse reactions or interactions with other medicinal products or other substances,

3. a change in either the type or quantity of the excipients, or in the quantity of active substances,

4. a change in the pharmaceutical form into a pharmaceutical form that is compatible with the approved pharmaceutical form,

5. a change in the manufacturing or test procedures, including the information pursuant to section 21a (2) sentence 1 no. 5,

6. a change in the conditions for storage and the shelf life, or

7. in the case of advanced therapy medicinal products consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, a change that is capable of modifying the risk assessment for the health of non-affected persons or the environment.

The decision on the application for approval must be taken within three months. Subsection (4) and section 27 (2) apply accordingly.
(10) By way of derogation from subsection (9), a new approval pursuant to subsection (3) is to be applied for in the following cases:

1. where the therapeutic indications are broadened, insofar as a change pursuant to subsection (9) sentence 1 no. 1 is not concerned,

2. where there is a change in the composition of the active substances in terms of the type,

3. where there is a change in the pharmaceutical form, insofar as a change pursuant to subsection (9) sentence 1 no. 4 is not concerned,

The competent higher federal authority decides on the obligation to obtain an approval pursuant to sentence 1.
(11) Enquiries about the obligation to obtain an approval for an advanced therapy medicinal product are decided by the competent authority in consultation with the competent higher federal authority. Section 21 (4) applies accordingly.

Division 2
Requirements on medicinal products

Section 5
Prohibition of unsafe medicinal products

(1) The placing on the market or the use of unsafe medicinal products on another human being is prohibited.
(2) Medicinal products are considered unsafe if, according to the current level of scientific knowledge, there is sufficient reason to suspect that, when used in accordance with their intended purpose, they have harmful effects that exceed the limits considered tolerable in the light of current medical knowledge.

Section 6
Prohibitions to protect health, power to issue ordinances

(1) It is prohibited to manufacture, place on the market, or administer medicinal products if in manufacturing the medicinal product a provision provided for in an ordinance pursuant to subsection (2) on the use of substances, preparations from substances or objects contained in the Annex is contravened.
(2) The Federal Ministry of Health (the Federal Ministry) is hereby empowered to stipulate, restrict or prohibit, by ordinance subject to the approval of the Bundesrat, the use of the substances, preparations from substances or objects named in the Annex in the manufacture of medicinal products insofar as this is deemed necessary to ward off risks to human health (risk prevention) or to prevent medicinal products from posing a direct or indirect hazard to human health.
(3) The Federal Ministry is hereby empowered to issue ordinances, subject to the approval of the Bundesrat, adding additional substances, preparations from substances or objects to the Annex, insofar as this is deemed necessary in the interest of risk prevention or in order to prevent medicinal products from posing a direct or indirect hazard to human health. By ordinance pursuant to sentence 1, substances, preparations from substances or objects are to be removed from Annex 1 if the prerequisites contained in sentence 1 are no longer met.
(4) The ordinances pursuant to subsections (2) and (3) are issued in agreement with the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used.

Section 6a
(repealed)

Section 7
Radiopharmaceuticals and medicinal products treated with ionising radiation

(1) The placing on the market of radiopharmaceuticals or medicinal products in the manufacture of which ionising radiation has been used is forbidden, unless the authorisation to do so has been granted by ordinance according to subsection (2).
(2) The Federal Ministry is hereby empowered to authorise, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, by means of an ordinance subject to the approval of the Bundesrat, the placing of radiopharmaceuticals on the market or the use of ionising radiation in the manufacture of medicinal products insofar as this is deemed, according to the current level of scientific knowledge, to be justified for medical purposes and insofar as it does not compromise human health. The ordinance may prescribe the channel of distribution for the medicinal products and specify that certain data concerning their radioactivity are to appear on the container, the outer packaging and the package leaflet.

Section 8
Prohibitions to prevent deception

(1) It is prohibited to manufacture or place on the market medicinal products or active substances, which:

1. by deviating from recognised pharmaceutical rules, are of considerably reduced quality, or

1a. (repealed)

2. bear a misleading name, information or presentation. Deception exists, in particular, in cases where:

a) claims are made to the effect that certain medicinal products have a therapeutic efficacy or effects that they do not possess or that active substances exhibit an activity that they do not,

b) the erroneous impression is given that success can be expected with certainty or that no harmful effects occur when the medicinal product is used in accordance with its intended purpose or over an extended period of time;

c) names, specifications or presentations, which have an influence on the assessment of the medicinal product or active substance, are employed to mislead others with regard to its quality.

(2) It is prohibited to manufacture, place on the market or otherwise trade in falsified medicinal products or falsified active substances.
(3) It is prohibited to manufacture or place medicinal products on the market past the expiry date.

Section 9
The party responsible for placing on the market

(1) Medicinal products that are placed on the market within the purview of this Act must carry the name or the company and the address of the pharmaceutical entrepreneur. This does not apply to medicinal products that are intended for clinical trials.
(2) Within the purview of this Act, medicinal products may only be placed on the market by a pharmaceutical entrepreneur whose registered place of business is situated within the purview of this Act, in another Member State of the European Union or another State Party to the Agreement on the European Economic Area. If the pharmaceutical entrepreneur appoints a local representative, this does not release him/her from his/her legal responsibility.

Section 10
Labelling

(1) Finished medicinal products that are not intended for clinical trials and are not exempted from the obligation to obtain a marketing authorisation pursuant to section 21 (2) no. 1a, 1b or 3 may only be placed on the market within the purview of this Act provided that the following information is displayed on the containers and, where used, on the outer packaging in easily legible and indelible characters, in readily comprehensible German and pursuant to the details referred to in section 11a:

1. the name or the company and the address of the pharmaceutical entrepreneur and, if available, the name of the local representative appointed by him,

2. the name of the medicinal product, followed by details of the strength and pharmaceutical form and, if applicable, the indication that it is intended for administration to babies, children or adults unless this information is already included in the name; if the medicinal product contains up to three active substances, the international non-proprietary name (INN) must be stated or, if one does not exist, the common name; this does not apply if the name contains the name of the active substance pursuant to no. 8,

3. the marketing authorisation number, with the abbreviation '*Zul.-Nr*',

4. the batch identification, if the medicinal product is placed on the market in batches, with the abbreviation 'Ch.-B.'; if it cannot be placed on the market in batches, the date of manufacture,

5. the pharmaceutical form,

6. the content by weight, nominal volume or number of items,

7. the method of administration,

8. the active substances by type and quantity and other constituents by type insofar as this is imposed as a condition by the competent higher federal authority pursuant to section 28 (2) no. 1 or provided for by an ordinance pursuant to section 12 (1)

no. 4, also in conjunction with subsection (2), or pursuant to section 36 (1); in the case of medicinal products intended for parenteral or topical use, including application to the eye, all constituents by type,

8a. in the case of medicinal products manufactured using genetic engineering, the active substance and the name of the genetically modified organism or the cell line used in manufacture,

9. the expiry date with the indication *'verwendbar bis*' (to be used by) or with the abbreviation '*verw. bis*',

10. in the case of medicinal products that may only be dispensed upon prescription pursuant to section 48, the indication '*Verschreibungspflichtig*' (prescription-only), in the case of other medicinal products that may only be dispensed to customers in pharmacies, the indication '*Apothekenpflichtig*' (pharmacy-only),

11. in the case of samples, the indication *'unverkäufliches Muster*' (sample – not for sale).

12. the indication that medicinal products are to be kept out of the reach of children unless they are curative waters,

13. where necessary, special precautions for the disposal of unused medicinal products or other special precautions to avoid hazards to the environment, and

14. in the case of non-prescription medicinal products, the intended use.

Insofar as the information pursuant to sentence 1 is also provided in another language, the information provided in that language must be identical. Furthermore, space should be provided to state the prescribed dose; this does not apply to the containers and ampoules referred to in subsection (8) sentence 3 and to medicinal products intended exclusively for use by members of the medical profession. Medicinal products that are manufactured using a homeopathic manufacturing procedure and are authorised pursuant to section 25, are to be additionally labelled so as to indicate their homeopathic nature. Additional information that is not stipulated by a regulation of the European Community or the European Union, or is already admissible pursuant to such a regulation, is permitted if it is linked to the use of the medicinal product, is important in providing health information to patients and is not inconsistent with the information referred to in section 11a.

(1a) In derogation of subsection (1) sentence 1, the competent higher federal authority can, in individual cases and at the request of the authorisation holder, permit medicinal products to be placed on the market temporarily with labelling in a language other than German in the event of an impending or existing supply-relevant bottleneck. In such cases, the competent higher federal authority will ensure that the consumer is given appropriate access to the necessary product information.

(1b) The name of the medicinal product is to be placed on the outer packaging in Braille as well. The other information specified in subsection (1) sentence 1 no. 2 on the pharmaceutical form and the group of persons for which the medicinal product is intended does not have to be written in Braille; this also applies if this information is contained in the name of the medicinal product. Sentence 1 does not apply to medicinal products that:

1. are intended exclusively for use by members of the medical profession, or

2. are placed on the market in containers with a nominal volume of not more than 20 millilitres or not more than 20 grams.

(1c) The outer packaging of medicinal products is to bear safety features, as well as a device to indicate possible tampering with the outer packaging of the medicinal product, insofar as this required by Article 54a of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for

Human Use (OJ L 311 of 28.11.2001, p. 67; L 239 of 12.8.2014, p.81), last amended by Regulation (EU) 2019/1243 (OJ L 198 of 25.7.2019, p.241) or stipulated on the basis of Article 54a of Directive 2001/83/EC.
(2) Moreover, warnings, specific storage instructions for the consumer as well as storage instructions for experts are to be given, insofar as this is deemed necessary according to the current level of scientific knowledge or has been imposed as a condition by the competent higher federal authority pursuant to section 28 (2) no. 1 or provided for by ordinance.
(3) In respect of sera, information on the type of living organism from which the sera were obtained and, in respect of virus vaccines, information about the host system that was used for the multiplication of the virus is to be indicated.
(4) In the case of medicinal products included in the Register of Homeopathic Medicinal Products, instead of the information referred to in subsection (1) sentence 1 nos. 1 to 14 and apart from the clearly recognisable indication: *'Homöopathisches Arzneimittel*' (homeopathic medicinal product), the following information is to be included:

1. the type and quantity of the stocks and the degree of dilution; in this regard, symbols from the pharmacopoeias currently used officially should be utilised; the scientific name of the stock can be supplemented by an invented name,

2. the name and address of the pharmaceutical entrepreneur and, if available, of his/her local representative,

3. method of administration,

4. expiry date; subsection (1) sentence 1 no. 9 and subsection (7) apply,

5. pharmaceutical form,

6. the content by weight, nominal volume or number of items,

7. indication that medicinal products should be kept out of the reach of children, other special precautions for storage and warnings, including additional information for safe use if required or if stipulated in subsection (2),

8. batch identification,

9. registration number abbreviated to *'Reg.-Nr*.' and the phrase *'Registriertes homöopathisches Arzneimittel, daher ohne Angabe einer therapeutischen Indikation*' (registered homeopathic medicinal product, therefore no therapeutic indication stated),

10. indication advising the user to seek medical advice if medical symptoms persist during the use of the medicinal product,

11. in the case of medicinal products that may only be dispensed to customers in pharmacies, the indication '*Apothekenpflichtig*' (pharmacy-only),

12. in the case of samples, the indication *'unverkäufliches Muster*' (sample – not for sale).

Sentence 1 applies accordingly to medicinal products exempted from registration pursuant to section 38 (1) sentence 3; subsection (1b) does not apply.
(4a) In the case of traditional herbal medicinal products pursuant to section 39a, the following indication must also be included in addition to the information pursuant to subsection (1):

1. the medicinal product is a traditional medicinal product registered for the therapeutic indication exclusively based on long-standing use, and

2. if medical symptoms persist, or in the event of adverse reactions other than those referred to in the package leaflet, the user should consult a physician or other medically qualified person.

The information in subsection sentence 1 no. 3 is replaced by the registration number abbreviated to '*Reg.-Nr*.'.

(5) (repealed)

(6) The following applies to the designation of the constituents:

1. in designating the type, the World Health Organization's international non-proprietary names or, if such names do not exist, other common scientific names are to be used; the Federal Institute for Drugs and Medical Devices stipulates, in agreement with the Paul Ehrlich Institute, the names to be used and publishes these in a database pursuant to section 67a;

2. in designating the amount, units of measure are to be used; if biological units or other particulars concerning the valency are scientifically common, they are to be used,

(7) The expiry date is to be indicated by month and year.

(8) Blister packaging is to bear the name or firm of the pharmaceutical entrepreneur, the name of the medicinal product, the batch identification and the expiry date. It is not necessary to indicate the name and firm of a parallel importer. In the case of containers with a nominal volume of not more than 10 millilitres and single-dose ampoules, the information specified in subsections (1), (2) to (5) need only be displayed on the outer packaging; the containers and the ampoules must, however, at least bear the information specified in subsection (1) sentence 1 no. 2 first half-sentence, nos. 4, 6, 7, 9 as well as pursuant to subsections (3) and (5) sentence 1 nos. 1, 3, 7, 9, 12 and 14; adequate abbreviations may be used. Sentence 3 also applies to small containers other than those mentioned therein insofar as divergent requirements are placed on small containers in procedures pursuant to section 25b.

(8a) In the case of fresh plasma preparations and preparations of blood cells, at least the information specified in subsection (1) sentence 1 nos. 1 and 2 must be included, without stating the strength, pharmaceutical form and target group, no. 3 or the approval number with the abbreviation '*Gen. Nr.*', nos. 4, 6, 7 and 9 as well as the name and volume of the anticoagulant and, if available, the additive solution, storage temperature, blood group and, in the case of allogenic preparations derived from red blood cells, the rhesus formula as well and, in the case of thrombocyte concentrates and autologous preparations from red blood cells, also the rhesus factor. In the case of autologous blood preparations, the information '*Nur zur Eigenbluttransfusion*' (Only for Autologous Blood Donation) must also be given and, in the case of autologous and directed blood preparations, also an indication of the recipient. In the case of haematopoietic stem cell preparations made from peripheral blood or umbilical cord blood, the Single European Code with the abbreviation 'SEC' must be given, as well as the information '*Biologische Gefahr*' (Biological Danger) in the event that infectivity has been detected.

(8b) In the case of tissue preparations, at least the information pursuant to subsection (1) sentence 1 nos. 1 and 2, without stating the strength, pharmaceutical form and target group, no. 3 or the approval number with the abbreviation '*Gen.Nr.*', nos. 4, 6 and 9 of the Single European Code with the abbreviation 'SEC' must be included, as well as the information '*Biologische Gefahr*' (Biological Danger) in the event that infectivity has been detected. In the case of autologous tissue preparations, the information '*Nur zur autologen Anwendung*' (Only for Autologous Use) must also be provided and, in the case of autologous and targeted tissue preparations, an additional indication as to the recipient.

(9) Abbreviations customary in the medicinal product trade may be used in the indications given in compliance with subsections (1) to (5). The company to be indicated under subsection (1) no. 1 may be abbreviated, provided that the firm is generally recognisable from the abbreviation.

(10) (repealed)
(11) Partial amounts removed from finished medicinal products may only be dispensed with labelling that corresponds at least to the requirements stipulated in subsection (8) sentence 1. Subsection (1b) does not apply.

Section 10a
Labelling of investigational and auxiliary medicinal products for clinical trials

(1) Investigational and auxiliary medicinal products for clinical trials must be labelled in German.
(2) Information that is also provided in another language must be identical in both language versions.

Section 11
Package leaflet

(1) Finished medicinal products that are not intended for clinical trials and not exempted from the obligation to obtain a marketing authorisation pursuant to section 21 (2) nos. 1a, 1b or 3, may only be placed on the market within the purview of this Act with a package leaflet bearing the heading '*Gebrauchsinformation*' (Instructions for Use) and containing, in the same order as below, in easily legible, readily comprehensible German and in conformity with the information referred to in section 11a:

1. for the purpose of identifying the medicinal product:

   a) the name of the medicinal product, section 10 (1) sentence 1 no. 2 applies accordingly,

   b) the substance or indication group or the mode of action;

2. the therapeutic indications;

3. a list containing information that must be known before the medicine is administered:

   a) contra-indications,

   b) corresponding precautions when administering the medicinal product,

   c) interaction with other medicinal products or other products if this is likely to influence the effect of the medicinal product,

   d) warnings, especially if imposed as a condition by the competent higher federal authority pursuant to section 28 (2) no. 2 or based on section 7 of the Anti-Doping Act (*Gesetz gegen Doping im Sport*) or stipulated by ordinance pursuant to section 12 (1) no. 3;

4. the instructions under normal conditions of use, relating to:

   a) dosage,

   b) method of administration,

   c) frequency of administration, where necessary indicating the exact time when the medicinal product can or must be administered,

   as well as, where necessary, and according to the type of medicinal product:

   d) the duration of treatment, if this is meant to be stipulated,

   e) information in the event of overdosage, failure to take the medicine or on the risk of undesirable consequences if discontinued,

f) the specific recommendation that a physician or pharmacist should be consulted in the event of queries relating to the use;

5. relating to adverse reactions:

a) a description of the adverse reactions that can occur when the medicinal product is used as intended,

b) the counter measures to be taken in the event of adverse reactions if required according to the current state of scientific knowledge, and

c) a standard text that explicitly instructs the patient to inform their physicians, pharmacists, health professionals or the competent higher federal authority directly of every suspected adverse reaction whereby the report can be made in any – in particular also electronic – form;

6. mention of the expiry date stated on the packaging and also:

a) a warning that the medicinal product may not be used after expiry of this date,

b) if required, special precautions for storage and information on shelf life after opening of the container or after preparation of the ready-to-use preparation by the user,

c) if required, a warning about specific visible signs indicating that the medicinal product may no longer be used,

d) complete qualitative composition in terms of active substances and other constituents and quantitative composition in terms of the active substances, using the usual common names for each of the medicinal product's pharmaceutical forms; section 10 (6) applies,

e) the pharmaceutical form and content by weight, nominal volume or number of items for each of the medicinal product's pharmaceutical forms,

f) the name and address of the pharmaceutical entrepreneur and, if available, of his/her local representative,

g) the name and address of the manufacturer or importer who released the finished medicinal product for placing on the market,

7. in the case of a medicinal product known by other names in other Member States of the European Union and approved for placing on the market pursuant to Articles 28 to 39 of Directive 2001/83/EC, a list of the names approved in each Member State;

8. the date of the last revision of the package leaflet.

Medicinal products that are included on a list compiled pursuant to Article 23 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136 of 30.4.2004, p. 138), last amended by Regulation (EU) 2019/5 (OJ L L4 f7.1.2019, p. 24), must, in addition, carry the following declaration: *'Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung'* (This medicinal product is subject to additional monitoring). This declaration must be preceded by a black symbol and be followed by an appropriate standardised explanatory text pursuant to Article 23 (4) of Regulation (EC) No. 726/2004. Explanatory information on the terms listed in sentence 1 is admissible. Insofar as information referred to in sentence 1 is also rendered on the package leaflet in another language, the information provided in this language must be identical. Sentence 1 does not apply to medicinal products that do not

require a marketing authorisation pursuant to section 21 (2) no. 1. Additional information that is not stipulated by a regulation of the European Community or the European Union, or is already permissible pursuant to such a regulation, is permitted provided it relates to the use of the medicinal product, is important for the health education of patients and is not inconsistent with the information referred to in section 11a. With regard to the information referred to in sentence 1 no. 3 letters a to d, account is to be taken of the special situation of specific groups of persons such as children, pregnant women or nursing mothers, the elderly or persons with specific diseases, insofar as this is deemed necessary in the light of the current level of scientific knowledge; furthermore, where necessary, the effects that the use of the medicinal product could have on a person's ability to drive or to operate specific machines should also be indicated. The marketing authorisation holder is required to keep scientifically up-to-date the package leaflet that includes the conclusions of assessments and recommendations published on the European internet portal set up pursuant to Article 26 of Regulation (EC) No. 726/2004.
(1a) A sample of the package leaflet and modified versions must be sent to the competent higher federal authority unless the medicinal product is exempted from the obligation to obtain a marketing authorisation or registration.
(1b) The standard texts required pursuant to subsection (1) sentence 1 no. 5 and sentence 3 are published by the competent higher federal authority in the Federal Gazette.
(1c) In derogation of subsection (1) sentence 1, the competent higher federal authority can, in individual cases and at the request of the authorisation holder, permit medicinal products to be placed on the market temporarily with a package leaflet in a language other than German in the event of an impending or existing supply-relevant bottleneck. In such cases, the competent higher federal authority will ensure that the consumer is given appropriate access to the necessary product information.
(2) Furthermore, the package leaflet must contain references to constituents, the knowledge of which is necessary for the safe and effective use of the medicinal product, as well as specific storage instructions for the consumer insofar as this is deemed necessary according to the current level of scientific knowledge or if imposed as a condition by the competent higher federal authority pursuant to section 28 (2) no. 2, or provided for by ordinance.
(2a) In the case of radiopharmaceuticals, subsection (1) applies accordingly with the proviso that the precautions that are to be taken by the user and the patient in the preparation and administration of the medicinal product, as well as special precautions for the disposal of the containers used for transport and for the disposal of medicinal products that are not used, are taken.
(3) In the case of medicinal products included in the register of homeopathic medicinal products, subsection (1) applies accordingly with the proviso that the information stipulated in section 10 (4), with the exception of the batch identification, the expiry date and the indication stipulated for samples, is included, as well as the name and address of the manufacturer who released the finished medicinal product for placing on the market, where this person is not the pharmaceutical entrepreneur. Sentence 1 applies accordingly to medicinal products that are exempted from registration pursuant to section 38 (1) sentence 3.
(3a) In the case of sera, subsection (1) applies accordingly with the proviso that the type of living organism from which they are derived and, in the case of virus vaccines, the host system used for virus multiplication and, in the case of medicinal products derived from human blood plasma for fractionation, the country of origin of the blood plasma should be stated.
(3b) In the case of traditional herbal medicinal products pursuant to section 39a, (1) applies accordingly with the proviso that the information referred to in subsection (1) sentence 1 no. 2 must state that the medicinal product is a traditional medicinal product registered for the specific therapeutic indication exclusively on the basis of long-standing use. In addition, the package leaflet should include the advice referred to in section 10 (4a) sentence 1 no. 2.

(3c) The marketing authorisation holder must ensure that at the request of patients' organisations, the package leaflet is made available in formats appropriate for the blind and partially-sighted persons.
(3d) In the case of spa-waters, notwithstanding the requirements referred to in subsection (2), the information referred to in subsection (1) sentence 1 no. 3 letter b no. 4 letters e and f no. 5, provided that the information stated therein is stipulated, and no. 6 letter c, can be omitted. Furthermore, in the case of spa-waters, the order stipulated in subsection (1) is not compulsory.
(4) (repealed)
(5) Should it not be possible to provide the information stipulated in subsection (1) sentence 1 no. 3 letters a and c as well as no. 5, the indication '*keine bekannt*' (none known) must be given. Should additional information be given on the package leaflet, it must be clearly set out and well separated from the information specified in subsections (1) to (3).
(6) The package leaflet may be omitted provided that the information specified in subsections (1) to (3) is to be found either on the container or on the outer packaging. Subsection (5) applies accordingly.
(7) Partial amounts removed from finished medicinal products may only be dispensed together with a copy of the package leaflet prescribed for the finished medicinal product. Subsection (6) sentence 1 applies accordingly. By way of derogation from sentence 1, in the case of the regular dispensing of partial amounts removed from finished medicinal products and dispensed in new, customised patient blisters in the context of long-term medication, copies of the package leaflet prescribed for the specific finished medicinal product must only be inserted if they have been modified compared with those previously inserted.

Section 11a
Expert information

(1) For finished medicinal products that are subject to or exempt from the obligation to obtain a marketing authorisation and released for trade outside of pharmacies, the pharmaceutical entrepreneur is obliged to make instructions for use by experts (expert information) available upon request to the following persons:

1. physicians, dentists, veterinarians, pharmacists, as well as
2. other persons practising medicine or dentistry professionally, if the medicinal products are not subject to prescription.

The instructions for expert use must carry the heading '*Fachinformation*' (expert information) and include the following information written in clearly legible type in conformity with the Summary of Product Characteristics approved within the framework of the marketing authorisation, and in the following order:

1. the name of the medicinal product followed by the strength and the pharmaceutical form;
2. information on the qualitative and quantitative composition in terms of active substance and other constituents, knowledge of which is required for proper administration of the product, with the usual common or chemical name indicated; section 10 (6) applies;
3. pharmaceutical form,
4. clinical particulars:
   a) therapeutic indications;
   b) dosage and method of administration for adults and, insofar as the medicinal product is indicated for administration to children, for children,

c) contra-indications,

d) special warnings and precautions for use, and in the case of immunological medicinal products, any special precautions to be taken by persons coming into contact with and administering these medicinal products to patients, together with any precautions to be taken by the patient, if required as a result of conditions imposed by the competent higher federal authority pursuant to section 28 (2) no. 1 letter a, or stipulated by section 7 of the Anti-Doping Act, or by an ordinance,

e) interaction with other medicinal products or other products if this is likely to influence the effect of the medicinal product,

f) use during pregnancy and nursing,

g) effects on ability to drive or operate machinery,

h) adverse reactions when used as intended,

i)overdosage: symptoms, emergency response measures, antidote;

5. pharmacological properties:

a) pharmacodynamic properties,

b) pharmacokinetic properties,

c) preclinical safety data;

6. pharmaceutical particulars:

a) list of the other constituents,

b) main incompatibilities,

c) shelf life and where necessary, the shelf life on manufacturing a ready-to-use preparation of the medicinal product or after first opening the container,

d) special precautions for storage;

e) type and content of the container,

f) special precautions for disposal of an opened medicinal product, or waste materials derived from it, in order to avoid any risk to the environment;

7. marketing authorisation holder;

8. marketing authorisation number;

9. the date of first authorisation or extension of the authorisation;

10. the date of revision of the expert information.

The expert information is to contain a standard text that explicitly calls upon health professionals to report every suspected adverse reaction to the competent higher federal authority whereby the report may take any – in particular also electronic – form. Medicinal products that are included on a list compiled pursuant to Article 23 of Regulation (EC) No. 726/2004 must, in addition, carry the following declaration: *'Dieses Arzneimittel unterliegt einer zusätzlichen Überwachung'* (This medicinal product is subject to additional monitoring). This declaration must be preceded by a black symbol and be followed by an appropriate standardised explanatory text pursuant to Article 23 (4) of Regulation (EC) No. 726/2004. Additional information that is not stipulated by a regulation of the European Community or the European Union, or is already permissible pursuant to such a regulation is permitted if it relates to the use of the medicinal product and is not inconsistent with the information

referred to in sentence 2; such information must be clearly separate and distinct from the information referred to in sentence 2. Sentence 1 does not apply to medicinal products that do not require a marketing authorisation pursuant to section 21 (2) or are manufactured according homeopathic procedures. The marketing authorisation holder is required to keep scientifically up-to-date the expert information, which includes the conclusions of assessments and recommendations published on the European internet portal set up pursuant to Article 26 of Regulation (EC) No. 726/2004. The standard texts required pursuant to sentences 3 and 5 are published by the competent higher federal authority in the Federal Gazette.
(1a) In the case of sera, the type of living organism from which they are derived, in the case of virus vaccines, the host system used for virus multiplication and, in the case of medicinal products derived from human blood plasma for fractionation, the country of origin of the blood plasma must be indicated.
(1b) In respect of radiopharmaceuticals, details of the internal radiation dosimetry, additional detailed instructions for the extemporaneous preparation and the quality control of this preparation must also be given and, where necessary, the maximum storage time must also be indicated during which an intermediate preparation, such as an eluate or the medicinal product when ready for use, corresponds to its specifications.
(1c) In the case of medicinal products available only on prescription pursuant to section 48, the information '*Verschreibungspflichtig*' (prescription only) should also be added, for narcotic drugs the information '*Betäubungsmittel*' (narcotic drugs), in the case of other medicinal products available to consumers only in pharmacies, the information '*Apothekenpflichtig*' (pharmacy only); in the case of medicinal products containing a substance or a preparation pursuant to section 48 (1) sentence 1 no. 2 corresponding information must be given.
(1d) For marketing authorisations of medicinal products pursuant to section 24b, the information referred to in subsection (1) relating to therapeutic indications, dosages or other objects of a patent can be omitted if it is still covered by patent law at the time of placing on the market.
(2) The pharmaceutical entrepreneur is obliged to make all modifications to the expert information that are relevant for therapy accessible to the experts in an appropriate form. Where necessary, the competent higher federal authority may, by imposition of a condition, stipulate the form in which the changes are to be made accessible to all or to certain groups of experts.
(3) A sample of the expert information and revised versions thereof must be sent immediately to the competent higher federal authority unless the medicinal product is exempted from the obligation to obtain a marketing authorisation.
(4) The obligations referred to in subsection (1) sentence 1 can also be fulfilled in the case of medicinal products that are administered exclusively by members of the health professions by including the information referred to in subsection (1) sentence 2 in the package leaflet. The package leaflet must be headed with the title *'Gebrauchsinformation und Fachinformation*' (instructions for use and expert information).

Section 12
Empowerment in respect of labelling, package leaflet and package sizes

(1) The Federal Ministry is hereby empowered, in agreement with the Federal Ministry for Economic Affairs and Energy by ordinance subject to the approval of the Bundesrat:

1. to extend the provisions of sections 10 and 11a to cover other medicinal products and to extend the expert information to include further details,

2. to stipulate that the information indicated in sections 10 and 11 is to be made known to the consumer in another way,

3. to stipulate that, for certain medicinal products or certain groups of medicinal products, warnings, warning symbols or recognition marks must be contained in or affixed to:

a) the containers, the outer packaging or the package leaflet or

b) the expert information,

4. to stipulate that specific constituents are to be listed by type on the containers and outer packaging or that attention should be drawn to them in the package leaflet,

if this is deemed necessary in order to ensure the proper handling and proper administration of medicinal products within the purview of this Act and in order to prevent any direct or indirect risk to human health that could occur as a result of inadequate information.
(1a) Furthermore, the Federal Ministry is hereby empowered to allow, by ordinance subject to the approval of the Bundesrat, the use of summarising names for substances or preparations from substances in the information provided on containers and outer packaging or in package leaflets or in expert information, as long as active constituents are not involved and no direct or indirect hazard to human health arising from inadequate of information is to be feared.
(1b) Furthermore, the Federal Ministry is hereby empowered, in agreement with the Federal Ministry for Economic Affairs and Energy, by means of an ordinance subject to the approval of the Bundesrat to regulate:

1. the labelling of starting materials intended for the manufacture of medicinal products, and

2. the labelling of medicinal products that are intended for clinical trials and do not fall within the scope of Regulation (EU) No 536/2014,

if this is necessary to prevent any direct or indirect risk to human health that could occur as a result of inadequate labelling.
(2) The ordinance pursuant to subsection (1), (1a) or (1b) must be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used or where, in the cases provided for in subsection (1) no. 3, warnings, warning symbols or recognition marks with regard to the information stipulated in section 10 (1) sentence 1 no. 13 or subsection (5) sentence 1 no. 10, section 11 (4) sentence 1 no. 9 or section 11a, (1) sentence 2 no. 6 letter f are required.
(3) Furthermore, the Federal Ministry is hereby empowered to stipulate, by ordinance not subject to the approval of the Bundesrat, that medicinal products may only be placed on the market in specific package sizes and that they must be labelled accordingly by the pharmaceutical entrepreneur on the container or, if used, on the outer packaging. The fixing of these package sizes is done for specific active substances and takes into account the therapeutic indications, the duration of application and the pharmaceutical form. In fixing the package size, the following trisection is, in principle, to be used as a basis:

1. packages for a short duration of application or tolerance tests,

2. packages for an intermediate duration of application,

3. packages for a relatively extended duration of application.

Division 3
Manufacture of medicinal products

Section 13
Manufacturing authorisation

(1) Any person who manufactures:

1. medicinal products,

2. (repealed),

3. active substances that are of human, animal or microbial origin or are manufactured using genetic engineering, or

4. other substances of human origin intended for the manufacture of medicinal products,

on a commercial or professional basis requires a permit by the competent authority. The same applies to legal persons, to associations that have not achieved the status of legal persons by being registered in the register of associations, and to business partnerships that manufacture medicinal products for distribution to their members. Sentence 1 applies accordingly to a trial on the basis of which the release of the medicinal product is explained. This is without prejudice to section 14 (4).

(1a) Subsection (1) does not apply to:

1. tissues within the meaning of section 1a no. 4 of the Transplantation Act that require a permit pursuant to section 20b or 20c,

2. the collection and the laboratory tests of autologous blood for the manufacture of biotechnologically processed tissue products that require a permit pursuant to section 20b,

3. tissue preparations that require a permit pursuant to section 20c,

4. reconstitution, insofar as it does not concern medicinal products that are intended for use in clinical trials outside of the scope of Regulation (EU) No 536/2014.

(2) The following does not require an authorisation pursuant to subsection (1):

1. the owner of a pharmacy manufacturing medicinal products within the scope of the normal operation of a pharmacy, reconstituting or packaging including the labelling of medicinal products intended for clinical trials outside of the scope of Regulation (EU) No 536/2014 insofar as this corresponds to the trial protocol,

2. the body responsible for a hospital, insofar as it is authorised to distribute medicinal products pursuant to the Pharmacies Act, reconstituting or packaging including the labelling of medicinal products intended for clinical trials outside of the scope of Regulation (EU) No 536/2014 insofar as this corresponds to the trial protocol,

2a. the pharmacy for the activities mentioned in Article 61 (5) of Regulation (EU) No 536/2014,

3. (repealed)

4. the wholesaler for:

   a) the decanting of liquefied oxygen into small portable containers for individual patients in hospitals or in physicians' practices including the required labelling,

   b) decanting, packaging or labelling other medicinal products without altering them, provided the packages concerned are not intended for direct distribution to the consumer,

5. the retailer who, in possession of the expert knowledge defined in section 50, decants, packages or labels medicinal products without altering them for direct distribution to the consumer,

6. the manufacturer of active substances that are intended for use in the manufacture of medicinal products, which are manufactured using a procedure described in the homeopathic section of the Pharmacopoeia.

(2a) The exceptions specified in subsection (2) nos. 1, 2 and 4 to 6 do not apply to the manufacture of blood preparations, tissue preparations, sera, vaccines, allergens, advanced therapy medicinal products, xenogeneic medicinal products and radiopharmaceuticals. Sentence 1 does not apply to the facilities specified in subsection (2) no. 1 or 2 insofar as

1. the decanting in an unchanged form for an individual patient, packaging or labelling of sera of non-human or non-animal origin authorised for marketing within the purview of this Act, or

2. the reconstitution or the packaging or labelling of medicinal products intended for clinical trials outside of the scope of Regulation (EU) No 536/2014 insofar as this corresponds to the trial protocol, or

3. the manufacture of test allergens

are concerned. The competent authority is to be notified of activities pursuant to sentence 2 nos. 1 and 3.

(2b) Furthermore, an authorisation pursuant to subsection (1) is not required by a person who is a physician, dentist or otherwise authorised to practise medicine on human beings insofar as the medicinal products are manufactured directly under his/her professional responsibility for personal use by a specific patient. Sentence 1 does not apply to:

1. advanced therapy medicinal products and xenogeneic medicinal products,

2. medicinal products intended for clinical trials if it is not merely a case of reconstitution, as well as

3. medicinal products that are subject to prescription pursuant to section 48, insofar as the manufacturer pursuant to sentence 1 is neither a physician nor a dentist.

(2c) (repealed)

(3) An authorisation issued pursuant to subsection (1) concerning the decanting of liquefied medicinal gases into the delivery receptacle of a tanker truck also covers the decanting of liquefied medicinal gases, without altering them, from a delivery receptacle of a tanker truck into containers installed at a hospital or on the premises of other consumers.

(4) The decision on the granting of the authorisation is taken by the competent authority of the federal Land where the factory site is situated or is to be situated. As far as blood products, tissue preparations, sera, vaccines, allergens, advanced therapy medicinal products, xenogeneic medicinal products, medicinal products manufactured using genetic engineering as well as active substances and other substances intended for the manufacture of medicinal products and which are of human, animal or microbial origin or are manufactured using genetic engineering are concerned, the decision on the authorisation is reached in consultation with the competent higher federal authority.

(5) The authorisation to manufacture investigational or auxiliary medicinal products within the meaning of Article 2 (2) nos. 5 and 8 of Regulation (EU) No. 536/2014 will be issued by the competent authority in accordance with Article 61 (1) to (3) of Regulation (EU) No 536/2014. Sections 16, 17 and 64 (3a) sentence 2 apply accordingly to the granting of the authorisation.

(6) The holder of the authorisation pursuant to Section 5 must make it possible for the qualified person pursuant to section 14 (1) no. 1 and section 15 to discharge his/her duties and must place, in particular, all of the necessary technical aids at his/her disposal.

Section 14
Decision on the manufacturing authorisation

(1) The authorisation may only be refused if:

1. there is not at least one person available with the expert knowledge required pursuant to section 15 (qualified person pursuant to section 14) who is responsible for the activity referred to in section 19,

2. (no longer applicable),

3. the qualified person pursuant to no. 1 or the applicant is not sufficiently reliable in the performance of his/her job,

4. the qualified person pursuant to no. 1 is unable to permanently meet the obligations incumbent on him/her,

5. the physician under whose responsibility the pre-treatment of the donor for the purpose of separating haematopoietic stem cells from peripheral blood or other blood components is conducted does not possess the necessary expert knowledge,

5a. in breach of section 4 sentence 1 no. 2 of the Transfusion Act (*Transfusionsgesetz*), no physician in charge has been appointed or said person does not possess the necessary professional knowledge according to the latest standards prevailing in medical science or, in breach of section 4 sentence 1 no. 3 of the Transfusion Act, no physician is present when the withdrawal procedure is carried out on a human donor,

6. suitable premises and equipment for the intended manufacture, testing and storage of the medicinal products are not available, or

6a. the manufacturer is unable to guarantee that the manufacture or testing of the medicinal products is conducted according to the latest standards prevailing in science and technology and, in the collection of blood and blood components, additionally according to the provisions of Division 2 of the Transfusion Act.

(2) (no longer applicable)
(2a) The physician in charge pursuant to section 4 sentence 1 no. 2 of the Transfusion Act can also be the qualified person pursuant to subsection (1) no. 1.
(2b) (no longer applicable)
(3) (no longer applicable)
(4) By way of derogation from subsection (1) no. 6, it is possible to conduct partly outside of the manufacturer's factory site:

1. the manufacture of medicinal products for clinical trials at a commissioned pharmacy,

2. the changing of the expiry date of medicinal products for clinical trials at a trial site by a person commissioned by the manufacturer, insofar as these medicinal products are exclusively intended for use at this trial site,

3. the testing of medicinal products at commissioned enterprises,

4. the collection or testing, including laboratory testing of the donor samples of substances of human origin intended for the manufacture of medicinal products, with the exception of tissues, in other enterprises or facilities,

which require no authorisation of their own, on condition that they have the premises and equipment suitable for this purpose and it is guaranteed that the manufacture and testing are carried out according to the latest standards prevailing in science and technology and the qualified person pursuant to subsection (1) no. 1 is able to assume his/her responsibilities.
(5) Should there be any objections to the submitted documents, the applicant is to be given an opportunity to correct the flaws within an appropriate period of time. If the flaws are not corrected, the authorisation is to be refused.

Section 15
Expert knowledge

(1) Proof of the required expert knowledge on the part of the qualified person referred to in section 14 is furnished by:

1. the licence to practise as a pharmacist, or
2. the certificate testifying to the successful completion of a course of university studies in pharmacy, chemistry, pharmaceutical chemistry and technology, biology, human or veterinary medicine of at least four years' duration,

as well as a period of at least two years' practical experience in the field of the qualitative and quantitative analysis and other quality testing of medicinal products or veterinary medicinal products. The minimum duration of the university studies can be three and a half years if studies are followed by theoretical and practical training of at least one year, which includes an internship of at least six months at a public pharmacy and is completed with a university-level examination. The duration of the practical experience pursuant to sentence 1 can be reduced by one year if the university studies are of at least five years' duration and by one and a half years if the university studies are of at least six years' duration. Where two university courses or two courses recognised as equivalent co-exist and where one of these extends over four years and the other over three years, it is to be assumed that the certificate awarded on completion of the university course or its recognised three-year equivalent is considered to fulfil the condition of duration referred to in sentence 2, insofar as the certificates awarded on completion of both courses are recognised as equivalent.
(2) In the cases specified in subsection (1) no. 2, proof must be furnished to the competent authority that the university studies comprised theoretical and practical instruction at least in the following basic subjects and that an adequate knowledge exists thereof:

experimental physics

general and inorganic chemistry

organic chemistry

analytical chemistry

pharmaceutical chemistry

biochemistry

physiology

microbiology

pharmacology

pharmaceutical technology

toxicology

pharmaceutical biology.

The theoretical and practical instruction and sufficient knowledge may also be acquired at a university upon completion of university studies within the meaning of subsection (1) no. 2 and may be proved by examination.
(3) Subsection (2) does not apply to the manufacture and testing of blood preparations, sera of human or animal origin, vaccines and allergens. In place of the evidence of practical experience required in subsection (1), proof must be furnished of at least three years' experience in the field of medical serology or medical microbiology. By way of derogation from sentence 2, in place of the practical experience required in subsection (1), proof must be furnished of:

1. at least three years' experience in manufacture or testing in plasma processing enterprises with a manufacturing authorisation, in addition to at least six months' experience in the field of transfusion medicine or medical microbiology, virology, hygiene or analytic procedure, in the case of blood preparations produced from blood plasma for the purpose of fractionation,

2. at least two years' experience in the field of transfusion medicine covering all the areas of manufacture and testing in the case of blood preparations made from blood cells and preparations made from fresh plasma as well as in the case of substances and blood components for the manufacture of blood preparations,

3. at least six months' experience in transfusion medicine or one year's experience in the manufacture of autologous blood preparations in the case of autologous blood preparations,

4. for haematopoietic stem cell preparations made from peripheral blood or umbilical cord blood, in addition to sufficient knowledge, at least two years' experience in this field of activity especially in the technology on which it is based.

With regard to the pre-treatment of patients for the purpose of separating haematopoietic stem cells from peripheral blood or from other blood components, the physician responsible must provide evidence of sufficient knowledge in addition to at least two years' experience in this or another, comparably qualifying field of activity. The prerequisites contained in subsection (1) remain valid for packaging and labelling.

(3a) Subsection (2) does not apply to the manufacturing and testing of advanced therapy medicinal products, xenogeneic medicinal products, tissue preparations, medicinal products for use in in-vivo diagnosis by means of marker genes, tissue preparations, radiopharmaceuticals and active substances. In place of the practical experience required in subsection (1), proof must be furnished of:

1. in the case of gene therapy medicinal products and medicinal products for use in in-vivo diagnosis by means of marker genes, at least two years' experience in a medically relevant field, in particular of genetic engineering, microbiology, cell biology, virology or molecular biology,

2. in the case of somatic cell therapy medicinal products and biotechnologically processed tissue products, at least two years' experience in a medically relevant field, in particular of genetic engineering, microbiology, cell biology, virology or molecular biology,

3. in the case of xenogeneic medicinal products, at least three years' experience in a medically relevant field including at least two years' activity particularly in one of the fields mentioned under no. 1,

4. in the case of tissue preparations, at least two years' experience in the manufacture and testing of such medicinal products in enterprises and facilities that require a manufacturing authorisation pursuant to this Act or possess a manufacturing authorisation under European Union legislation,

5. in the case of radiopharmaceuticals, at least three years' experience in the field of nuclear medicine or that of radiopharmaceutical chemistry, and,

6. in the case of active substances other than those listed under subsection (3) sentence 3 no. 2, at least two years' experience in the manufacture and testing of active substances.

(4) The period of practical experience specified in subsection (1) must be spent at a firm which has been granted a manufacturing authorisation by a Member State of the European Union, by another State Party to the Agreement on the European Economic Area or by a

state with which an agreement exists as to the mutual recognition of certificates pursuant to section 72a sentence 1 no. 1.
(5) (repealed)
(6) A legally exercised function as a qualified person, subsequent to an examination of the necessary expert knowledge by the competent authority, also entitles a person to exercise this function within the remit of another competent authority, unless there are substantiated grounds to suppose that the existing expert knowledge is insufficient for the new function.

Section 16
Limitation of the manufacturing authorisation

The authorisation is issued to the applicant for a specific factory site and for particular medicinal products and pharmaceutical forms of medicinal products and, in cases as defined in section 14 (4), also for a specific factory site of the commissioned company or the other company. Insofar as the authorisation includes the testing of medicinal products or active substances, the type of testing is to be specified.

Section 17
Deadlines for the granting of marketing authorisations

(1) The competent authority must take the decision on the application for authorisation within a period of three months.
(2) If the holder of the authorisation makes an application for the authorisation to be modified in respect of the medicinal products to be manufactured or the premises and equipment as defined in section 14 (1) no. 6, the authority must reach a decision within a period of one month. In exceptional cases, the deadline is extended by an additional two months. The applicant is to be notified thereof prior to the expiry of the deadline and notified of the grounds.
(3) If the authority gives the applicant the opportunity to correct the flaws pursuant to section 14 (5), the deadlines are interrupted until such flaws have been corrected or until the expiry of the deadline set pursuant to section 14 (5). The interruption of the deadline begins on the day the applicant receives the request to correct the flaws.

Section 18
Withdrawal, revocation, suspension

(1) The authorisation is to be withdrawn if it becomes known subsequently that one of the grounds for refusal, pursuant to section 14 (1), existed at the time the authorisation was granted. The authorisation is to be revoked if one of the grounds for refusal subsequently developed; the suspension of the authorisation may be ordered instead of its revocation. Section 13 (4) applies accordingly.
(2) The competent authority may issue a provisional order mandating that the manufacture of a medicinal product be discontinued if the manufacturer fails to furnish the evidence required for manufacture and testing. The provisional order may be restricted to one batch.

Section 19
Areas of responsibility

The qualified person pursuant to section 14 is responsible for ensuring that each batch of the medicinal product is manufactured and tested in accordance with the regulations applicable to the trade in medicinal products. He/she must certify the fulfilment of these provisions for each batch of medicinal products in a serially numbered register or comparable document before it is placed on the market.

Section 20
Obligations to notify

The marketing authorisation holder must notify the competent authority in advance of any change in the information referred to in section 14 (1) and submit evidence. Any unforeseen change in the qualified person referred to in section 14 must be notified immediately.

Section 20a
Applicability to active substances and other substances

Section 13 (2) and (4) and sections 14 to 20 apply accordingly to active substances and to other substances of human origin intended for use in the manufacture of medicinal products, insofar as their manufacture or testing pursuant to section 13 (1) requires an authorisation.

Section 20b
Authorisation for the collection of tissues and the pertinent laboratory tests

(1) Any establishment seeking to collect tissues intended for human applications within the meaning of section 1a no. 4 of the Transplantation Act (removal establishments) or seeking to conduct the laboratory testing necessary for such collection requires an authorisation from the competent authority. Collection within the meaning of sentence 1 is the direct or extracorporeal removal of tissues including all measures that are intended to maintain the tissues in a processable state, clearly identifiable and transportable. The authorisation may only be refused if:

1. an appropriately qualified person (the person responsible pursuant to section 20b) with the necessary professional experience who, in the case of a removal establishment, can also be the medical person within the meaning of section 8d (1) sentence 1 of the Transplantation Act is not present,

2. additional participating personnel is insufficiently qualified,

3. appropriate rooms for the specific tissue collection or for the laboratory testing are not available,

4. it is not guaranteed that the collection of tissues or the laboratory testing are conducted according to the latest standards prevailing in medical science and technology and according to the provisions contained in Divisions 2, 3 and 3a of the Transplantation Act, or

5. the person responsible pursuant to section 20b or the applicant is not sufficiently reliable in the performance of his/her job.

The competent authority may dispense with an inspection within the meaning of section 64 (3) sentence 2, prior to the granting of an authorisation pursuant to this provision. The authorisation is granted to the removal establishment by the competent authority for a specific facility and for a specific tissue and, to the laboratory, for a specific site and for specific activities and may provide for the possibility of tissue removal outside of the premises described in sentence 3 no. 3, by personnel dispatched by the removal facility. In the process, the competent authority may involve the competent higher federal authority.
(1a) Section 20c (4) sentences 1 and 2 and subsection (5) apply accordingly.
(2) An individual authorisation pursuant to subsection (1) is not required by a person conducting such activities on a contractual basis for a manufacturer or a processor who is in possession of an authorisation pursuant to section 13 or section 20c for the processing of tissue or tissue preparations. In this case, the manufacturer or processor must notify the local competent authority responsible for the removal establishment or the laboratory of the latter and is to include, with the notification, the information and documents pursuant to subsection (1) sentence 3. One month subsequent to the notification pursuant to sentence 2, the manufacturer or processor must notify the competent authority responsible for him/her of the removal establishment or the laboratory unless the competent authority responsible for the removal establishment or the laboratory has objected. In exceptional cases, the deadline pursuant to sentence 3 can be extended for an additional two months. The manufacturer or processor is to be informed thereof before expiry of the deadline and is to be notified of the grounds. If the competent authority has objected, the deadlines pursuant to sentences 3 and 4 are suspended until the grounds for the objection have been rectified. Subsection (1)

sentences 3 to 6 applies accordingly provided that the authorisation pursuant to subsection (1) sentence 5 is granted to the manufacturer or processor.
(3) The authorisation is to be withdrawn if it subsequently becomes known that one of the grounds for the rejection pursuant to subsection (1) sentence 3 existed at the time of the granting of the authorisation. The authorisation is to be revoked if one of the grounds for refusal developed subsequently, the suspension of the authorisation may be ordered instead of its revocation. The competent authority is entitled to prohibit the collection of tissue or the laboratory testing temporarily if the removal establishment, the laboratory, the manufacturer or the processor fail to submit the necessary supporting documents for the collection of tissue or the laboratory testing.
(4) Subsections (1) to (3) apply accordingly for the collection and the laboratory testing of autologous blood for the manufacture of biotechnologically processed tissue products.
(5) The marketing authorisation holder must notify the competent authority of every change in the prerequisites contained in subsection (1) sentence 3 regarding the marketing authorisation, in advance, presenting the necessary evidence and may make the change only after receiving written permission to do so from the competent authority. In the case of an unexpected change in the appropriately qualified person pursuant to section 20b, the notification must be immediate.

Section 20c
Authorisation for the processing, preservation, testing and storage or the placing on the market of tissues or tissue preparations

(1) Any establishment that wishes to process, preserve, test, store or place on the market tissues or tissue preparations that are not processed using industrial procedures and the essential processing procedures of which are sufficiently well known in the European Union, requires, by way of derogation from section 13 (1), an authorisation from the competent authority pursuant to the following provisions. This also applies to tissues or tissue preparations the processing procedures for which are new but comparable with a known procedure. The decision on whether to grant the authorisation is taken by the competent authority of the *Land* in which the facility is located or is to be located, in consultation with the competent higher federal authority.
(2) The authorisation may only be refused if:

1. a person with the necessary expert knowledge and experience pursuant to subsection (3) (person responsible pursuant to section 20c) responsible for ensuring that the tissue preparations and tissues are processed, preserved, tested, stored or placed on the market in keeping with the statutory provisions in force, is not available,

2. additional participating personnel is insufficiently qualified,

3. suitable premises and establishments are not available for the envisaged activities,

4. it is not guaranteed that the processing including the labelling, preservation and storage is conducted according to the latest standards prevailing in science and technology,

5. a quality management system pursuant to the principles of Good Practice has not been installed or has not been kept up to date, or

6. the person responsible pursuant to section 20c or the applicant is not sufficiently reliable in the performance of his/her job,

By way of derogation from sentence 1 no. 3, the testing of the tissues and tissue preparations may be conducted outside of the factory site, in commissioned factories which do not require an authorisation of their own, if suitable rooms and facilities are available there and if it is guaranteed that testing is conducted according to the latest standards

prevailing in science and technology and the person responsible pursuant to section 20c is able to assume his/her responsibilities.
(3) Proof that the person responsible pursuant to section 20c possesses the necessary expert knowledge, must be provided by a certificate testifying to the successful completion of university studies in human medicine, biology, biochemistry or a course of studies considered equivalent as well as at least two years' practical experience in the processing of tissues or tissue preparations. In the case of establishments that exclusively test tissue or tissue preparations, proof of practical experience pursuant to sentence 1 can also be provided in the form of at least two years' practical experience in the processing of tissues or tissue preparations.
(4) Should there be any objections to the submitted documents, the applicant is to be given an opportunity to correct the flaws within an appropriate period of time. If the flaws are not corrected, the authorisation is to be refused. The authorisation is granted for a specific facility and for specific tissues or tissue preparations.
(5) The competent authority must take the decision on the application for authorisation within a period of three months. Should the holder of an authorisation apply for a modification to the authorisation, the authority must reach the decision within a period of one month. In exceptional cases, the deadline will be extended by an additional two months. The applicant is to be notified thereof prior to the expiry of the deadline and notified of the grounds. If the authority gives the applicant pursuant to subsection (4) sentence 1 the opportunity to correct the flaws, the deadlines are interrupted until such flaws have been corrected or until the expiry of the deadline set pursuant to subsection (4) sentence 1. The interruption of the deadline begins on the day the applicant receives the request to correct the flaws.
(6) The holder of an authorisation must notify the competent authority in advance of any change in the information referred to in subsection (2) and must submit evidence thereof; the changes may be made only after receipt of a written authorisation from the competent authority. Any unforeseen change in the person responsible pursuant to section 20c must be notified immediately.
(7) The authorisation is to be withdrawn if it becomes known subsequently that one of the grounds for refusal pursuant to subsection (2) existed at the time the authorisation was granted. The authorisation is to be revoked if one of the grounds for refusal developed subsequently; the suspension of the authorisation may be ordered instead of its revocation. Subsection (1) sentence 3 applies accordingly. The competent authority may issue a provisional order mandating that the processing of tissues or tissue preparations be discontinued if the processor fails to furnish the evidence required for processing. If the processing of tissues or tissue preparations is terminated, the processor must ensure that stored tissue preparations and tissues continue to be stored in a quality-assured manner and are transferred to other manufacturers, processors or distributors in possession of an authorisation pursuant to subsection (1) or section 13 (1). This also applies to the information and data about the processing that is necessary for tracing these tissue preparations and tissues.

Section 20d
Exception from the obligation to obtain an authorisation for tissues and tissue preparations

An authorisation pursuant to section 20b (1) and section 20c (1) is not required by a person who is a physician and who performs the activities mentioned therein, with the exception of the placing on the market, in order to use the tissue or tissue preparation personally on their patient. This does not apply to medicinal products that are intended for clinical trials.

Division 4
Marketing authorisation of medicinal products

Section 21
Obligation to obtain a marketing authorisation

(1) Finished medicinal products may only be placed on the market within the purview of this Act if they have been authorised by the competent higher federal authority or if the European Community or the European Union has granted an authorisation for them to be placed on the market pursuant to Article 3 paragraph 1 or 2 of Regulation (EC) No. 726/2004. Sentence 1 also applies in conjunction with Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004 (OJ L 378 of 27.12.2006, p. 1, L 339 of 26.11.2014, p. 14), last amended by Regulation (EU) 2019/5 (OJ L 4 of 7.1.2019, p. 24) in conjunction with Regulation (EU) No. 536/2014 or in conjunction with Regulation (EC) No. 1394/2007.
(2) A marketing authorisation *(Zulassung)* is not required for medicinal products:

1. the essential manufacturing stages of which, owing to the documented frequency with which they are the subject of medical and dental prescriptions, are carried out in a pharmacy in an amount of up to one hundred packages ready for dispensing in the space of one day within the framework of the existing pharmacy operating licence,

1a. that are medicinal products manufactured from substances of human origin that are either intended for autologous use or for targeted administration to a specific person, or are prepared on prescription for individual persons, unless medicinal products pursuant to section 4 (4) are concerned,

1b. that are medicinal products other than those referred to in no. 1a that are manufactured for pharmacies that are in possession of a prescription for a patient for medicinal products authorised within the purview of this Act:

a) as cytostatic preparations or for parenteral nutrition, as well as in other medically justified cases of special need if it is necessary in order to provide adequate care for the patient and no other medicinal product with a marketing authorisation is available, or

b) as a blister from unmodified medicinal products, or

c) are decanted in an unmodified form,

1c. show antibacterial or antiviral efficacy and are intended for the treatment of a dangerous communicable disease – the spread of which renders necessary an immediate supply of specific medicinal products in excess of normal requirements – and are manufactured from active substances that have been stored for this purpose by Federal and Land health authorities, or agencies designated by them, provided that they are manufactured in a pharmacy for dispensing within the framework of the existing pharmacy operating licence of for dispensing to other pharmacies,

1d. are tissue preparations that are subject to the obligation to obtain an approval pursuant to the provisions contained in section 21a (1),

1e. are curative waters, moor muds for baths or other peloids that are not manufactured in advance and are not intended to be placed on the market in a specific packaging for sale to the consumer, or are intended exclusively for external use or for inhalation on the premises,

1f. are medicinal gases and are manufactured for individual persons from medicinal products authorised within the purview of this Act through filling and labelling in enterprises authorised pursuant to section 50 to conduct retail trade in medicinal products outside of pharmacies,

1g. are therapeutic allergens manufactured to order for individual patients,

2. are intended for clinical trials or

3. are made available free of charge under the conditions specified in Article 83 of Regulation (EC) No. 726/2004 for administration to patients with a seriously debilitating disease or whose disease is life-threatening and who cannot be treated satisfactorily with an authorised medicinal product; this applies equally to medicinal products that do not fall under the categories stipulated in Article 3 first or second paragraph of Council Regulation (EC) No. 726/2004; procedures are specified in an ordinance pursuant to section 80.

(3) The application for a marketing authorisation is to be made by the pharmaceutical entrepreneur. For a finished medicinal product manufactured in pharmacies or at other retail dealers using standardised procedures and distributed to the consumer under a standardised name, the application for a marketing authorisation is to be made by the party responsible for the issue of the master formula. If a finished medicinal product is manufactured for several pharmacies or other retail dealers and is to be distributed to the consumer under their name and under a standardised name, then the manufacturer must apply for the marketing authorisation.
(4) Furthermore, at the request of the competent authority of the Land, the competent higher federal authority decides on the obligation to obtain a marketing authorisation for a specific medicinal product, the obligation to obtain approval for a tissue preparation or a clinical trial, irrespective of an application for a marketing authorisation pursuant to subsection (3) or an application for approval pursuant to section 21a (1) or section 42 (2). The competent Land authority must include a reasoned opinion on the classification of the medicinal product or the clinical trial with the application.

Section 21a
Approval of tissue preparations

(1) Tissue preparations that are not manufactured using an industrial process and the essential processing procedures of which are sufficiently well known in the European Union, and the effects and adverse reactions of which are known and evident from scientific data, may only be placed on the market within the purview of this Act if they have been approved by the competent higher federal authority by way of derogation from the marketing authorisation obligations pursuant to section 21 (1). This also applies to tissue preparations the processing procedures for which are new but comparable with a known procedure. Sentence 1 applies accordingly to haematopoietic stem cell preparations derived from peripheral blood or umbilical cord blood intended for autologous use or for targeted administration to a specific person. The approval covers the procedures for the collection, processing and testing, the choice of donors and the documentation for each operational step as well as the quantitative and qualitative criteria for tissue preparations. Especially the critical operational steps are to be evaluated to ascertain that the functionality and the safety of the tissues are guaranteed.
(1a) An approval pursuant to subsection (1) is not required for tissue preparations that are intended for clinical trials.
(2) The application for approval is to be accompanied by the following information and documents to be supplied by the applicant:

1. the name or the company and the address of the applicant and the processors,

2. the name of the tissue preparation,

3. the components of the tissue preparation by type, pharmaceutical form and package size,

4. the therapeutic indications as well as the method of administration and, in the case of tissue preparations that are intended to be used for a limited period of time, the duration of the application,

5. Information on the collection of the tissue and on the laboratory testing necessary for such collection,

6. Information on the method of manufacture, including the processing procedures, the test procedures with their in-process and finished process controls, as well as the use of beta, gamma or x-rays,

7. Information on the method of preservation, shelf life, retention and storage conditions of the tissue preparations,

8. Information on the functionality and the risks of tissue preparations,

9. documents containing the results of microbiological, chemical, biological or physical examinations and the methods used in their determination, insofar as these documents are necessary,

10. documents containing the results of pharmacological and toxicological tests,

11. a risk-benefit assessment,

12. all of the information and documents that are relevant to the purpose of evaluation of the medicinal product, as well as

13. in the case of haematopoietic stem cell preparations, also information on the dosage and quantity of active substance.

The results and the information pursuant to sentence 1 nos. 7 to 10, as well as the results of clinical trials or other medical trials are to be documented in such a way that the type, scope and date of the tests are evident. Section 22 (4), (5) and (7) sentence 1 apply accordingly.
(3) In respect of the information pursuant to subsection (2) nos. 4, 8 and 10, scientific findings that are also able to compare with empirical medical findings prepared according to scientific methods can be submitted. These can include studies conducted by the manufacturer of the tissue preparation, data from publications or subsequent assessments of the clinical findings on the manufactured tissue preparations.
(4) The competent higher federal authority must reach a decision on the application for approval within a period of five months. If the applicant is given the opportunity to correct flaws, the deadlines are interrupted until such flaws have been corrected or until the expiry of the deadline set for the correction of the flaws. The interruption of the deadline begins on the day the applicant receives the request to correct the flaws.
(5) The competent higher federal authority grants approval in writing, together with an approval number. The authority may combine the approval with the imposition of conditions. Section 28 and section 34 apply accordingly.
(6) The competent higher federal authority may only refuse approval if:

1. the documents submitted are incomplete,

2. the tissue preparation does not correspond to the current state of scientific knowledge,

3. the tissue preparation does not fulfil the envisaged function or the risk-benefit balance is unfavourable, or

4. the placing of the tissue preparation on the market would violate legal regulations or a regulation, directive, decision or resolution by the European Community or the European Union.

(7) The applicant, or subsequent to the approval, the holder of the approval must immediately notify the competent higher federal authority of any changes in the information pursuant to subsections (2) and (3) and include the corresponding documents with the notification. The holder of the approval is required to inform the competent higher federal

authority of new or changed risks in connection with the tissue preparation or of changes in the tissue preparation's risk-benefit balance. Section 29 (1a), (1d) and (2) apply accordingly. The following changes may be made only if the competent higher federal authority has granted its approval:

1. a change in the information on the type, the duration of the administration, or the therapeutic indications,
2. a limitation of the risks,
3. a change in either the type or quantity of the excipients,
4. a change in the pharmaceutical form,
5. a change in the information on the collection of the tissue or on the laboratory testing necessary for such collection,
6. a change in the processing procedure or the test procedure,
7. a change in the method of preservation or an extension of the shelf life,
8. a change in the method of retention or storage of the tissue preparation, and
9. in the case of haematopoietic stem cell preparations, also a modification of the information on the dosage or the quantity of active substance.

The decision on the application for approval must be taken within three months. Section 27 (2) applies accordingly.
(8) The approval is to be withdrawn if it subsequently becomes known that one of the grounds for refusal pursuant to subsection (6) nos. 2 to 4 existed at the time the authorisation was granted. The authorisation is to be revoked if one of the grounds for refusal subsequently developed. In both cases, the temporary suspension of the approval may also be ordered. Before a decision is reached pursuant to sentences 1 to 3, the holder of the approval is to be heard unless danger is imminent. If the approval has been withdrawn, revoked or suspended, the tissue preparation may not be placed on the market, nor may it be introduced into the purview of this Act.
(9) By way of derogation from subsection (1), tissue preparations and haematopoietic stem cell preparations derived from peripheral blood or umbilical cord blood pursuant to subsection (1) sentence 3 that are allowed to be placed on the market in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area require an attestation from the competent higher federal authority before the first introduction into the purview of this Act for the purpose of being used. Before issuing the attestation, the competent higher federal authority must examine whether the processing of the tissue preparations meets the requirements with respect to the removal and processing procedures including the donor selection procedures and the laboratory examinations, and whether the quantitative and qualitative criteria for the tissue preparations meet the requirements of this Act and its ordinances. The competent higher federal authority must issue the attestation if the approval certificate or another attestation from the competent authority of the country of origin demonstrates the equivalence of the requirements pursuant to sentence 2 and the proof of approval in the Member State of the European Union or in another State Party to the Agreement on the European Economic Area is submitted. The competent higher federal authority is to be notified on time of any change in the requirements pursuant to sentence 2 prior to any further introduction of the tissue preparation into the purview of this Act. The attestation is to be withdrawn if one of the prerequisites pursuant to sentence 2 had not been met; it is to be revoked if one of the prerequisites pursuant to sentence 2 is subsequently no longer met. Section 73 (3a) applies accordingly.

Section 22
Marketing authorisation documents

(1) The applicant must attach the following information to his/her application for a marketing authorisation:

1. the name or the company and the address of the applicant and the manufacturer,
2. the name of the medicinal product,
3. the constituents of the medicinal product by type and quantity; section 10 (6) applies,
4. the pharmaceutical form,
5. the effects,
6. the therapeutic indications,
7. the contra-indications,
8. the adverse reactions,
9. the interactions with other products,
10. the dosage,
11. the medicinal product's method of manufacture,
12. the method of administration and, in the case of medicinal products that should only be administered for a limited period of time, the duration of the administration,
13. the package sizes,
14. the method of preservation, shelf life, storage conditions, results of stability tests,
15. the methods of quality control (test methods).

(1a) The information pursuant to subsection (1) nos. 1 to 10 must be provided in the German language, the other information in German or in English; other information or documents may also be provided or submitted in English instead of in German, within the framework of the marketing authorisation procedure, insofar as information for use in the labelling, the package leaflet or the expert information are not concerned.

(2) Furthermore, the following information is to be submitted:

1. the results of physical, chemical, biological or microbiological examinations and the methods used in their determination (analytical test),
2. the results of the pharmacological and toxicological tests,
3. the results of clinical trials or other medical and dental tests,
4. a statement to the effect that clinical trials conducted outside the European Union were conducted under ethical conditions that are equivalent to the ethical conditions laid down in Regulation (EU) No 536/2014,
5. a summarised description of the applicant's pharmacovigilance system, which must contain the following:

    a) evidence that the applicant has the services of a qualified person at his/her disposal pursuant to section 63a, as well as the Member State in which this person is domiciled and works and his/her contact information,

b) the name of the place where the pharmacovigilance system master file for the medicinal product in question is kept, and

c) a declaration signed by the applicant that he/she possesses the necessary funds in order to fulfil the tasks and obligations listed in Division 10,

5a. the risk management plan containing a description of the risk management system that the applicant will introduce for the medicinal product in question, together with a summary,

6. (repealed),

7. a copy of each orphan medicinal product designation pursuant to Regulation (EC) No. 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products (OJ L 18, p. 1), last amended by Regulation (EC) No. 596/2009 (OJ L 188 of 18.7.2009, p. 14),

8. a confirmation by the medicinal product manufacturer that he/she or another person designated by contract has satisfied him/herself, by means of an inspection on site, that good manufacturing practice is being applied in the manufacture of the active substances; the confirmation must also contain the date of the audit.

The results pursuant to sentence 1 nos. 1 to 3 are to be substantiated by documentary evidence in such a way that the type, scope and exact time of the tests are clearly evident. The application for a marketing authorisation is to be accompanied by all of the relevant information and documents necessary for the assessment of the medicinal product, whether favourable or unfavourable. This also applies to incomplete or discontinued toxicological or pharmacological tests or clinical trials carried out using the medicinal product in question.
(3) Instead of the results specified in subsection (2) sentence 1 nos. 2 and 3, other scientific documents may be presented:

1. in the case of a medicinal product which contains active substances that have been used for at least ten years in the European Union for general medical purposes, the effects and adverse reactions of which are known and evident from scientific data,

2. in the case of a medicinal product which, in its composition, is comparable to a medicinal product pursuant to no. 1,

3. for the constituents of the medicinal product, in the case of a medicinal product that is a new combination of constituents that are already known; however, other documents containing scientific findings may also be presented for the combination as such, if the efficacy and safety of the medicinal product according to its composition, dosage, pharmaceutical form and therapeutic indications can be determined by these documents.

Furthermore, the medical experience gained by the specific schools of therapy is also to be taken into consideration.
(3a) If the medicinal product contains more than one active substance, evidence is to be provided to prove that every active substance contributes to the positive assessment of the medicinal product.
(3b) In the case of radiopharmaceuticals that are generators, a general description of the system, including a detailed description of those components of the system that are able to influence the composition or quality of the secondary radioactive nuclide preparation, as well as the particular qualitative and quantitative characteristics of the eluate or the sublimate, are to be provided.
(3c) Documents should also be submitted for the evaluation of possible environmental risks and if the storage of the medicinal product or its administration or the disposal of its waste requires special safety precautions or measures to avoid endangering the environment or

impairing the health of human beings, animals or plants, this is also to be stated. Information on how to reduce these dangers is also to be submitted and substantiated.
(4) If an application is made for a marketing authorisation in respect of a medicinal product manufactured within the purview of this Act, proof must be furnished that the manufacturer is entitled to manufacture the medicinal product. This does not apply in the case of an application pursuant to section 21 (3) sentence 2.
(5) If an application is made for a marketing authorisation in respect of a medicinal product manufactured outside the purview of this Act, proof is to be furnished that the manufacturer is entitled to manufacture medicinal products in accordance with the legal regulations laid down by the country of manufacture and, in the event that the medicinal product is introduced from a country which is not a Member State of the European Union or a State Party to the Agreement on the European Economic Area, that the importer is in possession of an authorisation to introduce the medicinal product into the territory governed by this Act.
(6) If the medicinal product has already been granted a marketing authorisation in a foreign state, a copy of such authorisation and a copy of the summary of the safety data including the data from the periodic safety update reports, where available, and the reports on suspected adverse reactions are to be included. Where an application for a marketing authorisation has been denied in whole or in part, the details of that decision are to be furnished and the grounds for it explained. Where an application for a marketing authorisation is currently being examined in one or several Member States of the European Union, this is to be stated. Copies of the summaries of the product characteristics and package leaflets approved by the competent authorities of the Member States or, where these documents are not available, the versions of these documents proposed by the applicant in the course of a procedure pursuant to sentence 3, are also to be included. Furthermore, where an application for the recognition of the marketing authorisation of another Member State is submitted, the declarations required under Article 28 of Directive 2001/83/EC are to be submitted along with the other information stipulated therein. Sentence 5 does not apply to medicinal products that have been manufactured according to homeopathic manufacturing procedures.
(7) The application for a marketing authorisation is to be accompanied by the wording of the information that is meant to appear on the container, the outer packaging and the package leaflet as well as the draft of the Summary of Product Characteristics, which is also the expert information pursuant to section 11a (1) sentence 2, where such expert information is stipulated. In the case of medicinal products, the results of evaluations of the package leaflet conducted in collaboration with patient target groups are also to be submitted to the competent higher federal authority. The competent higher federal authority may require the submission of one or more samples or mock-ups of the sales presentation of the medicinal product, including the package leaflets, as well as starting materials, intermediate products and substances that are used in the manufacture or testing of the medicinal products, in a quantity sufficient to conduct the test and in a state suitable to the conduct of said test.

Section 23
(no longer applicable)

Section 24
Expert reports

(1) Expert reports in which the test methods and the test results are summarised and assessed must be included with the required documents pursuant to section 22 (1) no. 15, subsections (2) and (3). In particular, the following information must be included in detail in the expert reports presented:

1. the analytical expert report must state whether the medicinal product is of appropriate quality in accordance with recognised pharmaceutical rules, whether the proposed test methods comply with the prevailing standard of scientific knowledge and are suitable for quality assessment,

2. the pharmacological-toxicological expert report must state the medicinal product's toxic effects and pharmacological properties,

3. the clinical expert report must state whether the medicinal product has the required effect in the specified therapeutic indications, whether it is tolerated, whether the prescribed dosage is appropriate and which contra-indications and adverse reactions exist.

(2) Insofar as scientific documentation is presented pursuant to section 22 (3), it must be evident from the expert report that the documents on scientific findings were elaborated under analogous application of the Guidelines for the Testing of Medicinal Products.
(3) The expert report must be accompanied by information regarding the name, training and professional practice of the expert as well as his/her professional relationship with the applicant. The experts must confirm with their dated signature that they are the authors of the expert report.

Section 24a
Use of a previous applicant's documents

The applicant can refer to the documents referred to in section 22 subsections (2), (3) and (3c), including the expert report referred to in section 24 (1) sentence 2 submitted by an earlier applicant (previous applicant), if he/she submits the previous applicant's written agreement, including confirmation that the documents referred to meet the requirements of the Guidelines for the Testing of Medicinal Products pursuant to section 26. The previous applicant must respond to a request for agreement within a period of three months. A partial reference is not admissible.

Section 24b
Authorisation of a generic medicinal product, document protection

(1) In the case of a generic medicinal product within the meaning of subsection (2), reference can be made, without the previous applicant's agreement, to the documents referred to in section 22 (2) sentence 1 nos. 2 and 3, including the expert report referred to in section 24 (1) sentence 2 nos. 2 and 3 for the previous applicant's medicinal product (reference medicinal product), provided that the reference medicinal product has been authorised for at least eight years or was authorised at least eight years previously; this also applies to authorisation in another Member State of the European Union. A generic medicinal product authorised pursuant to this provision is not to be placed on the market until ten years have elapsed following the first authorisation of the reference medicinal product. The period referred to in sentence 2 will be extended to a maximum of eleven years if, during the first eight years of authorisation, the marketing authorisation holder obtains authorisation for one or more new therapeutic indications that during the scientific evaluation conducted prior to their authorisation by the competent higher federal authority are held to bring significant clinical benefit in comparison with existing therapies.
(2) Authorisation as a generic medicinal product pursuant to subsection (1) requires that the medicinal product in question has the same qualitative and quantitative composition of active substances and the same pharmaceutical form as the reference medicinal product and that the bioequivalence has been demonstrated in bioavailability studies. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance are considered to be one and the same active substance unless their properties differ significantly with regard to safety or efficacy. In such cases, the applicant must submit additional proof of the safety or efficacy of the different salts, esters, ethers, isomers, mixture of isomers, complexes or derivatives of the active substance. The various immediate release oral pharmaceutical forms are considered to be one and the same pharmaceutical form. The applicant is not required to submit bioavailability studies if he/she can otherwise demonstrate that the generic medicinal product meets the relevant bioequivalence criteria in accordance with current scientific knowledge. In cases where the medicinal product does not meet the requirements of a generic medicinal product or where the bioequivalence cannot be

demonstrated through bioequivalence studies or in the case of a change in the active substance, therapeutic indication, strength, pharmaceutical form or route of administration vis-à-vis the reference medicinal product, the results of appropriate preclinical tests or clinical trials are to be provided.
(3) If the reference medicinal product was not authorised by the competent higher federal authority but by the competent authority of another Member State, the applicant must indicate, in the application form, where the reference medicinal product is or has been authorised. In this case, the competent higher federal authority asks the competent authority of the other Member State to transmit within one month a confirmation that the reference medicinal product is or has been authorised, together with the full composition of the reference medicinal product and other documents relevant to the authorisation of the generic medicinal product. In the case where the reference medicinal product has been authorised by the European Medicines Agency, the competent higher federal authority asks the latter for the information and documents referred to in sentence 2.
(4) If the competent authority of another Member State where an application is submitted requests information or documents referred to in subsection (3) sentence 2 of the competent higher federal authority, the latter must respond to this request within one month, provided that at least eight years have elapsed since the reference medicinal product was first authorised.
(5) Where a biological medicinal product that is similar to a biological reference medicinal product does not meet the conditions for generic medicinal products referred to in subsection (2) owing to, in particular, differences relating to raw materials or differences between the manufacturing processes of the biological medicinal product and the reference biological medicinal product, the results of appropriate preclinical tests or clinical trials relating to these deviations are to be provided. The type and quantity of the supplementary data to be provided must comply with the relevant criteria according to current scientific knowledge. The results of other tests from the documents submitted for the reference medicinal product's authorisation are not to be provided.
(6) In addition to the provisions laid down in subsection (1), where an application is made for a new therapeutic indication for a known active substance that has been in general medical use for at least ten years in the European Union, a non-cumulative period of one year of data exclusivity is to be granted for the data gained from significant preclinical or clinical studies carried out in connection with the new therapeutic indication.

Section 24c
Additional requests

If several holders of a marketing authorisation have to be requested to submit additional documents, the competent higher federal authority notifies every holder of a marketing authorisation of the documents necessary for the further assessment as well as of the names and addresses of the other holders of a marketing authorisation who are involved. The competent higher federal authority gives those holders of the marketing authorisation who are involved the opportunity to decide among themselves as to who will submit the documents within a period of time to be determined by the authority. If an agreement is not reached, the competent higher federal authority decides and immediately informs all persons concerned. Unless the other holders of a marketing authorisation choose to forgo the marketing authorisation granted for their own pharmaceutical product, they are obliged to contribute proportionally to the expenditure incurred in the preparation of the documents, calculated according to the number of marketing authorisation holders involved; they are jointly and severally liable. Sentences 1 to 4 apply accordingly to persons using standard marketing authorisations, as well as in cases where documents with the same contents are requested from several applicants in ongoing marketing authorisation procedures.

Section 24d
General right of use

The competent higher federal authority is hereby empowered to utilise the documents submitted to it, with the exception of those referred to under section 22 (1) nos. 11, 14 and 15 as well as subsection (2) no. 1, and the expert report pursuant to section 24 (1) sentence 2 no. 1, in fulfilling its tasks under this Act, provided that at least eight years have elapsed since the medicinal product first received a marketing authorisation in one of the Member States of the European Union or a procedure pursuant to section 24c has not yet been terminated, or insofar as sections 24a and 24b do not contain more special provisions for referring to the documents of a previous applicant.

Section 25
Decision on the marketing authorisation

(1) The marketing authorisation, together with a marketing authorisation number, is issued in writing by the competent higher federal authority. The marketing authorisation is only applicable to the medicinal product specified in the marketing authorisation notice and, in the case of medicinal products manufactured according to homeopathic manufacturing procedures, it also applies to the degree of dilution specified in results published pursuant to section 25 (7) sentence 1 of the version in force prior to 17 August 1994 and specified in the marketing authorisation notice.
(2) The competent higher federal authority may only refuse to grant the marketing authorisation if:

1. the documents submitted, including such documents as are to be submitted pursuant to a regulation of the European Community or the European Union, are incomplete,

2. the medicinal product has not been sufficiently tested in accordance with the confirmed state of scientific knowledge or the other scientific information material referred to in section 22 (3) does not correspond to the confirmed state of scientific knowledge,

3. the medicinal product is not manufactured in accordance with recognised pharmaceutical rules or does not meet appropriate quality standards,

4. the therapeutic efficacy attributed to the medicinal product by the applicant is lacking or is insufficiently substantiated by the applicant in accordance with the confirmed state of scientific knowledge,

5. the benefit/risk profile is unfavourable,

5a. in the case of a medicinal product containing more than one active substance, insufficient grounds are provided to demonstrate that each active substance contributes towards a positive assessment of the medicinal product, whereby the special features of the particular medicinal product should be considered in a risk evaluation,

6. the placing of the medicinal product on the market would violate legal regulations or a regulation, directive, decision or resolution by the European Community or the European Union.

The marketing authorisation may not be refused pursuant to sentence 1 no. 4, because therapeutic results have been achieved in only a limited number of cases. Therapeutic efficacy is lacking if the applicant fails to prove, according to the confirmed state of scientific knowledge at the time, that a therapeutic effect can be produced with the medicinal product. Medical experience in the particular therapeutic field is to be considered.
(3) The marketing authorisation is to be refused for a medicinal product which differs, in the type or the quantity of its active substances, from a medicinal product bearing the same name that has been authorised for marketing or is already on the market. Deviating from sentence 1, a difference in the quantity of active substances is harmless if the medicinal products differ in their pharmaceutical form.

(4) If the competent higher federal authority is of the opinion that a marketing authorisation cannot be granted on the basis of the documents submitted, it notifies the applicant, stating reasons. The applicant is then to be given the opportunity to correct the flaw within an appropriate deadline, which may not exceed six months. In the event that the flaws are not corrected within this deadline, the marketing authorisation is to be refused. After the decision has been taken to refuse the marketing authorisation, the submission of documents in order to correct flaws is not allowed.
(5) The marketing authorisation is to be granted based on the examination of the documents submitted and on the expert reports. In assessing the documents, the competent higher federal authority may utilise its own scientific results, call in experts or request expert reports. The competent higher federal authority may examine authorisation-related data and documents, also in connection with a marketing authorisation pursuant to Article 3 paragraph 1 or 2 of Regulation (EC) No. 726/2004, in enterprises and facilities that develop, manufacture, test or clinically investigate medicinal products. For this purpose, persons commissioned by the competent higher federal authority, in consultation with the respective competent authorities, may enter the operating and business premises during usual business hours to inspect documents and request information. Moreover, in making a decision in respect of the marketing authorisation, the competent higher federal authority is also entitled to have the documents assessed by independent counter-experts and applies the results of their evaluation in deciding on the marketing authorisation and, insofar as medicinal products that are subject to mandatory prescription under section 48 (2) sentence 1 no. 1 are concerned, as a basis for the draft of the marketing authorisation decision that is to be submitted to the marketing authorisation commission pursuant to subsection (6) sentence 1. The competent higher federal authority may commission, as a counter-expert pursuant to sentence 5, any person who possesses the requisite expert knowledge and the reliability required to do the work of a counter-expert. Upon request, the applicant is to be permitted to peruse the expert reports. If the applicant requires that experts be called in whom he/she himself/herself selects, these persons are also to be heard. Subsection (6) sentences 5 and 6 apply accordingly for the appointment of experts and counter-experts.
(5a) The competent higher federal authority also prepares an assessment report on the quality, safety and efficacy documents submitted and makes a statement on the findings of pharmaceutical and pre-clinical tests, clinical trials, as well as on the risk management and the pharmacovigilance system. The assessment report is to be updated if any new information becomes available.
(5b) Subsection (5a) does not apply to medicinal products that have been manufactured according to homeopathic manufacturing procedures insofar as these medicinal products are subject to Article 16 paragraph 2 of Directive 2001/83/EC.
(6) Prior to the decision on the marketing authorisation of a medicinal product that is attributed to the phytotherapy, homeopathy or anthroposophy schools of therapy and which is subject to prescription pursuant to section 48 (2) sentence 1 no. 1, a marketing authorisation commission is to be consulted. The hearing covers the contents of the documents presented, the expert reports, the reports requested, the comments of the experts summoned, the result of the tests and the reasons which played an essential role in the decision taken on the marketing authorisation or the assessment of the counter-experts. Should the higher federal authority diverge from the result of the hearing in deciding on the application, it must set forth its reasons for doing so. The Federal Ministry appoints the members of the marketing authorisation commission, taking into account the proposals of the chambers of the medical professions, the professional societies of medical practitioners, dentists, pharmacists, alternative practitioners, as well as the main central associations of the pharmaceutical entrepreneurs, patients and consumers responsible for representing their interests. In appointing the commission’s members, consideration is to be given to the individual peculiarities of the medicinal products. The experts to be appointed to the marketing authorisation commission are persons who possess scientific knowledge and

have gained practical experience in the specific therapeutic indications as well as in the school of therapy in question (phytotherapy, homeopathy, anthroposophy).
(7) For medicinal products not subject to prescription pursuant to section 48 (2) sentence 1 no. 1, commissions are set up for specific therapeutic indications or schools of therapy at the competent higher federal authority. Subsection (6) sentences 4 to 6 apply accordingly. In preparing the decision regarding the extension of marketing authorisations pursuant to section 105 (3) sentence 1, the competent higher federal authority may involve the competent commission. If the decision pursuant to sentence 3 affects medicinal products from a specific school of therapy (phytotherapy, homeopathy, anthroposophy), the competent commission is to be involved if the intention is to refuse the extension pursuant to section 105 (3) sentence 1 entirely, or if the decision is of fundamental importance; the competent commission must be afforded a period of two months within which to respond. In cases where the competent higher federal authority does not take the comments of the commission into account in making its decision under sentence 4, it sets forth its reasons for not doing so.
(7a) In order to improve the safety of medicinal products for children and young people, a Commission on Medicinal Products intended for Children and Young People is to be set up at the Federal Institute for Drugs and Medical Devices. Subsection (6) sentences 4 to 6 apply accordingly. In preparing the decision regarding an application for a marketing authorisation for a medicinal product that is also intended for use in children and young people, the competent higher federal authority involves said commission. Furthermore, the competent higher federal authority is entitled to involve the commission when preparing a decision regarding an application for a marketing authorisation of a medicinal product, other than that specified in sentence 3, for which the administration to children or young people is envisaged. The commission has the opportunity to issue a report. In cases where the competent higher federal authority does not take the commission’s opinion into account in making its decision, it sets forth its reasons. Furthermore, in the case of medicinal products that have not been authorised for administration to children and young people, the commission may establish the prerequisites for their administration to children and young people in accordance with recognised scientific principles. In the case of medicinal products from the phytotherapeutic, homeopathic and anthroposophic schools of medicine, the tasks and authority conferred by sentences 3 to 7 are assumed by the commissions pursuant to subsection (7) sentence 4.
(8) In the case of sera, vaccines, blood preparations, tissue preparations, allergens, xenogeneic medicinal products that are not medicinal products pursuant to section 4 (9), the competent higher federal authority grants the marketing authorisation either on the basis of an examination of the documents submitted, its own tests or based on observation of the tests carried out by the manufacturer. For this purpose, persons commissioned by the competent higher federal authority, in consultation with the respective competent authorities, may enter the operating and business premises during usual business hours and carry out inspections, both of said premises and of the company’s means of transport. At the request of the competent higher federal authority, the applicant must submit information on the manufacturing process. Subsections (6), (7) and (7a) do not apply to these medicinal products.
(9) If an application is submitted for different strengths, pharmaceutical forms, administration routes or presentations of a medicinal product, at the applicant’s request, these can be the subject of a uniform comprehensive marketing authorisation; this also applies to subsequent amendments and extensions. This requires a uniform authorisation number to which further codes must be added to allow differentiation between the different pharmaceutical forms or concentrations. For authorisations pursuant to section 24b (1), individual authorisations of a reference medicinal product are regarded as a uniform comprehensive authorisation.
(10) The marketing authorisation is without prejudice to the pharmaceutical entrepreneur’s penal or civil liability.

Section 25a
Prior examination

(1) The competent higher federal authority can have the application for a marketing authorisation examined by independent experts to determine whether it is complete and whether the medicinal product has been sufficiently tested according to the current, recognised state of scientific knowledge. Section 25 (6) sentence 5 applies accordingly.
(2) Should flaws within the meaning of subsection (1) be identified, the expert must grant the applicant an opportunity to correct such flaws within a period of three months.
(3) If, on the basis of the final opinion delivered by the expert, the application for a marketing authorisation continues to be incomplete or flawed within the meaning of section 25 (2) sentence 1 no. 2 after the deadline has passed, the marketing authorisation is to be refused. Section 25 (4) and (6) does not apply to the prior examination.
(4) If the competent higher federal authority establishes that an identically worded marketing authorisation application is being reviewed in another EU Member State, it rejects the application and informs the applicant that a procedure pursuant to section 25b applies.
(5) If the competent higher federal authority referred to in section 22 is informed that an application relates to a medicinal product already authorised in another EU Member State, it rejects the application unless said application was submitted pursuant to section 25b.

Section 25b
Mutual-recognition procedure and decentralised procedure

(1) If the applicant is applying for a marketing authorisation or authorisation in more than one EU Member State, the applicant must submit an application based on identical documents in these Member States; this can be worded in English.
(2) If the medicinal product has already been approved or given a marketing authorisation in another EU Member State when the application is submitted, this marketing authorisation is to be recognised on the basis of the assessment report sent by this State, unless there is reason to believe that the authorisation of the medicinal product represents a serious risk to public health. In this case, the competent higher federal authority must proceed pursuant to Article 29 of Directive 2001/83/EC.
(3) If the medicinal product does not have a marketing authorisation at the time of the application, the competent higher federal authority, provided that it is a reference Member State within the meaning of Article 28 of Directive 2001/83/EC, must prepare drafts of the assessment report, the summary of the product characteristics of the medicinal product, the labelling and package leaflet and transmit them to the competent Member States and to the applicant. Section 25 (5) sentence 5 applies accordingly.
(4) With regard to recognition of the marketing authorisation granted by another Member State of the European Union, Chapter 4 of Directive 2001/83/EC applies.
(5) In the case of a divergent decision with regard to the marketing authorisation, its suspension or revocation, Articles 30, 32, 33 and 34 of Directive 2001/83/EC apply. In the case of a decision pursuant to Article 34 of Directive 2001/83/EC, a decision about the marketing authorisation is to be reached based on the decision taken or the resolution adopted pursuant to this Article by the European Community or the European Union. No preliminary procedure pursuant to section 68 of the Rules of the Administrative Courts is held in the event of an appeal against decisions by the competent higher federal authorities pursuant to sentence 2. In addition, section 25 (6) does not apply.
(6) Subsections (1) to (5) do not apply to medicinal products that have been manufactured according to homeopathic manufacturing procedures insofar as these medicinal products are subject to Article 16 paragraph 2 of Directive 2001/83/EC.

Section 25c
Measures taken by the competent higher federal authority on decisions or resolutions of the European Community or the European Union

The competent higher federal authority takes the necessary measures to implement decisions or resolutions adopted by the European Community or the European Union pursuant to Article 127a of Directive 2001/83/EC.

Section 26
Guidelines for the testing of medicinal products

(1) The Federal Ministry is empowered, with the approval of the Bundesrat, to regulate by ordinance the requirements for the information, documents and expert reports specified in sections 22 to 24, also in conjunction with section 38 (2) and section 39b (1), as well as for their examination by the competent higher federal authority. The regulations must comply with the prevailing state of scientific knowledge and are to be continually adjusted to it; animal tests, in particular, are to be replaced by other test methods if this is reasonable in the light of the state of scientific knowledge and considering the purpose of the test. The ordinance is issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, insofar as radiopharmaceuticals or medicinal products in the manufacture of which ionising radiation is used are concerned or insofar as tests for ecotoxicity are concerned.
(2) The competent higher federal authority and the commissions specified in section 25 (7) must apply the Guidelines for the Testing of Medicinal Products analogously to the documents on scientific findings specified in section 22 (3), whereby consideration is to be given to the peculiarities of the individual medicinal product. Documents on empirical medical findings prepared in accordance with scientific methods are also deemed to be documents on scientific findings.

Section 27
Deadlines for the granting of marketing authorisations

(1) The competent higher federal authority must reach its decision on the application for a marketing authorisation within a period of seven months. The decision on the recognition of a marketing authorisation is to be taken within a period of three months following receipt of the assessment report. An assessment report is to be drawn up within a period of three months.
(2) If the competent higher federal authority gives the applicant the opportunity to correct the flaws pursuant to section 25 (4), the deadlines are interrupted until the flaws are corrected or until the deadline set pursuant to section 25 (4) has expired. The interruption of the deadline begins on the day the applicant receives the request to correct the flaws. The same applies to the deadline granted to the applicant, at his/her request, for the purpose of giving his/her opinion, including the calling in of experts.
(3) In the case of procedures pursuant to section 25b (3), the period for completion of the procedure is extended by three months, pursuant to the provisions contained in Article 28 of Directive 2001/83/EC.

Section 28
Power to impose conditions

(1) The competent higher federal authority may combine the marketing authorisation with the imposition of conditions. In the case of conditions imposed pursuant to subsections (2) to (3d) for the protection of the environment, the competent higher federal authority decides, in agreement with the Federal Environmental Agency, if the impact on the environment is to be evaluated. For this purpose, the competent higher federal authority transmits the data and documents necessary for its evaluation of the environmental impact to the Federal Environmental Agency. Conditions may also be imposed subsequently.
(2) The conditions specified in subsection (1) may be imposed in order to ensure that:

1. the labelling of the containers and outer packaging complies with the regulations laid down in section 10; in this connection, it may be prescribed that the following details are given:

a) instructions or warnings, insofar as they are necessary to prevent a direct or indirect hazard to human health by administration of the medicinal product,

b) keeping instructions for the consumer and storage instructions for experts, insofar as they are deemed necessary in order to maintain the required medicinal product quality,

2. the package leaflet complies with the regulations laid down in section 11; in this connection it may be prescribed that the following details must be given:

a) the instructions or warnings specified in no. 1 letter a and

b) keeping instructions for the consumer, insofar as they are deemed necessary in order to maintain the required medicinal product quality,

2a. the expert information complies with the provisions of section 11a; in this connection it may be stipulated that the following details must be given:

a) the instructions or warnings specified in no. 1 letter a,

b) particular storage and keeping instructions, insofar as they are deemed necessary to maintain the required medicinal product quality,

c) references to conditions pursuant to subsection (3),

3. the details given pursuant to sections 10, 11 and 11a comply with the documents submitted for the marketing authorisation and that, in this connection, standardised and generally comprehensible terms as well as a standardised wording, also in keeping with the recommendations and opinions of the committees of the European Medicines Agency, are used, whereby the provision of information regarding additional contra-indications, adverse reactions and interactions remains admissible; the competent higher federal authority may generally make use of this authority for reasons of medicinal product safety, transparency or to ensure a rational method of working; in this connection, provisions may be imposed prescribing that certain therapeutic indications be omitted in respect of prescription-only medicinal products, if there is reason to fear that by giving such details, the therapeutic aim will be jeopardised,

4. the medicinal product is placed on the market in package sizes appropriate to the therapeutic indications and the envisaged duration of administration,

5. the medicinal product is placed on the market in a container of a particular form with a specific seal or some other kind of safety measure, insofar as it is deemed necessary to guarantee compliance with the dosage instructions or to prevent the danger of misuse by children.

(2a) Warnings pursuant to subsection (2) can also be stipulated so as to ensure that the medicinal product is only prescribed by physicians with a certain speciality and administered only under their supervision or in clinics or special clinics, or in collaboration with such institutions, where necessary, so as to avoid any direct or indirect danger to the health of human beings in its administration, especially when the administration of the medicinal product appears to be completely safe only in the presence of special knowledge or in special therapeutic facilities.

(3) Furthermore, the competent higher federal authority may impose conditions prescribing that additional analytical and pharmaceutical-toxicological tests or clinical trials are to be carried out and a report be submitted on the results if there is sufficient indication that the medicinal product can have a high therapeutic value and that, therefore, it is in the public interest to have the medicinal product introduced onto the market forthwith, even though further important details are still required to facilitate a comprehensive assessment of the

same. The competent higher federal authority reviews the findings of these tests and trials on an annual basis.
(3a) The competent higher federal authority may, in granting the marketing authorisation, also impose that:

1. specific measures contained in the risk management system be taken to ensure the safe use of the medicinal product if it is necessary in the interest of medicinal product safety,

2. post-authorisation safety studies must be conducted if this is in the interest of medicinal product safety,

3. obligations regarding the recording or reporting of suspected adverse reactions that go beyond those listed in Division 10 be observed if this is necessary in the interest of medicinal product safety,

4. other necessary measures regarding the safe and effective use of the medicinal product be taken if this is necessary in the interest of medicinal product safety,

5. an appropriate pharmacovigilance system be introduced if this is necessary in the interest of medicinal product safety,

6. where reservations exist regarding individual aspects of the efficacy of the medicinal product that can only be dispelled after its placing on the market, post-authorisation efficacy studies be conducted in keeping with the requirements stipulated in Article 21a first sentence point (f) of Directive 2001/83/EC.

(3b) The competent higher federal authority may, after granting the marketing authorisation, also impose conditions requiring that:

1. a risk management system and a risk management plan is introduced if this is in the interest of medicinal product safety,

2. post-authorisation safety studies must be conducted if this is in the interest of medicinal product safety,

3. a post-authorisation efficacy study must be conducted if findings regarding the disease or the clinical methodology indicate that earlier efficacy evaluations need to be significantly revised; the obligation to conduct this post-authorisation efficacy study subsequent to the granting of the marketing authorisation must be in keeping with the requirements stipulated in Article 22a (1) point (b) second sentence of Directive 2001/83/EC.

Should the prerequisites for the imposition of conditions pursuant to sentence 1 no. 2 exist for more than one medicinal product, and should these medicinal products be authorised for marketing in several Member States, the competent higher federal authority advises the marketing authorisation holders affected to conduct a joint post-authorisation safety study after consulting the Pharmacovigilance Risk Assessment Committee pursuant to Article 56 (1) (aa) of Regulation (EC) No. 726/2004.
(3c) Furthermore, the competent higher federal authority may impose conditions prescribing that, in the manufacture and control of such medicinal products and their starting materials that are of biological origin or are manufactured using biotechnology,

1. specific requirements have to be fulfilled and specific measures and procedures implemented,

2. documents have to be submitted substantiating the suitability of specific measures and procedures, including documents bearing on validation,

3. the introduction or modification of specific requirements, measures or procedures requires the prior approval of the competent higher federal authority,

insofar as this is deemed necessary to ensure adequate quality or to prevent risks. The conditions imposed are immediately enforceable. The lodging of an objection and action to rescind have no suspensive effect.
(3d) (repealed),
(3e) (repealed),
(3f) In the case of conditions pursuant to subsections (3), (3a) and (3b), the competent higher federal authority can stipulate the type, scope and duration of the studies or tests, as well as activities, measures and evaluations within the framework of the risk management system. The results are to be documented in such a way as to show the type, scope and date of the studies or tests.
(3g) The holder of a marketing authorisation for medicinal products must include all of the conditions pursuant to subsections (3), (3a) and (3b) in his/her risk management system. The competent higher federal authority informs the European Medicines Agency of the marketing authorisations it has granted subject to conditions pursuant to subsections (3), (3a) and (3b).
(3h) The competent higher federal authority can impose appropriate measures to improve the identifiability of adverse reaction reporting in the case of biological medicinal products.
(4) Should the marketing authorisation be subject to a condition, the deadline envisaged in section 27 (1) is interrupted until the deadline granted to the applicant for comment has expired. Section 27 (2) applies accordingly.

Section 29
Obligation to notify, renewal of the marketing authorisation

(1) The applicant must notify the competent higher federal authority forthwith, attaching the corresponding documents, in the event of any changes in the information or documents referred to in sections 22 to 24a and 25b. The marketing authorisation holder must comply with the requirement referred to in sentence 1 once the marketing authorisation has been granted.
(1a) The marketing authorisation holder must notify the competent higher federal authority immediately of all prohibitions or restrictions by the competent authorities of each country where the medicinal product in question is placed on the market and of all other new information that could affect the assessment of the benefit and risks of the medicinal product in question. In the case of medicinal products, this information includes both positive and negative results of clinical trials or other studies that may refer to all indications and population groups and not only to those specified in the marketing authorisation, as well as information regarding the use of the medicinal product beyond the terms of the marketing authorisation. The marketing authorisation holder must also submit to the competent higher federal authority, upon request, all information and documents demonstrating that the risk-benefit balance is still favourable. The competent higher federal authority can request a copy of the pharmacovigilance system master file at any time. The marketing authorisation holder must submit the pharmacovigilance system master file at the latest seven days after receiving the request. Sentences 1 to 3 do not apply to the parallel importer.
(1b) The marketing authorisation holder must notify the competent higher federal authority immediately of the date on which the medicinal product is to be placed on the market, taking into consideration the different pharmaceutical forms and strengths authorised.
(1c) The marketing authorisation holder must notify the competent higher federal authority in compliance with sentence 2 in the event of temporary or permanent cessation of the marketing of the medicinal product. Notification must be submitted at least two months before the suspension of marketing. This does not apply in the event of circumstances over which the marketing authorisation holder has no control.

(1d) The marketing authorisation holder must submit all sales data for the medicinal product as well as all data available on prescription levels if the competent higher federal authority requests them for reasons of medicinal product safety.
(1e) The marketing authorisation holder must notify the competent higher federal authority of the changed frequency and dates for the submission of the periodic safety update reports within the procedure pursuant to Article 107c paragraph 4, 5 or 6 of Directive 2001/83/EC. Changes in the dates or frequencies given in the manufacturing authorisation, arising from sentence 1, become effective six months after their publication on the European internet portal.
(1f) In the case of medicinal products, the marketing authorisation holder is required to inform the competent higher federal authority and the European Medicines Agency of new or changed risks or of changes in the medicinal products' risk-benefit balance.
(1g) The holder of a marketing authorisation for medicinal products must notify the competent higher federal authority immediately of the grounds for temporarily or permanently ceasing to market or recalling the medicinal product, renouncing or failing to apply for the extension of the marketing authorisation. In particular, the marketing authorisation holder must explain whether the measure pursuant to sentence 1 is based on one of the grounds listed in section 25 (2) sentence 1 nos. 3, 4 or no. 5, section 30 (2) sentence 1 no. 1 or section 69 (1) sentence 2 no. 4 or no. 5. The notification pursuant to sentence 1 is also to be made if the measure is taken in a third country and is based on one of the grounds pursuant to sentence 2. If a measure pursuant to sentence 1 or sentence 3 is based on one of the grounds listed in sentence 2, the marketing authorisation holder must also notify the European Medicines Agency thereof.
(2) In the case of a change in the name of the medicinal product, the marketing authorisation notice is to be amended accordingly. A pharmaceutical entrepreneur may place the medicinal product on the market under its current name for a further period of one year, wholesalers and retailers for a further period of two years, beginning on the following 1 January or 1 July after the promulgation of the change in the Federal Gazette.
(2a) A change:

1. in the information pursuant to sections 10, 11 and 11a bearing on the dosage, type or duration of the administration, the therapeutic indications, if it does not concern an addition or modification of an indication that is to be classified under another area of therapy, a limitation of the contra-indications, adverse reactions or interactions with other substances,

2. in the active substances, excluding the medically active constituents,

3. in a pharmaceutical form that is comparable with the one authorised for marketing,

3a. in treatment with ionising radiation,

4. in the context of considerable changes in the manufacturing process, the pharmaceutical form, specification or impurity profile of the active substance or the medicinal product that can have a clear effect on the quality, safety or efficacy of the medicinal product, as well as any changes in manufacturing procedures using genetic engineering technology; in the case of sera, vaccines, preparations derived from blood and allergens, every change in the manufacturing or test procedures or the indication of a longer shelf life, as well as

5. the package size,

may be made only if the competent higher federal authority has granted its approval. The approval is deemed to be granted if no objection to the change has been filed within a period of three months.
(2b) By way of derogation from subsection (1), the:

1. the closure of a location used in the manufacture if the medicinal product or its active substance or for its packaging or batch release,

2. any minor changes to an approved physico-chemical test procedure if the appropriate validation studies can demonstrate that the updated test procedure is at least equivalent to the former test procedure,

3. changes to the specification of an active substance or other substances used in the manufacture of medicinal products in order to comply with a monograph of the pharmacopoeia if the change is made exclusively to comply with the pharmacopoeia and the specifications for product specific properties remain unchanged,

4. changes to the packaging material if the latter does not come into contact with the medicinal product and the delivery, use, safety or stability of the medicinal product is demonstrably not affected, or

5. changes in the context of the tightening of specification limits where the change is not a consequence of any commitment from previous assessments to review specification limits and does not result from unexpected events arising during manufacture.

may be reported to the competent higher federal authority within twelve months following their introduction.
(3) In the following cases an application is to be made for renewal of the marketing authorisation for a medicinal product:

1. in the case of a change in the composition of the active substances either in type or quantity,

2. in the case of a change in the pharmaceutical form, insofar as a change pursuant to subsection (2a) sentence 1 no. 3 is not concerned,

3. where the therapeutic indications are broadened, insofar as a change pursuant to subsection (2a) sentence 1 no. 1 is not concerned, and

3a. in the case of the introduction of manufacturing procedures using genetic engineering.

The competent higher federal authority decides on the obligation to obtain a marketing authorisation pursuant to sentence 1.
(4) Subsections (1), (1a) sentences 4 and 5 subsections (1e) to (1g), (2), (2a) to (3) are not applicable to medicinal products that have been granted a marketing authorisation by the European Community or the European Union. For such medicinal products, the obligations of the pharmaceutical entrepreneur are those stipulated in Regulation (EC) No. 726/2004 on condition that, within the purview of this Act, an obligation on the part of the relevant competent higher federal authority to notify or to inform the Member States exists.
(5) Subsections (2a) to (3) do not apply to medicinal products governed by Commission Regulation (EC) No. 1234/2008 of 24 November 2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products (OJ L 334 of 12.12.2008, p. 7) in the latest applicable version. Subsections (2a) to (3) apply to:

1. homeopathic medicinal products that are subject to authorisation and were authorised before 1 January 1998 or were deemed to be authorised,

2. the blood preparations listed in Article 3 (6) of Directive 2001/83/EC, and

3. tissue preparations authorised pursuant to section 21, unless they are manufactured by a method involving an industrial process.

Section 30
Withdrawal, revocation, suspension

(1) A marketing authorisation is to be withdrawn if it becomes subsequently known that one of the grounds for refusal of marketing authorisations as defined in section 25 (2) sentence 1 nos. 2, 3, 5, 5a or 7 existed at the time of issuance; the marketing authorisation is to be revoked if one of the grounds for refusal pursuant to section 25 (2) sentence 1 nos. 3, 5, 5a or 7 has subsequently developed. Furthermore, the marketing authorisation is to be withdrawn or revoked if:

1. it comes to light that the medicinal product is lacking in therapeutic efficacy,

2. in the cases referred to in section 28 (3), the therapeutic efficacy has not been sufficiently proved according to the prevailing standard of scientific knowledge.

Therapeutic efficacy is lacking if it is clear that no therapeutic results can be achieved with the medicinal product. In the cases referred to in sentence 1, the suspension of the marketing authorisation may also be ordered for a limited period of time.
(1a) Furthermore, the authorisation may be partially or fully withdrawn or revoked if necessary to comply with a decision or resolution by the European Community or the European Union pursuant to Article 34 of Directive 2001/83/EC. No preliminary procedure pursuant to section 68 of the Rules of the Administrative Courts is held in the event of an appeal against decisions by the competent higher federal authority pursuant to sentence 1. In the cases referred to in sentence 1, the suspension of the marketing authorisation may also be ordered for a limited period of time.
(2) The competent higher federal authority may:

1. withdraw the marketing authorisation if incorrect or incomplete information has been given in the documents specified in section 22 or section 24,

2. revoke the marketing authorisation if the grounds for refusal as defined in section 25 (2) sentence 1 no. 2 subsequently developed or if one of the conditions imposed pursuant to section 28 has not been met and the flaw has not been corrected within a reasonable period of time that is to be specified by the competent higher federal authority; in this regard, the conditions referred to in section 28 (3) and (3a) should be reviewed annually,

3. revoke the marketing authorisation in consultation with the competent authority if the quality tests specified for the medicinal product are either not carried out at all or are not carried out adequately,

4. revoke the marketing authorisation in consultation with the competent authority if it becomes apparent that the medicinal product was not manufactured in accordance with recognised pharmaceutical rules.

In these cases, the suspension of the marketing authorisation may also be ordered for a limited period of time.
(2a) In the cases referred to in subsections (1) and (1a), the marketing authorisation is to be amended if, as a result, the reason for rejection referred to in subsection (1) becomes inapplicable, or in order to comply with the decision referred to in subsection (1a). In the cases referred to in subsection (2), the marketing authorisation can be amended by imposing a condition if this is sufficient to comply with the requirements of medicinal product safety.
(3) Before a decision is reached pursuant to subsections (1) to (2a), the holder of the marketing authorisation must be heard, unless danger is imminent. This also applies if a decision by the competent higher federal authority on changes to the authorisation, conditions for the authorisation, the withdrawal or the suspension of the authorisation is based on an agreement by the co-ordination group pursuant to Article 107g, 107k or Article 107q of Directive 2001/83/EC. A preliminary procedure pursuant to section 68 of the Rules of the Administrative Courts does not take place in the cases referred to in sentence 2. In the

cases set forth in section 25 (2) sentence 1 no. 5, the decision can be implemented immediately. The lodging of an objection and action to rescind have no suspensive effect.
(4) If the marketing authorisation of a medicinal product has been withdrawn or revoked or if the marketing authorisation has been suspended, the medicinal product:

1. may neither be placed on the market,

2. nor may it be introduced into the purview of this Act.

It is permitted to return the medicinal product, appropriately marked, to the pharmaceutical entrepreneur. The competent authority may order the return of a medicinal product.

Section 31
Expiry, extension

(1) The marketing authorisation expires:

1. if the authorised medicinal product is not placed on the market within three years of the granting of the marketing authorisation, or if the authorised medicinal product that was placed on the market in accordance with the marketing authorisation is not placed on the market for three successive years,

2. by written renouncement,

3. five years after it was granted unless an application for the extension of the marketing authorisation is submitted to the competent higher federal authority not less than nine months before expiry of the term.

3a. (repealed),

4. if the extension of the marketing authorisation is refused.

In the cases referred to in sentence 1 no. 1, the competent higher federal authority can allow exceptions if required to protect health.
(1a) A marketing authorisation that is extended is valid for an unspecified period unless, in the case of extension pursuant to subsection (1) sentence 1 no. 3, the competent higher federal authority considers it necessary to grant an extension of a further five-year period pursuant to the provisions of subsection (1) sentence 1 no. 3, in conjunction with subsection (2), also taking into account the exposure of an insufficient number of patients to the medicinal product in question, in order to ensure the continued safe placing of the medicinal product on the market.
(2) The application for extension is to be supplemented by a report giving details of whether, and to what extent, the criteria by which the medicinal product is assessed have altered over the previous five years. To this end, the marketing authorisation holder must submit to the competent higher federal authority a revised version of the quality, safety and efficacy documents including all amendments made since the marketing authorisation was granted.
(3) The marketing authorisation in the cases referred to in subsection (1) sentence 1 no. 3 or subsection (1a) is to be extended based on an application pursuant to subsection (2) sentence 1 for a further five years within the six months prior to its expiry, on condition that none of the grounds for refusal pursuant to section 25 (2) sentence 1 nos. 3, 5, 5a or 6 exist, that the marketing authorisation is not to be withdrawn or revoked pursuant to section 30 (1) sentence 2 and that no use is to be made of the possibility of withdrawal pursuant to section 30 (2) no. 1 or of revocation pursuant to section 30 (2) no. 2. Section 25 (5) sentence 5 and subsection (5a) apply accordingly. In respect of the decision regarding extension, it is to be verified whether findings exist that could influence the subordination of the medicinal product to the prescription requirement.
(4) If the marketing authorisation expires pursuant to subsection (1) no. 2 or 3, the medicinal product may be placed on the market for a further two years, commencing on the 1 January or 1 July following the promulgation of the expiry pursuant to section 34. This does not apply

if the competent higher federal authority ascertains that a condition for the withdrawal or the revocation of the marketing authorisation as defined in section 30 existed; section 30 (4) applies.

Section 32
Official batch testing

(1) A batch of a serum, a vaccine or an allergen may only be placed on the market, without prejudice to the marketing authorisation, if it has been released by the competent higher federal authority. The batch is to be released if a test (official batch test) has shown that the batch has been manufactured and tested by methods of manufacture and control which comply with the prevailing standard of scientific knowledge and that it possesses the required quality, efficacy and safety. The batch is also to be released if the competent authority of another Member State of the European Union has decided, on the basis of an experimental investigation, that the prerequisites stated in sentence 2 are met.
(1a) The competent higher federal authority must reach a decision pursuant to subsection (1) within two months of receipt of the batch sample to be tested. Section 27 (2) applies accordingly.
(2) The Federal Ministry issues general administrative regulations on the requirements to be set by the higher federal authority for methods of manufacture and control, as defined in subsection (1), following consultation with experts from the fields of medical and pharmaceutical science and practice and promulgates them as Guidelines for the Testing of Medicinal Products in the Federal Gazette. The regulations must comply with the prevailing standard of scientific knowledge and are to be continually adjusted to it.
(3) Section 25 (8) and section 22 (7) sentence 3 apply accordingly to the execution of the official batch testing.
(4) Release pursuant to subsection (1) sentence 1 is not necessary if the medicinal products specified therein are exempted by ordinance pursuant to section 35 (1) no. 4 or by the competent higher federal authority; the competent higher federal authority is to grant an exemption if the manufacturing and test methods of the manufacturer have reached a level of development that guarantees the quality, efficacy and safety required.
(5) The release as defined in subsection (1) or the exemption by the competent higher federal authority as defined in subsection (4) is to be withdrawn if one of their conditions has not been fulfilled; it is to be revoked if one of the conditions is subsequently no longer fulfilled. Sentence 1 applies accordingly if, in the case of a released batch, one of the medicinal products named in subsection (1) sentence 1, or in the case of an exempted medicinal product, there is sufficient reason to suspect that the medicinal product is counterfeit.

Section 33
Reimbursement of expenses and fees

(1) By way of derogation from section 18 (1) sentence 1 of the Federal Act on Fees, the right to the payment of fees and expenses which are to be charged pursuant to section 33 (1) of the Medicinal Products Act in the version in force until 14 August 2013 in conjunction with the Ordinance on Therapy Allergens lapses three years after the notification of the final decision on the marketing authorisation.
(2) If a protest against an administrative act based on this Act or against the determination of fees for an individually attributable public service according to this Act is successful, necessary expenses are reimbursed according to section 80 (1) of the Administrative Procedures Act, up to the level of the fees envisaged for the rejection of a corresponding protest procedure and, in the case of framework fees, up to the level of their mean value.
(3) The Federal Institute for Drugs and Medical Devices charges fees for the use of monographies for medicinal products that are exempted from the obligation to obtain a marketing authorisation pursuant to section 36. In such a case, flat-rate fee agreements can be concluded with the associations to which the users belong. The corresponding regulations on fees apply accordingly in determining fees.

(4) The competent higher federal authority is to be reimbursed by the competent authority of the Land for costs incurred by the former within the framework of the co-operation measures pursuant to this Act, if these costs are borne by the party responsible.

Section 34
Informing the public

(1) The competent higher federal authority must promulgate the following in the Federal Gazette:

1. the granting and extension of a marketing authorisation,
2. the withdrawal of a marketing authorisation,
3. the revocation of a marketing authorisation,
4. the suspension of a marketing authorisation,
5. the expiry of a marketing authorisation,
6. the ascertainment pursuant to section 31 (4) sentence 2,
7. the change in the name pursuant to section 29 (2),
8. the withdrawal or revocation of the release of a batch pursuant to section 32 (5),
9. a decision to extend a protection period pursuant to section 24b (1) sentence 3 or subsection (7) or to grant a data protection period pursuant to section 24b (6) or (8).

Sentence 1 nos. 1 to 5 and no. 7 apply accordingly to decisions or resolutions adopted by the European Community or the European Union.

(1a) The competent higher federal authority makes the following information as well as all changes to such information immediately available to the public via an internet portal and, if necessary, by other means as well:

1. information on the granting of a marketing authorisation together with the package leaflet and the expert information in the currently approved version,
2. the public assessment report containing the information pursuant to section 25 (5a) for each therapeutic indication applied for, as well as a generally comprehensible summary containing a division on the conditions for the use of the medicinal product,
3. summaries of the risk management plans,
4. information on the conditions along with time limits and deadlines for fulfilment,
5. pharmacovigilance-related reservations.

In the case of information pursuant to sentence 1 nos. 2 and 5, industrial and commercial secrets and personal data are to be deleted unless their disclosure is necessary for the protection of public health. If the pharmacovigilance reservations pursuant to sentence 1 no. 5 refer to medicinal products that are authorised in several Member States, the publication takes place in consultation with the European Medicines Agency.

(1b) The withdrawal of an application for authorisation as well as the refusal of the marketing authorisation and the grounds are to be made publicly accessible. In addition, decisions relating to the withdrawal, revocation or suspension of a marketing authorisation are also to be made publicly available. The competent higher federal authority is empowered to disclose information regarding the submission of a proper application for authorisation, the submission of a proper application for the approval of a confirmatory clinical trial, as well as on the approval or refusal of a confirmatory clinical trial.

(1c) Subsections (1a) and (1b) sentences 1 and 2 do not apply to medicinal products approved pursuant to Regulation (EC) No. 726/2004.

(1d) The competent higher federal authority makes the information referred to in subsections (1a), (1b) and (1f) available in electronic format. After taking the decision, the competent higher federal authority makes available the information pursuant to subsections (1) and (1b), referring to the lack of enforceability.
(1e) The competent higher federal authority must publish at least the following supplementary information through its internet portal for medicinal products pursuant to section 67a (2) in addition to the information provided for in subsection (1a) sentence 1 nos. 1 to 4 and subsection (1a) sentence 2:

1. the list of medicinal products pursuant to Article 23 of Regulation (EC) No. 726/2004,

2. information on the notification channels for informing the competent higher federal authority of suspected adverse reactions to medicinal products to be used by health professionals and patients, including the internet forms made available by the competent higher federal authority.

3. the name and address of the active substance manufacturer or manufacturers who was/were inspected on site by the medicinal product manufacturer or another person he/she has designated by contract pursuant to section 22 subsection 2 sentence 1 no. 8.

(1f) The competent higher federal authority may make approved educational material on medicinal products available to the public through an internet portal and, where required, by other means as well, insofar as this is necessary in the interest of medicinal product safety. It makes available a version of the educational material that is suitable for reproduction in electronic programmes in keeping with section 73 (9) of the Fifth Book of the Social Code.
(1g) In the case of medicinal products that are subject to official batch testing pursuant to section 32, the competent higher federal authority may publish information on the number of batches released. Information on the size of the released batches may be published if necessary to protect the health of the public.
(1h) The competent higher federal authority provides the public, via an internet portal and if necessary also by other means, with the necessary information for health professionals on the risks associated with medicinal products to enable their safe use furnished by the marketing authorisation holder. If necessary, the competent higher federal authority provides the public with its own version of necessary information for health professionals on the risks associated with medicinal products to enable their safe use. It makes available a version of the information according to sentences 1 and 2 that is suitable for rendering in electronic programmes according to section 73 (9) of the Fifth Book of the Social Code.
(2) The competent higher federal authority may promulgate an administrative act based on this Act in the Federal Gazette if more than 50 addressees are affected. Two weeks after publication of the administrative act in the Federal Gazette, the Act is considered to be promulgated. Other notifications by the competent higher federal authority, including the letters giving the parties affected the opportunity to submit comments pursuant to section 28 (1) of the Administrative Procedures Act, may also be published in the Federal Gazette if more than 50 addressees are affected. Sentence 2 applies accordingly.

Section 35
Empowerments in respect of marketing authorisation and exemptions

(1) The Federal Ministry is hereby empowered to issue ordinances, subject to the approval of the Bundesrat, in order to:

1. (repealed)

2. extend the provisions on the marketing authorisation to medicinal products that are not subject to the obligation to obtain a marketing authorisation pursuant to section 21 (1), as well as to medicinal products that have been exempted from the marketing

authorisation under section 21 (2) no. 1g, insofar as it is deemed necessary to prevent direct or indirect hazards to human health,

3. extend the provisions on the release of a batch and on official batch testing to other medicinal products that are subject to variation in their composition or in their content of active substances, insofar as it is deemed necessary to prevent direct or indirect hazards to human health,

4. exempt certain medicinal products from the official batch testing, if the manufacturing and testing procedures of the manufacturer have attained a level of development that guarantees quality, efficacy and safety.

(2) The ordinances, pursuant to subsection (1) nos. 2 to 4, are issued in agreement with the Federal Ministry for Economics and Energy and, in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety.

Section 36
Empowerment in respect of standard marketing authorisations

(1) The Federal Ministry is hereby empowered to exempt, by ordinance subject to the approval of the Bundesrat, certain medicinal products or groups of medicinal products or medicinal products presented in particular pharmaceutical forms from the obligation to obtain a marketing authorisation, insofar as no direct or indirect danger to human health is to be feared, as it is evident that the requirements with regard to the necessary quality, efficacy and safety have been met. The Federal Ministry can transfer this authority to the competent higher federal authority without the approval of the Bundesrat. For the sake of the protection of human health, the exemption may be made dependent on a particular manufacturing procedure, composition, labelling, package leaflet, expert information or pharmaceutical form and be limited to certain methods of administration, therapeutic indications or fields of application. It is admissible for the pharmaceutical entrepreneur to provide information regarding additional contra-indications, adverse reactions and interactions.
(2) When selecting the medicinal products to be exempted from the obligation to apply for a marketing authorisation, account must be taken of the legitimate interests of the consumer of the medicinal product, the health professions and the pharmaceutical industry. The pharmaceutical entrepreneur is free to choose the name of the medicinal product.
(3) The ordinance pursuant to subsection (1) is issued in agreement with the Federal Ministry for Economics and Energy and, in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety.
(4) (repealed)
(5) The monographies on which the ordinance pursuant to subsection (1) is based are to be regularly examined by the competent higher federal authority and, where necessary, adapted to the currently recognised standards prevailing in science and technology. In the process, the monographs are to be examined to determine whether the requirements regarding the necessary quality, efficacy and safety, including a positive risk-benefit balance, can continue to be considered fulfilled for medicinal products exempted from the obligation to obtain a marketing authorisation.

Section 37
Authorisation by the European Community or the European Union for placing on the market, marketing authorisation of medicinal products from other states

(1) The marketing authorisation issued by the European Community or the European Union pursuant to Regulation (EC) No. 726/2004, also in conjunction with Regulation (EC) No. 1901/2006 or Regulation (EC) No. 1394/2007 ranks equally with a marketing authorisation issued pursuant to section 25 insofar as the provisions of section 11a, section 13 (2a), section 21 (2), sections 40, 67, 69, 73, 84 or 94 are geared to a marketing authorisation. The

marketing authorisation issued for a medicinal product by another state is considered a valid marketing authorisation as defined in section 21, insofar as this is stipulated in an ordinance issued by the Federal Ministry.
(2) The Federal Ministry is hereby empowered to issue an ordinance pursuant to subsection (1), which is not subject to the approval of the Bundesrat, in order to implement a directive of the Council or where the marketing authorisation of medicinal products is mutually recognised in international treaties as being of equivalent value.

Division 5
Registration of medicinal products

Section 38
Registration of homeopathic medicinal products

(1) Finished medicinal products may only be placed on the market as homeopathic medicinal products within the purview of this Act if they have been entered into the Register for Homeopathic Medicinal Products kept by the competent higher federal authority (registration). A marketing authorisation is not necessary; section 21 (3) applies accordingly. A registration is not required for medicinal products that are placed on the market by a pharmaceutical entrepreneur in amounts of up to 1,000 packages per year, unless these are medicinal products:

1. that contain preparations made from substances pursuant to section 3 no. 3 or 4,

2. that contain more than the one-hundredth part of the smallest dose used in non-homeopathic medicinal products that are subject to prescription pursuant to section 48 or,

3. in which the conditions contained in section 39 (2) nos. 3, 4, 6, 7 or 9 are present.

(2) The information, documents and expert reports specified in sections 22 and 24 are to be enclosed with the application for registration. This does not apply to the information regarding the effects and therapeutic indications, the documents and expert reports on the clinical trials, nor to information pursuant to section 22 (2) sentence 1 nos. 5 and 5a and subsection (7) sentence 2. The documents on the pharmaceutical-toxicological test are to be submitted if the safety of the product, especially as results from an adequately high degree of dilution, is not otherwise evident. Section 22 (1a) applies accordingly.

Section 39
Decision on the registration of homeopathic medicinal products, procedural provisions

(1) The competent higher federal authority must register the homeopathic medicinal product and assign the applicant the registration number in writing. Section 25 (4) and (5) sentence 5 apply accordingly. The registration is valid only for the homeopathic medicinal product and its degrees of dilution as specified in the notice of registration. The competent higher federal authority can make the registration notification subject to conditions. Conditions may also be imposed subsequently. Section 28 (2) and (4) apply.
(2) The competent higher federal authority must refuse registration if:

1. the documents submitted are incomplete,

2. the medicinal product has not been sufficiently tested analytically in compliance with the prevailing standard of scientific knowledge,

3. the medicinal product does not possess the appropriate quality according to recognised pharmaceutical rules,

4. there is sufficient reason to suspect that, if used in keeping with its designated purpose, the medicinal product has harmful effects that exceed the bounds considered justifiable in the light of the knowledge available to medical science,

4a. (repealed),

5. (repealed),

5a. the medicinal product is intended neither for oral administration nor for external use,

5b. the medicinal product contains more than one part per 10,000 of the stock or more than 1/100th part of the smallest dose used in allopathic medicinal products that are subject to prescription pursuant to section 48,

6. the medicinal product is subject to prescription pursuant to section 48,

7. the medicinal product is not manufactured according to a procedure described in the homeopathic section of the Pharmacopoeia,

7a. the use of the individual active substances as homeopathic or anthroposophic medicinal products is not generally known,

8. a marketing authorisation has been granted for the medicinal product,

9. the placing on the market of a medicinal product would be in breach of legal provisions.

(2a) If the medicinal product has already been registered in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area, the registration is to be carried out on the basis of this decision unless a reason to refuse pursuant to subsection (2) is present. For recognition of the registration by another Member State, Chapter 4 of Directive 2001/83/EC applies accordingly; Article 29 paragraphs 4, 5 and 6, and Articles 30 to 34 of Directive 2001/83/EC do not apply.
(2b) The applicant must notify the competent higher federal authority forthwith, enclosing the corresponding documents, in the event of any changes in the information and documents referred to in section 38 (2) sentence 1. Section 29 (1a), (1e), (1f) and (2) to (2b) apply accordingly. The obligation pursuant to sentence 1 is to be fulfilled by the registration holder after the registration has been granted. In the following cases, an application for a new registration is to be required:

1. in the case of a change in the composition of the active substances either in type or quantity, including a change in the potency level,

2. in the case of a change in the pharmaceutical form, insofar as a change pursuant to section 29 (2a) sentence 1 no. 3 is not concerned,

3. (repealed)

(2c) The registration lapses after five years unless an application for extension is submitted not less than nine months before expiry of the term. For the expiry and extension of the registration, section 31 applies accordingly provided that the grounds for refusal pursuant to subsection (2) nos. 3 to 9 apply.
(2d) With respect to the withdrawal, revocation and suspension of the registration, section 30 (1) sentence 1, subsections (2), (2a), (3) and (4) apply accordingly, under the proviso that the grounds for refusal pursuant to subsection (2) nos. 2 to 9 apply.
(2e) Section 34 (1) sentence 1 nos. 1 to 7, subsection (1a) sentence 1 nos. 1, 4 and 5, subsections (1b), (1d) and (1h) apply accordingly.

(3) For homeopathic medicinal products, the Federal Ministry is hereby empowered to issue, in compliance with the provisions on marketing authorisation by ordinance, not subject to the approval of the Bundesrat, provisions governing the exemption from registration.

Section 39a
Registration of traditional herbal medicinal products

Finished medicinal products that are herbal medicinal products and medicinal products within the meaning of section 2 (1) may be placed on the market as traditional herbal medicinal products only if they are registered by the competent higher federal authority. This also applies to herbal medicinal products containing vitamins or minerals provided that the action of the vitamins or minerals is ancillary to that of the traditional herbal medicinal product regarding the therapeutic indication or indications.

Section 39b
Registration documents for traditional herbal medicinal products

(1) The applicant must enclose the following information and documents with the registration application:

1. the information and documents referred to in section 22 (1), (3c), (4), (5) and (7) and section 24 (1) sentence 2 no. 1,

2. the results of analytical tests referred to in section 22 (2) sentence 1 no. 1,

3. the summary of the product characteristics of the medicinal product with the information referred to in section 11a (1), taking into consideration the fact that it is a traditional herbal medicinal product,

4. bibliographic evidence of the traditional use or expert reports showing that the medicinal product in question, or a corresponding product has been in medicinal use for at least 30 years preceding the date of the application, including at least 15 years within the European Union and that under the stated conditions of use, the medicinal product is safe and the pharmacological effects or efficacy of the medicinal product are plausible based on use and experience over many years,

5. a bibliographic review of safety data together with an expert report pursuant to section 24 and, where required, additional information and documents necessary for assessing the safety of the medicinal product,

6. any registrations or marketing authorisations obtained by the applicant in another Member State, or in a third country, to place the medicinal product on the market, and details of any decision to refuse to grant a registration or marketing authorisation and the reasons for any such decision.

Evidence of use over a period of 30 years pursuant to sentence 1 no. 4 can also be provided if no special authorisation has been granted for placing a medicinal product on the market. It can also be provided if the number or quantity of active substances of the medicinal product has been reduced over this period. A corresponding medicinal product as referred to in sentence 1 no. 4 is characterised by having the same or comparable active substances, irrespective of the excipients used, the same or similar intended use, equivalent strength and dosage and the same or similar route of administration as the medicinal product for which registration is applied.

(1a) The information pursuant to section 22 (1) sentence 1 nos. 1 to 10 must be provided in German, the other information in the German or English language; other information or documents may also be submitted in the registration procedure in English instead of in German, insofar as information that is used for the labelling, the packaging leaflet or the expert information is not concerned.

(2) Instead of submitting the information and documents referred to in subsection (1) sentence 1 nos. 4 and 5, reference can also be made to a Community or European Union

herbal monograph pursuant to Article 16h paragraph 3 of Directive 2001/83/EC or its presence on the list pursuant to Article 16f of Directive 2001/83/EC.
(3) If the medicinal product contains more than one herbal active substance or substance pursuant to section 39a sentence 2, the information referred to in subsection (1) sentence 1 no. 4 is to be submitted for the combination. If the individual active substances are not sufficiently well known, information is to be provided about the individual active substances.

Section 39c
Decision on the registration of traditional herbal medicinal products

(1) The competent higher federal authority must register traditional herbal medicinal products and notify the applicant of the registration number in writing. Section 25 (4) and (5) sentence 5 apply accordingly. The registration applies only to the herbal medicinal product listed in the notification. The competent higher federal authority can make the registration notification subject to conditions. Conditions may also be imposed subsequently. Section 28 (2) and (4) apply accordingly.
(2) The registration is to be refused by the competent higher federal authority if the application does not contain the information and documents stipulated in section 39b, if:

1. the qualitative or quantitative composition does not correspond to the information referred to in section 39b (1) or the pharmaceutical quality is otherwise inadequate,

2. the therapeutic indications do not comply exclusively with those of traditional herbal medicinal products which, according to their composition and intended use, are intended for use without the need for medical supervision with respect to making a diagnosis, prescription or supervising the treatment,

3. the medicinal product can be harmful under normal conditions of use,

4. the safety of vitamins or minerals contained in the medicinal product has not been proved,

5. the information on traditional use is insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience,

6. the medicinal product is not exclusively intended for administration in a specific strength or dosage,

7. the medicinal product is not exclusively intended for oral or external use or for inhalation,

8. the time requirement stipulated in section 39b (1) sentence 1 no. 4 has not been fulfilled, or

9. a marketing authorisation pursuant to section 25 or a registration pursuant to section 39 has been granted for the traditional herbal medicinal product or a corresponding medicinal product,

10. the placing on the market of a medicinal product would be in breach of legal provisions.

(3) The registration ends after five years unless an application for extension is submitted not less than nine months before expiry of the term. For the expiry and extension of the registration, section 31 applies accordingly provided that the reasons for rejection referred to in subsection (2) apply.

Section 39d
Other procedural provisions for traditional herbal medicinal products

(1) On request, the competent higher federal authority notifies the applicant and the European Commission and the competent authority of an EU Member State of any decision it takes to refuse traditional-use registration and the reasons for the refusal.
(2) For medicinal products corresponding to Article 16d paragraph 1 of Directive 2001/83/EC, section 25b applies accordingly. For medicinal products referred to in Article 16d paragraph 2 of Directive 2001/83/EC, a registration by another Member State is to be duly considered.
(3) On application, the competent higher federal authority can request the Committee on Herbal Medicinal Products, set up pursuant to Article 16h of Directive 2001/83/EC, for an opinion on the evidence of traditional use if there are doubts as to the fulfilment of the conditions referred to in section 39b (1) sentence 1 no. 4.
(4) Where a medicinal product has been used in the European Union for less than 15 years, but is otherwise eligible for registration pursuant to sections 39a to 39c, the competent higher federal authority must initiate the procedure envisaged under Article 16c paragraph 4 of Directive 2001/83/EC with the participation of the Committee for Herbal Medicinal Products.
(5) If a herbal substance, a herbal preparation or a combination thereof is removed from the list referred to in Article 16f of Directive 2001/83/EC, registrations pursuant to section 39b (2) granted for traditional herbal medicinal products containing this substance are to be revoked unless the information and documents referred to in section 39b (1) are submitted within three months.
(6) Section 34 (1) sentence 1 nos. 1 to 7, subsection (1a) sentence 1 nos. 1, 4 and 5, subsections (1b), (1d) and (1h) apply accordingly.
(7) The applicant must notify the competent higher federal authority forthwith, enclosing the corresponding documents, in the event of any changes in the information and documents pursuant to section 39b (1) sentence 1, in conjunction with subsection (2). Section 29 (1a), (1e), (1f) and (2) to (2b) apply accordingly. The obligation pursuant to sentence 1 is to be fulfilled by the registration holder after the registration has been granted. In the following cases, an application for a new registration is to be required:

1. in the case of a change in the therapeutic indications, insofar as a change pursuant to section 29 (2a) sentence 1 no. 1 is not concerned,

2. in the case of a change in the composition of the active substances either in type or quantity,

3. in the case of a change in the pharmaceutical form, insofar as a change pursuant to section 29 (2a) sentence 1 no. 3 is not concerned,

(8) With respect to the withdrawal, revocation and suspension of the registration, section 30 (1) sentence 1, subsections (2), (2a), (3) and (4) apply accordingly with the proviso that the grounds for refusal pursuant to section 39c (2) apply.

Division 6
Protection of human subjects in clinical trials

Section 40
Procedure for authorising clinical trials

(1) The clinical trial of medicinal products may only be commenced if the competent higher federal authority has approved the clinical trial pursuant to Article 8 of Regulation (EU) No. 536/2014.
(2) The application for the approval of a clinical trial to be made according to Article 5 (1) of Regulation (EU) No. 536/2014 is to be submitted in German or English via the EU portal. The documents intended for the person concerned or his/her legal representative are to be submitted in German.
(3) The application is validated according to Article 5 (3) of Regulation (EU) No. 536/2014 by the competent higher federal authority. The ethics committee responsible according to the

schedule of responsibilities pursuant to section 41b (2) gives its opinion on the application documentation with respect to the prerequisites pursuant to Article 6 (1) (a), (b) and (e) of Regulation (EU) No 536/2014, and according to section 40a sentence 1 no. 4 and section 40b (4) sentence 3. The deadline stipulated in the procedure according to section 41b (1) applies to the opinion. Section 41 (3) sentence 1 applies accordingly. In validating the application with respect to the prerequisites according to Article 7 of Regulation (EU) No 536/2014, also in conjunction with Article 11 of Regulation (EU) No 536/2014, as well as according to section 40a sentence 1 nos. 2, 3 and 5, sentences 2 and 3 and section 40b (2), (3) sentence 1, subsection (4) sentences 1 and 9, subsections (5) and (6) the higher federal authority is bound to the assessment conducted by the ethics committee responsible according to the schedule of responsibilities pursuant to section 41b (2).
(4) The competent higher federal authority performs the tasks according to Article 6 of Regulation (EU) No 536/2014, also in conjunction with Article 11 of Regulation (EU) No 536/2014, and examines the prerequisites according to section 40a sentence 1 nos. 1 and 4 and section 40b (4) sentence 3 with respect to the -risk-benefit assessment according to Article 6(1) (b) of Regulation (EU) No 536/2014. The ethics committee responsible according to the schedule of responsibilities pursuant to section 41b (2) gives its opinion on the application documentation with respect to the prerequisites pursuant to Article 6 (1) (a), (b) and (e) of Regulation (EU) No 536/2014, and according to section 40a sentence 1 no. 4 and section 40b (4) sentence 3 with respect to the -risk-benefit assessment according to Article 6(1) (b) of Regulation (EU) No 536/2014. The deadline stipulated in the procedure according to section 41b (1) applies to the opinion.
(5) The ethics committee responsible according to the schedule of responsibilities pursuant to section 41b (2) performs the tasks according to Article 7 of Regulation (EU) No 536/2014, also in conjunction with Article 11 of Regulation (EU) No 536/2014, and examines the prerequisites according to section 40a sentence 1 nos. 2, 3 and 5, sentences 2 and 3 and section 40b (2), 3 sentence 1, subsection (4) sentence 1, sentence 3 with respect to the declaration of consent, sentences 4 to 9, subsections (5) and (6). Section 41 (2) applies accordingly.
(6) The competent higher federal authority charges an overall fee in keeping with Articles 86 and 87 of Regulation (EU) No 536/2014. The competent ethics committee charges a fee to process an application in compliance with the ordinance pursuant to section 41b (1) and informs the competent higher federal authority thereof. Said fee is to be included in the notification of charges regarding the overall fee pursuant to sentence 1.
(7) In the case of investigational medicinal products consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, the following documents are to be submitted to the competent higher federal authority, along with the application pursuant to subsection (2), pursuant to Annexes III and III of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC (OJ L 106 of 17.4.2001, p. 1), last amended by Directive (EU) 2015/412 (OJ L 68 of 13.3.2015, p. 1):

1. a description and assessment of the risk to the health of uninvolved third parties and the environment, as well as a description of the proposed precautions,

2. information on the genetically modified organism, the conditions of the clinical trial and the environment that might absorb the genetically modified organism, as well as information on the interactions between the genetically modified organism and the environment.

3. an observation plan to determine the impact on the health of uninvolved third parties and the environment, as well as a description of the planned supervisory measures and data on the resulting residues and their treatment, as well as on emergency plans.

In this respect, the sponsor may refer to documents submitted by a third party in the course of a previous procedure, insofar as no confidential information is concerned. The competent higher federal authority consults with the Federal Office for Consumer Protection and Food Safety. The authorisation of the clinical trial by the competent higher federal authority includes authorising the release of the genetically modified organisms within the framework of the clinical trial.
(8) The competent higher federal authority transmits the decision pursuant to Article 8 (1) first subparagraph of Regulation (EU) No 536/2014 to the sponsor via the EU portal. In doing so, it is bound by the assessment report produced by the ethics committee under subsection (5). If the higher federal authority deviates from the statement of the ethics committee pursuant to subsection (4) sentence 2, it must name the ethics committee, state the result of the opinion given by the ethics committee and provide justification for its deviation from said opinion. In the justification, reference may be made to the English language assessment report. The competent higher federal authority transmits the decision according to Article 8 (2) third subparagraph of Regulation (EU) No 536/2014.

Section 40a
General prerequisites for clinical trials

Beyond the prerequisites contained in Regulation (EU) No 536/2014, a clinical trial may only be conducted if:

1. in the case of purely national clinical trials or clinical trials conducted in a third country a sponsor or a representative of the sponsor whose registered place of business is situated in a Member State of the European Union or in another State Party to the Agreement on the European Economic Area is available,

2. the person on whom the clinical trial is to be conducted (person concerned) has not been committed to an institution by virtue of an order issued either by the judicial or the administrative authorities,

3. in the event that a person is killed or a person's body or health is injured during the course of the clinical trial, an insurance policy that provides benefits, even when no one else is liable for the damage, exists in accordance with the provisions contained below:

   a) the insurance must be taken out in favour of the person concerned in a clinical trial with an insurance carrier authorised to conduct business in a Member State of the European Union or another State Party to the Agreement on the European Economic Area,

   b) its scope must be reasonably commensurate with the risks involved in a clinical trial and determined on the basis of the risk assessment in such a way as to ensure that, for every case of the death or permanent occupational disability of a person concerned in the clinical trial, at least 500,000 euros are available.

4. according to the latest standards prevailing in medical science in relation to the purpose of the clinical trial of a medicinal product consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms, unjustifiable harmful effects are not to be expected on:

   a) the health of third persons and

   b) the environment,

5. it takes place in a suitable facility pursuant to Article 50 in conjunction with Annex I (67) to Regulation (EU) No. (EU) No 536/2014.

In the case of xenogeneic medicinal products, the requirements stipulated in sentence 1 no. 3 regarding the insurance of third-party risks must be fulfilled. Insurance pursuant to sentence 1 no. 3 is not necessary for a minimally interventional clinical trial pursuant to Article 2 (2) no.3 of Regulation (EU) No 536/2014 if the investigator and the sponsor are otherwise insured. Insofar as benefits are paid by the insurance pursuant to sentence 1 no. 3, all claims to damages are extinguished.

Section 40b
Special prerequisites for clinical trials

(1) Supplementing Article 29 of Regulation (EU) No 536/2014, the conditions pursuant to subsections (2) to (5) apply to the consent of the person concerned or, if he/she is incapable of granting informed consent, to his/her legal representative.
(2) The person concerned or, if he/she is incapable of granting informed consent, his/her legal representative is to be informed by an investigator who is a physician, or in the case of a dental trial, a dentist, or by a member of the investigating team who is a physician, or in the case of a dental trial, a dentist, during the interview referred to in Article 29 (2) (c) of Regulation (EU) No 536/2014.
(3) A clinical trial may only be conducted on a minor who is incapable of comprehending the nature, significance and implications of the clinical trial and of determining his/her will in the light of these facts if his/her written informed consent in accordance with Article 29 of Regulation (EU) No 536/2014 has also been presented, in addition to the informed consent given in writing by his/her legal representative. If a minor who is incapable of comprehending the nature, significance and implications of the clinical trial and of determining his/her will in the light of these facts declares or expresses in any other way that he/she does not wish to take part in the clinical trial, this shall be considered to be his/her explicit wish within the meaning of Article 31 (1) (c) of Regulation (EU) No 536/2014.
(4) A clinical trial may only be conducted with a person who is incapable of comprehending the nature, significance and implications of the clinical trial and of determining his/her will in the light of these facts, if:

1. the prerequisites of Article 31 (1) of Regulation (EC) No 536/2014 and
2. the prerequisites of Article 31 (3) of Regulation (EC) No 536/2014

are fulfilled.
If a person who is incapable of comprehending the nature, significance and implications of the clinical trial and of determining his/her will in the light of these facts declares or expresses in any other way that he/she does not wish to take part in the clinical trial, this shall be considered to be his/her explicit wish within the meaning of Article 31 (1) (c) of Regulation (EU) No 536/2014.
In the case of a person of legal age who is incapable of comprehending the nature, significance and implications of the clinical trial and of determining his/her will in the light of these facts, a clinical trial within the meaning of Article 31 (1) (g) (ii) of Regulation (EU) No 536/2014, which will be exclusively of benefit for the population represented by the concerned person (group-benefiting clinical trial) may only be conducted if the concerned person, as a person of full age with the capacity to consent, for the event of his/her incapacity to consent, has declared in writing after having been informed by a physician that he/she consents to specific group-benefiting clinical trials that are not yet directly imminent at the time of the declaration. The guardian verifies whether this declaration matches the current situation. The declaration may be revoked without formality at any time. Section 1901a (1), (4) and (5) of the Civil Code (*Bürgerliches Gesetzbuch*) apply otherwise accordingly. The person concerned is to be informed of all circumstances that are essential to consent. This includes in particular information on the nature, objectives, consequences, risks and disadvantages of clinical trials that are conducted under the conditions provided for in Article 31 of Regulation (EU) No 536/2014, as well as in the contents of Article 29 (2) (a) (ii) and (iv) of Regulation (EU) No 536/2014. Such a group-benefiting clinical trial may not be

conducted in the case of minors to whom sentence 1 would apply when they are of legal age.
(5) A clinical trial may be conducted in emergencies only if the prerequisites of Article 35 of Regulation (EU) No 536/2014 are fulfilled.
(6) The person concerned or, if this person is incapable of giving informed consent, his/her legal representative must consent explicitly and in writing to the collection, processing and use of personal data, in particular health data. He/she is to be informed of the purpose and scope of the collection and use of these data. The person concerned is to be informed especially of the fact that:

1. where necessary, the recorded data:

   a) will be kept available for inspection by the supervisory authority or the sponsor's representative in order to verify the proper conduct of the clinical trial,

   b) will be passed on in a pseudonymised form to the sponsor or to an agency commissioned by the latter for the purpose of scientific evaluation,

   c) will be passed on, in a pseudonymised form, to the applicant and the competent authority for the marketing authorisation if an application for a marketing authorisation is filed,

   d) will be passed on, in a pseudonymised form, by the investigator to the sponsor in the event of adverse events or serious adverse events pursuant to Article 41 (1), (2) and (4) of Regulation (EU) No 536/2014,

   e) will be passed on, in a pseudonymised form, by the sponsor to the database pursuant to Article 40 (1) of Regulation (EU) No 536/2014 in the event of suspected unexpected serious adverse reactions pursuant to Article 42 of Regulation (EU) No 536/2014,

   f) will be passed on, in a pseudonymised form, by the sponsor to the EU portal in the event of unexpected events pursuant to Article 53 (1) of Regulation (EU) No 536/2014,

2. in the case of a revocation of a declaration of consent pursuant to sentence 1 and subsection (1) , it is permissible for the stored data to be continued to be used where necessary, in order to:

   a) determine the effects of the investigational medicinal product,

   b) to ensure that those interests of the person concerned, which are worthy of special protection, are not prejudiced,

   c) satisfy the obligation to provide complete marketing authorisation documents,

3. The data are archived by the investigator and the sponsor for the period specified pursuant to Article 58 first subparagraph of Regulation (EU) No 536/2014.

(7) The contact entity in accordance with Article 28 (1) (g) of Regulation (EU) No 536/2014 is to be set up at the competent higher federal authority pursuant to section 77.

Section 40c
Procedure to extend an authorised clinical trial to another Member State, procedure with regard to modifications as well as assessment procedures

(1) Sections 40 to 40b apply correspondingly to the procedures to subsequently extend an authorised clinical trial to another Member State concerned according to Article 14 of Regulation (EU) No 536/2014 and to approve a substantial modification of a clinical trial in accordance with Articles 15 to 24 of Regulation (EU) No 536/2014.

(2) The assessment by the competent ethics committee is included in the assessment procedure pursuant to Article 44 of Regulation (EU) No 536/2014.
(3) Modifications of a clinical trial approved by the competent higher federal authority using medicinal products consisting of or containing genetically modified organisms and which are capable of changing the risk assessment regarding the health of uninvolved third parties and the environment may only be made by the sponsor if these modifications have been approved by the competent higher federal authority. The application for approval is to be made to the competent higher federal authority. Justification must be provided for the application.

Section 40d
Special obligations of the investigator, the sponsor and the competent higher federal authority

In the case of clinical trials using medicinal products consisting of a genetically modified organism or a combination of genetically modified organisms or containing such organisms:

1. independent of the existence of an approval pursuant to section 40c (3), the sponsor and the investigator take all measures necessary to protect the health of uninvolved third parties and the environment from direct danger;

2. the sponsor immediately informs the investigator of observations made of possible harmful effects on the health of uninvolved third parties and the environment that were not foreseen in the risk assessment;

3. the sponsor immediately informs the competent higher federal authority of all new information that has come to his/knowledge on dangers to the health of uninvolved third parties and the environment;

4. after completing the clinical trial, the sponsor immediately informs the competent higher federal authority of the results in terms of danger to human and environment;

5. the competent higher federal authority informs the public of any sufficient suspicion of danger to the health of third parties or to the environment in its ecosystem, including the precautions to be taken; if the approval is withdrawn or revoked, the temporary suspension of the approval or a change in the conditions for the clinical trial imposed, and if this measure has become incontestable or immediately enforceable, the public is also to be informed of this by the competent higher federal authority; sections 17a and 28a (2) sentences 2 and 3, subsections (3) and (4) of the Genetic Engineering Act apply accordingly.

Section 41
Ethics committee opinion

(1) The opinion of the ethics committee pursuant to section 40 (4) sentence 2 must contain a clear opinion in terms of consent, of consent subject to conditions within the meaning of Article 8 (1) third subparagraph of Regulation (EU) No 536/2014 or a rejection of the acceptability of the conduct of the clinical trial, as well as a corresponding justification.
(2) The ethics committee may use its own scientific findings, consult experts or request reports from experts. It must call in experts or request expert reports in the case of clinical trials of xenogeneic medicinal products or gene therapy medicinal products.
(2a) Where necessary for the proper fulfilment of their tasks according to Regulation (EU) No 536/2014 and the Medicinal Products Act, the registered ethics committees may transmit the personal data of the investigator and other persons participating in the conduct of the clinical trial necessary for these tasks within the meaning of Article 49 of Regulation (EU) No 536/2014 amongst themselves and to the competent authorities and bodies responsible for the enforcement of the Medicinal Products Act.

(3) The opinion is to be duly considered by the competent higher federal authorities in fulfilling their tasks pursuant to section 40 (4) sentence 1. If the competent higher federal authority deviates from the opinion of the ethics committee, it must provide justification in writing to the ethics committee for its deviation from said opinion.

Section 41a
Registration process for ethics committees

(1) Only the public sector ethics committees of the Laender that are responsible under Land law for evaluating and assessing clinical trials and are registered pursuant to subsections (2) to (5) may participate in the procedure to assess an application for the approval of a clinical trial pursuant to Regulation (EU) No. 536/2014.
(2) The application for registration is to be submitted to the Federal Institute for Drugs and Medical Devices by the specific body responsible for the public sector ethics committees of the Laender.
(3) In agreement with the Paul Ehrlich Institute, the Federal Institute for Drugs and Medical Devices authorises the application for registration if the following prerequisites are fulfilled through the submission of suitable documents:

1. the requisite up-to-date scientific expertise of the Member States, as well as that of external experts,

2. the interdisciplinary composition of the ethics committee, with the participation of at least one '*Jurist'*, one person with scientific or professional experience in the field of ethics in medicine, one person with experience in the field of experimental design and statistics, three physicians who possess experience in clinical medicine, including one specialist in clinical pharmacology or in pharmacology and toxicology, as well as one layperson,

3. the ethics committee comprises female and male members and, with the aim of equal participation, women and men are given equal consideration when members and external experts are selected,

4. rules of procedure that, in particular, draw up binding regulations on the ethics committee's methods of working; this includes, in particular, regulations on management, the chair, the preparation of decisions, the adoption of decisions as well as on honorary activities and the confidentiality obligations of members and external experts,

5. a managing office with the necessary qualified personnel to organise the tasks incumbent on the ethics committee,

6. material resources that make it possible to conduct voting procedures on short notice and to draw up statements and assessment reports on time,

7. for each application, the ethics committee obtains declarations of independence from the participating members and external experts stating that they have no financial or personal interests that could affect their impartiality.

(4) Registered ethics committees notify the Federal Institute for Drugs and Medical Devices of changes that affect the registration prerequisites, without delay.
(5) The Federal Institute for Drugs and Medical Devices can, in agreement with the Paul Ehrlich Institute, order the registration to be suspended, or rescind the registration if it becomes known that the prerequisites for the registration do not or no longer exist, or in the presence of a violation of the rules of procedure stipulated in section 41b (1).
(6) The Federal Institute for Drugs and Medical Devices publishes a list of the registered ethics committees in the Federal Gazette. Personal data may be published only with the consent of the specific individual. The list is to be updated regularly.

Section 41b
Rules of procedure and schedule of responsibilities

(1) The Federal Ministry creates, by ordinance subject to the approval of the Bundesrat, rules of procedure governing cooperation among the higher federal authorities and the registered ethics committees when processing applications for the authorisation of clinical trials pursuant to Regulation (EU) No. 536/2014. The rules of procedure stipulate in particular the details of the registration procedure, the deadlines for opinions by the registered ethics committees, the fixed fee scales or guideline rates, depending in each case on the number of personnel and amount of material required for the opinions and assessment reports by the registered ethics committees, the criteria for a schedule of responsibilities, including the factors that are decisive for the distribution of the applications to be processed, as well as who bears responsibility for requesting additional information from the sponsor pursuant to Regulation (EU) No. 536/2014.
(2) The ethics committees that were registered by 30 September 2017, or a body notified by them, issue a joint schedule of responsibilities for all registered ethics committees, by 1 January 2018. This schedule of responsibilities is to be updated annually by 1 January of each year. In special cases, the schedule of responsibilities can be updated and modified by way of derogation from sentence 2. The Federal Institute for Drugs and Medical Devices publishes each new updated schedule of responsibilities. Personal data may be published only with the consent of the specific individual.

Section 41c
Power to issue ordinances

The Federal Ministry is hereby empowered to set up, by ordinance not subject to the approval of the Bundesrat, a Federal Ethics Committee at the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute, if this is necessary to ensure the conduct of the procedures provided for in Regulation (EU) No. 536/2014. The provisions contained in this Division apply accordingly to the Federal Ethics Committee, subject to the proviso that the Federal Ethics Committee is deemed to be registered.

Section 42
Corrective measures

(1) The competent higher federal authority takes the corrective measures listed in Article 77 of Regulation (EU) No 536/2014 in accordance with the following subsections.
(2) The approval of a clinical trial is to be withdrawn if it becomes known that the prerequisites contained in Regulation (EU) No 536/2014 or the prerequisites contained in section 40a or section 40b (2) to (6) were not fulfilled at the time of approval. In such a case, the suspension of the authorisation can also be ordered for a limited period of time.
(3) The approval is to be revoked if it becomes known that the prerequisites contained in subsection (2) no longer exist. The authorisation may be withdrawn if the conditions surrounding the clinical trial do not correspond to the information contained in the authorisation application or if facts give reason to doubt the safety or the scientific basis of the clinical trial. In the cases referred to in sentences 1 and 2, the suspension of the authorisation can also be ordered for a limited period of time.
(4) If the competent higher federal authority, in the context of its activities, becomes aware of facts that justify the assumption that the prerequisites contained in Regulation (EU) No 536/2014 or in section 40a or section 40b (2) to (6) no longer exist, it can require that the sponsor modify aspects of the clinical trial. This is without prejudice to measures taken by the competent supervisory authority pursuant to section 69.
(5) In the cases provided for in subsections (2) to (4), the competent ethics committee gives an opinion before the decision is taken by the competent higher federal authority unless danger is imminent. If the corrective measures are based on the absence of the prerequisites pursuant to Article 6 (1) (a), (b) and (e) of Regulation (EU) No 536/2014 or prerequisites pursuant to section 40a sentence 1 no. 4 or pursuant to section 40b (4) sentence 3, section 41 (3) sentence 1 applies accordingly. If the corrective measures are to

be based on the absence of the prerequisites pursuant to Article 7 Regulation (EU) Nr. 536/2014 or prerequisites pursuant to section 40a sentence 1 nos. 2, 3 and 5, sentences 2 and 3 or on section 40b (2), (3), (4) sentences 1, 2 and 9, subsections (5) and (6), the higher federal authority is bound by the opinion of the ethics committee,
(6) If the authorisation to conduct a clinical trial is withdrawn, revoked or suspended, the clinical trial may not be continued.
(7) The competent higher federal authority may order the immediate interruption of the clinical trial; in such a case, it informs the sponsor immediately of this order.
(8) The lodging of an objection and action to rescind the revocation, the withdrawal or the order to suspend the authorisation, the order to immediately interrupt the clinical trial as well as against orders pursuant to subsection (4) have no suspensive effect.

Section 42a
Data protection

Personal data are to be pseudonymised prior to transmission pursuant to Article 41 (2) and (4) of Regulation (EU) Nr. 536/2014 by the investigator or pursuant to Article 42 or Article 53 (1) of Regulation (EU) Nr. 536/2014 by the sponsor using the concerned person's identification code.

Section 42b
Publication of the results of clinical trials

(1) Pharmaceutical entrepreneurs who place a medicinal product that requires a marketing authorisation or an authorisation on the market, within the purview of this Act, must place reports on all the results of confirmatory clinical trials in third countries to prove the efficacy and safety of the medicinal product at the disposal of the competent higher federal authority for entry into the database referred to in section 67a (2). These reports are to be made available within six months subsequent to the granting or modification, if the modification is based on confirmatory clinical trials, of the marketing authorisation or authorisation.
(2) The reports pursuant to subsection (1) must contain all of the results of the clinical trials, whether they are favourable or not. In addition, information regarding subsequent essential modifications to the trial protocol, as well as interruptions and early termination of the clinical trial, are to be included in the report. Furthermore, the report of findings is to be drawn up according to the requirements of good clinical practice. With the exception of the name and address of the pharmaceutical entrepreneur or the sponsor, as well as the name and the address of the consenting investigators pursuant to section 4a of the Federal Data Protection Act, the reports pursuant to sentence 1 may not contain personal nor especially patient-related data. The report may be written in German or English. Section 63b (3) sentence 1 does not apply. This is without prejudice to the provisions protecting intellectual property and those protecting operating and trade secrets, as well as sections 24a and 24b.

Section 42c
Inspections

The following inspections according to Article 78 of Regulation (EU) No 536/2014 are conducted by the competent higher federal authority:

1. inspections to verify that the clinical trial is in compliance with:

   a) the authorisation-related information and documents,

   b) the information contained in an application for authorisation pursuant to Regulation (EC) No. 726/2004, or

   c) the documents pursuant to section 22 (2) no. 3,

2. inspections in third countries,

3. inspections to verify the obligation to notify pursuant to Article 52 of Regulation (EU) No 536/2014, as well as

4. inspections to decide on measures pursuant to Article 77 of Regulation (EU) No 536/2014 pertaining to the authorisation of a clinical trial.

All other inspections pursuant to Article 78 of Regulation (EU) No 536/2014 for the surveillance of compliance with Regulation (EU) No 536/2014 are conducted by the competent authority. If not otherwise specified in implementing acts pursuant to Article 78 (7) of Regulation (EU) No 536/2014, the higher federal authority has the powers to conduct the inspection pursuant to section 64 (4) nos. 1 to 3 and subsection (4a), which are exercised in consultation with the competent authority. The competent authority has the powers pursuant to section 64 (4) and (4a) to conduct the inspection. The basic right to the inviolability of the home (Article 13 para 1 of the Basic Law (*Grundgesetz*)) is limited in this respect.

Division 7
Sale of medicinal products

Section 43
Pharmacy-only requirement

(1) Medicinal products that are not released for trade outside of pharmacies by the provisions either of section 44 or of the ordinance issued in compliance with section 45 (1) may, except for the cases provided for in section 47, be sold to the consumer, professionally or on a commercial basis, exclusively in pharmacies and not by sale at a distance without official authorisation; further details are regulated by the Act on Pharmaceutical Services (*Apothekengesetz*). With the exception of the cases provided for in section 47 (1), no trade may be conducted outside of pharmacies with those medicinal products reserved exclusively for sale in pharmacies pursuant to sentence 1. The information on the issuing or modification of an authorisation for the sale at a distance of medicinal products pursuant to sentence 1 is to be entered into the database referred to in section 67a.
(2) Medicinal products reserved in compliance with subsection (1) sentence 1 for trade in pharmacies, may not be dispensed by legal persons, by associations that have not achieved the status of legal persons by being registered in the register of associations, or by business partnerships to their members, unless these members are either pharmacies themselves or persons and establishments as defined in section 47 (1) and the dispensing of medicinal products is carried out under the conditions specified therein.
(3) Medicinal products may only be dispensed by pharmacies upon prescription.
(3a) By way of derogation from subsections (1) to (3), medical facilities that have specialised in the treatment of coagulation dysfunctions in haemophilia may maintain a stock of medicinal products for the specific treatment of coagulation dysfunctions in haemophilia on their premises so as to be able to meet an unforeseen and urgent demand (emergency stocks). Within the framework of emergency care, a haemostaseologically qualified physician may dispense medicinal products from the emergency stocks pursuant to sentence 1 to patients or healthcare facilities.

Section 44
Exceptions to the pharmacy-only requirement

(1) Medicinal products that are intended by the pharmaceutical entrepreneur solely to serve purposes other than the curing or alleviation of disease, suffering, bodily injuries or symptoms of illness are released for trade outside of pharmacies.
(2) The following are also released for trade outside of pharmacies:

1.

a) natural curative waters as well as their salts, also in the form of tablets or pastilles,

b) synthetic curative waters as well as their salts, also in the form of tablets or pastilles, but only if they are equivalent in their composition to natural curative waters,

2. therapeutic clays, moor muds for baths and other peloids, preparations for the manufacturing of baths, soaps for external use,

3. designated by their customary German names,

a) plants and parts of plants, also chopped,

b) mixtures of whole or cut plants or parts of plants as finished medicinal products,

c) distillates made from plants and parts of plants,

d) juices pressed from fresh plants and parts of plants insofar as they are prepared without the use of any solvents other than water,

4. plasters,

5. disinfectants intended exclusively or mainly for external use as well as disinfectants for the mouth and the throat.

(3) Subsections (1) and (2) do not apply to medicinal products that:

1. are subject to mandatory prescription under section 48, or

2. are excluded by ordinance pursuant to section 46 from trade outside of pharmacies.

Section 45
Authority to allow further exceptions to the pharmacy-only requirement

(1) The Federal Ministry is hereby empowered to release, in agreement with the Federal Ministry for Economic Affairs and Energy and upon consultation with experts, by ordinance, subject to the approval of the Bundesrat, substances, preparations made from substances or objects that are intended to be used either in part or exclusively in curing or alleviating diseases, suffering, bodily injuries or symptoms of diseases, for trade outside of pharmacies:

1. insofar as they are not subject to prescription pursuant to section 48,

2. insofar as they do not require testing, storage and dispensing to be carried out in a pharmacy, as a result of their composition or effect,

3. insofar as a direct or indirect hazard to human health need not be feared as a result of their release or in particular as a result of inappropriate handling or

4. insofar as the proper supply of medicinal products is not jeopardised by their release.

(2) The release may be limited to finished medicinal products, certain dosages, therapeutic indications or pharmaceutical forms.
(3) The ordinance is issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, insofar as radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used are concerned.

Section 46
Authority to extend the pharmacy-only requirement

(1) The Federal Ministry is hereby empowered to exclude, in agreement with the Federal Ministry for Economics and Energy and upon consultation with experts, by ordinance subject to the approval of the Bundesrat, medicinal products as defined in section 44 from trade

outside of pharmacies, if a direct or indirect hazard to human health is to be feared even when such medicinal products are used in keeping with their designated purpose or in the customary manner.
(2) The ordinance in compliance with subsection (1) may be limited to certain dosages, therapeutic indications or pharmaceutical forms.
(3) The ordinance is issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, insofar as radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used are concerned.

Section 47
Distribution channel

(1) Pharmaceutical entrepreneurs and wholesalers may only supply medicinal products reserved for pharmacies to the following parties other than pharmacies:

1. other pharmaceutical entrepreneurs and wholesalers,

2. hospitals and physicians as far as the following items are concerned:

   a) blood preparations obtained from human blood with the exception of clotting factor preparations,

   b) tissue preparations or animal tissue,

   c) infusion solutions in containers of at least 500ml intended for the replacement or the correction of body fluid, as well as solutions for haemodialysis and transperitoneal dialysis that, insofar as solutions for transperitoneal dialysis are concerned, may be dispensed on prescription by the physician qualified in nephrology, in the context of a physician-supervised self-treatment, to his/her dialysis patients,

   d) preparations that are exclusively intended for the diagnosis of the nature, state or functions of the body or mental health conditions,

   e) medicinal gases that are authorised also for distribution to alternative practitioners,

   f) radiopharmaceutical or,

   g) medicinal products that are labelled *'Zur klinischen Prüfung bestimmt'* (for clinical trial), insofar as they are furnished free of charge,

   h) leeches and fly larvae (maggots) that are also authorised for dispensing to alternative practitioners, or

   i)medicinal products that are made available in the case specified under section 21 (2) no. 3,

3. hospitals, public health offices and physicians, in the case of vaccines intended for use in a vaccination programme conducted free of charge, on the basis of section 20 (5), (6) or (7) of the Federal Protection against Infection Act of 20 July 2000 (Federal Law Gazette I, p.1045), or supplies of vaccines required to avoid the risk of an epidemic or threat to life,

3a. special yellow fever vaccination centres pursuant to section 7 of the Act Implementing the International Health Regulations (2005), insofar as yellow fever vaccines are concerned,

3b. hospitals and public health offices, in the case of medicinal products with an antibacterial or antiviral action intended for use on the basis of section 20 (5), (6) or (7) of

the Protection against Infection Act for specific prophylaxis against communicable diseases,

3c. federal health authorities or health authorities of the Laender or agencies designated by them in individual cases, in the case of medicinal products that are being stockpiled in case of a dangerous, communicable disease, the spread of which renders necessary an immediate supply of specific medicinal products in excess of normal requirements,

4. veterinary authorities, as far as medicinal products intended for use in the execution of public health measures are concerned,

5a. agencies responsible for medevacuation designated under Land law, insofar as erythrocyte concentrates obtained from human blood are concerned,

5. central medicinal product purchasing agencies, established on a statutory basis or approved by the competent authority in consultation with the Federal Ministry,

6. veterinarians, within the framework of the operation of a veterinary in-house dispensary, insofar as finished medicinal products are concerned, for administration to animals undergoing treatment by them and for dispensing to the owners of those animals,

7. persons entitled to practise dentistry, as far as finished products used exclusively in the field of dentistry and in the treatment of a patient or as far as medicinal gases are concerned,

8. research and scientific institutions that have been granted an authorisation pursuant to section 3 of the Narcotic Drugs Act (*Betäubungsmittelgesetz*) entitling them to purchase the medicinal product in question,

9. universities, as far as medicinal products needed for the education of students of pharmacy and veterinary medicine are concerned,

10. state-recognised teaching facilities for pharmaceutical-technical assistants, insofar as medicinal products needed for the education of students are concerned.

(2) The recipients specified in subsection (1) nos. 5 to 9 may only obtain medicinal products for their own use within the framework of the fulfilment of their duties. The central purchasing agencies specified in subsection (1) no. 5 may only be officially recognised if evidence is produced that they are operated under the professional supervision of a pharmacist and provided that suitable premises and equipment are available for the testing, control and storing of the medicinal products.
(3) Pharmaceutical entrepreneurs may supply samples of finished medicinal products or have samples of finished medicinal products supplied to:

1. doctors or dentists,

2. other persons practising medicine or dentistry on human beings as a profession, provided no prescription-only medicinal products are involved,

3. training centres for health professions in human medicine.

Pharmaceutical entrepreneurs may supply samples of a finished medicinal product or have samples of a finished medicinal product supplied to training centres for health professions in human medicine only in the amounts required for the purpose of training. Samples may not contain any of the substances or preparations:

1. referred to in section 2 of the Narcotic Drugs Act or listed as such in Annexes II or III of the Narcotic Drugs Act, or

2. that, pursuant to section 48 (2) sentence 3, may only be prescribed by special prescription.

(4) Pharmaceutical entrepreneurs may supply samples of a finished medicinal product or have samples of a finished medicinal product supplied to persons pursuant to subsection (3) sentence 1 only upon written request in the smallest package size and, in the course of one year, not more than two samples of one finished medicinal product. Samples are to be accompanied by the relevant expert information insofar as such information is provided for in section 11a. The sample particularly serves the purpose of informing the physician about the medicinal product itself. Records are to be kept on the recipients of samples, the kind and extent as well as the date on which the samples were supplied, under separate cover for each recipient, and these are to be submitted to the competent authority upon request.

Section 47a
Special distribution channels, obligation to keep records

(1) Pharmaceutical entrepreneurs may supply a medicinal product that is authorised for the conduct of abortions only to facilities within the meaning of section 13 of the Pregnancy Conflicts Act of 27 July 1992 (Federal Law Gazette I, p. 1398) amended by Article 1 of the Act of 21 August 1995 (Federal Law Gazette I, p. 1050) and only on the prescription of one of the physicians administering treatment in said facility. Other persons are not authorised to place the medicinal products specified in sentence 1 on the market.
(2) Pharmaceutical entrepreneurs must give serial numbers to the packages of the medicinal products specified in subsection (1) sentence 1 that are intended for delivery; the medicinal products may not be delivered without this labelling. The pharmaceutical entrepreneur must keep records of the delivery and both the facility and the attending physician must keep records of the receipt and use of said medicinal products and must submit them for inspection to the competent authority upon request.
(2a) Both the pharmaceutical entrepreneur and the facility must store the medicinal products specified in subsection (1) sentence 1 which are in their possession in a separate place and secure them against unauthorised removal.
(3) Sections 43 and 47 do not apply to the medicinal products specified in subsection (1) sentence 1.

Section 47b
Special distribution channels, diamorphine

(1) Pharmaceutical entrepreneurs may supply a finished medicinal product containing diamorphine, which is authorised for opioid substitution treatment, only to a recognised facility pursuant to section 13 (3) sentence 2 no. 2a of the Narcotic Drugs Act and only on prescription by a physician treating at that facility. Other persons may not place the medicinal products specified in sentence 1 on the market.
(2) Sections 43 and 47 do not apply to the medicinal products specified in subsection (1) sentence 1.

Section 48
Prescription requirement

(1) The following medicinal products may be dispensed to consumers only on prescription by a physician, dentist or veterinarian:

1. medicinal products which, pursuant to the ordinance issued in subsection (2), also in conjunction with subsection (5), are certain substances, preparations from substances or objects or have such substances or preparations from substances added to them, as well as

2. medicinal products that contain:

   a) substances the effects of which are not generally known in medical science,

b) preparations from substances within the meaning of letter a), or

c) preparations from substances the effects of which are generally known, if

aa) the effects of these preparations are neither generally known in medical science, nor can they be determined on the basis of the preparation's composition, dosage, pharmaceutical form or therapeutic indication, and

bb) these preparations may not be dispensed outside of pharmacies.

Sentence 1 no. 1 does not apply to dispensing by pharmacies for the equipping of merchant ships with the medicinal products necessary, according to maritime labour regulations, to protect the health of persons on board and enable their immediate, appropriate medical treatment on board. With the inclusion of the substance or preparation in question into the ordinance pursuant to subsection (2) no. 1, the obligation to obtain a prescription pursuant to the ordinance supersedes the obligation to obtain a prescription pursuant to sentence 1 no. 2.

(2) The Federal Ministry is hereby empowered, in agreement with the Federal Ministry for Economic Affairs and Energy by ordinance subject to the approval of the Bundesrat:

1. to specify substances or preparations made of substances for which the prerequisites pursuant to subsection (1) sentence 1 no. 2, are fulfilled,

2. to specify substances, preparations thereof or objects:

a) that can either directly or indirectly endanger human health even when used in accordance with their intended purpose, if used without the supervision of a doctor or dentist, or

b) that are frequently used in considerable quantity, in a manner which is not in keeping with their designated purpose, if this might represent a direct or indirect risk to human health,

3. to repeal the prescription-only status of medicinal products if experience gained from using them shows that the conditions referred to in no. 2 do not or no longer exist; in the case of medicinal products referred to in no. 1, the prescription-only status cannot be repealed until at least three years have elapsed since entry into force of the ordinance on which it is based,

4. for substances or preparations thereof, to stipulate that they may be supplied only if certain maximum quantities for single and daily use are not exceeded in the prescription or if, when they are exceeded, the prescriber has expressly made this clear,

5. to specify whether and how often a medicinal product can be repeatedly dispensed on the same prescription,

6. to stipulate that a medicinal product can be supplied only on prescription by a physician with a specific specialty or for use in facilities authorised to carry out treatment with the medicinal product or that records must be kept of the prescription, dispensing and use of the medicinal product,

7. to issue provisions on the form and content of the prescription, including prescriptions in electronic form.

The ordinances pursuant to sentence 1 nos. 2 to 7 are issued after hearing experts, unless medicinal products are concerned that are authorised pursuant to Article 3 (1) or (2) of Regulation (EC) No. 726/2004 or that correspond to such medicinal products with respect to their active substances, indications, strength and pharmaceutical form. In the case of medicinal products that can be prescribed only in compliance with special safety requirements, it may be stipulated in the ordinance pursuant to sentence 1 no. 7 that:

1. the prescription may only be written on an official form that is either issued or made available in an electronic form by the competent higher federal authority at the request of a physician,

2. the form must contain information on the use as well as confirmations, especially regarding obligations to inform patients about the use and risks of the medicinal product, and

3. a copy of the prescription is to be returned to the competent higher federal authority by the pharmacy, or a copy of the prescription issued in electronic form must be automatically transmitted to the competent higher federal authority.

(3) The ordinance referred to in subsection (2), also in conjunction with subsection (5), can be restricted to specific dosages, strengths, pharmaceutical forms, finished medicinal products or therapeutic indications. Similarly, an exception to the prescription-only requirement may be envisaged for dispensing to midwives and obstetric nurses where this is deemed necessary for the proper exercise of their profession. The restriction to specific finished medicinal products pursuant to sentence one applies if, pursuant to Article 74a of Directive 2001/83/EC, the prescription-only requirement is repealed on the basis of significant preclinical tests or clinical trials; in this regard, the period of one year referred to in Article 74a is to be observed.

Section 49
(no longer applicable)

Section 50
Retail trading of over-the-counter medicinal products

(1) The retailing, outside of pharmacies, of medicinal products that are released for trade outside of pharmacies, may only be carried out if the entrepreneur, the legally appointed representative of the enterprise or a person commissioned by the entrepreneur either to head the enterprise or to head its sales section, is in possession of the necessary expert knowledge. Enterprises with several branch premises require a person who has the necessary expert knowledge for each of the branch premises.
(2) To be considered as possessing the necessary expert knowledge, the person in question must furnish proof of experience and skills in respect of the proper filling, packaging, labelling, storing and marketing of medicinal products that are released for trade outside of pharmacies, as well as knowledge of the existing regulations applicable to these medicinal products. The Federal Ministry is hereby empowered to issue, in agreement with the Federal Ministry for Economic Affairs and Energy and the Federal Ministry for Education and Research, by ordinance subject to the approval of the Bundesrat, regulations as to how proof of the necessary expert knowledge is to be furnished in order to guarantee a proper trade in medicinal products. It may hereby recognise certificates of professional training or of attendance at further education courses. Furthermore, it may stipulate that proof of the expert knowledge is furnished by means of an examination set by the competent authority or by an office accordingly designated by that same authority and may regulate the particulars of the examination requirements and procedure.
(3) Expert knowledge pursuant to subsection (1) is not required by a person retailing finished medicinal products that:

1. may be distributed in itinerant trading,

2. are intended for use as a contraceptive or for the prevention of venereal diseases,

3. (no longer applicable)

4. are disinfectants intended exclusively for external use, or

5. are oxygen.

Section 51
Sale by itinerant traders

(1) Itinerant traders are prohibited from offering medicinal products for sale or seeking to procure orders for medicinal products; exempted from the prohibition are finished medicinal products released for trade outside of pharmacies that:

1. are plants, parts of plants or juices pressed from fresh plants or parts of plants, the effects of which are generally known and which are designated by their customary German names, provided they are manufactured without the use of any solvent other than water, or

2. are curative waters and their salts in their natural mixing proportions or imitations thereof.

(2) The prohibition contained in the first half-sentence of subsection (1) does not apply if the trader visits other persons within the framework of their business activities. The same also applies to commercial travellers and other persons active on behalf of and in the name of a trader.

Section 52
Prohibition of self-service

(1) Medicinal products may not be placed on the market using vending machines or other forms of self-service.
(2) Subsection (1) does not apply to finished medicinal products that:

1. may be distributed in itinerant trading,

2. are intended for use as contraceptives or for the prevention of venereal disease and which have been released for trade outside of pharmacies,

3. (no longer applicable)

4. are disinfectants intended exclusively for external use, or

5. are oxygen.

(3) In derogation of subsection (1), medicinal products released for trade outside of pharmacies may be placed on the market using forms of self-service except for vending machines in cases where a person in possession of the expert knowledge required under section 50 is available.

Section 52a
Wholesale trading of medicinal products

(1) Any person who engages in the wholesale trading of medicinal products requires an authorisation to do so. Exempted from this obligation to obtain an authorisation are the finished medicinal products specified in section 51 (1) no. 2 and released for trade outside of pharmacies.
(2) In submitting the application, the applicant must:

1. name the specific sites, as well as the activities and the medicinal products for which the authorisation is to be issued,

2. submit evidence that he/she is in possession of suitable and adequate premises, installations and facilities in order to ensure the proper storage and distribution and, where envisaged, proper decanting, packaging and labelling of medicinal products,

3. appoint a person responsible who possesses the required expert knowledge to perform the activity and

4. enclose a statement in which he/she commits himself/herself in writing to observe the regulations governing the proper operation of a wholesale enterprise.

(3) The decision on the granting of the authorisation is taken by the competent authority of the federal Land where the factory site is situated or is to be situated. The competent authority must reach a decision on the application for an authorisation within a period of three months. Should the competent authority require additional information from the applicant on the prerequisites pursuant to subsection (2), the deadline specified in sentence 2 is interrupted until such time as the competent authority has received the necessary additional information.
(4) The authorisation may only be refused if:

1. the prerequisites pursuant to subsection (2) are not fulfilled,

2. facts justify the assumption that the applicant or the person responsible pursuant to subsection (2) no. 3 does not possess the necessary reliability to perform the activity, or

3. the wholesaler is unable to guarantee that the regulations governing proper operations are being observed.

(5) The authorisation is to be withdrawn if it becomes known subsequently that one of the grounds for refusal pursuant to subsection (4) existed at the time the authorisation was granted. The authorisation is to be revoked if the prerequisites for the granting of an authorisation no longer exist; instead of the revocation, the suspension of the authorisation may also be ordered.
(6) An authorisation pursuant to section 13 or section 72 also includes authorisation for the wholesale trading of the medicinal products covered by the authorisation referred to in section 13 or section 72.
(7) Subsections (1) to (5) do not apply to the activities conducted by pharmacies within the framework of normal pharmacy operations.
(8) The authorisation holder must notify the competent authority in advance of any changes in the information specified in subsection (2), as well as any fundamental change in the wholesale trading activity, submitting evidence to that effect. In the case of an unforeseen change with respect to the person responsible pursuant to subsection (2) no. 3, the notification is to be immediate.

Section 52b
Supply of medicinal products

(1) Pharmaceutical entrepreneurs and operators of wholesale businesses for medicinal products who, within the purview of this Act, distribute a medicinal product actually placed on the market that has been authorised for marketing by the competent higher federal authority or for which a marketing authorisation pursuant to Article 3 (1) or (2) of Regulation (EC) No. 726/2004 has been granted by the European Community or the European Union ensure an adequate and continuous supply of the medicinal product so that the demand from patients within the purview of this Act is met.
(2) Pharmaceutical entrepreneurs must guarantee, within the framework of their responsibility, a demand-oriented and continuous supply to the full-range wholesalers of medicinal products. Full-range wholesalers of medicinal products are wholesale businesses that maintain a complete, manufacturer-independent assortment of pharmacy-only medicinal products which, in terms of depth and scope, is constituted in such a way that the demand from patients from the pharmacies with which the wholesaler does business can be met within an appropriate space of time on weekdays; the medicinal products to be kept in stock must correspond, in such a case, to at least two weeks' average demand; the medicinal products to be kept in stock that are listed in the list prepared under section 35 (5a) sentence 1 of the Fifth Book of the Social Code must correspond to at least four weeks' average demand. Sentence 1 does not apply to medicinal products that are subject to the distribution

channels specified in section 47 (1) nos. 2 to 10 or section 47a or section 47b or which, for other legal or practical reasons, cannot be supplied through the wholesale business.
(3) Full-range wholesalers of medicinal products must, within the framework of their responsibility, guarantee a demand-oriented and continuous supply to the pharmacies with which they do business. Sentence 1 applies accordingly to other medicinal product wholesale businesses for the totality of the medicinal products they hold in stock in each case.
(3a) Pharmaceutical entrepreneurs must, within the framework of their responsibility, inform hospitals without delay once they become aware of delivery bottlenecks for prescription-only medicinal products used in inpatient care.
(3b) An advisory council is set up at the Federal Institute for Drugs and Medical Devices to continuously monitor and assess the supply situation of medicinal products. The advisory council is to comprise representatives of patient interests as well as the following associations, organisations and authorities:

1. the professional societies of medical practitioners,
2. the professional representatives of the pharmacists,
3. the medicinal product committees of the chambers of the health professions,
4. the main central associations of the pharmaceutical entrepreneurs responsible for representing their interests,
5. the association of the full-range wholesalers of medicinal products,
6. the Central Federal Association of the Health Insurance Funds,
7. the National Association of Statutory Health Insurance Physicians,
8. the German Hospital Federation,
9. the competent higher federal authorities and the competent authorities.

The Federal Ministry appoints associations and organisations to participate on the advisory council. The Federal Institute for Drugs and Medical Devices publishes the names of the associations and organisations participating on the advisory council on its website. The Central Federal Association of the Health Insurance Funds takes part in the meetings with up to five representatives, providing for involvement on the part of its members. The representatives on the advisory council have a personal obligation to maintain confidentiality in relation to their activities on the advisory council and the facts and other information that come to their attention and may use these solely for the purpose of fulfilling the tasks of the advisory council. The advisory council will adopt rules of procedure for itself in which it stipulates further details on the procedure and the advisory council’s mode of operation, including documenting the main reasons for majority and minority votes. The rules of procedure are subject to the approval of the Federal Ministry of Health.
(3c) After hearing the advisory council, the Federal Institute for Drugs and Medical Devices draws up a current list of supply-relevant and supply-critical active substances and publishes this list on its website. Furthermore, the Federal Institute for Drugs and Medical Devices publishes on its website:

1. the supply bottlenecks of which it is informed, and
2. a current list of medicinal product supply bottlenecks with supply-relevant and supply-critical active substances. Insofar as active substances fall within the remit of the Paul Ehrlich Institute (Federal Agency for Sera and Vaccines), the publication pursuant to sentences 1 and 2 is carried out in agreement with the Paul Ehrlich Institute.

(3d) In the event of an impending or existing supply-relevant bottleneck regarding a medicinal product, the competent higher federal authority may take suitable measures to

prevent or mitigate such a bottleneck after hearing the advisory council. In particular, the competent higher federal authority may mandate that pharmaceutical entrepreneurs and wholesalers of medicinal products take specific measures to guarantee the adequate and continuous supply of medicinal products pursuant to subsection (1); this includes measures to ration medicinal products. In the case of medicinal products that contain supply-relevant active substances, the higher federal authority may, after hearing the advisory council, mandate stockpiling measures to prevent or mitigate an impending or existing supply-relevant bottleneck.
(3e) At the request of the Federal Institute for Drugs and Medical Devices, pharmaceutical entrepreneurs, manufacturers and wholesalers of medicinal products must transmit data electronically on available stocks, production, including the manufacturing site of the active substances actually used to manufacture the medicinal product, and volume of sales, as well as information on impending supply bottlenecks regarding the specific medicinal product, so as to prevent or mitigate an impending or existing supply-relevant bottleneck for a specific medicinal product. At the request of the Federal Institute for Drugs and Medical Devices, hospital pharmacies and pharmacies that supply hospitals must transmit data electronically on the available stocks of the medicinal product so as to prevent or mitigate an impending or existing supply-relevant bottleneck for that medicinal product. The Federal Institute for Drugs and Medical Devices specifies the procedure and the templates for the electronic transmission of the data and publishes this information on its website. Insofar as active substances or medicinal products within the remit of the Paul Ehrlich Institute are affected, the request for data pursuant to sentences 1 and 2 and the specification of the procedure and the templates for the electronic transmission of the data is made in agreement with the Paul Ehrlich Institute. The data may be transmitted in anonymised form to the advisory council, upon request, for observation and assessment.
(3f) After hearing the advisory council, the Federal Institute for Drugs and Medical Devices draws up a list of finished medicinal products for which a regular transmission of data is necessary to assess the supply situation and publishes this list on its website. Pharmaceutical entrepreneurs transmit data on available stocks, production, including the manufacturing site of the active substances actually used to manufacture the medicinal product, and the volume of sales of finished medicinal products, included in the list referred to in sentence 1, in electronic form, to the Federal Institute for Drugs and Medical Devices at regular intervals of no longer than eight weeks. Where necessary to assess the supply situation, the Federal Institute for Drugs and Medical Devices may also require that wholesalers of medicinal products regularly transmit data electronically on their stocks and the volume of sales of the finished medicinal products on the list referred to in sentence 1. The Federal Institute for Drugs and Medical Devices specifies the procedure and the templates for the electronic transmission of the data and publishes this information on its website. Insofar as finished medicinal products within the remit of the Paul Ehrlich Institute are affected, the drawing up of the list of finished medicinal products, the specification of the procedure and the templates as well as the publication of the data is conducted in agreement with the Paul Ehrlich Institute. The data may be transmitted in anonymised form to the advisory council, upon request, for observation and assessment.
(3g) An early warning system will be established at the Federal Institute for Drugs and Medical Devices to identify impending supply-relevant bottlenecks for medicinal products. The Federal Institute for Drugs and Medical Devices will develop criteria for identifying impending supply-relevant bottlenecks on which the early warning system must be based. The Federal Ministry is hereby empowered to issue ordinances, subject to the approval of the Bundesrat, to specify the detailed design of the early warning system.
(4) This is without prejudice to the provisions contained in the Act against Restraints of Competition (*Gesetz gegen Wettbewerbsbeschränkungen*).

Section 52c
Brokering of medicinal products

(1) A medicinal product broker may only operate within the purview of this Act if his/her registered place of business is situated within the purview of this Act, in another Member State of the European Union or another State Party to the Agreement on the European Economic Area.
(2) The medicinal product broker may begin his/her activities only after notifying the competent authority pursuant to section 67 (1) sentence 1 and being registered by the authority in a public database pursuant to section 67a or a database of another Member State of the European Union or in that of another State Party to the Agreement on the European Economic Area. The notification is to state the type of activity as well as the name and address of the medicinal product broker. The competent authority pursuant to sentence 1 is the authority in whose remit the medicinal product broker has his/her domicile.
(3) If the medicinal product broker fails to meet the requirements stipulated in this Act or in an ordinance issued based on this Act, the competent authority can refuse to register him/her in the database or erase him/her from it.

Section 53
Expert consultation

(1) Insofar as expert opinions need to be heard pursuant to section 45 (1) and section 46 (1) prior to the issue of ordinances, the Federal Ministry establishes an expert committee by ordinance not subject to the approval of the Bundesrat. The committee is to comprise experts from the field of medical and pharmaceutical science, from hospitals, from the health professions, from the business circles involved and from the social security institutions. In the ordinance, the exact details of the composition, appointment of the members and the procedure of the committee may be determined.
(2) Insofar as the opinion of experts needs to be heard pursuant to section 48 (2), prior to the issue of an ordinance, subsection (1) applies accordingly, subject to the provision that the committee is to comprise experts from the fields of medical and pharmaceutical science, as well as experts from the drug commissions of the physicians and pharmacists. The representatives of medical and pharmaceutical practice, as well as representatives from the pharmaceutical industry, participate in the meeting without the right to vote.

Division 8
Safety and quality control

Section 54
Internal regulations

(1) The Federal Ministry is hereby empowered to issue in agreement with the Federal Ministry for Economic Affairs and Energy, by ordinance subject to the approval of the Bundesrat, internal regulations for enterprises or facilities that introduce medicinal products into the purview of this Act or in which medicinal products are developed, manufactured, tested, stored, packaged or placed on the market or in which medicinal products are otherwise traded, insofar as it is deemed necessary in order to ensure the proper operation of the enterprise or facility and the quality required of the medicinal products and pharmacovigilance; this applies accordingly to active substances and other substances as well as tissues intended for the manufacture of medicinal products. The ordinance is issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, insofar as radiopharmaceuticals or medicinal products in the manufacture of which ionising radiation is used are concerned.
(2) In the ordinance pursuant to subsection (1), regulations may be laid down in particular concerning:

1. the development, manufacture, testing, storage, packaging, quality assurance, acquisition, supply, stockpiling and placing on the market,

2. the maintaining and keeping of records on the operational processes specified in no. 1,

3. the keeping and monitoring of the animals used in the manufacture and testing of medicinal products and the records kept on them,

4. staffing requirements,

5. the nature, size and equipment of the premises,

6. sanitation requirements,

7. the nature of the containers,

8. the labelling of the containers in which medicinal products and their starting materials are stored,

9. the stand-by obligation for medicinal product wholesalers,

10. the retention of batch samples including quantities and duration of storage,

11. the labelling, separation or destruction of medicinal products that are unfit for marketing.

(2a) (repealed)
(3) The regulations under subsections (1) and (2) also apply to persons practising the activities indicated in subsection (1) professionally.
(4) Subsections (1) and (2) apply to pharmacies as defined in the Pharmacies Act, insofar as these require an authorisation pursuant to section 13 section 52a or section 72.

Section 55
Pharmacopoeia

(1) The Pharmacopoeia is a collection of recognised pharmaceutical rules regarding the quality, testing, storage, dispensing and designation of medicinal products, veterinary medicinal products and the substances used in their manufacture, published by the Federal Institute for Drugs and Medical Devices in agreement with the Paul Ehrlich Institute and the Federal Agency for Consumer Protection and Food Safety. The Pharmacopoeia also contains requirements regarding the nature of containers and outer packaging.
(2) The rules contained in the Pharmacopoeia are laid down by the German Pharmacopoeia Commission or by the European Pharmacopoeia Commission. Publication of the rules can be refused or annulled for legal or technical reasons.
(3) It is incumbent upon the German Pharmacopoeia Commission to stipulate the rules contained in the Pharmacopoeia and to assist the competent higher federal authority pursuant to section 77 or, insofar as veterinary medicinal products are concerned, the higher federal authority pursuant to section 65 of the Veterinary Medicinal Products Act with its work within the framework of the Convention on the Elaboration of a European Pharmacopoeia.
(4) The German Pharmacopoeia Commission will be set up at the Federal Institute for Drugs and Medical Devices. In consultation with the Paul Ehrlich Institute and the Federal Agency for Consumer Protection and Food Safety, the Federal Institute for Drugs and Medical Devices appoints the members of the German Pharmacopoeia Commission, proportionally, from among experts in the fields of medical and pharmaceutical science, the health professions, the business circles affected and the field of pharmacovigilance, provides the chairperson and issues by-laws. The by-laws require the consent of the Federal Ministry in agreement with the Federal Ministry of Food and Agriculture. Members are bound to maintain confidentiality.
(5) In principle, the German Pharmacopoeia Commission is to decide unanimously on the rules contained in the Pharmacopoeia. Decisions taken by three-quarters of the members of the Commission or less are not valid. The detailed provisions are laid down in the by-laws.
(6) Subsections (2) to (5) apply accordingly to the work of the German Homeopathic Pharmacopoeia Commission.

(7) Promulgation takes place in the Federal Gazette. It can be limited to indicating the source of the version of the Pharmacopoeia in question and the date on which the revised version becomes valid.
(8) Only substances and the containers and outer packaging, insofar as they come into contact with the medicinal products, and only pharmaceutical forms that are in compliance with recognised pharmaceutical rules, may be used in the manufacture of medicinal products. Sentence 1 applies to medicinal products that are manufactured exclusively for export with the proviso that the regulations in force in the receiving country can be taken into consideration.
(9) By way of derogation from subsection (1) sentence 1, the promulgation is conducted by the Federal Agency for Consumer Protection and Food Safety in agreement with the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute, insofar as veterinary medicinal products are concerned.

Section 55a
Official compilation of test procedures

The competent higher federal authority publishes an official compilation of test procedures for the sampling and testing of medicinal products, veterinary medicinal products and their starting materials. The procedures are established in consultation with pharmacovigilance experts, scientists and pharmaceutical entrepreneurs. The compilation of procedures is to be kept up to date.

Division 9
(repealed)

Division 10
Monitoring, compiling and evaluating the risks of medicinal products

Section 62
Organisation

(1) In the interests of preventing direct or indirect hazards to human health, it is the responsibility of the competent higher federal authority to centrally record and evaluate those risks associated with the administration of medicinal products, in particular adverse reactions, interactions with other products and risks associated with counterfeit medicinal products or counterfeit active substances and to co-ordinate the measures to be adopted in accordance with this Act. In particular, it coordinates measures in the event of recalls of medicinal products and in the context of quality defects in active substances. For this purpose, the higher federal authority co-operates with the offices of the World Health Organization, the European Medicines Agency, the medicinal product authorities of other countries, the health authorities of the federal Laender, the medicinal product committees of the chambers of the health professions and national pharmacovigilance centres, as well as with others who, in the execution of their work, keep records on medicinal product risks. The competent higher federal authority may inform the public about medicinal product-related risks and envisaged measures. The competent higher federal authority operates a pharmacovigilance system. It conducts regular audits of its pharmacovigilance system and report to the European Commission every two years, for the first time on 21 September 2013.
(2) The competent higher federal authority records all cases of suspected adverse reactions that come to its attention. Reports from patients and health care professionals can take any form, especially also electronic. Reports from marketing authorisation holders pursuant to section 63c are transmitted electronically. By collecting information and, when necessary, following up on reports of suspected adverse reactions, the competent higher federal authority ensures that all suitable measures are taken so as to clearly identify all biological medicinal products that are prescribed, dispensed or sold and pertaining to which reports of

suspected adverse reactions have been made, whereby the name of the medicinal product and the number of the manufacturing batch are to be specified.
(3) The competent higher federal authority must transmit every serious suspected adverse reaction reported that occurs on the territory governed by this Act within 15 days and on every reported non-serious suspected adverse reaction that occurs on the territory governed by this Act within 90 days, electronically, to the database referred to in Article 24 of Regulation (EC) 726/2004 (EudraVigilance database). The competent higher federal authority works together with the European Medicines Agency and the marketing authorisation holder to determine in particular whether there has been duplication in the recording of reported suspected adverse reactions. Where necessary, the competent higher federal authority also involves patients, health care professionals or the marketing authorisation holder in the follow-up of the reports received.
(4) The competent higher federal authority controls the management of the funds intended for the performance of pharmacovigilance activities, the operation of the communication networks and market supervision in order to guarantee its independence in the performance of these pharmacovigilance activities.
(5) The competent higher federal authority takes the following measures in cooperation with the European Medicines Agency:

1. monitoring the outcome of the risk minimisation measures contained in risk management plans as well as the conditions referred to in section 28 (3) and (3a) and (3b),

2. assessing updates to the risk management system,

3. evaluating the data in the EudraVigilance database to determine whether there are new or changed risks, and whether this has an impact on the risk-benefit balance of medicinal products.

(6) The competent higher federal authority can inspect the collection and evaluation of medicinal product risks and the co-ordination of necessary measures in enterprises and facilities that manufacture, place on the market or clinically test medicinal products. To this end, the representatives of the competent higher federal authority, in consultation with the competent authority, can enter the production areas and business premises during regular working hours, inspect documents including the pharmacovigilance master file and request information. Sentence 1 also applies to undertakings commissioned by enterprises and facilities pursuant to sentence 1. A report is to be drawn up on the inspection. The report is to be submitted to the enterprises and facilities pursuant to sentence 1 for comments. If an inspection results in the conclusion that the marketing authorisation holder fails to meet the requirements of the pharmacovigilance system as described in the pharmacovigilance master file, and above all the requirements of Division 10, the competent higher federal authority draws the attention of the marketing authorisation holder to the detected deficiencies and give the latter the opportunity to submit comments. In such cases, the competent higher federal authority informs the competent authorities of other Member States, the European Medicines Agency and the European Commission.

Section 63
Graduated plan

By means of general administrative regulations subject to the approval of the Bundesrat, the Federal Government draws up a graduated plan detailing the execution of the tasks indicated in section 62. This plan specifies the details of the co-operation to take place between the authorities and the services involved at the various danger levels, the intervention of the pharmaceutical entrepreneurs as well as the participation of the Federal Government Commissioner for Patient Affairs and stipulates the various measures to be taken in compliance with the provisions of this Act. In the graduated plan, information means and channels may also be specified.

Section 63a
Graduated plan officer

(1) Anyone who, in his/her capacity as a pharmaceutical entrepreneur, places finished medicinal products on the market, must appoint a qualified person who is resident in a Member State of the European Union, who has the required expert knowledge and the reliability necessary for exercising his/her function (graduated plan officer) to set up and manage a pharmacovigilance system and to collect and evaluate notifications on medicinal product risks that have become known and co-ordinate the necessary measures. Sentence 1 does not apply to persons who do not require a manufacturing authorisation pursuant to section 13 (2) nos. 1, 2, 5 or subsection (2b). The graduated plan officer is responsible for meeting the obligations to notify insofar as they concern medicinal product risks. He/she must also ensure that additional information for the evaluation of the risk-benefit profile of a medicinal product, including his/her own evaluations, are sent immediately and in full, if requested by the competent higher federal authority. The details are stipulated by the Ordinance on the Manufacture of Medicinal Products and Active Substances (*Arzneimittel- und Wirkstoffherstellungsverordnung*). Persons other than those specified in sentence 1 are not authorised to perform the duties of the graduated plan officer.
(2) The graduated plan officer may be a qualified person pursuant to section 14 or a person responsible pursuant to section 20c at the same time.
(3) The pharmaceutical entrepreneur must notify the competent authority and the competent higher federal authority about the identity of the graduated plan officer and must make notification of any change beforehand. In the case of an unforeseen change in the person of the graduated plan officer, notification is to be made immediately.

Section 63b
General pharmacovigilance obligations of the marketing authorisation holder

(1) The marketing authorisation holder is obligated to set up and operate a pharmacovigilance system.
(2) The marketing authorisation holder is obligated to:

1. scientifically evaluate all of the information, based on its pharmacovigilance system, examine risk minimisation and prevention measures and, if necessary, take risk minimisation and prevention measures immediately,

2. audit its pharmacovigilance system regularly at appropriate intervals; in the process, it must make a note of the most important findings in its pharmacovigilance master file and ensure that corrective measures are taken to remedy deficiencies; once the corrective measures have been fully implemented, the note may be deleted,

3. maintain a pharmacovigilance master file and to make this file available upon request,

4. operate a risk management system for every medicinal product authorised after 26 October 2012 or for which a condition pursuant to section 28 (3b) sentence 1 no. 1 has been imposed,

5. monitor the outcome of risk minimisation measures that are part of the risk management plan or have been imposed as conditions pursuant to section 28 (3) to (3c), and

6. to update the risk management system and monitor pharmacovigilance data so as to determine whether there are new risks, whether risks have changed or whether there are changes to the risk-benefit balance of medicinal products.

(3) In connection with the authorised medicinal product, the marketing authorisation holder may not make any pharmacovigilance information public without prior or simultaneous notification of the competent higher federal authority, the European Medicines Agency and

the European Commission. He/she ensures that such information is presented objectively and is not misleading.

Section 63c
Documentation and reporting obligations of the holder of a marketing authorisation in the case of suspected adverse reactions

(1) The marketing authorisation holder must keep documents on all suspected adverse reactions as well as information on the quantities supplied.
(2) The marketing authorisation holder transmits all of the information on every suspected case of:

1. serious adverse reactions that occur domestically or abroad, within a period of 15 days,

2. non-serious adverse reactions that occur domestically or in a Member State of the European Union, within 90 days after acquiring this knowledge of it, electronically, to the EudraVigilance database pursuant to Article 24 of Regulation (EC) 726/2004.

In the case of medicinal products containing active substances to which the list of publications evaluated by the European Medicines Agency pursuant to Article 27 of Regulation (EC) No. 726/2004 refers, the marketing authorisation holder does not have to transmit the suspected adverse reactions listed in the specialist medical literature to the EudraVigilance database; however, he/she must assess the other specialist medical literature and report all suspected adverse reactions pursuant to sentence 1. Holders of the registration pursuant to section 38 or section 39a or pharmaceutical entrepreneurs who are not holders of the registration pursuant to section 38 or section 39a and who place a homoeopathic medicinal product or a traditional herbal medicinal product that is not subject to registration on the market, transmit information pursuant to sentence 1 to the competent higher federal authority.
(3) The marketing authorisation holder must guarantee that all reports of suspected adverse reactions from medicinal products are available at a central location belonging to the enterprise within the European Union.
(4) Subsections (1) to (3), section 62 (6) and section 63b apply accordingly to:

1. to the holder of a registration pursuant to section 39a,

2. to a pharmaceutical entrepreneur who is neither the holder of the marketing authorisation nor the holder of a registration pursuant to section 39a and who places a medicinal product on the market that is subject to marketing authorisation or exempt from marketing authorisation or is a traditional herbal medicinal product.

Subsections (1) to (3) apply:

1. to the holder of the registration pursuant to section 38,

2. to a pharmaceutical entrepreneur who is not the holder of the registration pursuant to section 38 and places a homeopathic medicinal product that is subject to registration or exempt from the obligation to obtain a registration on the market,

3. to the applicant before the marketing authorisation is granted.

Subsections (1) to (3) apply regardless of whether the medicinal product is still on the market or the marketing authorisation or registration still exists. The fulfilment of the obligations pursuant to subsections (1) to (3) can be fully or partly transferred to the marketing authorisation holder by means of a written agreement between the marketing authorisation holder and the pharmaceutical entrepreneur who is not the holder of the marketing authorisation.
(5) Subsections (1) to (4) do not apply to medicinal products for which a marketing authorisation has been granted by the European Community or the European Union. For

such medicinal products, the obligations of the pharmaceutical entrepreneur are those stipulated in the latest applicable version of Regulation (EC) No. 726/2004. In the case of medicinal products for which a marketing authorisation by the competent higher federal authority forms the basis for mutual recognition or for which a competent higher federal authority is the rapporteur in arbitration proceedings pursuant to Article 32 of Directive 2001/83/EC, the competent higher federal authority assumes the responsibility for the analysis and supervision of all serious suspected adverse reactions that occur in the European Union; this also applies to medicinal products that were authorised for marketing in the decentralised procedure.

Section 63d
Periodic safety update reports

(1) The marketing authorisation holder transmits periodic safety update reports containing the following:

1. a summary of the data that is of interest in assessing the benefits and risks of a medicinal product, including the results of all studies that can have an effect on the marketing authorisation,

2. a scientific evaluation of the medicinal product's risk-benefit balance that is based on all of the available data, including data from clinical trials for therapeutic indications and population groups that are not covered by the marketing authorisation,

3. all of the data relating to the medicinal product's volume of sales as well as all of the data at his/her disposal relevant to the volume of prescriptions, including an estimate of the number of persons using the medicinal product.

(2) The periodic safety update reports are to be transmitted electronically:

1. in the case of medicinal products for which frequency and dates of submission of the periodic safety update reports are stipulated in the marketing authorisation or in accordance with the procedure pursuant to Article 107c paragraph 4, 5 and 6 of Directive 2001/83/EC, to the European Medicines Agency,

2. in the case of medicinal products that were authorised before 26 October 2012 and for which frequency and dates of submission of the periodic safety update reports are not stipulated in the marketing authorisation, to the competent higher federal authority,

3. in the case of medicinal products that were only authorised domestically and for which no frequency and dates of submission of the periodic safety update reports are not stipulated in the marketing authorisation pursuant to Article 107c paragraph 4 of Directive 2001/83/EC, to the competent higher federal authority.

The safety reports are to be transmitted electronically to the competent higher federal authority.

(3) The frequency for the submission of periodic safety update reports pursuant to subsection (1) is specified in the marketing authorisation. The date for submission is calculated from the date on which the marketing authorisation is granted. The submission frequency and the submission dates can be laid down in the European Union according to the procedure pursuant to Article 107c paragraph 4 of Directive 2001/83/EC. The marketing authorisation holder can apply to the Committee on Medical Products for Human Use or to the co-ordination group pursuant to Article 27 of Directive 2001/83/EC to have a single reference date pursuant to Article 107c (6) of Directive 2001/83/EC stipulated in the European Union or that the frequency for the submission of periodic safety update reports is changed. In the case of medicinal products that are authorised before 26 October 2012 or are authorised only for the national market and for which the submission frequency and dates are not specified in the marketing authorisation or pursuant to Article 107c paragraph 4, 5 or 6 of Directive 2001/83/EC, the marketing authorisation holder transmits the periodic

safety update reports pursuant to subsection (1) immediately upon request or in the following cases:

1. if a medicinal product has not yet been placed on the market: at least every six months after the marketing authorisation has been granted and until it is placed on the market,

2. if a medicinal product has been placed on the market: at least every six months during the first two years following the first placing on the market, once a year in the following two years and at three-yearly intervals thereafter.

(4) By way of derogation from subsection (1), periodic safety update reports are transmitted for medicinal products that are authorised for marketing pursuant to section 22 (3) or section 24b (2) only in the following cases:

1. if a condition pursuant to section 28 (3) or (3a) has been imposed,

2. if they are requested by the competent higher federal authority for an active substance, after the marketing authorisation has been granted, owing to reservations in connection with pharmacovigilance data or owing to reservations due to insufficient availability of periodic safety update reports,

3. if the frequency and dates for the submission of periodic safety update reports pursuant to Article 107c (4) of Directive 2001/83/EC were specified in the marketing authorisation.

The competent higher federal authority transmits the assessment reports on the requested periodic safety update reports pursuant to sentence 1 no. 2 to the Pharmacovigilance Risk Assessment Committee which examines whether it is necessary to initiate the procedure pursuant to Article 107c paragraph 4 of Directive 2001/83/EC. Sentence 1 nos. 2 and 3 apply accordingly to the holder of registrations pursuant to section 38 or section 39a, as well as to the pharmaceutical entrepreneur who is not the holder of the marketing authorisation or the registration pursuant to section 38 or section 39a and who places a traditional herbal medicinal product that is subject to authorisation or registration or exempt from the obligation to obtain an authorisation or registration on the market.

(5) The competent higher federal authority assesses the periodic safety update reports to determine whether there are new risks or whether risks have changed and whether there are changes to the risk-benefit balance of medicinal products and takes the necessary measures. In the case of medicinal products for which a single Union reference date or a single frequency date for the submission of reports pursuant to Article 107c paragraph 4 of Directive 2001/83/EC has been stipulated, as well as for medicinal products that are authorised in more than one Member States and for which periodic safety update reports are specified in the marketing authorisation, the procedure pursuant to Articles 107e and 107g applies to the assessment.

(6) The fulfilment of the obligations pursuant to subsections (1) to (3) can be fully or partly transferred to the marketing authorisation holder by means of a written agreement between the marketing authorisation holder and the pharmaceutical entrepreneur who is not the holder of the marketing authorisation. Subsections (1) to (5) do not apply to parallel importers.

Section 63e
European procedure

With regard to the cases governed by Article 107i of Directive 2001/83/EC, the competent higher federal authority takes the measures provided for therein. Articles 107i to 107k of Directive 2001/83/EC apply to the procedure.

Section 63f
General prerequisites for non-interventional post-authorisation safety studies

(1) Notification of non-interventional post-authorisation safety studies that are conducted voluntarily by the marketing authorisation holder is to be made to the competent higher federal authority. The competent higher federal authority can require that the marketing authorisation holder submit the protocol and the progress reports. The marketing authorisation holder must transmit the final report to the competent higher federal authority within one year after data collection is completed.
(2) In the case of non-interventional post-authorisation safety studies that are conducted by the marketing authorisation holder pursuant to a condition imposed pursuant to section 28 (3), (3a) or (3b), the procedure pursuant to section 63g applies.
(3) It is not admissible to conduct non-interventional post-authorisation safety studies pursuant to subsections (1) and (2) if:

1. conducting the study promotes the use of the medicinal product,

2. payments for the participation of the health professionals involved in such studies is not restricted in type and amount to compensation for time and expenses incurred, or

3. an incentive is created for the preferential prescription or recommendation of specific medicinal products.

(4) The marketing authorisation holder must also immediately notify the National Association of Statutory Health Insurance Physicians, the Central Federal Association of the Health Insurance Funds and the German Association of Private Health Insurance Funds of post-authorisation safety studies pursuant to subsections (1) and (2). In doing so, he/she is also to provide information on the location, time, purpose and the protocol of the study as well as the name and lifelong physician identification number of the participating physicians. Insofar as participating physicians provide benefits that are reimbursed by the statutory health insurance, the type and amount of the compensation actually paid to them in each case is to be communicated as well as a copy of each of the contracts signed with them and, in each case, a description of the costs incurred for the participating physicians and a justification for the appropriateness of the compensation are to be submitted in the case of notifications pursuant to sentence 1. Insofar as modifications are made to the information specified in sentence 3, the information pursuant to sentence 3 is to be communicated in its entirety, in the modified, updated form within four weeks following the end of each quarter; the compensation actually paid is to be communicated and assigned to the participating physicians giving the name and the lifelong physician identification number. Within one year following the completion of the data collection process, the number of patients participating in each case, and in total, as well as the type and amount of the compensation paid in each case and in total are to be communicated giving the total number of participating physicians. The information pursuant to this subsection is to be transmitted electronically according to the format specifications provided for in section 67 (6) sentence 13.

Section 63g
Special prerequisites for imposed non-interventional post-authorisation safety studies

(1) In the case of non-interventional post-authorisation safety studies that were imposed pursuant to section 28 (3), (3a) or (3b), the marketing authorisation holder must submit the draft study protocol before conducting the study to:

1. the competent higher federal authority in the case of a study that is only conducted on the territory governed by this Act,

2. the Pharmacovigilance Risk Assessment Committee in the case of a study that is conducted in several Member States of the European Union.

(2) A non-interventional post-authorisation safety study pursuant to subsection (1) may only be commenced if the draft protocol in the case of studies pursuant to subsection (1) no. 1

has been authorised by the competent higher federal authority or, in the case of studies pursuant to subsection (1) no. 2, has been authorised by the Pharmacovigilance Risk Assessment Committee and the draft protocol submitted to the competent higher federal authority. The competent higher federal authority must take a decision on the authorisation of the study within 60 days following the submission of the draft protocol. The authorisation is to be refused if the use of the medicinal product is to be promoted, the aims cannot be achieved with the study design in question or the study is a clinical trial pursuant to section 4 (23) sentence 1.
(3) Once a study pursuant to subsection (1) has started, any substantial modifications to the protocol must be authorised before implementation:

1. by the competent higher federal authority, if the study is being conducted only on the territory governed by this Act,

2. by the Pharmacovigilance Risk Assessment Committee, if the study is being conducted in several Member States of the European Union.

If the study described in sentence 1 no. 2 is also being conducted on the territory governed by this Act, the marketing authorisation holder informs the competent higher federal authority of the authorised modifications.
(4) On completion of a study pursuant to subsection (1), the final study report is to be submitted:

1. to the competent higher federal authority in the cases pursuant to subsection (1) no. 1,

2. to the Pharmacovigilance Risk Assessment Committee in the cases pursuant to subsection (1) no. 2,

within twelve months after data collection is completed if the competent authority pursuant to sentence 1 no. 1 or 2 has not waived the submission. The final report is to be transmitted electronically together with a short description of the study findings.

Section 63h
(repealed)

Section 63i
Documentation and notification obligations in respect of blood and tissue preparations and tissues

(1) The holder of a marketing authorisation for blood preparations within the meaning of Article 3 (6) of Directive 2001/83/EC or a marketing authorisation or approval for tissue preparations or for haematopoietic stem cell preparations within the meaning of Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102 of 7.4.2004, p. 48), last amended by Regulation (EC) No. 596/2009 (OJ L 188 of 18.7.2009, p. 14) or a marketing authorisation for tissue preparations pursuant to section 21 must keep documents on all suspected serious incidents or serious adverse reactions that have occurred in a Member State of the European Union, in a State Party to the Agreement on the European Economic Area or in a third country, as well as the number of recalls.
(2) The holder of a marketing authorisation or authorisation for blood or tissue preparations pursuant to subsection (1) must, furthermore, document every suspected serious incident and every suspected serious adverse reaction and notify the competent higher federal authority thereof immediately, or at the latest within 15 days of acquiring this knowledge. The notification must contain all of the necessary information, especially the name or firm and address of the pharmaceutical entrepreneur, name and number or code of the blood or tissue preparation, date and documentation of the emergence of the suspicion of the serious incident or the serious adverse reaction, date and place where the removal of the blood

components or tissue took place, enterprises or facilities supplied as well as information on the donor. Furthermore, in the case of tissue preparations as well as haematopoietic stem cell preparations derived from peripheral blood or umbilical cord blood, the EU tissue establishment code must be given, if available, and when making a notification of a suspected serious adverse reaction, the Single European Code, if available, must be given. The incidents or reactions notified pursuant to sentence 1 are to be examined with respect to their causes and effects and subsequently evaluated and notification of the results, together with the measures to trace and protect both the donor and the recipient, is to be made immediately to the competent higher federal authority.
(3) In the case of blood and tissue preparations as well as blood and blood components, and tissues that are not subject to marketing authorisation or approval, the blood and plasma donation facilities or the tissue establishments must document every suspected serious incident and every suspected serious adverse reaction and notify the competent authority immediately thereof. The notification must contain all the necessary information such as the name or firm and address of the donation or tissue establishment, name and number or code of the blood or tissue preparation, date and documentation of the occurrence of the suspected serious incident or the serious adverse reaction, date on which the blood or tissue preparation was manufactured as well as information on the donor. Furthermore, in the case of tissues and tissue preparations as well as haematopoietic stem cells and stem cell preparations derived from peripheral blood or umbilical cord blood, the EU tissue establishment code must be given, if available, and when making a notification of a suspected serious adverse reaction, the Single European Code, if available, must be given. Subsection (2) sentence 4 applies accordingly. The competent authority transmits the notifications pursuant to sentences 1 to 3 as well as the notifications pursuant to sentence 4 to the competent higher federal authority.
(4) The holder of a marketing authorisation for blood or tissue preparations within the meaning of subsection (1) must submit, to the competent higher federal authority, on the basis of the obligations contained in subsection (1), an updated report on the safety of the medicinal product immediately upon request or, where recalls, cases or suspected cases of serious incidents or serious adverse reactions are involved, at least once a year. Sentence 1 does not apply to parallel importers.
(5) Section 62 (1), sentences 1 and 2, subsections (4) and (6) and section 63 apply accordingly. Sections 63a and 63b (1) and (2) apply accordingly to the holder of an authorisation for blood or tissue preparations. The details are laid down in the Ordinance on the Manufacture of Medicinal Products and Active Substances; the general administrative regulation pursuant to section 63 sentence 1 applies. Furthermore, sections 62 to 63g do not apply.
(6) A serious incident within the meaning of the foregoing provisions is any undesired event in connection with the collection, testing, processing, preserving, storage or supply of blood and blood components, tissues, tissue or blood preparations, which could lead to the transmission of an infectious disease, the death of a patient, a life-threatening state, disability or invalidity of patients, the need for or prolongation of hospitalisation as well as to the genesis or prolongation of a disease. A serious incident is also any incorrect identification or confusion of germ cells or impregnated egg cells within the framework of medically-assisted insemination measures.
(7) A serious adverse reaction within the meaning of the foregoing provisions is an unintended reaction, including an infectious disease in the donor or recipient in connection with the collection of tissues or blood or the transplanting of tissue or blood preparations which is fatal or life-threatening or leads to disability or invalidity or requires hospitalisation or the prolongation of existing hospitalisation or causes or prolongs a disease.
(8) The holder of a marketing authorisation or an approval for blood or tissue preparations, within the meaning of subsection (1), may not make public any information regarding the haemo- or tissue vigilance, in connection with a medicinal product that has a market authorisation or approval, without prior or simultaneous notification of the competent higher

federal authority and the European Commission. He/she ensures that such information is made public in a manner that is objective and not misleading.

Section 63j
Documentation and notification obligations on the part of the person conducting treatment, in respect of advanced therapy medicinal products that require neither a marketing authorisation nor approval

(1) Any person conducting treatment who administers advanced therapy medicinal products that require neither a marketing authorisation nor approval to a patient must keep records of all suspected cases of adverse reactions and must immediately notify the competent higher federal authority electronically of any suspected case of a serious adverse reaction. The notification must contain all of the necessary information, especially:

1. the name and address of the facility at which the patient was treated,
2. the onset date of the serious adverse reaction,
3. the type of serious adverse reaction,
4. the date on which the medicinal product was manufactured,
5. information on the type of medicinal product, as well as
6. the initials, gender and date of birth of the patient who was treated with the medicinal product.

The competent higher federal authority publishes the form to be used for the notification on its website.
(2) The person conducting treatment must examine and assess the adverse reactions notified pursuant to subsection (1) with respect to their cause and effect and report immediately to the competent authority the results of the assessment, as well as the measures taken by him/her to protect the patient.
(3) The competent authority immediately forwards the notification and reports pursuant to subsections (1) and (2) to the competent higher federal authority.
(4) At the request of the competent authorities of the Laender or the Federal Government, the person conducting treatment must transmit additional information for the evaluation of the risks posed by the medicinal product used, including his/her own evaluations, immediately and in full.

Section 63k
Exceptions

The provisions of Division 10 do not apply to medicinal products that are used as investigational medicinal products within the framework of a clinical trial.

Division 11
Surveillance

Section 64
Conducting supervision

(1) Subject to supervision by the competent authority regarding the activities specifically mentioned are enterprises and establishments:

1. in which medicinal products are manufactured, tested, stored, packaged or placed on the market,
2. in which medicinal products are otherwise traded,
3. which import medicinal products,
4. which develop medicinal products or subject them to clinical trials,

5. which purchase or use medicinal products pursuant to section 47a (1) sentence 1,

6. in which records of the activities mentioned in nos. 1 to 5 are kept, or

7. which set up or manage a repository that is part of the repositories system referred to in Article 31 of Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32, 9.2.2016, p. 1).

The development, manufacture, testing, storage, packaging, import and placing on the market of active substances and other substances and tissues intended for the manufacture of medicinal products, any other form of trade in such active substances and substances, as well as the keeping of records connected to the stated activities, are subject to supervision insofar as they are regulated by an ordinance pursuant to section 54, pursuant to section 12 of the Transfusion Act or pursuant to section 16a of the Transplantation Act. In the case of section 14 (4) no. 4 and section 20b (2), the removal facilities and the laboratories are subject to supervision by the competent authority responsible for them locally; in the case of section 20c (2) sentence 2, the commissioned enterprises are subject to supervision by the competent authority responsible for them locally. Sentence 1 also applies to persons carrying out these activities professionally, to persons carrying with them medicinal products not exclusively intended for personal use, to the sponsor of a clinical trial or his/her representative, as well as to persons or associations collecting medicinal products for others. Sentence 1 does not apply to reconstitution insofar as medicinal products that are intended for use in clinical trials are not concerned.

(2) Persons in charge of supervision must carry out this activity as their main profession. The competent authority may call in experts. Insofar as blood preparations, tissues and tissue preparations, radiopharmaceuticals, medicinal products produced using genetic engineering, sera, vaccines, allergens, advanced therapy medicinal products, xenogeneic medicinal products or active substances or other substances of human, animal or microbial origin or which have been manufactured using genetic engineering are concerned, the competent authority is to summon staff of the competent higher federal authority to participate as experts. With regard to pharmacies that are not hospital pharmacies or that do not require an authorisation in compliance with section 13, the competent authority may commission experts to carry out the supervision.

(3) The competent authority is to satisfy itself that the provisions on medicinal products, on active substances and other substances intended for use in the manufacture of medicinal products, as well as on tissues, on advertising in the field of medicine, of Division 2 of the Transfusion Act, of Divisions 2, 3 and 3a of the Transplantation Act, and those on pharmacies, are observed. To this end, the competent authority is to, based on a supervision system, paying special attention to possible risks, with appropriate frequency and to an appropriate extent, also conduct unannounced inspections where necessary and stipulate effective follow-up measures. It is to also commission the official testing of medicinal product samples.

Unannounced inspections are necessary particularly:

1. in cases of suspected counterfeiting of medicinal products or active substances,

2. where there is indication of a serious defects in medicinal products or active substances, as well as

3. at appropriate intervals, within the framework of supervising the manufacture of medicinal products pursuant to section 35 of the Ordinance on the Operation of Pharmacies (*Apothekenbetriebsordnung*) and the manufacture of medicinal products for parenteral use for pharmacies.

(3a) Enterprises and establishments requiring an authorisation pursuant to sections 13, 20c, 72, 72b (1) or section 72c, as well as pharmacies that manufacture medicinal products pursuant to section 35 of the Ordinance on the Operation of Pharmacies are to be inspected every two years, as a rule, pursuant to subsection (3). The competent authority grants an authorisation pursuant to sections 13, 20c, 52a, 72, 72b (1) or section 72c only after having satisfied itself, by means of an inspection, that the requirements for granting an authorisation are fulfilled.
(3b) The competent authority conducts the inspections to monitor compliance with the provisions governing the trade in medicinal products in accordance with the guidelines of the European Commission pursuant to Article 111a of Directive 2001/83/EC, insofar as the supervision of the conduct of clinical trials is not concerned. It co-operates with the European Medicines Agency by exchanging information on planned and conducted inspections as well as in the co-ordination of inspections of enterprises and facilities in countries that are not Member States of the European Union or other States Party to the Agreement on the European Economic Area.
(3c) The inspections can also be carried out at the request of another Member State, the European Commission or the European Medicines Agency. Without prejudice to any other agreements between the European Union and countries that are not members of the European Union or other States Party to the Agreement on the European Economic Area, the competent authority can require a manufacturer in the country that is not a member of the Union or a State Party to the Agreement on the European Economic Area to submit him/herself to an inspection in accordance with the requirements of the European Union.
(3d) A report is to be drawn up on the inspection. The competent authority that conducted the inspection notifies the inspected enterprises, facilities or persons of the content of the draft report and gives them opportunity for comment before it is completed.
(3e) If, after evaluation of the comments pursuant to subsection (3d) sentence 2, the inspection leads to the conclusion that the enterprises, facilities or persons do not comply with the statutory provisions, this information is entered into the database referred to in section 67a, insofar as the principles and guidelines of good manufacturing practice or good distribution practice as provided for by Community legislation on medicinal products for human use are affected.
(3f) Within a period of 90 days following an inspection to determine compliance with good manufacturing practice or good distribution practice, the inspected enterprises, facilities or persons are issued with a certificate if the inspection has resulted in the conclusion that the corresponding principles and guidelines are being complied with. The certificate of compliance with the principles and guidelines of good manufacturing practice are to be valid for not more than three years, the certificate on compliance with the principles and guidelines of good distribution practice no more than five years. The certificate is to be withdrawn if it subsequently becomes known that the conditions were not fulfilled; it is to be revoked if the conditions no longer apply.
(3g) The information regarding the issue, refusal, withdrawal or revocation of a certificate on compliance with the principles and guidelines of good manufacturing practice is to be entered into a database pursuant to section 67a. This also applies to the issuing, withdrawal, revocation or suspension of an authorisation pursuant to section 13, or section 72 (1) and (2), as well as to the registration and deletion of medicinal product brokers or of enterprises and facilities that manufacture, import or otherwise trade in active substances without requiring an authorisation. The information regarding the issue, refusal, withdrawal or revocation of an authorisation pursuant to section 52a, as well as a certificate of compliance with the principles and guidelines of good distribution practice, is to be entered into a database of the European Medicines Agency pursuant to Article 111 (6) of Directive 2001/83/EC.
(3h) Subsections (3b), (3c) and (3e) to (3g) do not apply to enterprises and establishments that set up or manage a repository that is part of the repositories system referred to in Article 31 of Commission Delegated Regulation (EU) 2016/161.

(3i) By way of derogation from subsection (3c), the competent authority must decide, on a duly justified request by another Member State of the European Union into which tissues or tissue preparations that were previously imported into the territory governed by this Act are to be imported, to inspect an importing tissue establishment that is subject to the obligation to obtain an authorisation pursuant to section 72b (1) or section 72c (1), or take other supervisory measures. The other Member State is first given an opportunity to comment. Sentences 1 and 2 apply accordingly to a duly justified request by another Member State of the European Union, into which haematopoietic stem cells and stem cell preparations derived from peripheral blood or umbilical cord blood that were previously imported into the territory governed by this Act are to be imported, to inspect an importing establishment that is subject to the obligation to obtain an authorisation pursuant to section 72b (4) or section 72c (4) sentence one in conjunction with subsection (1), or take other supervisory measures.
(3j) In the event of an inspection pursuant to subsection (3i), the competent authority can, based on the request by the competent authority of the other Member State, permit persons designated by said Member State to attend the inspection. The competent authority must justify its rejection of the request to the competent authority of the other Member State. The accompanying persons are authorised, together with the persons in charge of supervision, to enter and inspect properties, office premises and means of transport during normal business hours.
(3k) The competent authority informs the competent higher federal authority of planned inspections of manufacturers of medicinal products or active substances in third countries. Officials of the competent higher federal authority may participate in such inspections as experts, in consultation with the competent authority. This is without prejudice to subsection (2) sentence 3.
(4) The persons charged with monitoring are authorised

1. to enter and inspect during normal business hours properties, office premises, operating rooms, transport facilities and also, for the prevention of imminent danger to public order and security, residential housing and to take pictures for documentation purposes in office premises, operating rooms and means of transport in which the activities referred to in subsection (1) are carried out; the fundamental right to the inviolability of the home (Article 13 of the Basic Law) is limited in this regard,

2. to review documentation on the development, manufacture, testing, clinical trial, acquisition, import, storing, packaging, billing, placing on the market and other whereabouts of the medicinal products, active substances and other substances intended for the manufacture of medicinal products, as well as on the advertising material currently in circulation and on the liability coverage required pursuant to section 94,

2a. to prepare or request transcripts or photocopies of documents pursuant to no. 2 or printouts or copies of data storage media on which documents pursuant to no. 2 are stored insofar as personal data from patients are not concerned,

3. to demand from natural and legal persons and associations without legal capacity all the necessary information, in particular on the company operations specified in no. 2,

4. to issue provisional orders also on the closing of the company or facility, insofar as this is deemed necessary for the prevention of imminent danger to public order and safety.

(4a) If it is required for the implementation of this Act or of ordinances issued on the basis of this Act or Regulation (EC) No. 726/2004, experts from the Member States of the European Union may exercise the powers contained in subsection (4) no. 1, if they are in the company of the persons responsible for the supervision.
(5) The person under obligation to give information may refuse to answer certain questions if he/she has reason to fear that answering them could expose him/her or one of the relatives

specified in section 383 (1) nos. 1 to 3 of the German Code of Civil Procedure (*Zivilprozeßordnung*) to the danger of prosecution under criminal law or to a lawsuit under the Act on Administrative Offences (*Gesetz über Ordnungswidrigkeiten*).
(6) The Federal Ministry is hereby empowered, to issue, by ordinance subject to the approval of the Bundesrat, regulations governing the fulfilment of supervisory tasks in cases where medicinal products are imported into the territory governed by this Act, by a pharmaceutical entrepreneur who has no registered place of business in the territory governed by this Act, insofar as necessary for the implementation of the provisions governing the trade in medicinal products as well as advertising in the field of medicine. In the process, the main responsibility for supervisory tasks, which arise out of the import of a medicinal product from a specific Member State of the European Union, can be assigned in each case to a specific Land or to a facility supported by one of the Laender.

Section 65
Sampling

(1) To the extent necessary for the implementation of the provisions on the trade in medicinal products, on advertising in the field of medicine of Division 2 of the Transfusion Act, of Divisions 2, 3 and 3a of the Transplantation Act and on pharmacies, those persons in charge of supervision are authorised to demand or to take samples of their own selection, against receipt, for the purposes of testing them. Insofar as the pharmaceutical entrepreneur does not explicitly waive his/her right thereto, a part of the sample or, if the sample is not divisible in parts of equal quality without endangering the purpose of the test, a second sample of the same type as the sample taken, is to be left behind.
(2) The samples left behind are to be officially closed or sealed. They are to be marked with the date on which the sample was taken and the date after which the closing or sealing of the sample is deemed to have been removed.
(3) For samples that are not drawn from the pharmaceutical enterprise, an appropriate compensation is to be paid by the pharmaceutical entrepreneur if this right is not explicitly waived.
(4) Eligible for appointment as a private expert for the testing of samples left behind pursuant to subsection (1) sentence 2 may only be a person who:

1. has the expert knowledge pursuant to section 15. The practical experience pursuant to section 15 (1) and (4) can be replaced by practical experience in the control and assessment of medicinal products in medicinal product control laboratories or in other similar medicinal product institutes,

2. is reliable enough to perform his/her duties as an expert for the testing of official samples and

3. has adequate premises and facilities at his/her disposal for the intended testing and assessment of medicinal products.

Section 66
Obligation to tolerate and collaborate

(1) The party subject to supervision in compliance with section 64 (1) is obliged to tolerate the measures defined in sections 64 and 65 and to give full support to the persons in charge of supervision in the fulfilment of their duties, in particular, indicating to them, upon request, the premises and transport facilities, opening rooms, containers and receptacles, giving information and enabling the taking of samples. The same requirement applies to the qualified person referred to in section 14, the person responsible pursuant to section 20c, the graduated plan officer, information officer, the person responsible pursuant to section 52a, as well as their representatives and the chief investigator and the investigator, also with regard to enquiries by the competent higher federal authority.

(2) The obligation to tolerate and collaborate pursuant to subsection (1) applies accordingly to measures by the higher federal authorities pursuant to section 25 (5) sentence 4 or subsection (8) sentences 2 and 3 or pursuant to section 62 (6).

Section 67
General notification requirement

(1) Enterprises and establishments that develop or manufacture medicinal products, subject medicinal products to clinical trials, test, store, package, import and place them on the market, or are otherwise engaged in the trade in medicinal products, must accordingly notify the competent authorities before taking up these activities. Sentence 1 applies accordingly to facilities that collect tissues, conduct the laboratory test necessary for the procurement, process, preserve, test, store, import or place them on the market. Notification is to be given of the development of medicinal products insofar as it is governed by an ordinance pursuant to section 54. The same applies to persons practising these activities on a self-employed and professional basis as well as to persons or associations who collect medicinal products for others. The notification is to state the type of activity and the factory site; if medicinal products are collected, details are to be given regarding the type of collection made and the place of storage. Sentences 1 and 3 to 5 apply accordingly to enterprises and establishments that manufacture, test, store, package, import, market or otherwise trade in active substances or other substances intended for use in the manufacture of medicinal products, insofar as these activities are regulated by an ordinance pursuant to section 54. Sentence 1 does not apply to reconstitution insofar as medicinal products that are intended for use in clinical trials are not concerned. Sentences 1 to 6 also apply to enterprises and establishments that keep records associated with the above-mentioned activities. Sentences 1 and 5 also apply to enterprises and establishments that set up or manage a repository that is part of the repositories system referred to in Article 31 of Commission Delegated Regulation (EU) 2016/161.
(2) If medicinal product manufacture is envisaged, for which an authorisation as defined in section 13 is not necessary, notification is to be made of the medicinal products indicating their name and composition.
(3) Notification is likewise to be made of subsequent changes. In the case of enterprises and facilities that manufacture, import or otherwise trade in active substances, a yearly notification is sufficient if the changes do not affect the quality or safety of the active substances.
(3a) Enterprises and establishments that keep records associated with the activities specified in subsection (1) sentences 1 to 4 and 6, outside of the premises listed in the authorisation pursuant to sections 13, 20b, 20c, 52a, 72b or 72c, must notify the competent authorities accordingly prior to commencing activities; this also applies to subsequent changes.
(4) Subsections (1) to (3) do not apply to those persons holding an authorisation under section 13, section 20b, section 20c, section 52a, section 72, section 72b or 72c, to pharmacies pursuant to the Pharmacies Act and to clinical trials using medicinal products that fall within the scope of Regulation (EU) No 536/2014.
(5) A person who, in his/her capacity as a pharmaceutical entrepreneur, places on the market a medicinal product which, pursuant to section 36 (1), is exempted from the obligation to obtain a marketing authorisation must notify the competent higher federal authority and the competent authority of this beforehand. The notification must include the name used for the medicinal product and the non-active substances used, insofar as they are not specified in the ordinance pursuant to section 36 (1), as well as the actual composition of the medicinal product insofar as the ordinance pursuant to section 36 (1) allows for differences in this respect. Also to be notified are any changes in the information and the termination of the placing on the market.
(6) Any person who conducts tests that serve the purpose of gathering knowledge resulting from the use of authorised or registered medicinal products must immediately notify the

competent higher federal authority, the National Association of Statutory Health Insurance Physicians, the Central Federal Association of the Health Insurance Funds, as well as the Association of Private Health Insurance Funds. In this regard, the location, time, purpose and observation plan of the non-interventional study is to be stated and the National Association of Statutory Health Insurance Physicians and the Central Federal Association of the Health Insurance Funds informed of the names and the lifelong physician identification number of the participating physicians, the business premises number and the practice address. Remuneration paid to physicians for their participation in tests pursuant to sentence 1 is to be calculated, as to type and amount, in such a way as to provide no incentive for the preferential prescription or recommendation of specific medicinal products. Insofar as participating physicians provide benefits that are reimbursed by the statutory health insurance, the type and amount of the compensation actually paid to them in each case is to be communicated as well as a copy of each of the contracts signed with them and, in each case, a description of the costs incurred for the participating physicians and a justification for the appropriateness of the compensation are to be submitted in the case of notifications pursuant to sentence 1. Insofar as changes are made to the information specified in sentence 4, the information pursuant to sentence 4 is to be communicated in its entirety, in the modified, updated form within four weeks following the end of each quarter; the compensation actually paid is to be communicated and assigned to the participating physicians giving their name and lifelong physician identification number, the business premises number and the practice address. Within one year following the completion of the data collection process, the number of patients participating in each case, and in total, as well as the type and amount of the compensation paid in each case and in total are to be communicated giving the total number of participating physicians. A final report is to be transmitted to the competent higher federal authority within one year following completion of the data collection process. Section 42b (2) sentences 1 and 4 apply accordingly. The information pursuant to this subsection is to be transmitted electronically. For this purpose, the competent higher federal authorities are to publish electronic format specifications; the competent higher federal authority is to make the notifications received and the final reports available to the public through an internet portal. Section 42b (2) sentence 4 applies accordingly to the publication of the notifications. Sentences 4 to 6 do not apply to notifications to the competent higher federal authority. The National Association of Statutory Health Insurance Physicians, the Central Federal Association of the Health Insurance Funds, as well as the Association of Private Health Insurance Funds stipulate formatting specifications for the electronic transmission of the information to be sent to them by mutual agreement and publish these. Sentences 1 to 12 and 14 do not apply to post-authorisation safety studies pursuant to section 63f.

(7) Any person who intends to introduce medicinal products that are authorised for placing on the market, by another pharmaceutical entrepreneur, in another Member State of the European Union into the territory governed by this Act on a commercial or professional basis, for the purpose of placing them on the market within the purview of this Act, must notify the marketing authorisation holder of this intention before commencing activities. In the case of medicinal products that have been authorised for marketing pursuant to Regulation (EC) No. 726/2004, sentence 1 applies subject to the proviso that the notification must be transmitted to the marketing authorisation holder as well as the European Medicines Agency. A fee is to be paid to the Agency for monitoring compliance with the requirements laid down in the European Union legislation on medicinal products and in the marketing authorisations; the fee is determined based on European Union legislation.

(8) Any person who, for the purpose of retail trading, wishes to offer medicinal products on the internet for sale at a distance, must notify the competent authority before commencing activities and do so stating his/her name or company name and the address of the location from which the medicinal products are to be supplied and the address of every internet portal including all of the necessary information for their identification. Notification is likewise to be made of subsequent changes. The competent authority transmits this information to a

database pursuant to section 67a. The internet portal pursuant to sentence 1 must carry the name and address of the competent authority and its other contact data, the common logo for sale at a distance pursuant to Article 85c of Regulation 2001/83/EC, as well as a hyperlink to the internet portal of the Federal Institute for Drugs and Medical Devices (BfArM).
(9) Any person who administers advanced therapy medicinal products that require neither a marketing authorisation nor approval, to a patient, must notify the competent higher federal authority thereof pursuant to sentences 2 and 3. The notification is to be submitted immediately after the administration begins. The notification must contain the following information:

1. the name and address of the person conducting treatment,
2. the name and address of the facility at which the patient was treated,
3. the name of the medicinal product,
4. the active substances by type and quantity and other constituents of the medicinal product by type,
5. the pharmaceutical form,
6. the method of administration,
7. evidence that the person conducting treatment is authorised to manufacture the medicinal product,
8. the initials, gender and date of birth of the patient who was treated with the medicinal product.
9. the treatment day or treatment period, and
10. the indication for which the medicinal product is used.

The competent higher federal authority publishes the form to be used for the notification on its website.

Section 67a
Database-supported information system

(1) The federal and Land authorities responsible for the implementation of this Act collaborate with the Federal Institute for Drugs and Medical Devices (BfArM) to set up a central information system for medicinal products and active substances as well as their manufacturer or importer, which can be used jointly. This information system collates all of the important data necessary for the fulfilment of the specific tasks affecting more than one authority. The Federal Institute for Drugs and Medical Devices (BfArM) sets up this information system on the basis of the data supplied to it by the competent authorities or higher federal authorities pursuant to the ordinance issued pursuant to subsection (3) and is responsible for its operation. Data from the information system are transmitted to the competent authorities and higher federal authorities for fulfilment of their legally stipulated duties and to the European Medicines Agency. The competent authority and higher federal authorities receive access, in addition, to current data from the information system for the fulfilment of their legally stipulated duties. Transmission to other agencies is permissible insofar as this is provided for in the ordinance issued pursuant to subsection (3). The Federal Institute for Drugs and Medical Devices (BfArM) is entitled to charge fees for its services. Such fees are listed in a catalogue of fees that is subject to the consent of the Federal Ministry.
(2) The Federal Institute for Drugs and Medical Devices (BfArM) and Information provides access to generally available databases that contain information on medicinal products through an internet portal. The internet portal will be connected with the European internet

portal for medicinal products set up by the European Medicines Agency pursuant to Article 26 of Regulation (EC) No. 726/2004. Furthermore, the Federal Institute for Drugs and Medical Devices (BfArM) provides information on the offering of medicinal products for sale at a distance by means of a generally accessible internet portal. This internet portal will be connected with the website operated by the European Medicines Agency that contains information on sale at a distance and on the logo for sale at a distance. The Federal Institute for Drugs and Medical Devices (BfArM) publishes the addresses of the internet portals in the Federal Gazette.
(3) The Federal Ministry is hereby empowered, in agreement with the Federal Ministry of the Interior, Building and Community and the Federal Ministry for Economic Affairs and Energy by ordinance subject to the approval of the Bundesrat:

1. to grant the power to collect data for the purposes defined in subsection (2) and the power to otherwise process data for the purposes contained in subsections (1) and (2), and

2. to adopt regulations governing the transmission of data, including personal and enterprise-related data, to the Federal Institute for Drugs and Medical Devices by the federal and Land authorities for the purposes regulated by this Act, as well as the type and scope and the requirements to be placed on such data.

The ordinance in question may also contain provisions stipulating that notifications may or must be made on electronic or optical storage media, insofar as required for the proper implementation of the regulations governing the trade in medicinal products.
(4) The ordinance referred to in subsection (3) is issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used.
(5) The Federal Institute for Drugs and Medical Devices and Information takes the necessary measures to ensure that the data are transmitted only to authorised persons and that only such persons receive access to them.

Section 67b
EU Compendium of Tissue Establishments, EU Compendium of Tissue and Cell Products, obligations to inform

(1) The competent authorities of the Laender enter the information contained in Annex VIII of Directive 2006/86/EC in the latest applicable version into the EU Compendium of Tissue Establishments. They ensure that every establishment is unmistakably issued an EU tissue establishment number.
(2) In the case of necessary changes, the competent authorities update the EU Compendium of Tissue Establishments without delay, at the latest within ten working days. The following are considered to be changes pursuant to sentence 1, in particular:

1. the first granting of an authorisation to facilities that conduct activities that require an authorisation, involving tissues, tissue preparations, haematopoietic stem cells, or stem cell preparations derived from peripheral blood or from umbilical cord blood,

2. modifications to the authorisation, including modifications regarding:

   a) a new type of tissues, tissue preparations, haematopoietic stem cells, or stem cell preparations derived from peripheral blood or from umbilical cord blood,

   b) a new activity involving tissues, tissue preparations, haematopoietic stem cells, or stem cell preparations derived from peripheral blood or from umbilical cord blood, or

   c) new incidental provisions regarding the authorisation,

3. every withdrawal or revocation of the authorisation,

4. the voluntary, also partial, discontinuance of the activity by a facility,

5. changes in the information on a facility, within the meaning of Annex VIII of Directive 2006/86/EC in the latest applicable version, as well as

6. changes as a result of incorrect data entered into the EU Compendium of Tissue Establishments.

(3) The competent authorities inform the competent authorities of another Member State of the European Union if:

1. they become aware of incorrect information in the EU Compendium of Tissue Establishments that concerns said Member State, or

2. they become aware of a serious breach of the provisions governing the Single European Code (SEC) in connection with said Member State.

(4) The competent authorities inform the European Commission and the competent authorities of the other Member States of the European Union if the EU Tissue and Cell Product Compendium needs to be updated.

Section 68
Obligations to notify and to inform

(1) The federal and Land authorities and agencies responsible for the implementation of this Act must:

1. notify each other of the authorities, agencies and experts responsible for the enforcement of the Act,

2. in instances of contravention and suspected contravention of the provisions contained in the medicinal product legislation, the legislation on health products advertising or on pharmacies, for their individual jurisdictions, inform each other immediately and support each other’s investigative activities and,

3. provide information on the recall of medicinal products and measures in connection with quality defects in active substances that can lead to a shortage in the supply of medicinal products.

(2) The authorities specified in subsection (1):

1. furnish the competent authority of another Member State of the European Union with information, or the European Medicines Agency, in response to a duly justified request, and transmit to it the necessary certificates and documents insofar as necessary to monitor compliance with the medicinal product-related regulations, the legislation on health products advertising and on pharmacies or for the prevention of medicinal product risks,

2. investigate all of the facts of which it is notified by the requesting authority of another Member State and notify said authority of the results of the investigation.

(3) The authorities specified in subsection (1) provide the competent authorities of another Member State and the European Medicines Agency or the European Commission with all of the information that is necessary to monitor compliance with the medicinal product-related regulations, as well as the legislation on health products advertising and on pharmacies in force in that Member State or for the prevention of medicinal product risks. In cases of infringement or suspected infringement, the competent authorities of other Member States, the Federal Ministry, the European Medicines Agency and the European Commission may also be informed.

(4) The authorities specified in subsection (1) may, if necessary for the implementation of requirements stipulated in medicinal product-related legislation, the legislation on health products advertising and on pharmacies, or for the prevention of medicinal product risks, also inform the competent authorities of other states and the competent offices at the Council of Europe. Subsection (2) no. 1 applies accordingly. States Party to the Agreement on the European Economic Area that are not Member States of the European Union are informed through the European Commission.
(5) Communication with the competent authorities of other states, Council of Europe offices, the European Medicines Agency, and with the European Commission is the prerogative of the Federal Ministry. The Federal Ministry may transfer this power to the competent higher federal authority or, by means of an ordinance with the approval of the Bundesrat, to the competent higher authorities of the Laender. Furthermore, in individual cases, the Federal Ministry can transfer the above-mentioned power to the competent higher authority of the Land if the latter gives its consent. The higher authorities of the Laender are authorised to transfer the powers specified in sentences 2 and 3 to other authorities.
(5a) (repealed)
(6) In the cases provided for in subsection (4), personal data are not transmitted if interests of the person affected that are worthy of protection preponderate.

Section 69
Measures by the competent authorities

(1) The competent authorities issue the necessary directives to rectify any offences that have been identified and to prevent offences in the future. They may, in particular, prohibit the marketing of medicinal products or active substances and order their recall from the market and seize them if:

1. the required marketing authorisation or registration of the medicinal product has not been submitted or if their suspension has been ordered,

2. the medicinal product or the active substance has not been manufactured according to the recognised pharmaceutical rules or does not possess the appropriate quality in keeping with recognised pharmaceutical rules,

2a. there is sufficient reason to suspect that the medicinal product or the active substance is counterfeit,

3. the medicinal product is lacking in therapeutic efficacy,

4. there is sufficient reason to suspect that the medicinal product has harmful effects that exceed the bounds considered justifiable according to the prevailing standard of scientific knowledge,

5. the prescribed quality controls have not been carried out, or

6. the authorisation required for the manufacture of the medicinal product or the active substances or the introduction into the purview of this Act has not been granted or a reason for the withdrawal or the revocation of the permit pursuant to section 18 (1) exists.

7. the authorisation required to engage in wholesale trading under section 52a has not been granted or a reason for the withdrawal or the revocation of the authorisation pursuant to section 52a (5) exists.

(1a) In the case of medicinal products for which a marketing authorisation or an authorisation has been issued:

1. pursuant to Regulation (EC) No. 726/2004, or

2. within the framework of the recognition procedure pursuant to Chapter 4 of Directive 2001/83/EC, or

3. on the basis of an expert report of the committee provided for in Article 4 of Directive 87/22/EEC of 22 December 1986 prior to 1 January 1995, the competent higher federal authority informs the Committee on Human Medicinal Products of any observed violation of the medicinal product regulations, in accordance with the procedures provided for in the above-mentioned legal acts, submitting detailed grounds and details of the proposed procedure.

In the case of these medicinal products, the competent authorities may take the measures necessary to eliminate observed violations and to prevent future violations before informing the Committee, insofar as these are urgently needed to guarantee the protection of human health or the protection of the environment. In the cases described in sentence 1 nos. 2 and 3, the competent authorities inform the European Commission and the other Member States, in the cases described in sentence 1 no. 1, the Commission of the European Communities and the Medicines Agency, of the reasons for these measures by the following working day, at the latest, through the channel of the competent higher federal authority. In the case of subsection (1) sentence 2 nos. 2, 2a and 4, the competent higher federal authority can also order the suspension of the marketing authorisation or the recall of a medicinal product if such action is urgently needed to ensure the protection of the legal rights specified in sentence 2; in such a case sentence 3 applies accordingly.
(1b) In the case of medicinal products other than those named in subsection (1a) sentence 1, the competent higher federal authority, in the case of subsection (1) sentence 2 nos. 2, 2a and 4, can order the recall of medicinal product if its action is required to protect human health or for the protection of the environment. If the recall is conducted pursuant to sentence 1 in conjunction with measures pursuant to sections 28, 30, 31 (4) sentence 2 or pursuant to section 32 (5), the decision of the competent higher federal authority is immediately enforceable.
(2) The competent authorities may prohibit the collection of medicinal products if suitable storage of the medicinal products is not guaranteed or if there is sufficient reason to suspect that the medicinal products collected are used improperly. Collected medicinal products may be seized if, as a result of inappropriate storage or through their distribution, human health is endangered.
(3) The competent authorities may seize advertising material that fails to comply with the regulations governing the trade in medicinal products and advertising in the field of health.
(4) In the case of a recall pursuant to subsection (1a) sentence 4, or subsection (1b) sentence 1, the competent higher federal authority can also issue a public warning.
(5) In the case of a medicinal product the dispensing of which was prohibited or that was removed from the market because:

1. the prerequisites for the placing on the market did not exist or no longer exist,

2. the medicinal product does not match the declared composition with regard to type and quantity, or

3. the testing of the medicinal product or of the ingredients and intermediate products was not conducted or another requirement or prerequisite for the granting of the manufacturing authorisation was not fulfilled,

the competent authority can, in consultation with the competent higher federal authority, in exceptional cases, allow its supply to patients who are already being treated with the product during a transition period if this is medically justifiable and indicated for the person affected.

Section 69a
(no longer applicable)

Section 69b
(no longer applicable)

Division 12
Special provisions for the Federal Armed Forces, Federal Police, Public Order Police, Civil Protection

Section 70
Application and enforcement of the Act

(1) The provisions of this Act apply accordingly to the establishments that supply the Federal Armed Forces, the Federal Police and the Public Order Police of the Laender with medicinal products as well as to the stockpiling of medicinal products for civil protection purposes.
(2) In the sphere of the Federal Armed Forces, the execution of this Act in respect of the supervision of the trade in medicinal products is incumbent upon the competent agencies and experts of the Federal Armed Forces. In the sphere of the Federal Police, it is incumbent upon the competent agencies and experts of the Federal Police. With regard to the stockpiling of medicinal products for civil protection, it is incumbent on the agencies designated by the Federal Ministry of the Interior, Building and Community; insofar as offices of the individual Laender are designated, the approval of the Bundesrat is required.

Section 71
Exceptions

(1) The indication of the expiry date stipulated in section 10 (1) no. 9 and subsection (8) is not necessary in the case of medicinal products that are supplied to the Federal Armed Forces, the Federal Police, as well as to the Federal Government and the Laender or purchased and placed on the market under Section 79 (4a) by the Federal Ministry for the purpose of civil protection and disaster control. The competent Federal Ministries or, in cases where medicinal products are supplied to the Laender, the competent Land authorities ensure that quality, efficacy and safety are also guaranteed with respect to these medicinal products.
(2) The Federal Ministry is hereby empowered to permit, by means of ordinance, exceptions to the regulations contained in this Act and the ordinances issued by virtue of this Act for the sphere of the Federal Armed Forces, the Federal Police, the Public Order Police of the Laender, civil protection, disaster control and for tasks of the Federal Ministry pursuant to Section 79 (4a), insofar as this is justified in the execution of the specific duties, including participation in international relief efforts, in these areas and insofar as the protection of human health continues to be guaranteed.
(3) The ordinance is issued, insofar as it concerns the Federal Armed Forces, in agreement with the Federal Ministry of Defence and, insofar as it concerns the Federal Police and Civil Protection, in agreement with the Federal Ministry of the Interior, Building and Community without, in either instance, the approval of the Bundesrat; insofar as the ordinance concerns the Public Order Police of the individual federal Laender or the Disaster Control Service, it is issued in agreement with the Federal Ministry of the Interior and subject to the approval of the Bundesrat.

Division 13
Import and export

Section 72
Import authorisation

(1) Any person who wishes to import:

1. medicinal products,

2. active substances that are of human, animal or microbial origin or are manufactured using genetic engineering, or

3. other substances of human origin intended for the manufacture of medicinal products,

on a commercial or professional basis, into the purview of this Act, from countries that are not Member States of the European Communities or other States Party to the Agreement on the European Economic Area requires a permit from the competent authority. Section 13 (4) and sections 14 to 20a apply accordingly.

(2) Subsection (1) applies to persons or facilities wishing to import medicinal products of human origin for direct human use, on a commercial or professional basis, with the proviso that the authorisation may only be refused if the applicant fails to show evidence that qualified personnel and suitable premises are available for the assessment of the quality and safety of the medicinal products and for the conversion of the medicinal product into its usable form, should this prove necessary, according to the latest standards prevailing in science and technology.

(2a) The competent authority grants the authorisation to import investigational or auxiliary medicinal products within the meaning of Article 2 (2) nos. 5 and 8 of Regulation (EU) No. 536/2014 in accordance with Article 61 (1) to (3) of Regulation (EU) No 536/2014. Section 13 (5) sentence 2 and subsection (6) apply accordingly.

(3) Subsections (1) and (2) do not apply to:

1. tissues within the meaning of section 1a no. 4 of the Transplantation Act,

2. autologous blood for the manufacture of biotechnologically processed tissue products,

3. tissue preparations within the meaning of section 20c and

4. active substances intended for the manufacture of medicinal products according to a procedure described in the homeopathic section of the Pharmacopoeia.

(4) By way of derogation from subsection (1), haematopoietic stem cells or stem cell preparations derived from peripheral blood or umbilical cord blood may only be imported by an importing establishment pursuant to section 72b (1) sentence 1, from states that are neither Member States of the European Union nor other States Party to the Agreement on the European Economic Area. The importing establishment requires a permit from the competent authority. The decision on whether to grant the permit is taken by the competent authority of the Land in which the factory premises of the importing establishment are located or are to be located, in consultation with the competent higher federal authority. Subsection (2) applies accordingly to the import for direct use.

(5) The application for a permit pursuant to subsection (4) sentence 2 is to be accompanied by the information and documents specified in Annexes I and III part A of Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells (OJ L 93 of 9.4.2015, p. 56) in the latest applicable version. By way of derogation from sentence 1, an application for a permit to import haematopoietic stem cells or stem cell preparations derived from peripheral blood or from umbilical cord blood for direct human use, must be accompanied only by the information and documents specified in Annex I Parts A, B and C nos. 1 to 3 and in Annex III Part A nos. 1 and 3 of Commission Directive (EU) 2015/566. Sections 14 to 19 and section 72b (2c) and (2d) apply accordingly.

Section 72a
Certificates

(1) The importer may import medicinal products or active substances only if:

1. the competent authority of the manufacturing country has confirmed by certificate that the medicinal products or active substances are manufactured in compliance with the requirements of recognised Good Practices in the Manufacture and Quality Control of Medicinal Products of the European Union, or equivalent standards,

that the manufacturing facilities are regularly monitored, that appropriate measures including repeated and unannounced inspections are used for monitoring and, in the event of essential deviations from recognised principles, that the competent authority is informed and that such certificates as refer to medicinal products and active substances that are of human, animal or microbial origin, or are active substances manufactured using genetic engineering are mutually recognised,

2. the competent authority has attested that the afore-mentioned requirements have been adhered to in manufacturing and assuring the quality of the medicinal products and the active substances used in their manufacture insofar as they are of human or animal origin or are manufactured using genetic engineering, or in the manufacture of the active substances, or

3. the competent authority has attested that the import is in the interests of the general public.

In the case of haematopoietic stem cells, or stem cell preparations derived from peripheral blood or from umbilical cord blood with the exception of those intended for direct human use and those intended for targeted administration to a specific person, the importing establishment must keep the documents specified in Annex III part B of Commission Directive (EU) 2015/566 available and present them to the competent authorities upon request.
The competent authority may only issue an attestation pursuant to:

1. sentence 1 no. 2, if no certificate pursuant to sentence 1 no. 1 exists and

   a) it or a competent authority of a Member State of the European Union or of another State Party to the Agreement on the European Economic Area has satisfied itself regularly in the country of manufacture that the above-mentioned requirements are being observed in manufacturing the medicinal products or the active substances, or

   b) an agreement on the mutual recognition of good manufacturing practice regarding medicinal products exists between a state and the European Union and the competent authority of that state has regularly satisfied itself that the above-mentioned requirements are being observed in manufacturing the medicinal products or active substances, on the territory of that state,

2. sentence 1 no. 3, if no certificate pursuant to sentence 1 no. 1 exists and an attestation pursuant to sentence 1 no. 2 is not envisaged or not possible.

(1a) Subsection (1) sentence 1 does not apply to:

1. medicinal products intended for clinical trials, auxiliary medicinal products within the meaning of Article 2 (2) nos. 8 and 10 of Regulation (EU) No. 536/2014, or medicinal products intended for use in the context of a compassionate use programme,

2. medicinal products of human origin for direct use or haematopoietic stem cell preparations made from peripheral blood or umbilical cord blood intended for targeted administration to a specific person,

3. active substances that are of human, animal or microbial origin and are intended for the manufacture of a medicinal product according to a procedure described in the homeopathic section of the Pharmacopoeia,

4. active substances that are or contain substances pursuant to section 3 nos. 1 to 3, insofar as they are not subject to the requirements of Good Manufacturing Practice in keeping with the principles and guidelines of the European Commission,

5. tissues within the meaning of section 1a no. 4 of the Transplantation Act,

6. autologous blood for the manufacture of biotechnologically processed tissue products,

7. tissue preparations within the meaning of section 20c and

8. active substances that are manufactured in and imported from a state that is not a member of the European Union or another State Party to the Agreement on the European Economic Area and that is specified in the list published by the European Commission pursuant to Article 11 (1b) of Directive 2001/83/EC.

(1b) The provisions laid down in subsection (1) sentence 1 nos. 1 and 2 for active substances of human, animal or microbial origin or for active substances manufactured using genetic engineering apply accordingly to other substances of human origin intended for the manufacture of medicinal products.
(1c) Medicinal products and active substances of human, animal or microbial origin or active substances manufactured using genetic engineering as well as other substances of human origin intended for the manufacture of medicinal products with the exception of those medicinal products specified in subsection (1a) nos. 1 and 2 may not be imported on the basis of a certificate pursuant to subsection (1) sentence 1 no. 3.
(1d) Subsection (1) sentence 1 is applicable to the import of active substances as well as other substances of human origin intended for the manufacture of medicinal products, insofar as their supervision is regulated by an ordinance pursuant to section 54.
(1e) The competent authority issues the holder of the permit pursuant to section 72 (4) sentence 2 with an attestation pursuant to the provisions of Annex II of Directive (EU) 2015/566, if a certificate pursuant to subsection (1) sentence 1 no. 1 has been issued, or the prerequisites are fulfilled for a certificate pursuant to subsection (1) sentence 1 no. 2 in conjunction with subsection (1) sentence 3 no. 1.
(2) The Federal Ministry is hereby empowered to mandate, by ordinance subject to the approval of the Bundesrat, that substances and preparations from substances that can be used as medicinal products or in the manufacture of medicinal products may not be imported, insofar as this is necessary to prevent hazards to human health or for the purpose of taking precautions against risks.
(3) The Federal Ministry is hereby also empowered to specify, by means of ordinance with the approval of the Bundesrat, the additional requirements for the import of the medicinal products specified under (1a) nos. 1 and 2 from countries that are not Member States of the European Union or other States Party to the Agreement on the European Economic Area, insofar as necessary to ensure that the medicinal products are of proper quality. In this context, the Ministry can lay down regulations, in particular such as govern the tests to be carried out by the competent person pursuant to section 14 and the possibility of supervision in the manufacturing country by the competent authority.

Section 72b
Import authorisations and certificates for tissues and specific tissue preparations

(1) Tissues within the meaning of section 1a no. 4 of the Transplantation Act or tissue preparations within the meaning of section 20c (1) sentence 1 or sentence 2 may only be imported by an importing tissue establishment that conducts this activity commercially or professionally and has signed a contract on the importation, with a third-country supplier. A third-country supplier is a tissue establishment or other agency of a state that is neither a Member State of the European Union nor another State Party to the Agreement on the European Economic Area, which is responsible for the export of tissues or tissue preparations that it delivers to the importing tissue establishment. The importing tissue establishment requires an authorisation from the competent authority. The decision on whether to grant the permit is taken by the competent authority of the Land in which the factory premises of the importing establishment are located or are to be located, in consultation with the competent higher federal authority. Section 72 (2) applies accordingly to the import of tissue preparations for direct use.

(1a) The application for authorisation pursuant to subsection (1) sentence 3 is to be accompanied by the information and documents specified in Annexes I and III part A of Commission Directive (EU) 2015/566. By way of derogation from sentence 1, an application for authorisation to import tissue preparations for direct human use, must be accompanied only by the information and documents specified in Annex I parts A, B and C nos. 1 to 3 of Commission Directive (EU) 2015/566. Section 20c (2) to (5) and (7) apply accordingly.
(2) The importing tissue establishment pursuant to subsection (1) may only import tissues or tissue preparations into the territory governed by this Act if:

1. the authorities of the country of origin have confirmed in a certificate that the collection, laboratory tests, processing, preservation, storage or testing were conducted according to standards that are at least equivalent to the Standards of Good Practice laid down by the European Union, and such certificates are mutually recognised, or

2. the authority responsible for the importing tissue establishment certifies that the standards of Good Practice for the collection, laboratory tests, processing, preservation, storage or testing of tissues are being observed after that authority or a competent authority of another Member State of the European Union, or a State Party to the Agreement on the European Economic Area has satisfied itself thereof, in the manufacturing country, or

3. the authority responsible for the importing tissue establishment has certified that importing is in the public interest, if a certificate pursuant to no. 1 is not available and an attestation pursuant to no. 2 is not possible.

The importing tissue establishment must keep the documents specified in Annex III part B of Commission Directive (EU) 2015/566 available and present them to the competent authorities upon request. By way of derogation from sentence 1 no. 2, the competent authority can dispense with an inspection of the removal facility in the country of origin, if the documents submitted by the importing tissue establishment give no reason for complaint or if his/her facilities or factory sites, as well as the quality assurance system of the party collecting the tissue in the country of origin, is already known to them.
(2a) The competent authority issues the holder of an authorisation pursuant to subsection (1) with a certificate pursuant to Annex II of Directive (EU) 2015/566, if a certificate pursuant to subsection (2) sentence 1 no. 1 has been issued, or the prerequisites are fulfilled for an attestation pursuant to subsection (2) sentence 1 no. 2 also in conjunction with subsection (2) sentence 3.
(2b) Subsections (2) and (2a) do not apply to haematopoietic stem cell preparations from bone marrow that are intended for targeted administration to a specific person.
(2c) The holder of an authorisation pursuant to subsection (1) sentence 3 must make prior notification of any modification to the prerequisites specified in section 20c (2), and of any substantial modification in its importing activities, to the competent authority and must submit evidence thereof. The holder of the authorisation may only conduct the modification when the competent authority has authorised it in writing. In particular, modifications referring to the following are considered to be substantial modifications to the importing activity:

1. the type of tissue or tissue preparation imported,

2. activities conducted in a third country that is neither a Member State of the European Union nor another State Party to the Agreement on the European Economic Area, which can have an effect on the quality and safety of the imported tissues and tissue preparations, or

3. the third-country suppliers used.

If the holder of the authorisation undertakes a one-off import, within the meaning of section 72c (2), of tissues or tissue preparations from a third-country supplier that does not fall under that authorisation, such a one-off import is not considered a substantial modification, insofar

as the authorisation of the importing tissue establishment covers the importation of the same type of tissue or tissue preparation from another third-country supplier.
(2d) The holder of the authorisation must notify the competent authority immediately of the following:

1. the revocation, the withdrawal or the order to suspend the authorisation, permit, attestation of a third-country supplier of tissues or tissue preparations by the competent authority of the State in which the third-country supplier is domiciled,

2. every other decision that:

   a) was taken because of non-compliance with provisions of the competent authority of the State in which the third-country supplier is domiciled, and

   b) can be relevant for the quality and safety of the imported tissues and tissue preparations,

3. the complete or partial discontinuance of its import activity and

4. an unforeseen change in the person responsible pursuant to section 20c.

(3) The Federal Ministry is hereby empowered to stipulate the additional requirements for the import of tissues or tissue preparations pursuant to subsection (2), by ordinance subject to the approval of the Bundesrat, so as to guarantee that tissues and tissue preparations are of proper quality. It can lay down, in particular, regulations concerning the tests to be conducted by the person responsible pursuant to section 20c and the conduct of supervision in the country of origin by the competent authority.
(4) Subsection (2) sentence 1 applies to the import of tissues and tissue preparations within the meaning of subsection (1), insofar as its supervision is regulated by an ordinance pursuant to section 54, section 12 of the Transfusion Act or pursuant to section 16a of the Transplantation Act.
(5) (no longer applicable)

Section 72c
One-off import of tissues and tissue preparations

(1) Tissues within the meaning of section 1a no. 4 of the Transplantation Act or tissue preparations within the meaning of section 20c, (1) sentence 1 or sentence 2 that are the object of a one-off import may only be imported by an importing tissue establishment within the meaning of section 72b (1) sentence 1. The importing tissue establishment requires an authorisation for the one-off import from the competent authority. The decision on whether to grant the authorisation is taken by the competent authority of the Land in which the factory premises of the importing tissue establishment are located or are to be located.
(2) A one-off import is the import of any tissue or tissue preparation on behalf of a specific person who has stored this tissue or tissue preparation with a third-country supplier for future personal use or for that of first-degree or second-degree relatives. It is permitted to dispense the tissue or the tissue preparation to a person who is a physician and who is intended to administer the tissue or tissue preparation to the specific person or his/her close relative. The dispensing of the tissue or tissue preparation to persons other than the above-mentioned persons is prohibited.
(3) The application for authorisation pursuant to subsection (1) sentence 2 is to be accompanied by the information and documents specified in Annex I with the exception of part F of Commission Directive (EU) 2015/566. Section 20c (2) to (5) and (7) apply accordingly. The competent authority issues the holder of an authorisation pursuant to subsection (1) sentence 2 with a certificate pursuant to Annex II of Directive (EU) 2015/566. Section 72b (2c) sentences 1 and 2 and subsection (2d) apply accordingly.
(4) Subsections (1) to (3) apply accordingly to haematopoietic stem cells and stem cell preparations derived from peripheral blood or from umbilical cord blood. By way of

derogation from subsection (3) sentence 2, the requirements contained in sections 14 to 19 are to be applied accordingly.

Section 73
Prohibition of introduction

(1) Medicinal products that are subject to compulsory marketing authorisation, to authorisation pursuant to section 21a or registration may only be introduced into the purview of this Act, if they are authorised, authorised pursuant to section 21a, or registered for placing on the market within the purview of this Act or if they have been exempted from the obligation to obtain the marketing authorisation or registration and if:

1. in the case of introduction from a Member State of the European Union or another State Party to the Agreement on the European Economic Area, the recipient is a pharmaceutical entrepreneur, a wholesaler or veterinarian or runs a pharmacy or, as a hospital operator pursuant to the Pharmacy Act (*Apothekengesetz*), is supplied by a pharmacy from a Member State of the European Union or of another State Party to the Agreement on the European Economic Area,

1a. in the case of shipment to the final consumer, the medicinal product is shipped, according to the German regulations governing sale at a distance or electronic commerce, by a pharmacy of a Member State of the European Union or another State Party to the Agreement on the European Economic Area, which is authorised to conduct sale at a distance under its national laws, insofar as they correspond to German pharmacy law as regards the provisions governing sale at a distance, or according to the German Act on Pharmaceutical Services, or

2. in the case of introduction from a country that is not a Member State of the European Union or another State Party to the Agreement on the European Economic Area, the recipient is the holder of an authorisation pursuant to section 72, section 72b or section 72c.

The medicinal products specified in section 47a (1) sentence 1 may only be introduced into the purview of this Act if the recipient is one of the facilities mentioned there. The Federal Ministry publishes at regular intervals an updated overview of the Member States of the European Union and the other States Party to the Agreement on the European Economic Area in which safety standards exist with respect to sale at a distance and electronic commerce in medicinal products which are comparable with those laid down in German law.
(1a) (repealed).
(1b) It is prohibited to introduce counterfeit medicinal products or counterfeit active substances into the purview of this Act. The competent authority can, in justified cases, make exceptions for the purposes of testing or criminal prosecution.
(2) Subsection (1) sentence 1 does not apply to medicinal products that:

1. (repealed),

2. are intended for scientific and research establishments' own requirements and needed for scientific purposes or are intended for use by the sponsor of a clinical trial, or a person authorised by him/her, as an auxiliary medicinal product pursuant to Article 59 of Regulation (EU) No 536/2014 for a clinical trial in accordance with the specifications of the trial protocol.

2a. are needed in small quantities by a pharmaceutical entrepreneur, an enterprise with an authorisation pursuant to section 13 or a testing laboratory as samples for inspection or for analysis purposes,

2b. are introduced from a Member State of the European Union or another State Party to the Agreement on the European Economic Area by an enterprise authorised pursuant to section 13, either for the purpose of treating or processing and the

subsequent shipping onwards or shipping back or for the purpose of manufacturing a medicinal product authorised for placing on the market on the territory governed by this Act,

3. are conveyed under customs supervision through the territory governed by this Act or are transferred to a bonded warehouse procedure or a free zone of control type II or to a free zone of control type I or to a bonded warehouse,

3a. are authorised in a Member State of the European Union or another State Party to the Agreement on the European Economic Area and even after transit storage with a pharmaceutical entrepreneur, manufacturer or wholesaler, are to be re-exported, shipped onwards or shipped back,

4. are introduced for the head of state of a foreign country or for his/her escort and are intended for use during his/her stay within the purview of this Act,

5. are intended for the personal use or consumption of members of diplomatic missions or consular representations within the purview of this Act or of officials of international organisations located there or of their family members, insofar as these persons are neither German nor have their permanent residence within the purview of this Act,

6. are introduced when entering into the purview of this Act in an amount corresponding to the normal personal requirement,

6a. may be placed on the market in the country of origin and are purchased, without a commercial or professional intermediary, in a quantity that corresponds to the amount needed for normal personal use in a Member State of the European Union or another State Party to the Agreement on the European Economic Area,

7. are carried on board any means of transport and are intended exclusively for the use of or consumption by persons conveyed by these means of transport,

8. are intended for use or consumption on sea-going vessels and are consumed on board ships,

9. are sent as samples to the competent higher federal authority for the purpose of obtaining a marketing authorisation or for official batch testing,

9a. are needed by the competent higher federal authority as samples for analytical purposes within the framework of pharmacovigilance,

10. are procured by federal or Land authorities in interstate commerce.

(3) By way of derogation from subsection (1) sentence 1, finished medicinal products are not authorised for marketing or registered for trade within the purview of this Act or that are not exempted from the obligation to obtain a marketing authorisation or registration, may be introduced into the purview of this Act:

1. if they are ordered by pharmacies on the basis of an order received from individual persons in a small quantity and are dispensed by these pharmacies within the framework of the existing pharmacy operating licence,

2. if they may be legally placed on the market in the State from which they are introduced into the purview of this Act, and

3. if no medicinal product for the therapeutic indication in question, which is identical in terms of the active substance and comparable in terms of the strength, is available within the purview of the Act,

or if they are ordered in the appropriate quantity needed to ensure the proper treatment of the hospital's patients, for the purpose of temporarily stocking a hospital pharmacy or a hospital supply pharmacy, under the prerequisites contained in no. 2, and dispensed by this hospital pharmacy or hospital supply pharmacy under the prerequisites contained in no. 3 within the framework of the existing pharmacy operating licence, for the purpose of administration to a patient of said hospital, under the direct personal responsibility of a physician, or if they are to be held in stock for emergencies pursuant to the provisions of the legislation on pharmacies or the requirements of occupational accident insurance, or within the sphere of responsibility of the Federal Ministry of Defence, or must be procured at short notice if, within the purview of this Act, medicinal products for the therapeutic indication are not available. Ordering pursuant to sentence 1 no. 1 and dispensing pursuant to sentence 1 of medicinal products introduced into the territory governed by this Act from a country that is not a Member State of the European Union or other States Party to the Agreement on the European Economic Area require a prescription from a physician or dentist. Further details are settled by the Ordinance on the Operation of Pharmacies.
(3a) By way of derogation from subsection (1) sentence 1, tissue preparations that are not approved pursuant to section 21a (1) for placing on the market within the purview of this Act and haematopoietic stem cell preparations made from peripheral blood or umbilical cord blood that are not authorised pursuant to section 21 for placing on the market within the purview of this Act, nor approved pursuant to section 21a (1) for import into the territory governed by this Act if:

1. they are ordered, in small quantities, by a facility that is the holder of an authorisation pursuant to sections 13, 20c, 52a, 72, 72b, or pursuant to section 72c to conduct activities with these tissue preparations or haematopoietic stem cell preparations from peripheral blood or from umbilical cord blood, based on an existing order placed by an individual, and dispensed by this establishment to the administrating hospital or the administrating position,

2. they may be legally placed on the market in the state from which they are imported into the purview of this Act,

3. for the therapeutic indication in question, no medicinal product that is comparable in terms of functionality is available within the purview of this Act, and

4. in the event that the medicinal product is imported from a country that is not a Member State of the European Union or a State Party to the Agreement on the European Economic Area, ordering and dispensing is based on a medical prescription.

(4) The provisions of this Act are not applicable to medicinal products pursuant to subsection (2) nos. 4 and 5. The provisions of this Act are not applicable to medicinal products pursuant to subsection (2) nos. 2 and 3 and 6 to 10 and subsections (3) and (3a), with the exception of sections 5, 8, 13 to 20a, 52a, 64 to 69 and 78, and furthermore in the cases referred to in subsection (2) no. 2 and subsections (3) and (3a), also with the exception of sections 48, 95 (1) nos. 1 and 3a, subsections (2) to (4), section 96 nos. 3, 10 and 11 and section 97 (1), (2) no. 1 as well as subsection (3), and furthermore in the cases referred to in subsection (3a) and also with the exception of sections 20b to 20d, 72, 72b, 72c, 96 no. 18b and 18d and of section 97 (2) no. 7a.
(5) When exercising their profession in the context of local border traffic within the meaning of Regulation (EC) No. 1931/2006 of the European Parliament and of the Council of 20 December 2006 laying down rules on local border traffic at the external land borders of the Member States and amending the provisions of the Schengen Convention (OJ L 405 of 30.12.2006, p. 1; L 29 of 3.2.2007, p. 3), amended by Regulation (EU) Nr. 1342/2011 (OJ L 347 of 30.12.2011, p. 41), physicians and veterinarians may only carry with them medicinal products that have been authorised for marketing or registered within the purview of this Act or are exempted from the obligation to obtain a marketing authorisation or registration. By

way of derogation from subsection (1) sentence 1, physicians who provide health care services within the meaning of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border health care (OJ L 88 of 4.4.2011, p. 45) amended by Regulation 2013/64/EU (OJ L 353 of 28.12.2013, p. 8), may carry with them small amounts of medicinal products authorised in the place where they are established, in the original packaging, in the quantity that is necessary for providing their cross-border health care services, if and insofar as medicinal products with the same composition and intended for the same therapeutic indications are also authorised for marketing within the purview of this Act; the physician may only administer these medicinal products himself/herself.
(6) In the case of subsection (1) sentence 1 no. 2, the presentation of a certificate issued by the authorities competent in the recipient's case, containing information on the type and quantity of the medicinal product and confirming that the requirements specified in subsection (1) have been met, is necessary for customs clearance for free circulation. The customs office forwards the certificate to the authorities that issued it, at the expense of the party paying the customs duties.
(7) In the case of subsection (1) sentence 1 no. 1, a recipient who is a wholesaler or who runs a pharmacy must prove the existence of the provision for coverage pursuant to section 94.

Section 73a
Export

(1) By way of derogation from sections 5 and 8 (1) and (2), the medicinal products referred to there may be exported or removed from the purview of this Act if the competent authority of the country of destination has authorised the import or introduction of such medicinal products. The authorisation pursuant to sentence 1 must state that the competent authority of the country of destination is cognisant of the grounds for refusal that prevent the marketing of said medicinal products within the purview of this Act.
(2) The competent authority or the competent higher federal authority, insofar as authorisation-related information is concerned and the authorisation holder has his/her place of business outside of the purview of this Act, issues a certificate corresponding to the World Health Organization's Certification Scheme at the request of the pharmaceutical entrepreneur, the manufacturer, the exporter or the competent authority of the country of destination. If the request is submitted by the competent authority of the country of destination, the consent of the manufacturer is to be obtained prior to issuing the certificate.

Section 74
Participation of customs offices

(1) The Federal Ministry of Finance and the customs offices specified by it participate in the supervision of the introduction of medicinal products and active substances into the purview of this Act and of the export of the same. The authorities named may:

1. retain for inspection consignments of the type named in sentence 1, as well as their means of conveyance, containers, loading and packing material,

2. notify the competent administrative authorities of suspected violations of prohibitions and restrictions of this Act or of the ordinances issued pursuant to this Act, if this suspicion becomes evident during the execution of their duties,

3. issue instructions to the effect that, in instances defined in no. 2, consignments of the type named in sentence 1 are presented to a competent medicinal product supervision authority at the cost and at the risk of the person holding the right of disposal of the consignment.

The inviolability of the secrecy of mail pursuant to Article 10 of the Basic Law is restricted in compliance with sentences 1 and 2.

(2) The Federal Ministry for Finance settles the details of the procedure indicated in subsection (1), in agreement with the Federal Ministry, by ordinance not subject to the approval of the Bundesrat. In particular, it may thereby envisage obligations to notify, register, submit information and provide assistance, as well as to tolerate the inspection of business papers and other documents and of premises and the taking of samples free of charge. The ordinance is issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, insofar as radiopharmaceuticals and active substances or medicinal products and active substances in the manufacture of which ionising radiation is used are concerned.

Division 14
Information officer, pharmaceutical consultant

Section 74a
Information officer

(1) Any person who, as a pharmaceutical entrepreneur, places medicinal products on the market, must commission a person with the necessary expert knowledge and the reliability required to perform his/her activities, to responsibly fulfil the tasks of providing scientific information on the medicinal products (information officer). The information officer is, in particular, responsible for ensuring compliance with the prohibition contained in section 8 (1) no. 2 and ensuring that the labelling, the package leaflets, the expert information and advertisements correspond with the content of the marketing authorisation or registration or, insofar as the medicinal product is exempted from the need for a marketing authorisation or registration, with the content of the ordinances governing the exemption from marketing authorisations or registrations pursuant to section 36 or section 39 (3). Sentence 1 does not apply to persons who do not require a manufacturing authorisation pursuant to section 13 (2) nos. 1, 2 or 5. Persons other than those specified in sentence 1 may not exercise the functions of an information officer.
(2) The information officer may be the graduated plan officer at the same time.
(3) The pharmaceutical entrepreneur must notify the competent authority about the identity of the information officer and make notification of any change beforehand. In the event of an unforeseen change in the person of the information officer, a notification is to be made immediately.

Section 75
Expert knowledge

(1) Pharmaceutical entrepreneurs may only appoint persons in possession of expert knowledge, as defined in subsection (2), to visit members of the medical professions on a full-time basis, in order to give technical information on medicinal products (pharmaceutical consultant). Sentence 1 also applies to information given by telephone. The activities of a pharmaceutical consultant may not be carried out by persons other than those indicated in sentence 1.
(2) The following persons possess the necessary expert knowledge:

1. pharmacists or persons holding a certificate testifying to a successfully completed course of university studies in pharmacy, chemistry, biology, human or veterinary medicine and the corresponding passed examination,

2. assistants of pharmacists, as well as persons who have completed training as technical assistants in the fields of pharmacy, chemistry, biology, human or veterinary medicine,

3. pharmaceutical sales representatives.

(3) The competent authority is hereby empowered to recognise a passed examination or a successfully completed course of training as being sufficient if it is at least equivalent to the level of training of any of the persons specified in subsection (2).

Section 76
Duties

(1) The pharmaceutical consultant must make the expert information pursuant to section 11a available, insofar as he/she provides expert information on individual medicinal products to members of the medical professions. He/she must record, in writing or electronically, any notifications made to him/her by members of the medical professions on adverse reactions and contraindications or other risks associated with the medicinal products and notify his/her contract-giver thereof in writing.
(2) Insofar as the pharmaceutical consultant is commissioned by the pharmaceutical entrepreneur to distribute samples of finished medicinal products to those persons entitled to receive them pursuant to section 47 (3), he/she must keep a record of the recipients of the samples, as well as the type and quantity thereof and the time and date of their distribution and must present these records, upon request, to the competent authorities.

Division 15
Designation of the competent higher federal authorities and other provisions

Section 77
Competent higher federal authority

(1) The competent higher federal authority is the Federal Institute for Drugs and Medical Devices unless the Paul Ehrlich Institute (the Federal Agency for Sera and Vaccines) is competent.
(2) The Paul Ehrlich Institute is competent for sera, vaccines, blood preparations, tissue preparations, tissues, allergens, advanced therapy medicinal products, xenogeneic medicinal products and blood components manufactured using genetic engineering.
(3) (repealed).
(4) The Federal Ministry is hereby empowered, by means of ordinance not subject to the approval of the Bundesrat, to modify the competences of the Federal Institute for Drugs and Medical Devices and the Paul Ehrlich Institute, insofar as this is necessary to take account of new scientific developments or if such a change is required for reasons of a more uniform distribution of the workload.

Section 77a
Independence and transparency

(1) As regards the guarantee of independence and transparency, the competent higher federal authorities and the competent authorities shall ensure that staff employed by the authorising authorities or other competent authorities who are involved with marketing authorisations and supervision, or experts appointed by them, have no financial or other interests in the pharmaceutical industry that could influence their neutrality. These persons make an annual declaration in this regard. The competent higher federal authorities and the competent authorities make the declarations pursuant to sentence 2 accessible to the public.
(2) Within the framework of performing the tasks referred to in this Act, the competent higher federal authorities and the competent authorities make the procedural rules of their committees, the agendas and minutes of their meetings accessible to the public; manufacturing and business secrets are to be protected in the process.

Section 78
Prices

(1) The Federal Ministry for Economic Affairs and Energy is empowered, in agreement with the Federal Ministry, by ordinance subject to the approval of the Bundesrat, to specify:

1. price margins for medicinal products that are supplied for resale in wholesale commerce or in pharmacies,

2. prices for medicinal products that are manufactured and supplied in pharmacies, as well as for the containers in which they are supplied,

3. prices for particular services rendered by pharmacies in connection with the dispensing of medicinal products.

By way of derogation from sentence 1, the Federal Ministry for Economic Affairs and Energy is hereby empowered to adjust that portion of the fixed mark-up that does not serve to promote the provision of emergency pharmacy services according to how pharmacy costs develop given cost-effective management, in agreement with the Federal Ministry, by ordinance not subject to the approval of the Bundesrat. The price regulations for wholesale commerce based on sentence 1 no. 1 also apply to pharmaceutical entrepreneurs or other natural or legal persons who pursue an activity pursuant to section 4 (22) in supplying pharmacies that purchase the medicinal products for the purpose of supplying consumers.

(2) The prices and price margins must take into account the legitimate interests of the medicinal product consumers, the pharmacies and the wholesale trade; the legitimate interests of consumers of medicinal products includes ensuring supply as well as the provision of medicinal products pursuant to section 52b. A uniform pharmacy retail price is to be guaranteed for medicinal products that are to be dispensed exclusively in pharmacies. Sentence 2 does not apply to prescription-only medicinal products that are not subject to reimbursement by the statutory health insurance.

(3) In the case of medicinal products pursuant to subsection (2) sentence 2 for which prices and price ranges have been specified by an ordinance pursuant to subsection (1), the pharmaceutical entrepreneurs must guarantee a uniform sales price; in the case of non-prescription medicinal products that are to be reimbursed by the statutory health insurance, the pharmaceutical entrepreneurs must specify their uniform sales price from which exceptions may be made in individual cases, for the purpose of the settlement of accounts between the pharmacy and the statutory health insurance. Social insurance carriers, private health insurances, as well as their individual associations, can come to an agreement with the pharmaceutical entrepreneur on discounts off the uniform sales price for the prescription of medicinal products which they have to reimburse. When dispensing medicinal products for which the prices and price margins according to the ordinance pursuant to subsection (1) are excluded from the price-fixing process, the uniform sales price pursuant to sentence 1 may not be exceeded.

(3a) If a reimbursement value applies to a medicinal product pursuant to section 130b of the Fifth Book of the Social Code, the pharmaceutical entrepreneur sells the medicinal product at a price that amounts to the reimbursement value. By way of derogation from sentence 1, the pharmaceutical entrepreneur can sell the medicinal product for an amount that is lower than the specific refund amount; this is without prejudice to the obligation contained in subsection (3) sentence 1 first half sentence. The sale price pursuant to sentence 1 or sentence 2 also applies for persons who do not obtain the medicinal product as members of a statutory health insurance in the form of a benefit in kind. In the cases not covered by the reimbursement according to section 130b (3a) sentence 9 or subsection (4) sentence 3 of the Fifth Book of the Social Code, the natural or legal persons who purchased the medicinal product from the pharmaceutical entrepreneur may demand from the pharmaceutical entrepreneur the reimbursement of the difference between the specific refund amount applicable under section 130b (3a) or subsection (4) sentence 3 of the Fifth Book of the Social Code and the pharmacy retail price effectively paid up until its agreement or determination, including the excess supplements pursuant to the Drug Price Ordinance paid and the excess value added tax paid.

(4) In the case of medicinal products which, in the event of a threatening infectious disease the spread of which requires an immediate supply of specific medicinal products which goes beyond the normal amount, are dispensed by pharmacies and which have been stored for this purpose pursuant to section 47 (1) no. 3c, the prices and price ranges to be specified pursuant to subsection (2) are based on the sales price in the Laender. The same applies to medicinal products manufactured in pharmacies from active substances stored for this purpose and dispensed in such cases. In these cases, subsection (2) sentence 2 applies at Land level.

Section 79
Authority to permit exceptions in times of crisis

(1) The Federal Ministry is hereby empowered to permit exceptions to the regulations laid down by this Act and by the ordinances issued by virtue of this Act, in agreement with the Federal Ministry for Economic Affairs and Energy, by ordinance subject to the approval of the Bundesrat, if the necessary supply of medicinal products to the population would otherwise be seriously jeopardised and if a direct or indirect hazard by medicinal products to human health is not to be feared; in particular, regulations can be adopted to counter the spread of risks that might occur in reaction to the presumed or confirmed spread of pathogenic substances, toxins, chemicals or exposure to ionising radiation.
(2) (repealed).
(3) The ordinances pursuant to subsection (1) are issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, insofar as radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used or regulations to protect against the risks of ionising radiation are concerned.
(4) The term of validity of the ordinance pursuant to subsection (1) is limited to six months.
(4a) If, in the case of an existing or imminent serious infectious disease, the necessary supply of medicinal products to the population would otherwise be seriously jeopardised, the Federal Ministry can, without prejudice to the tasks of other bodies, manufacture, procure, stockpile and place medicinal products, active substances, starting materials and excipients as well as packaging materials for medicinal products on the market, itself or through commissioned agencies, to guarantee the population's medicine supply. Appropriate reimbursement for expenditure can be required from the recipients of the medicinal products, active substances, starting materials and excipients and packaging materials for medicinal products. This regulation is without prejudice to budgetary requirements.
(4b) Without prejudice to the tasks of other bodies, the Federal Ministry can, itself or through commissioned agencies, procure, stockpile and place COVID-19 vaccines on the market up until 31 December 2027. Section 3 of the Ordinance to Safeguard the Supply of Products for Medical Need during the Epidemic Caused by the Coronavirus SARS-Cov-2 of 25 May 2020 (*Verordnung zur Sicherstellung der Versorgung der Bevölkerung mit Produkten des medizinischen Bedarfs bei der durch das Coronavirus SARS-CoV-2 verursachten Epidemie)* (Federal Gazette AT 26 May 2020 V1), most recently amended by Article 8b of the COVID-19 Protection Act of 16 September 2022 (Federal Law Gazette I p. 1454), applies accordingly. Insofar as liability is excluded or limited pursuant to section 3 (4) sentence 1 and 2 of the Ordinance to Safeguard the Supply of Products for Medical Need during the Epidemic Caused by the Coronavirus SARS-Cov-2 in conjunction with sentence 2, this does not apply to liability under the Product Liability Act. Section 15 (1) of the Product Liability Act does not apply in such cases.
(5) In the event of a shortage of medicinal products necessary for the prevention or treatment of life-threatening diseases in the population or in the event of a dangerous communicable disease the spread of which calls for the provision of specific medicinal products immediately and in a quantity that considerably exceeds the norm, the competent authorities may permit, on a case-by-case basis, that medicinal products that are not authorised or registered for placing on the market within the purview of this Act:

1. may be placed on the market temporarily, and
2. may be introduced into the purview of this Act by way of derogation from section 73 (1).

Sentence 1 applies if the medicinal products may be legally placed on the market in the State from which they are being introduced into the purview of this Act, or the competent higher federal authority has determined that the quality of the medicinal product is guaranteed and its use according to the findings of medical science is expected to have a positive benefit-risk balance in the prevention or treatment of the specific disease. The

granting of permission by the competent authority also counts as an attestation pursuant to section 72a (1) sentence 1 no. 3 or pursuant to section 72b (2) sentence 1 no. 3 that the import is in the public interest. In the event of a shortage or a dangerous communicable disease within the meaning of sentence 1, the competent authorities can, on a case-by-case basis, also permit a temporary deviation from the authorisation requirements or from other prohibitions contained in this Act. The Federal Ministry is responsible for assessing whether a shortage or a dangerous communicable disease within the meaning of sentence 1 exists or no longer exists. The assessment is made known by way of a notification published in the Federal Gazette. The notification is issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, insofar as radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used are concerned.
(6) Measures by the competent authorities pursuant to subsection (5) are to be restricted to the minimum necessary and must be appropriate to counter the health threats that could be created by the shortage or by the dangerous communicable disease. The lodging of an objection and action to rescind taken in respect of measures pursuant to subsection (5) have no suspensive effect.

Section 80
Authority to issue procedural and compassionate use regulations

The Federal Ministry is hereby empowered to regulate, by ordinance not subject to the approval of the Bundesrat, further details regarding the procedure in respect of:

1. the marketing authorisation including the extension of the manufacturing authorisation,

1a. the approval pursuant to section 21a (1) or the attestation pursuant to section 21a (9),

1b. approval pursuant to section 4b (3),

2. the official batch testing and batch release,

3. the notifications in respect of changes in the marketing authorisation documents,

3a. the notifications of changes in the information and documentation submitted for the authorisation pursuant to section 21a (1) or changes in the requirements for the attestation pursuant to section 21a (9),

3b. the notifications of changes in the information and documentation submitted for the authorisation pursuant to section 4b (3),

3c. the competent higher federal authority and the persons involved in the placing on the market in cases of compassionate use pursuant to section 21 (2) no. 3 in conjunction with Article 83 of Regulation (EC) No. 726/2004,

4. the registration, including the extension of the registration,

4a. the notifications of changes in the registration documents,

4b. the publication of the results of clinical trials pursuant to section 42b,

5. the reporting of medicinal product risks, and

6. the electronic submission of documents pursuant to nos. 1 to 5 including the formats to be used,

in the process, it may require the forwarding of duplicates to the competent authorities and stipulate that the documents are to be submitted in multiple copies as well as on electronic or optical storage media. The Federal Ministry can transfer this authority to the competent

higher federal authority without the approval of the Bundesrat. In the ordinance pursuant to sentence 1 no. 3a, in particular, the tasks of the competent higher federal authority with regard to the participation of the European Medicines Agency and the Committee for Medicinal Products for Human Use, pursuant to Article 83 of Regulation (EC) No. 726/2004, and the areas of responsibility of the treating physicians and pharmaceutical entrepreneurs or sponsors can be regulated, including notification, documentation and reporting requirements for adverse reactions in particular, pursuant to Article 24 paragraph and Article 25 of Regulation (EC) No. 726/2004. In this regard, regulations can also be laid down for medicinal products that, under the conditions laid down in Article 83 of Regulation (EC) No. 726/2004, relate to medicinal products that are not among those referred to in Article 3 (1) or (2) of this Regulation.

Section 81
Relation to other laws

The regulations contained in the legislation on narcotic medicinal products and on nuclear energy, the Anti-Doping Act and those contained in the Law on the Protection of Animals (*Tierschutzgesetz*) are not affected.

Section 82
General administrative regulations

The Federal Government issues, with the approval of the Bundesrat, the general administrative regulations required for the implementation of this Act. Insofar as these apply to the competent higher federal authority, the general administrative regulations are issued by the Federal Ministry.

Section 83
Approximation to European Union legislation

Ordinances or general administrative regulations issued in compliance with this Act may also be issued for the purpose of approximation to the legal and administrative regulations of the Member States of the European Union, insofar as this is necessary for the implementation of regulations, directives, decisions or resolutions adopted by European Community or the European Union, which affect fields covered by this Act.

Section 83a
Ordinances for specific cases

The Federal Ministry is hereby empowered to amend, by ordinance not subject to the approval of the Bundesrat, references to regulations contained in legal instruments of the European Community or the European Union in this Act, or in ordinances issued on the basis of this Act, insofar as necessary to adapt to changes in these regulations.

Division 16
Liability for damages caused by medicinal products

Section 84
Absolute liability

(1) If, as a result of the administration of a medicinal product intended for human use, which was distributed to the consumer within the purview of this Act and which is subject to compulsory marketing authorisation or is exempted by ordinance from the need for a marketing authorisation, a person is killed, or the body or the health of a person is substantially damaged, the pharmaceutical entrepreneur who placed the medicinal product on the market within the purview of this Act is obliged to compensate the injured party for the damage caused. The liability to compensate only exists if:

1. when used in accordance with its intended purpose, the medicinal product has harmful effects that exceed the limits considered tolerable in the light of current medical knowledge, or

2. the damage has occurred as a result of labelling, expert information or instructions for use that do not comply with current medical knowledge.

(2) If the medicinal product administered is capable of causing the damage, in the circumstances pertaining to the individual case, the damage is presumed to have been caused by the medicinal product in question. The capability in the individual case is determined according to the composition and the dosage of the administered medicinal product, the manner and duration of its administration when used as intended, the temporal relationship to the occurrence of the damage, the damage symptoms and the person's state of health at the time of the administration as well as all other circumstances which, in the individual case, speak for or against the causation of damage. The presumption does not apply if, in the light of the circumstances pertaining to the individual case, another fact is capable of causing the damage. However, the administration of additional medicinal products that, in the circumstances pertaining to the individual case, are capable of causing the damage is not considered as another fact unless the administration of these medicinal products does not create claims under this provision for reasons other than the lack of causation.
(3) The pharmaceutical entrepreneur is exempted from liability to pay damages pursuant to subsection (1) sentence 2 no. 1 if the facts indicate that the damaging effect of the medicinal product is not attributable to its development and manufacturing process.

Section 84a
Right to disclosure

(1) Where facts exist to justify the assumption that a medicinal product has caused the damage, the injured party can request information from the pharmaceutical entrepreneur unless such information is not necessary to verify a right to compensation pursuant to section 84. The right refers to effects, adverse reactions and interactions known to the pharmaceutical entrepreneur as well as suspected adverse reactions and interactions brought to his/her attention and all further knowledge that could be of significance in assessing the justifiability of harmful effects. Sections 259 to 261 of the Civil Code are to be applied accordingly. A right to disclosure does not exist where statutory provisions require that the data remain secret or when non-disclosure is justified by an overriding interest of the pharmaceutical entrepreneur or a third party.
(2) A right to disclosure also exists, under the conditions laid down in subsection (1) vis-à-vis the authorities responsible for the authorisation and supervision of medicinal products. The authority is not obliged to disclose the information where provisions require that the data remain secret or when non-disclosure is justified by an overriding interest of the pharmaceutical entrepreneur or a third party. This is without prejudice to claims under the Freedom of Information Act (*Informationsfreiheitsgesetz*).

Section 85
Contributory negligence

If negligence on the part of the injured party has helped to cause the injury, section 254 of the Civil Code applies.

Section 86
Extent of liability for damages in the case of death

(1) In the case of death, compensation is to be made by reimbursing the costs of an attempted cure as well as the costs incurred by the pecuniary prejudice sustained by the deceased party as a result of the suspension or reduction of his/her earning capacity or the resultant increase in his/her needs for the duration of the disease. The party liable for damages must furthermore reimburse the funeral costs to the party who is responsible for defraying these expenses.
(2) If at the time of injury, the deceased party maintained a relationship with a third party by virtue of which he/she was or was liable to come under the legal obligation to support this third party and if the third party was deprived of the right to maintenance as a result of the

death, the party liable for damages must indemnify the third party, guaranteeing maintenance to the extent to which the deceased party would have been liable for the length of lifespan he/she would probably have had. Liability for damages also exists if, at the time of injury, the third party had been conceived but not yet born.
(3) The party liable for damages must pay the surviving dependent who, at the time of the injury, was in a special personal, close relationship with the deceased party, appropriate pecuniary damages for the emotional suffering caused to the surviving dependent. A special personal, close relationship is assumed if the surviving dependent was the spouse, life partner, parent or child of the deceased party.

Section 87
Extent of liability for damages in the case of bodily injury

In the case of injury to a person's body or damage to his/her health, compensation is to be given by reimbursing the costs of the treatment as well as the costs incurred by the pecuniary prejudice sustained by the injured party as a result of the temporary or permanent suspension or reduction of his/her earning capacity or the resultant increase in his/her needs. In this case, reasonable financial compensation can also be claimed when the damage is not of a pecuniary nature.

Section 88
Maximum amounts

The party liable for damages bears liability:

1. in the case of the death of or injury to a person, only up to a capital amount of 600,000 euros or an annuity of up to 36,000 euros per year,

2. in the case of the death of or injury to several persons by the same medicinal product, notwithstanding the limits stipulated in no. 1, up to a capital amount of 120 million euros or an annuity of up to 7.2 million euros per year.

Should, in the case of sentence 1 no. 2, the combined indemnification to be paid to several injured parties exceed the maximum amounts specified therein, then the individual compensation is to be reduced pro-rata to the maximum total given.

Section 89
Compensation in the form of annuities

(1) Compensation on account of the suspension or reduction of earning capacity and on account of increased need on the part of the injured party, as well as the compensation to be afforded a third party pursuant to section 86 (2), is to be paid in the future by means of an annuity.
(2) The provisions of section 843 (2) to (4) of the Civil Code and of section 708 no. 8 of the Code of Civil Procedure apply accordingly.
(3) If a security bond was not awarded when the party liable was sentenced to pay the annuity, the entitled party may, nevertheless, demand a security bond if the pecuniary circumstances of the liable party have deteriorated considerably; under the same circumstances, he/she may demand an increase in the security bond specified in the verdict.

Section 90
(no longer applicable)

Section 91
Extended liability

This is without prejudice to legal provisions according to which the party liable for damages under section 84 is liable to a greater extent than stipulated by the provisions in this Division, or according to which another party is responsible for the damage incurred.

Section 92
Mandatory provision

The liability for damages pursuant to this Division may neither be excluded nor restricted beforehand. All agreements to the contrary are void.

Section 93
Several parties liable for damages

If several parties are liable for damages, they are jointly and severally liable. With regard to the relationship of the liable parties to one another, the obligation to pay compensation as well as the extent of the compensation to be paid depends on the extent to which the damage was predominantly caused by one or the other party.

Section 94
Coverage provision

(1) The pharmaceutical entrepreneur must ensure that he/she is able to meet his/her legal commitments in respect of compensation for the damage incurred as a result of the administration of a medicinal product intended for human use, placed by him/her on the market, and subject to a compulsory marketing authorisation or exempted by ordinance from a marketing authorisation (provision for coverage). The provision for coverage must be made available in the amounts specified in section 88 sentence 1. It may only be made available by means of:

1. a third-party insurance taken out with an independent insurance company authorised to conduct business within the purview of this Act, for which, in the event of a reinsurance, a reinsurance contract exists only with a reinsurance company that is established within the purview of this Act, in another Member State of the European Union, in another State Party to the Agreement on the European Economic Area or in another state recognised by the European Commission as equivalent according to Article 172 of Directive 2009/138/EC of the European Parliament and of the Council of 25 November 2009 on the taking-up and pursuit of the business of Insurance and Reinsurance (Solvency II) (OJ L 335 of 17.12.2009, p. 1), or

2. an exemption or warranty obligation issued by a domestic credit institution, or a credit institution of one of the other Member States of the European Union or another State Party to the Agreement on the European Economic Area.

(2) If the provision for coverage is afforded by a third-party insurance, section 113 (3) and sections 114 to 124 of the Law on Insurance Contracts apply accordingly.
(3) Provision for coverage may only be made available using exemption or warranty obligations issued by a credit institution if it is guaranteed that the credit institution will be in a position to meet its commitments within the framework of the provision for coverage for such time as it can be expected to be called upon to do so. Section 113 (3) and sections 114 to 124 of the Law on Insurance Contracts (*Versicherungsvertragsgesetz*) apply accordingly with respect to exemption or warranty obligations.
(4) The competent office within the meaning of section 117 (2) of the Law on Insurance Contracts is the authority competent for carrying out supervision pursuant to section 64.
(5) The Federal Republic of Germany and the federal Laender are not obliged to provide coverage in compliance with subsection (1).

Section 94a
Local jurisdiction

(1) In the case of legal actions initiated on the basis of section 84 or section 84a (1), the court in whose district the plaintiff has his/her domicile or, failing this, has his/her usual place of abode at the time of filing the action has jurisdiction.
(2) No account is taken of subsection (1) when determining the international jurisdiction of the courts of a foreign nation pursuant to section 328 (1) no. 1 of the Code of Civil Procedure.

Division 17
Penal provisions and provisions on administrative fines

Section 95
Penal provisions

(1) A period of imprisonment not exceeding three years or a fine is imposed on any person who:

1. in breach of section 5 (1), places a medicinal product on the market or uses a medicinal product on another,

2. in breach of section 6 subsection 1 in conjunction with an ordinance pursuant to section 6 subsection 2, in each case also in conjunction with an ordinance pursuant to section 6 subsection 3, places a medicinal product on the market or administers it to another person,

2a. (repealed),

2b. (repealed),

3. in breach of section 7 (1), places radiopharmaceuticals and medicinal products in the manufacture of which ionising radiation is used on the market,

3a. in breach of section 8 (1) no. 1 or subsection (2), also in conjunction with section 73 (4) or section 73a, manufactures or places medicinal products or active substances on the market or otherwise trades in them,

4. in breach of section 43 (1) sentence 2, subsection (2) or (3), trades in or dispenses medicinal products that may be dispensed to the consumer on prescription only,

5. in breach of section 47 (1) dispenses medicinal products that may be dispensed to the consumer on prescription only, to persons or bodies other than those specified therein, or obtains them in breach of section 47 subsection (2) sentence 1,

5a. in breach of section 47a (1), dispenses one of the medicinal products specified therein to any facility other than those specified therein or places such a medicinal product on the market.

(2) The attempt to commit such acts is punishable.

(3) In particularly serious cases, the penalty is imprisonment from one to ten years. A particularly serious case is usually deemed to exist if the perpetrator:

1. by means of one of the actions indicated in subsection (1):

   a) endangers the health of a large number of persons,

   b) exposes another person to the risk of death or the risk of serious injury to that person’s body or health,

   c) acquires a considerable pecuniary gain for himself/herself or another person out of gross self-interest, or

2. in the cases mentioned in subsection (1) no. 3a, manufactures or places counterfeit medicinal products or active substances on the market acting, in the process, commercially or as a member of a gang that has come together for the recurrent commission of such acts.

(4) If the perpetrator has acted negligently in the instances cited in subsection (1), the penalty is imprisonment for a period of up to one year or a fine.

Section 96
Penal provisions

Any person who:

1. dispenses a medicinal product in breach of section 4b (3) sentence 1,

2. manufactures a medicinal product in breach of section 6 subsection 1 in conjunction with an ordinance pursuant to section 6 subsection 2, in each case also in conjunction with an ordinance pursuant to section 6 subsection 3.

3. manufactures or places medicinal products or active substances on the market in breach of section 8 (1) no. 2, also in conjunction with section 73a,

4. manufactures or imports a medicinal product, an active substance or other substance specified therein without either the authorisation required by section 13 (1) sentence 1 or section 72 (1) sentence 1,

4a. collects tissues or carries out laboratory testing without an authorisation pursuant to section 20b (1) sentence 1 or subsection (2) sentence 7 or, without an authorisation pursuant to section 20c (1) sentence 1, processes, preserves, tests, stores or places tissues or tissue preparations on the market,

5. places a finished medicinal product or a medicinal product on the market, in breach of section 21 (1) sentence 1, also in conjunction with an ordinance pursuant to section 35 (1) no. 2,

5a. places tissue preparations on the market without an authorisation pursuant to section 21a (1) sentence 1,

5b. introduces tissue preparations for the first time without a certificate pursuant to section 21a (9) sentence 1,

6. fails to submit fully or correctly the information required pursuant to section 22 (1) nos. 3, 5 to 9, 11, 12, 14 or 15, subsection (3b) or (3c) sentence 1 or fails to submit a document required according to section 22 (2) or (3), in each case also in conjunction with section 38 (2) sentence 1, or a document required according to an enforceable order pursuant to section 28 (3), (3a), (3b) or subsection (3c) sentence 1 no. 2 fully or with the correct contents,

7. places a medicinal product on the market in breach of section 30 (4) sentence 1 no. 1, also in conjunction with an ordinance pursuant to section 35 (1) no. 2,

8. places a batch that has not been released for trade on the market, in breach of section 32 (1) sentence 1, also in conjunction with an ordinance pursuant to section 35 (1) no. 3,

9. places finished medicinal products as homeopathic or as traditional herbal medicinal products without registration on the market, in breach of section 38 (1) sentence 1 or section 39a sentence 1,

10. begins the clinical trial in breach of section 40 (1),

11. conducts a clinical trial in breach of section 40a sentence 1 no.2 or no.3, also in conjunction with sentence 2, in breach of section 40a sentence 1 no. 4 letter a or no. 5, or section 40b (3), subsection (4) sentence 1 no. 1, sentence 2, sentence 3 or sentence 9 or subsection (5),

12. dispenses one of the medicinal products specified therein without a prescription if the act is not punishable pursuant to section 95 (1) no. 5a, in breach of section 47a (1) sentence 1,

13. dispenses medicinal products in breach of section 48 (1) sentence 1 no. 1, in conjunction with an ordinance pursuant to section 48 (2) no. 1, 2 or no. 7 or in breach of section 48 (1) sentence 1 no. 2, also in conjunction with an ordinance pursuant to section 48 (2) sentence 1 no. 1,

14. engages in wholesale trade without an authorisation pursuant to section 52a (1) sentence 1,

14a. engages in the activity of a medicinal product broker, in breach of section 52c (2) sentence 1,

15.-18a. (no longer applicable),

18b. without an authorisation pursuant to section 72 (4) sentence 2, section 72b (1) sentence 3 or section 72c (1) sentence 2, also in conjunction with section 72c (4) sentence 1, imports haematopoietic stem cells, stem cell preparations, tissues or tissue preparations specified therein,

18c. in breach of section 72a (1) sentence 1, also in conjunction with subsection (1b) or (1d), or in breach of section 72a (1c), imports a medicinal product, an active substance or another substance listed in the subsections cited,

18d. in breach of section 72b (2) sentence 1, imports tissues or tissue preparations,

18e. in breach of section 73 (1b) sentence 1, introduces a counterfeit medicinal product or a counterfeit active substance into the purview of this Act,

19. places a medicinal product on the market even though the third-party insurance or the exemption or warranty obligation required in compliance with section 94 does not or no longer exists, or

20. in breach of sentence 1 of Article 6 (1) of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency (OJ L 136 of 30.4.2004, p. 1), last amended by Regulation (EU) 2019/5 (OJ L 4 of 7.1.2019, p. 24) in conjunction with Article 8 (3) first subparagraph, point (c), (ca) first sentence, points (d), (e), (h) to (iaa) or point (ib) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311 of 28.11.2001, p. 67; L 239 of 12.8.2014, p.81), last amended by Regulation (EU) 2019/1243 (OJ L 198 of 25.7.2019, p.241) fails to attach information or a document correctly or fully, or

21. fails to comply with Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158 of 27.5.2014, p. 1), by:

a) failing to transmit an application dossier correctly or fully in breach of Article 5 (1) first subparagraph in conjunction with Article 25 (1) first sentence (c) or Annex I (41) first sentence, or

b) conducts a clinical trial in breach of Article 28 (1) (a), (c) or (e) in conjunction with Article 29 (1) (1) or (3), in breach of Article 32 (1) or Article 33.

Section 97
Provisions on administrative fines

(1) An administrative offence is deemed to have been committed by any person who negligently commits one of the acts indicated in:

1. Section 96 nos. 1 to 5b, 7 to 18e or no. 19, or

2. Section 96 nos. 6, 20 or no. 21.

(2) An administrative offence is deemed to have been committed by any person who wilfully or negligently:

1. places medicinal products on the market, in breach of section 8 (3),

2. places medicinal products that do not bear the name or the company name of the pharmaceutical entrepreneur on the market, in breach of section 9 (1),

3. places medicinal products on the market, in breach of section 9 (2) sentence 1 without having his/her place of business within the purview of this Act or in another Member State of the European Union or another State Party to the Agreement on the European Economic Area,

4. places medicinal products without the prescribed labelling on the market, in breach of section 10, also in conjunction with section 109 (1) sentence 1 or an ordinance pursuant to section 12 (1) no. 1,

5. places medicinal products on the market without the required package leaflet, in breach of section 11 (1) sentence 1, also in conjunction with subsections (2a) to (3b) or (4), each also in conjunction with an ordinance pursuant to section 12 (1) no. 1,

5a. dispenses a partial amount in breach of section 11 (7) sentence 1,

6. contravenes an enforceable order pursuant to

   a) section 18 (2),

   b) section 52b (3d) sentence 2 or sentence 3, or

   c) section 52b (3f) sentence 3,

7. in breach of

   a) section 20, section 20b (5), section 20c (6), section 52a (8), section 67 (8) sentence 1 or section 72b (2c) sentence 1,

   b) section 21a (7) sentence 1, section 29 (1) sentence 1, also in conjunction with sentence 2, in breach of section 29 (1c) sentence 1, section 63c (2), section 63i (2), sentence 1, section 67 (6) sentence 1 or

   c) section 67 (1), sentence 1, also in conjunction with sentence 2, in breach of section 67 (5) sentence 1 or section 67 (9) sentence 1,

   fails to notify or fails to do so correctly, fully or on time,

7a. in breach of section 29 (1a) sentence 1, subsection (1b) or (1d), fails to notify or fails to do so correctly, fully or on time,

8. introduces medicinal products into the purview of this Act in breach of section 30 (4) sentence 1 no. 2 or section 73 (1),

9. in breach of section 42b (1), fails to make the reports available, or fails to do so correctly, fully or on time,

10. in breach of section 43 (1), (2) or (3), places medicinal products on the market professionally or commercially or trades in or dispenses any medicinal products that may be dispensed to consumers without prescription,

11. (no longer applicable),

12. in breach of section 47 (1) dispenses medicinal products that may be dispensed to the consumer without a prescription, to persons or bodies other than those specified therein, or obtains them in breach of section 47 subsection (2) sentence 1,

12a. in breach of section 47 (4) sentence 1, dispenses samples or has samples dispensed without a written request, in a package size other than the smallest one or in quantities exceeding the admissible limit,

13. fails to keep the records specified in section 47 (4) sentence 3 or in section 47a (2) sentence 2, fails to do so correctly or fails to submit them to the competent authority upon request,

13a. in breach of section 47a (2) sentence 1, dispenses any medicinal product specified therein without the prescribed labelling,

14. retails medicinal products in breach of section 50 (1),

15. in breach of section 51 (1), offers medicinal products for sale in the context of itinerant trading or seeks to procure orders for medicinal products,

16. in breach of section 52 (1), places medicinal products on the market on a self-service basis,

16b. in breach of section 52b (3f) sentence 2, fails to transmit data or fails to do so correctly, fully, in the manner prescribed or on time,

16a. in breach of section 52b (3e) sentence 1, fails to make a notification or fails to do so correctly, fully or on time,

17. in breach of section 55 (8) sentence 1, also in conjunction with sentence 2, uses a substance, container or packaging or manufactures a pharmaceutical form,

17a.-24b.(no longer applicable)

24c. in breach of section 63a (1) sentence 1, fails to appoint a graduated plan officer or, in breach of section 63a (3), fails to make a notification or fails to do so fully or on time,

24d. in breach of section 63a (1) sentence 5, works as a graduated plan officer,

24e. in breach of section 63b (1), fails to operate a pharmacovigilance system,

24f. in breach of section 63b (2) no. 1, fails to take a measure specified therein, or fails to do so on time,

24g. in breach of section 63b (2) no. 3, fails to keep a pharmacovigilance master file, fails to do so correctly or fully, fails to make it available or fails to do so correctly, fully, or on time,

24h. in breach of section 63b (2) no. 4, fails to put into place a risk management system for each individual medicinal product, or fails to do so correctly or fully,

24i. in breach of section 63b (3) sentence 1, publishes information specified therein without the prior or simultaneous notification specified therein,

24j. in breach of section 63d (1), also in conjunction with subsection (3) sentence 1 or subsection (3) sentence 4, fails to submit a safety report or fails to do so correctly, fully or on time,

24k. in breach of section 63f (1) sentence 3, fails to transmit a final report or fails to do so on time,

24l. in breach of section 63g (1), fails to submit a draft of the study protocol or fails to do so correctly or on time,

24m. in breach of section 63g (2) sentence 1, commences a safety study,

24n. in breach of section 63g (4) sentence 1, fails to submit a study report or fails to do so correctly, fully or on time,

24o. (no longer applicable),

24p. in breach of section 63i (3) sentence 1, fails to make a notification or fails to do so correctly or on time,

24q. in breach of section 63i (4) sentence 1, fails to submit a report or fails to do so correctly or on time,

25. contravenes an enforceable order pursuant to section 64 (4) no. 4,

26. contravenes an obligation to tolerate or to collaborate in accordance with section 66,

27. in breach of an enforceable order pursuant to section 74 (1) sentence 2 no. 3, fails to present a consignment for clearance,

27a. in breach of section 74a (1) sentence 1, fails to appoint an information officer or, in breach of section 74a (3), fails to make a notification or fails to do so fully or on time,

27b. in breach of section 74a (1) sentence 4, works as an information officer,

28. in breach of section 75 (1) sentence 1, appoints a person as pharmaceutical consultant,

29. in breach of section 75 (1) sentence 3, works as a pharmaceutical consultant,

30. contravenes an obligation to keep records, to make notifications or to present records in compliance with section 76 (1) sentence 2 or subsection (2),

30a. (no longer applicable),

31. contravenes an ordinance pursuant to section 7 (2) sentence 2, section 12 (1) no. 3 letter a, section 12 (1b), section 54 (1), or section 74 (2) or an enforceable order based on such an ordinance, insofar as the ordinance refers to this provision on administrative fines for specific cases.

(2a) (no longer applicable)
(2b) Any person who fails to comply with Regulation (EC) No. 726/2004, by wilfully or negligently:

1. failing to make a notification specified therein to the European Medicines Agency or the competent higher federal authority, or failing to do so correctly, fully or in time, in breach of Article 16 (2) sentence 1 or sentence 2 of Regulation (EC) No. 726/2004, in either case in conjunction with Article 8 (3) first subparagraph, points (c) to (e), (h) to (iaa), or (ib) of Directive 2001/83/EC, each in conjunction with section 29 (4) (2), or

2. failing to ensure that a notification is available at a location specified therein, in breach of Article 28 (1) of Regulation (EC) No. 726/2004 in conjunction with Article 107 (1) second subparagraph of Directive 2001/83/EC,

(2c) An administrative offence is deemed to have been committed by any person who, in breach of Regulation (EC) No. 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation

(EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No. 726/2004 (OJ L 378 of 27.12.2006, p. 1, L 339 of 26.11.2014, p. 14), last amended by Regulation (EU) 2019/5 (OJ L 4 of 7.1.2019, p. 24), wilfully or negligently:

1. fails to place a medicinal product mentioned therein on the market or fails to do so on time in breach of Article 33 first sentence,

2. contravenes an enforceable order pursuant to Article 34 (2) fourth sentence,

3. Fails to submit the report specified therein or fails to do so on time in breach of Article 34 (4) first sentence,

4. Fails to transfer the marketing authorisation to one of the third parties specified therein or fails to do so on time and not allowing the latter to use the documentation specified therein or fails to do so in time, in breach of Article 35 first sentence,

5. fails to inform or fails to do so correctly or on time in breach of Article 35 second sentence, or

6. fails to submit the results of the test mentioned therein or fails to do so correctly or on time in breach of Article 41 (2) second sentence.

(2d) An administrative offence is deemed to have been committed by any person who contravenes Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC (OJ L 158 of 27.5.2014, p. 1, L 311 of 17.11.2016, p. 25), by wilfully or negligently:

1. failing to inform the competent higher federal authority or failing to do so on time, in breach of Article 36, Article 37 (1), (2), (3) or (5) or Article 54 (2),

2. in breach of Article 37 (4) first subparagraph, first sentence in conjunction with second sentence, second subparagraph or third subparagraph, in breach of Article 37 (4) fourth subparagraph 4 or paragraph (8) or Article 43 (1) fails to transmit a document mentioned therein or fails to do so accurately, completely or on time,

3. in breach of Article 37 (6) fails to inform the competent higher federal authority or fails to do so on time,

4. in breach of Article 38 (1) fails to make a notification or fails to do so on time,

5. in breach of:

   a) Article 41 (1) or (2) first subparagraph second sentence in conjunction with second subparagraph first sentence or in breach of Article 41 (4), or

   b) Article 42 (1) in conjunction with paragraph 2 first sentence, in breach of Article 52 (1) or Article 53 (1),

fails to make a notification or fails to do so correctly, fully or on time,

(2e) Any person who fails to comply with Commission Delegated Regulation (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use (OJ L 32 of 9.2.2016, p. 1), by wilfully or negligently:

1. placing a medicinal product mentioned therein on the market or failing to inform or failing to do so on time in breach of Article 18,

2. supplying or exporting a medicinal product mentioned therein in breach of Article 24 first sentence,

3. failing to inform or failing to do so on time in breach of Article 24 second sentence,

4. supplying a medicinal product or failing to inform or failing to do so on time in breach of Article 30, or

5. failing to have a national competent authority, the European Medicines Agency and the Commission alerted in breach of Article 37, point (d), is deemed to have committed an administrative offence.

(3) The administrative offence is punishable with a fine not exceeding 25,000 euros.
(4) The administrative authority within the meaning of section 36 (1) no. 1 of the Act on Administrative Offences, in the cases provided for in:

1. subsection (1) no. 2, subsection (2) no. 7 (b), nos. 7a, 9b and 24d to 24q, subsections (2a) to (2c) and subsection (2d) nos.1 to 4 and 5 letter b, and

2. subsection (2) no. 6 letter b, no. 7 letter c, nos. 24c and 31 insofar as the act is committed against the competent higher federal authority,

is the competent higher federal authority pursuant to section 77. In the case of subsection (2) no. 6, letter c, nos. 16a and 16b, the Federal Institute for Drugs and Medical Devices is the administrative authority within the meaning of section 36 (1) no. 1 of the Act on Administrative Offences (*Gesetz über Ordnungswidrigkeiten*).

Section 98
Confiscation

Objects connected with an offence as defined in section 95 or section 96 or an administrative offence as defined in section 97 may be confiscated. Section 74a of the Criminal Code (*Strafgesetzbuch*) and section 23 of the Act on Administrative Offences apply.

Section 98a
(no longer applicable)

Division 18
Transitional provisions

Subdivision 1
Transitional provisions arising out of the Law on the Reform of Drug Legislation

Section 99
1961 Drug Law

The 1961 Drug Law (*Arzneimittelgesetz 1961*) within the meaning of this Act is the Law on the Trade in Drugs of 16 May 1961 (Federal Law Gazette I p. 533), last amended by the law of 2 July 1975 (Federal Law Gazette I p. 1745).

Section 100

(1) Any authorisation that had been granted pursuant to section 12 (1) or section 19 (1) of the 1961 Drug Law and was still valid on 1 January 1978 continues to be valid to the previous extent as an authorisation within the meaning of section 13 (1) sentence 1.
(2) Any authorisation that is considered as granted pursuant to section 53 (1) or section 56 of the 1961 Drug Law and was still valid on 1 January 1978, continues to be valid to the previous extent as an authorisation within the meaning of section 13 (1) sentence 1.
(3) Where the manufacture of medicinal products did not require an authorisation pursuant to the 1961 Drug Law, but requires an authorisation pursuant to section 13 (1) sentence 1, such an authorisation is deemed to be granted to any person who had been carrying out the activity of manufacturing medicinal products, with an authorisation to do the same, for a period of at least three years on 1 January 1978; however, only insofar as manufacture is

restricted to such medicinal products as had been manufactured previously or medicinal products that are similar in composition.

Section 101
(no longer applicable)

Section 102

(1) Any person who exercises the function of Production Manager, with an authorisation to do so, on 1 January 1978 may continue to exercise this function to the same extent as hitherto.
(2) Any person who, on 1 January 1978, is in possession of the expert knowledge pursuant to section 14 (1) of the 1961 Drug Law and does not exercise the function of Production Manager, may exercise the function of Production Manager if evidence of two years of practical experience in the manufacture of medicinal products can be shown. If the practical experience was obtained prior to 10 June 1965, proof is to be submitted of an additional year of practical experience prior to the commencement of this person's activity.
(3) Any person who had commenced university studies pursuant to section 15 (1), prior to 10 June 1975 is deemed to have acquired expert knowledge as a Production Manager, if he/she completed his/her studies by 10 June 1985 and exercised a function pursuant to section 15 (1) and (3), for at least two years. This is without prejudice to subsection (2).
(4) Subsections (2) and (3) apply accordingly to any person seeking to work as a Quality Control Manager.

Section 102a
(no longer applicable)

Section 103

(1) In the case of medicinal products that, pursuant to section 19a or section 19d in conjunction with section 19a of the 1961 Drug Law, are authorised for marketing on 1 January 1978 or that are deemed to have been granted a marketing authorisation on 1 January 1978 pursuant to Article 4 (1) of the Law on the Establishment of a Federal Agency for Sera and Vaccines of 7 July 1972 (*Gesetz über die Errichtung eines Bundesamtes für Sera und Impfstoffe*) (Federal Law Gazette I, p. 1163), a marketing authorisation pursuant to section 25 is deemed to be granted. Sections 28 to 31 apply accordingly to the marketing authorisation.
(2) (no longer applicable).

Section 104
(no longer applicable)

Section 105

(1) Finished medicinal products that are on the market on 1 January 1978 are deemed to be authorised for marketing if they are on the market on 1 September 1976 or, by virtue of an application submitted by this date, are registered in the register for proprietary medicinal products pursuant to the 1961 Drug Law.
(2) Notification of finished medicinal products pursuant to subsection (1) must be made to the competent higher federal authority indicating the designation of the active substances according to their type and quantity as well as their therapeutic indications, within a period of six months from 1 January 1978. In making a notification regarding a homeopathic medicinal product, the information bearing on the therapeutic indications may be omitted. A copy of the notification is to be sent to the competent authority indicating the stipulated information. The finished medicinal products may only be kept on the market if the deadline for notification is observed.
(3) The marketing authorisation for a medicinal product, notification of which has been submitted within the deadline pursuant to subsection (2) expires in derogation of section 31 (1) sentence 1 no. 3, on 30 April 1990 unless an application for an extension of the

marketing authorisation, or for registration, is submitted prior to the date of expiry or the medicinal product is exempted by ordinance from the need for a marketing authorisation or registration. Section 31 (4) sentence 1 does not apply to the marketing authorisation pursuant to sentence 1 if the renouncement pursuant to section 31 (1) sentence 1 no. 2 is submitted by 31 January 2001.
(3a) Until the first extension of the marketing authorisation, a modification pursuant to section 29 (2a) sentence 1 no. 1, in the case of finished medicinal products pursuant to subsection (1), insofar as it concerns the therapeutic indications, and no. 3 is only admissible if it is necessary to correct the flaws, bearing on the efficacy or safety of the medicinal product, indicated to the applicant by the competent higher federal authority; furthermore, section 29 (2a) sentence 1 nos. 1, 2 and 5 do not apply to finished medicinal products pursuant to subsection (1), until the first extension of the marketing authorisation. By way of derogation from section 29 (3), a finished medicinal product pursuant to subsection (1), which has been manufactured using a manufacturing procedure described in the homeopathic section of the Pharmacopoeia, may be placed on the market up until the first extension of the marketing authorisation:

1. with a change in the composition of the medically active constituents in type and quantity, if the change consists only in the fact that one or several medically active constituents contained up to that point in the medicinal product are no longer present after the change or are present in lesser quantities,

2. with a change in the quantity of the medically active constituent and, within the hitherto existing area of application, with a change in indication if the medicinal product is adjusted as a whole to the results published pursuant to section 25 (7) sentence 1, in the version in force before 17 August 1994,

3. (no longer applicable),

4. with a change in the quantity of the medically active constituents, insofar as it is a medicinal product with several active constituents the number of which has been reduced, or

5. with a change in the type or quantity of the medically active constituents without increasing their number within the same therapeutic indication and the same school of therapy if the medicinal product, as a whole, is adjusted to a result published pursuant to section 25 (7) sentence 1, in the version in force before 17 August 1994 or to a medicinal product model submitted by the Federal Institute for Drugs and Medical Devices and the medicinal product does not become subject to prescription as a result of the adjustment;

a change is only admissible insofar as it is necessary for the purpose of correcting the flaw bearing on the efficacy or safety of the medicinal product indicated to the applicant by the competent higher federal authority. The pharmaceutical entrepreneur must make notification of the change and in the event of a change in the composition, must cause a clearly differentiating addition, which rules out any possibility of confusion with the previous name, to be made to the previous name of the medicinal product for a period of at least five years. Upon expiry of a period of six months following the notification, the pharmaceutical entrepreneur may place the medicinal product on the market henceforth only in its changed form. In the event that the competent higher federal authority has stipulated the use of a package leaflet with a standard wording for specific medicinal products, by imposition of a condition pursuant to section 28 (2) no. 3, the medicinal product may be placed on the market when changed pursuant to sentence 2 no. 2, by way of derogation from section 109 (2), only with a package leaflet pursuant to section 11.
(4) In applying for an extension of the marketing authorisation, documents pursuant to section 22 (1) nos. 1 to 6 are to be submitted in derogation of section 31 (2). The competent higher federal authority determines, on a case by case basis, when the documents pursuant to section 22 (1) nos. 7 to 15 subsection (2) no. 1 and subsection (3a) as well as the

analytical expert report pursuant to section 24 (1) are to be submitted. If requested by the competent authority, documents are also to be submitted providing evidence that the medicinal product's medically active constituents possess sufficient bioavailability insofar as this is required according to the current state of scientific knowledge. An appraising expert report is also to be submitted. Section 22 (2) sentence 2 and subsections (4) to (7) and section 23 (3) apply accordingly. The documents referred to in sentences 2 to 5 are to be submitted within a period of four months following the request by the competent higher federal authority.
(4a) In applying for an extension of the marketing authorisation pursuant to subsection (3), documents pursuant to section 22 (2) sentence 1 nos. 2 and 3, as well as the expert reports pursuant to section 24 (1) sentence 2 nos. 2 and 3 are to be submitted by 1 February 2001 in cases where these documents have not already been submitted by the applicant; section 22 (3) applies accordingly. Sentence 1 does not apply to medicinal products that have been manufactured using a manufacturing procedure described in the homeopathic section of the Pharmacopoeia. In the case of whole blood, plasma and blood cells of human origin, by way of derogation from sentence 1, the documents pursuant to section 22 (2) sentence 1 no. 2 and the expert report pursuant to section 24 (1) sentence 2 no. 2 are not required unless substances are contained therein that do not exist naturally in the human body. With the exception of the cases specified in section 109a, the marketing authorisation expires if the documents stipulated in sentences 1 to 3 are not submitted on time.
(4b) (no longer applicable).
(4c) If the medicinal product pursuant to subsection (3) has already been authorised for marketing in another Member State of the European Union or another State Party to the Agreement on the European Economic Area, in keeping with Directive 2001/83/EC, the extension of the marketing authorisation is to be granted if:

1. the medicinal product is on the market in the other Member State and
2. the applicant:

   a) provides all of the information stipulated under section 22 (6) and submits the necessary copies and

   b) declares in writing that the documents submitted pursuant to subsections (4) and (4a) match the marketing authorisation documents on the basis of which the authorisation was granted in the other Member States, unless the extension of the medicinal product's marketing authorisation might constitute a danger to public health.

(4d) In applying for registration, documents pursuant to section 22 (1) nos. 1 to 4 are to be submitted along with the application in derogation of section 38 (2). The documents pursuant to section 22 (1) nos. 7 to 15 and subsection (2) no. 1, as well as the analytical expert report pursuant to section 24 (1) are to be submitted to the competent higher federal authority if requested. Section 22 (4) to (7), with the exception of the draft of the expert information, apply accordingly. The documents stipulated in sentences 2 and 3 are to be submitted within a period of two months following a request by the competent higher federal authority.
(4e) In deciding on an application for extension of a marketing authorisation or registration pursuant to subsection (3) sentence 1, section 25 (5) sentence 5 and section 39 (1) sentence 2 apply accordingly.
(4f) The manufacturing authorisation pursuant to subsection (1) is to be extended upon request pursuant to subsection (3) sentence 1, for a period of five years if no reason for a refusal pursuant to section 25 (2) exists; for additional extensions, section 31 applies. The particularities of a specific substance group or school of therapy (phytotherapy, homeopathy, and anthroposophy) are to be taken into consideration.
(4g) In the case of medicinal products that are blood preparations, section 25 (8) apply accordingly.

(5) In the case of flaws, the applicant must correct the flaws within a reasonable deadline which may, however, not exceed twelve months following the notification of flaws; the correcting of flaws is to be recorded in writing. In the event that the flaws are not corrected within this deadline, the marketing authorisation is to be refused. After the decision has been taken to refuse the marketing authorisation, the submission of documents in order to correct flaws is not allowed. In all appropriate cases, the competent authority must refrain from giving notice of flaws pursuant to sentence 1 first half-sentence and must instead extend the marketing authorisation on the basis of subsection (5a) sentences 1 and 2, with a proviso requiring the applicant to correct the flaws within a deadline that it sets according to its best judgement.
(5a) The competent higher federal authority is empowered to impose conditions on the extension of the marketing authorisation pursuant to subsection (3) sentence 1. Apart from ensuring the requirements stipulated in section 28 (2), the contents of conditions may also be geared towards guaranteeing the requirements of quality, safety and efficacy, unless notice must be given of flaws pursuant to subsection (5) or the extension of the marketing authorisation refused as a result of serious deficiencies in the pharmaceutical quality, efficacy or safety. The notice regarding the extension is to state whether the condition imposed must be met immediately or by a deadline to be specified by the competent higher federal authority. Notification is to be made to the competent higher federal authority of the fulfilment of the conditions, accompanied by a statutory declaration from an independent counter-expert confirming that the quality of the medicinal product corresponds to the current state of scientific knowledge. Section 25 (5) sentences 5, 6 and 8 as well as section 30 (2) sentence 1 no. 2, second alternative apply accordingly. Sentences 1 to 5 apply accordingly to the registration pursuant to subsection (3) sentence 1.
(5b) No preliminary procedure pursuant to section 68 of the Rules of the Administrative Court is to be held in the event of an appeal against the decision regarding the extension of the marketing authorisation pursuant to subsection (3) sentence 1. Immediate execution is to be ordered pursuant to section 80 (2) no. 4 of the Rules of the Administrative Court, unless the execution would result in undue hardship for the pharmaceutical entrepreneur, which is not justified by overriding public interest.
(5c) By way of derogation from subsection (3) sentence 1, the marketing authorisation for a medicinal product for which a notification was made within the specified time pursuant to subsection (2) and for which the pharmaceutical entrepreneur declared his/her intention to withdraw the application to extend the marketing authorisation pursuant to subsection (3) sentence 1 by 31 December 1999, expires on 1 February 2001 unless the procedure to extend the marketing authorisation pursuant to sentence 2 is to be resumed. In cases where the pharmaceutical entrepreneur submitted the necessary documents on time in response to a request to that effect issued before 17 August 1994 pursuant to subsection (4) sentence 2, or if the date of submission of documents for the medicinal product in question was subsequent to that date, or if the request for documents regarding the medicinal product in question was issued after said date, the procedure to extend the marketing authorisation is to be resumed by the competent federal higher authority upon application by the entrepreneur; the application is to be submitted by 31 January 2001, accompanied by the documents specified in subsection (4a) sentence 1.
(5d) Subsection (3) sentence 2 and subsections (3a) to (5c) apply accordingly to medicinal products for which an application for extension was submitted by 30 June 1991, pursuant to section 4 (2) of the EC Transition Ordinance of 18 December 1990 (Federal Law Gazette I p. 2915) Annex 3 to section 2 no. 2, Chapter II nos. 1 and 2.
(6) (no longer applicable)

Section 105a

(1) (no longer applicable)
(2) (no longer applicable)

(3) In the case of finished medicinal products that are not subject to prescription pursuant to section 48, the competent higher federal authority may, in the first instance, forego the examination of the expert information submitted and exempt the pharmaceutical entrepreneur from his/her duties pursuant to section 11a, and the pharmaceutical consultant from his/her duty pursuant to section 76 (1) sentence 1, until the standardised wording of the expert information for the medicinal products in question is stipulated by imposition of conditions pursuant to section 28 (2) no. 3.
(4) Subsections (1) to (3) do not apply to medicinal products that fall within the competence of the Paul Ehrlich Institute.

Section 105b
(no longer applicable)

Section 106
(no longer applicable)

Section 107
(no longer applicable)

Section 108
(no longer applicable)

Section 108a
Any batch of serum, vaccine or test allergen that was already released at the time of the coming into effect of the accession pursuant to section 16 of the Second Regulations Implementing the Drug Law of 1 December 1986 (Law Gazette I, No. 36 p. 483) is deemed to be released within the meaning of section 32 (1) sentence 1, in the territory stipulated in Article 3 of the Unification Treaty. Section 32 (5) applies accordingly to the release.

Section 108b
(no longer applicable)

Section 109
(1) Finished medicinal products that were already on the market on 1 January 1978 are governed by section 10 with the proviso that the marketing authorisation number stipulated in section 10 (1) sentence 1 no. 3 be replaced, where available, by the registration number recorded in the specialty register pursuant to the 1961 Drug Law with the abbreviation '*Reg.-Nr.*'. Sentence 1 is valid until the extension of the marketing authorisation or registration.
(2) The text for labels and package leaflets is to be submitted by 31 July 2001 at the latest. Until that date, medicinal products pursuant to subsection (1) sentence 1 may be placed on the market by the pharmaceutical entrepreneur, thereafter by wholesalers and retailers with labels and package leaflets that are in keeping with the regulations in force up to the date specified in sentence 1.
(3) Finished medicinal products that are medicinal products within the meaning of section 105 (1), and are released for trade outside of pharmacies pursuant to section 44 (1) or (2) nos. 1 to 3 or section 45 and fall under letters a to e may, without prejudice to subsections (1) and (2), be placed on the market from 1 January 1992 by the pharmaceutical entrepreneur if they carry one or several of the following indications on their containers and, if used, on their outer packaging and package leaflet:
'*Traditionell angewendet* (Traditionally used):

a) to strengthen and fortify,

b) to improve the state of health,

c) to support the functioning of the organs,

d) for prevention,

e) as a mild-action medicinal product.'

Sentence 1 does not apply in cases where the therapeutic indications are restricted to the results published within the framework of a marketing authorisation pursuant to section 25 (1), or a marketing authorisation pursuant to the version in force before 17 August 1994.

Section 109a

(1) In the case of medicinal products specified in section 109 (3), as well as medicinal products that are not subject to a prescription and are not excluded from trade outside of pharmacies by virtue of an ordinance issued on the basis of section 45 or 46, as a result of their components, their pharmaceutical forms or because they are chemical compounds with specific pharmacological effects or because such compounds have been added to them, the extension of the marketing authorisation can be granted pursuant to section 105 (3) and, furthermore, pursuant to section 31, pursuant to subsections (2) and (3).
(2) The requirements in respect of the necessary quality are deemed to be met when the documents pursuant to section 22 (2) sentence 1 no. 1, as well as the analytical expert reports pursuant to section 24 (1), have been submitted and the pharmaceutical entrepreneur has made a statutory declaration that the medicinal product has been tested in accordance with the general administrative regulation pursuant to section 26 and displays the necessary pharmaceutical quality. The form and content of the statutory declaration are stipulated by the competent higher federal authority.
(3) The requirements in respect of the efficacy are deemed to be met when the medicinal product claims efficacy in therapeutic indications that are recognised in a list of the therapeutic indications for substances or combinations of substances compiled by the competent higher federal authority after a hearing by a commission set up by the Federal Ministry to which section 25 (6) sentences 4 to 6 apply accordingly. These therapeutic indications are stipulated taking into account the peculiarities of the particular medicinal product and the experience that has been handed down and documented and are accompanied by the additional remark: '*Traditionell angewendet*' (Traditionally used). Such therapeutic indications are: 'to strengthen and fortify the ...', 'to improve the state of health ...', 'to support the functioning of the ...', 'for prevention against ...', 'as a mild-action medicinal product for use in ...'. Therapeutic indications that would result in the medicinal product being excluded from trade outside of pharmacies may not be recognised.
(4) Subsections (1) to (3) apply only in cases where the documents pursuant to section 105 (4a) have not been submitted and the applicant declares in writing that he or she is pursuing an extension of the marketing authorisation pursuant to section 105 (3), pursuant to subsections (2) and (3).
(4a) By way of derogation from subsection (4), subsections (2) and (3) apply to medicinal products pursuant to subsection (1), if the extension of the marketing authorisation would normally be refused owing to the fact that one of the published results substantiating the medicinal product's efficacy pursuant to section 25 (7) sentence 1 of the version in force prior to 17 August 1994, can no longer be recognised.

Section 110

In the case of medicinal products that are subject to a marketing authorisation pursuant to section 21, or to registration pursuant to section 38, and that are on the market on 1 January 1978, the competent higher federal authority can stipulate, by imposing conditions, the affixing of warnings insofar as they are necessary to prevent a direct or indirect health hazard to human beings by the administration of the medicinal product.

Section 111
(no longer applicable)

Section 112

Any person who, on 1 January 1978, places medicinal products that are released for trade outside of pharmacies on the market, on a retail basis outside of pharmacies, may continue

to pursue this activity insofar as he or she was entitled to do so pursuant to the Act on the Exercise of Professions in the Retail Trade (*Gesetz über die Berufsausübung im Einzelhandel*) of 5 August 1957 (Federal Law Gazette I, p. 1121), amended by Article 150 (2) no. 15 of the Law of 24 May 1968 (Federal Law Gazette I, p. 503).

Section 113
(no longer applicable)

Section 114
(no longer applicable)

Section 115

A person who exercises the function of a pharmaceutical consultant pursuant to section 75 on 1 January 1978, does not need to provide the proof of training stipulated therein.

Section 116

Physicians who are entitled, on 1 January 1978, under provisions contained in the legislation of the individual Land to manufacture and dispense medicinal products to persons being treated by them, may continue to pursue this activity to the same extent as hitherto. Section 78 is applicable.

Section 117
(no longer applicable)

Section 118

Section 84 does not apply to damage caused by medicinal products that were dispensed prior to 1 January 1978.

Section 119

Finished medicinal products that are on the market in the territory referred to in Article 3 of the Unification Treaty, at the time when accession takes effect, may continue to be placed on the market by wholesalers and retailers without the package leaflet required under section 11, insofar as they correspond to the provisions contained in the medical legislation of the German Democratic Republic in force before accession took effect. The competent higher federal authority may, by imposition of conditions, stipulate that warnings must be affixed, insofar as this is deemed necessary for the prevention of direct or indirect danger to human beings as a result of the application of the medicinal product.

Section 120

In the case of a clinical trial that is being conducted within the territory specified in Article 3 of the Unification Treaty at the time when accession takes effect, the insurance policy required under section 40 (1) no. 8 is to be taken out.

Section 121
(no longer applicable)

Section 122

The obligation to notify pursuant to section 67 shall not apply to undertakings, facilities and persons in the territory specified in Article 3 of the Unification Treaty who are already pursuing an activity within the meaning of that provision at the time when accession takes effect.

Section 123

A person is also deemed to possess the necessary expert knowledge as a pharmaceutical consultant pursuant to section 75 (2) no. 2 if he or she has successfully completed a course of studies as a pharmaceutical engineer, a pharmacy assistant or veterinary engineer in the territory specified in Article 3 of the Unification Treaty.

Section 124

Sections 84 to 94a are not applicable to medicinal products that were dispensed to consumers in the territory specified in Article 3 of the Unification Treaty before accession took effect.

Subdivision 2

Section 125
(repealed)

Section 126

In the case of medicinal products that are intended for administration to animals and authorised for marketing in the territory specified in Article 3 of the Unification Treaty at the time when accession takes effect; section 125 subsections 1 and 3 apply accordingly.

Subdivision 3
Transitional provisions arising out of the Second Act Amending the Drug Law (Act on Medicinal Products)

Section 127

(1) Medicinal products that are on the market on 1 February 1987 and are subject to the labelling provisions contained in section 10 must be placed on the market by the pharmaceutical entrepreneur pursuant to the provision contained in section 10 (1) no. 9 within a period of one year after the first extension of the marketing authorisation on 1 February 1987, or after the exemption from the marketing authorisation or, in the case of homeopathic medicinal products, five years after the 1 February 1987. Up to this point in time, medicinal products pursuant to sentence 1 may be placed on the market by the pharmaceutical entrepreneur; after this, they may continue to be placed on the market by wholesalers and retailers without indication of an expiry date if the medicinal product's shelf life is more than three years or, in the case of medicinal products governed by the provisions contained in section 109, more than two years. This is without prejudice to section 109.
(2) Medicinal products that are on the market on 1 February 1987 and are subject to the labelling regulations of section 10 (1a) may be placed on the market until 31 December 1988 by the pharmaceutical entrepreneur and even after this deadline by wholesalers and retailers without the information stipulated in section 10 (1a).

Section 128

(1) In the case of finished medicinal products that are on the market on 1 February 1987, the pharmaceutical entrepreneur must submit the wording of the expert information to the competent higher federal authority along with the first application for the extension of the marketing authorisation or registration filed on 1 February 1987. Sentence 1 does not apply insofar as the competent higher federal authority has exempted medicinal products that are not subject to prescription pursuant to section 49, from the obligations contained in section 11a, until further notice; in this case, the draft of the expert information is to be submitted upon request to the competent higher federal authority.
(2) In the cases described in subsection (1) section 11a, section 47 (3) sentence 2 and section 76 (1) apply from the date of the extension of the marketing authorisation or the registration or the stipulation of a specific expert information by means of section 36 (1), or in the cases described in subsection (1) sentence 2, six months after the decision of the competent higher federal authorities on the contents of the expert information. Finished medicinal products, the package leaflet of which fails to comply with the provisions contained in section 11 (1), in the version of the Second Law Amending the Drug Law, may be placed on the market until this point in time.

Section 129

Section 11 (1a) applies to medicinal products that are on the market on 1 February 1987 subject to the proviso that their package leaflet must be forwarded to the competent authority after the next extension of the authorisation or registration.

Section 130

Any person who is appointed as a private expert by 1 February 1987 to test samples pursuant to section 65 (2) may continue to exercise this function to the same extent as hitherto.

Section 131

In respect of the obligation to submit or pass on expert information pursuant to section 11a, section 128 applies accordingly to medicinal products that are on the market in the territory stipulated in Article 3 of the Unification Treaty at the time of the coming into effect of accession.

Subdivision 4
Transitional provisions arising out of the Fifth Act Amending the Drug Law (Act on Medicinal Products)

Section 132

(1) Medicinal products that are on the market on 17 August 1994 and are subject to the provisions contained in sections 10 and 11, must be placed on the market by the pharmaceutical entrepreneur pursuant to the provisions contained in sections 10 and 11 within a period of one year after the first extension of the marketing authorisation granted on 17 August 1994, or insofar as they are exempt from the need for a marketing authorisation, at the time stipulated in the ordinance pursuant to section 36 or, insofar as homeopathic medicinal products are concerned, five years after 17 August 1994. Until such time, medicinal products pursuant to sentence 1 may continue to be placed on the market by the pharmaceutical entrepreneur; thereafter, such medicinal products may continue to be placed on the market by wholesalers and retailers with labelling and package leaflets that comply with the provisions in force up to 17 August 1994. This is without prejudice to section 109.
(2) In the case of finished medicinal products that are on the market on 17 August 1994, the pharmaceutical entrepreneur must submit the wording of the expert information in compliance with section 11a of the current version of this Act to the competent higher federal authority along with the first application for the extension of the marketing authorisation filed on 17 August 1994. This is without prejudice to section 128 (1) sentence 2.
(2a) Marketing authorisations that are not in compliance with section 16 are to be adapted to section 16 by 17 August 1996. Sentence 1 applies to section 72 accordingly.
(2b) Any person who exercises the function of Production Manager for the manufacture of blood preparations or as Quality Control Manager for the testing of blood preparations on 17 August 1994 and fulfils the prerequisites of section 15 (3), as contained in the version in force up until 17 August 1994, may continue to exercise this function.
(3) (no longer applicable)
(4) Section 39 (2) no. 5a does not apply to medicinal products that were registered by 31 December 1993 or for which an application for registration was submitted by that date or for which a notification was made pursuant to section 105 (2) and which were placed on the market pursuant to section 38 (1) sentence 3, in the version valid before 11 September 1998. Furthermore, section 39 (2) no. 5a does not apply in the case of decisions bearing on the registration or on its extension, to medicinal products that are identical, in the type and quantity of their components as well as with regard to their pharmaceutical forms, with medicinal products specified in sentence 1.

Subdivision 5
Transitional provision arising of the Seventh Act Amending the Drug Law

Section 133
(no longer applicable)

Subdivision 6
Transitional provisions arising out of the Transfusion Act

Section 134

Any person who, at the time of the entry into force of the Transfusion Act of 1 July 1998 (Federal Law Gazette I p. 1752), exercises the function of Production Manager in the manufacture of or as Quality Control Manager for the testing of blood preparations or sera from human blood and meets the requirements stipulated by section 15 (3), in the version valid until that date, may continue to exercise that function. Any person who, at the time specified in sentence 1, exercises the function of pre-treating persons for the separation of blood stem cells or other blood components according to the latest standards prevailing in science and technology, may continue to exercise this function.

Subdivision 7
Transitional provisions arising out of the Eighth Act Amending the Drug Law (Act on Medicinal Products)

Section 135

(1) Medicinal products that are on the market on 11 September 1998 and are subject to the provisions contained in sections 10 and 11, must be placed on the market by the pharmaceutical entrepreneur one year after the first extension of the marketing authorisation on 11 September 1998 or, if they are exempt from the marketing authorisation, on the date specified in the ordinance pursuant to section 36 or, if they are homeopathic medicinal products, on 1 October 2003, pursuant to the provisions contained in sections 10 and 11. Until such time, medicinal products pursuant to sentence 1 may continue to be placed on the market by the pharmaceutical entrepreneur; thereafter, such medicinal products may continue to be placed on the market by wholesalers and retailers with labelling and package leaflets that comply with the provisions in force up to 11 September 1998. This is without prejudice to section 109.
(2) Any person who on 11 September 1998 exercises the function of Production Manager or Quality Control Manager for the medicinal products or active substances named in section 15 (3a) and is authorised to do so, may continue to exercise this function to the same extent as hitherto. Until 1 October 2001, section 15 (4) does not apply to the practical activities involved in the manufacture of medicinal products and active substances pursuant to section 15 (3a).
(3) Homeopathic medicinal products that are on the market on 11 September 1998, and for which an application for registration was submitted by 1 October 1999 may, by way of derogation from section 38 (1) sentence 3, continue to be placed on the market until a decision has been taken on the application for registration as long as they are in compliance with the provisions in force until 11 September 1998.
(4) In the amended version, section 41 no. 6 does not apply to declarations of consent that were made prior to 11 September 1998.

Subdivision 8
Transitional provisions arising out of the Tenth Act Amending the Drug Law (Act on Medicinal Products)

Section 136

(1) In the case of medicinal products for which the extension applied for under section 105 (3) sentence 1 has already been granted, the documents specified in section 105 (4a) sentence 1 are to be submitted, at the latest, with the application pursuant to section 31 (1) sentence 1 no. 3. In the case of such medicinal products, the marketing authorisation is to be

extended if no reason for refusal pursuant to section 25 (2) exists; section 31 applies to further extensions.
(1a) With regard to medicinal products pursuant to section 105 (3) sentence 1 that are manufactured according to a procedure which is not described in the homeopathic section of the Pharmacopoeia, section 105 (3) sentence 2 in the version in force up to 12 July 2000 applies until such time as a decision is made by the Commission pursuant to section 55 (6), on the inclusion of this manufacturing procedure, insofar as an application has been submitted by 1 October 2000 regarding its inclusion in the homeopathic section of the Pharmacopoeia.
(2) In the case of medicinal products with respect to which the applicant has been notified prior to 12 July 2000 of flaws regarding their efficacy or safety, section 105 (3a) in the version in force up to 12 July 2000 applies.
(2a) Section 105 (3a) sentence 2, in the version in force up to 12 July 2000, applies up to 31 January 2001 with the proviso that a notification of flaws is not necessary and a modification is admissible only if it is restricted to the fact that one or several medically active constituents contained up to that point in the medicinal product are no longer present after the modification.
(3) In the case of medicinal products that have been manufactured according to a manufacturing procedure described in the homeopathic section of the Pharmacopoeia, section 105 (5c) continues to apply in the version in force prior to 12 July 2000.

Subdivision 9
Transitional provisions arising out of the Eleventh Act Amending the Drug Law (Act on Medicinal Products)

Section 137
(no longer applicable)

Subdivision 10
Transitional provisions arising out of the Twelfth Act Amending the Act on Medicinal Products

Section 138
(1) With regard to the manufacture and import of active substances of microbial origin, as well as other substances of human origin intended for the manufacture of medicinal products that are manufactured or imported into the territory governed by this Act, commercially or professionally, for the purpose of distribution to others, sections 13, 72 and 72a in the version in force until 5 August 2004 is applicable until 1 September 2006, unless blood and blood components of human origin destined for the manufacture of medicinal products are concerned. If blood is withdrawn for the processing and multiplication of autologous somatic cells within the framework of tissue engineering for the purpose of tissue regeneration, and if an application has not yet been made for a manufacturing authorisation for this purpose, section 13 is not applicable until 1 September 2006.
(2) Any person who, on 5 August 2004, is authorised to exercise the functions of a Production or Quality Control Manager may continue to exercise this function, in derogation of section 15 (1).
(3) Sections 40 to 42, 96 no. 10 and section 97 (2) no. 9, in the version in force until 6 August 2004, apply to clinical trials of medicinal products for which the documents required pursuant to section 40 (1) sentence 2 in the version in force until 6 August 2004 were submitted to the ethics committee responsible for the chief investigator before 6 August 2004.
(4) Any person who is authorised to exercise the function of wholesaler on 6 August 2004 and submits an application pursuant to section 52a (1) for an authorisation to conduct the wholesale distribution of medicinal products, by 1 December 2004, may, in derogation of

section 52a (1), continue to exercise this function until the decision has been taken with respect to the application; section 52a (3) sentences 2 to 3 do not apply.
(5) (repealed)
(6) Any person who was allowed to import substances other than active substances of human or animal origin or those manufactured using genetic engineering, without an import authorisation pursuant to section 72, into the territory governed by this Act on 6 August 2004, may continue to pursue this activity until 1 September 2005.
(7) Medicinal products that are authorised by the competent higher federal authority before 30 October 2005, may continue to be placed on the market by pharmaceutical entrepreneurs, in derogation of section 10 (1b), up to the next extension but not after 30 October 2007. Medicinal products that are placed on the market by pharmaceutical entrepreneurs pursuant to sentence 1, may continue to be placed on the market by wholesalers and retailers, in derogation of section 10 (1b).

Subdivision 11
Transitional provisions arising out of the First Act Amending the Transfusion Act and the Regulations on Medicinal Products

Section 139
Any person who, on entry into force of Article 2 no. 3 of the First Act amending the Transfusion Act and Regulations on Medicinal Products of 10 February 2005 (Federal Law Gazette I p. 234), carries out the functions of a Production or Control Manager for the testing of haematopoietic stem cell preparations from peripheral blood or from umbilical cord blood and fulfils the conditions contained in section 15 (3) of the version in force at the time, may continue to exercise these functions.

Subdivision 12
Transitional provisions arising out of the Thirteenth Act Amending the Act on Medicinal Products

Section 140
(no longer applicable)

Subdivision 13
Transitional provisions arising out of the Fourteenth Act Amending the Act on Medicinal Products

Section 141
(1) Medicinal products that are on the market on 5 September 2005 and are subject to sections 10 and 11 must be placed on the market by the pharmaceutical entrepreneur two years after the first extension of the marketing authorisation or registration following 6 September 2005 or, if they are exempted from the need for a marketing authorisation or registration at the time referred to in the ordinance pursuant to section 36 or section 39, or if they do not require an extension, on 1 January 2009 pursuant to sections 10 and 11. Up to the relevant dates referred to in sentence 1, medicinal products may be placed on the market by pharmaceutical entrepreneurs and, after these dates, also by wholesale and retail distributors with labelling and a package leaflet complying with the provisions applicable up to 5 September 2005. This is without prejudice to section 109.
(2) In the case of finished products that are on the market on 5 September 2005, the pharmaceutical entrepreneur must submit to the higher federal authority the wording of the expert information pursuant to section 11a with the first application for extension submitted after 6 September 2005; if the medicinal products in question do not require extension, the requirement applies from 1 January 2009.
(3) A person who does not have the experience referred to in section 15 but who is authorised on 5 September 2005 to engage in the activities of the qualified person described in section 19 is regarded as a qualified person pursuant to section 14.

(4) Finished medicinal products that are on the market on 5 September 2005 and which, pursuant to section 4 (1), require a marketing authorisation pursuant to section 21, for the first time after 6 September 2005, can still be placed on the market if a marketing authorisation application has been submitted by 1 September 2008.
(5) The periods for the protection of documents according to section 24b (1) and (4) do not apply to reference medicinal products the marketing authorisation of which was applied for before 30 October 2005; for such medicinal products, the protection periods according to section 24a in the version in force up to the expiry of 5 September 2005 apply and the period according to section 24b (4) is ten years.
(6) Medicinal products with a marketing authorisation that was extended before 1 January 2001, shall be subject to section 31 (1) sentence 1 no.3, in the version applicable until 5 September 2005; section 31 (1a) shall apply to these medicinal products only if their marketing authorisation was extended after 6 September 2005. For marketing authorisations with a five-year validity that has expired by 1 July 2006, the deadline referred to in section 31 (1) sentence 1 no. 3 in the version applicable on 6 September 2005 shall continue to apply. For medicinal products with a marketing authorisation that was extended after 1 January 2001 and before 6 September 2005, the competent higher federal authority can stipulate the requirement of a further extension, if this is necessary to guarantee the safe placing on the market of the medicinal product. Marketing authorisation extension applications submitted before 6 September 2005 which, according to this subsection, no longer require extension, shall be regarded as settled. Sentences 1 and 4 apply accordingly to registrations. Marketing authorisation extensions or registrations of medicinal products that were considered authorised pursuant to section 105 (1) are considered extensions within the meaning of this subsection. This is without prejudice to section 136 (1).
(7) The holder of the authorisation for a medicinal product that is authorised on 5 September 2005 but is not on the market at this time is to notify the competent higher federal authority immediately of the fact that the medicinal product will not be placed on the market.
(8) Section 33 in the version applicable until 5 September 2005 is applicable to protests that are lodged before 5 September 2005.
(9) Section 25 (9) and section 34 (1a) are not applicable to medicinal products for which the application for marketing authorisation was submitted before 6 September 2005.
(10) Medicinal products that were registered as homeopathic medicinal products by 6 September 2005 or for which an application for registration was submitted before 30 April 2005 shall still be subject to the provisions applicable up to that date. The same applies to medicinal products that have been notified and placed on the market pursuant to section 38 (1) sentence 3 of the version valid before 11 September 1998. Furthermore, section 39 (2) no. 5b does not apply, in the case of decisions bearing on the registration or on its extension, to medicinal products that are identical, in the nature and quantity of their components as well as with regard to their pharmaceutical forms, with medicinal products specified in sentence 1.
(11) (no longer applicable)
(12) (no longer applicable)
(13) In the case of medicinal products that are on the market on 5 September 2005, for which the obligation to report pursuant to section 63b (5) sentence 2 exists in the version valid up to 5 September 2005, section 63b (5) sentence 3 applies to the next report to be submitted on 6 September 2005.
(14) The marketing authorisation of a traditional medicinal product that was extended pursuant to section 105 in conjunction with section 109a, expires on 30 April 2011 unless an application for marketing authorisation or registration pursuant to section 39a was submitted before 1 January 2009. The marketing authorisation pursuant to section 105, in conjunction with section 109a moreover expires on 30 April 2011 after the decision on the application for a marketing authorisation or registration pursuant to section 39a has been taken. After the decision, the medicinal product may continue to be placed on the market for a further twelve months in its present form.

Subdivision 14

Section 142
Transitional provisions arising out of the Tissues Act

(1) Any person who, by 1 August 2007, possesses the expert knowledge required pursuant to section 15 (3a), in the version in force up to that date, may continue to exercise the function of qualified person.
(2) Any person who had applied for an authorisation pursuant to section 20b (1) or (2) or section 20c (1), or a manufacturing authorisation pursuant to section 13 (1) by 1 October 2007, or an authorisation pursuant to section 21a (1) by 1 February 2008 or a marketing authorisation pursuant to section 21 (1) by 30 September 2008 for tissues or tissue preparations, may continue to collect these tissues or tissue preparations, test them in laboratories, process, preserve, store or place them on the market until a decision is taken on the application.
(3) Any person who, on 1 August 2007, possesses a manufacturing authorisation pursuant to section 13 (1), for tissues or tissue preparations within the meaning of section 20b (1) or section 20c (1), or a marketing authorisation pursuant to section 21 (1) for tissue preparations within the meaning of section 21a (1) is not obliged to submit a new application pursuant to section 20b (1), section 20c (1) or section 21a (1).

Section 142a
Transitional provision and grandfathering provision arising out of the Act Implementing Commission Directive (EU) 2015/566 and (EU) 2015/565 on the import and coding of human tissue and tissue products

(1) Section 72b, in the version in force up to and including 25 November 2016 applies to autologous blood for the manufacture of biotechnologically processed tissue products.
(2) Any person who, on 26 November 2016, possesses an authorisation pursuant to the version of section 72 (1) in force up to and including 25 December 2016, to import haematopoietic stem cells and stem cell preparations derived from peripheral blood or umbilical cord blood, or an authorisation pursuant to the version of section 72b (1) in force up to and including 25 December 2016, must meet the requirements of section 72 (4) and (5), section 72a (1) sentence 2 and subsection (1e), section 72b (1), (1a), (2) sentence 2, subsections (2a), (2c), (2d) and of section 72c, from 29 April 2017 onwards.
(3) The obligation to label haematopoietic stem cell preparations derived from peripheral blood or umbilical cord blood with the Single European Code, abbreviated ‘SEC’, pursuant to section 10 (8a) sentence 3 and the application to label tissue preparations with the Single European Code, abbreviated ‘SEC’, pursuant to section 10 (8b) sentence 1, are to be fulfilled from 29 April 2017.

Section 142b
Transitional provisions arising out of the Act Updating the Regulations governing Blood and Tissue Preparations and Amending Additional Provisions

(1) Any person who possesses an authorisation for advanced therapy medicinal products pursuant to section 4b (3) in the version valid until 28 July 2017, must meet the requirements contained in section 4b (3) sentences 3 and 4, from 29 July 2019 onwards.
(2) Any person who, on 29 July 2017, possesses an authorisation pursuant to section 21a (1), must fulfil the requirements contained in section 21a (2) and (3), from 29 July 2019.

Subdivision 15

Section 143
Transitional provisions arising out of the Act on improving measures against doping in sport
(no longer applicable)

Subdivision 16

Section 144
Transitional provisions arising out of the Act amending the regulations on medicinal products and other regulations

(1) Any person who manufactures the advanced therapy medicinal products specified in section 4b (1) with permission on 23 July 2009 and applies for a manufacturing authorisation by 1 January 2010 may continue to manufacture these medicinal products until such time as a decision has been taken on the application.
(2) Any person who places the advanced therapy medicinal products specified in section 4b (1) with the exception of biotechnologically processed tissue products on the market on 23 July 2009 with permission and applies for an authorisation pursuant to section 4b (3) sentence 1 by 1 August 2010, may continue to place these medicinal products on the market until such time as a decision has been taken on the application.
(3) Any person who places biotechnologically processed tissue products within the meaning of section 4b (1) on the market on 23 July 2009 with permission and applies for an authorisation pursuant to section 4b (3) sentence 1 by 1 January 2011 may continue to place these medicinal products on the market until such time as a decision has been taken on the application.
(4) Any person who, on 23 July 2009, possesses the expert knowledge required pursuant to section 15 (3a), in the version in force up to that date, as a qualified person, may continue to exercise the function of qualified person.
(4a) Any person who, prior to 23 July 2009, as the qualified person, possessed the expert knowledge pursuant to section 15 (1) and (2) for medicinal products that, owing to the amendment of section 4 (3) in the version in force from 23 July 2009, are classified as sera and require expert knowledge pursuant to section 15 (3), was allowed to continue to perform his/her activities as the qualified person from 23 July 2009 to 26 October 2012. This also applies to any person who from 23 July 2009, as a qualified person, possessed the expert knowledge pursuant to section 15 (1) and (2) for these medicinal products.
(5) Any person who, on 23 July 2009, holds a manufacturing authorisation pursuant to section 13 (1) for the collection or the laboratory testing of autologous blood for the manufacture of biotechnologically processed tissue products does not require a new authorisation pursuant to section 20b (1) or (2).
(6) The obligation to notify pursuant to section 67 (5), exists from 1 January 2010 onwards for medicinal products that were already on the market on 23 July 2009.

Subdivision 17

Section 145
Transitional provisions arising out of the Act on the Reform of the Market for Medicinal Products

In the case of medicinal products that are already authorised when this Act enters into force, the pharmaceutical entrepreneur and the sponsor must place the reports requested pursuant to section 42b (1) and (2) at the disposal of the competent higher federal authority for the first time at the latest 18 months subsequent to the entry into force of this Act. Sentence 1 applies to clinical trials for which sections 40 to 42 in the version valid from 6 August 2004 applied.

Subdivision 18
Transitional provision

Section 146
Transitional provisions arising out of the Second Act amending regulations on medicinal products and other regulations

(1) Medicinal products that are on the market on 26 October 2012 and are governed by the provisions contained in section 10 (1) no. 2 must be placed on the market by the pharmaceutical entrepreneur, pursuant to the provisions contained in section 10 (1) no. 2,

two years after the first extension of the authorisation or registration after 26 October 2012 or, if they are exempt from the authorisation or registration or do not require an extension, on 26 October 2014. Up until the dates specified in sentence 1, medicinal products may be placed on the market by the pharmaceutical entrepreneur; after these dates they may continue to be placed on the market by wholesalers and retailers bearing labelling that corresponds to the regulations in force up until 26 October 2012.
(2) In respect of the incorporation of the standard text pursuant to section 11 (1) sentence 1 number 5, medicinal products that are on the market on 26 October 2012 and are governed by the provisions contained in section 11, must be placed on the market by the pharmaceutical entrepreneur in keeping with the provisions contained in section 11 two years after the first extension of the marketing authorisation or registration after the publication pursuant to section 11 (1b) regarding the standard text pursuant to section 11 (1) sentence 1 no. 5 or, if they are exempt from the marketing authorisation or if they do not require an extension, two years or, if they are registered medicinal products pursuant to section 38 or medicinal products exempted from registration pursuant to section 38 or section 39 (3), five years following the publication pursuant to section 11 (1b) regarding the standard text pursuant to section 11 (1) sentence 1 number 5. Up until the dates specified in each case pursuant to sentence 1, medicinal products may be placed on the market by the pharmaceutical entrepreneur; after these dates they may continue to be placed on the market by wholesalers and retailers bearing labelling that corresponds to the regulations in force up until 26 October 2012.
(2a) Any person who manufactures medicinal products pursuant to section 13 subsection 2a sentence 2 number 1 or 3 on 26 October 2012 shall notify the competent authority pursuant to section 13 subsection 2a sentence 3 thereof by 26 February 2013.
(3) In respect of the incorporation of the standard text pursuant to section 11a (1) sentence 3, in the case of finished medicinal products that are on the market on 26 October 2012, the pharmaceutical entrepreneur must submit to the competent higher federal authority the wording of the summary of expert information that corresponds to section 11a together with the first application for the extension of the authorisation after the publication pursuant to section 11a (1) sentence 9 regarding the standard text pursuant to section 11a (1) sentence 3; if such medicinal products do not require an extension, the obligation is valid for two years following the publication.
(4) In the case of marketing authorisations or registrations, the five-year validity period of which ends by 26 October 2013, the deadline contained in section 31 (1) sentence 1 no. 3, section 39 (2c) and section 39c (3) sentence 1 continues to apply in the version in force up to 26 October 2012.
(5) The obligation pursuant to section 22 (2) sentence 1 no. 5a does not apply to medicinal products that were authorised for placing on the market prior to 26 October 2012 or for which a proper application for authorisation was already submitted before 26 October 2012.
(6) Any person who is authorised to pursue the activity of a wholesaler up until 26 October 2012 and applied for a permit to operate a wholesale business in medicinal products by 26 February 2013 may, by way of derogation from section 52a (1), pursue the medicinal product wholesale business until a decision is taken on the application submitted; section 52a (3) sentences 2 to 3 does not apply.
(7) The obligation pursuant to section 63b subsection 2 number 3 shall apply from 21 July 2015 to medicinal products authorised for marketing before 26 October 2012 or from the date on which the marketing authorisation is extended, should this be earlier. The obligation pursuant to section 63b (2) no. 3 applies from 21 July 2015 for medicinal products for which a proper application for marketing authorisation was submitted before 26 October 2012.
(8) Sections 63f and 63g shall apply to studies commenced after 26 October 2012.
(9) Any person who, on 2 January 2013 lawfully engages in the activity of a medicinal product broker and informs the competent authority of his/her activity by 2 May 2013 may continue to pursue this activity until such time as a decision is taken on the registration pursuant to section 52c.

(10) Enterprises and establishments that otherwise trade in active substances must notify the competent authority of their activity by 26 April 2013.
(11) Any person who for retail trade purposes offers medicinal products for sale at a distance on the internet must notify the competent authority of his/her activity, providing the particulars specified under section 67 (8) by 24 March 2017.
(12) The requirements specified in section 94 (1) sentence 3 no. 1 apply to re-insurance contracts from 1 January.

Subdivision 19
Transitional provision

Section 147
Transitional provision arising out of the Third Act amending the regulations pertaining to medicinal products and other regulations

Section 63f (4) and section 67 (6) apply until 31 December 2013 in the version in force until 12 August 2013 to non-interventional post-authorisation safety studies pursuant to section 63f and tests pursuant to section 67 (6), commenced prior to 13 August 2013.

Subdivision 20
Transitional provision

Section 148
Transitional provision arising out of the Fourth Act amending regulations pertaining to medicinal products and other regulations, as well as the Act enacting a Veterinary Medicinal Products Act and adapting regulations pertaining to medicinal products and other regulations

(1) In the case of clinical trials for which the application for authorisation was submitted before the end of the day in the sixth calendar month following the month of the publication of the communication of the European Commission on the functionality of the EU portal and the EU database according to Article 82 of Regulation (EU) No. 536/2014 in the Official Journal of the European Union, whose number corresponds to that of the date of the publication or, if such a calendar date does not exist, submitted before the end of the first day of the subsequent calendar month according to Division 6 of the Medicinal Products Act, the Medicinal Products Act and the German Ordinance on Good Clinical Practice of 9 August 2004 (*GCP-Verordnung*) (Federal Law Gazette p. 2081), repealed by Article 13 (3) of the Fourth Act Amending Regulations pertaining to Medicinal Products and other Regulations of 20 December 2016 (Federal Law Gazette I p. 3048), in the version applicable up to 26 January 2022 continue to apply up until the end of the day in the forty-second calendar month following the month of the publication of the communication of the European Commission on the functionality of the EU portal and the EU database according to Article 82 of Regulation (EU) No. 536/2014 in the Official Journal of the European Union, whose number corresponds to that of the date of the publication or, if such a calendar date does not exist, until the end of the first day of the subsequent calendar month.
(2) A clinical trial for which the application for authorisation was submitted before the end of the day in the eighteenth calendar month following the month of the publication of the communication of the European Commission on the functionality of the EU portal and the EU database according to Article 82 of Regulation (EU) No. 536/2014 in the Official Journal of the European Union, whose number corresponds to that of the date of the publication or, if such a calendar date does not exist, before the expiry of the first day of the subsequent calendar month, may be commenced according to the Medicinal Products Act and the German Ordinance on Good Clinical Practice in the version applicable up to 26 January 2022. For the specific clinical trial, the Medicinal Products Act and the German Ordinance on Good Clinical Practice in the version applicable up to 26 January 2022 continue to be applicable until the end of the day in the forty-second calendar month following the month of the publication of the communication of the European Commission on the functionality of the

EU portal and the EU database according to Article 82 of Regulation (EU) No. 536/2014 in the Official Journal of the European Union, whose number corresponds to that of the date of the publication or, if such a calendar date does not exist, until the expiry of the first day of the subsequent calendar month.
(3) In the case of clinical trials using medicinal products that do not fall within the scope of Regulation (EU) No. 536/2014, the Medicinal Products Act and the German Ordinance on Good Clinical Practice in the version applicable up to 26 January 2022 continue to be applicable until 23 December 2029.

Annex:
(to section 6)

Aflatoxins
Ethylene oxide
Colouring matter
Fresh cells
Substances, preparations made from substances or objects of animal origin that risk transmitting transmissible spongiform encephalopathies