DRUG LAW
of the
FEDERAL REPUBLIC OF GERMANY

(Revised version of 21st December 1998, including the amendments contained in the
Ninth Law Amending the Drug Law of 30th July 1999, and the
Tenth Law Amending the Drug Law of 30th July 2000,
as well as the amendments pursuant to the
Federal Law Gazette I, p. 1043 and 1072)
Notification
of the Revised Version of the Drug Law

of 11th December 1998

Pursuant to Article 3 of the Eighth Law Amending the Drug Law of 7th September 1998 (Federal Law Gazette I, p. 2649), the following wording of the Drug Law in the version in force since 11th September 1998 is hereby notified. The revised version incorporates:

1. the version of the notification of 19th October 1994 (Federal Law Gazette I, p. 3018),


3. Article 3 of the Ordinance of 21st September 1997 (Federal Law Gazette I, p. 2390), which entered into force effective as of 14th October 1997,

4. section 21 of the Law of 5th November 1997 (Federal Law Gazette I, p. 2631), which entered into force on 1st December 1997,


Bonn, 11th December 1998

THE FEDERAL MINISTER FOR HEALTH

ANDREA FISCHER
Law on the Trade in Drugs
(Drug Law)

Gesetz über den Verkehr mit Arzneimitteln
(Arzneimittelgesetz)

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FIRST CHAPTER
PURPOSE OF THE LAW AND DEFINITIONS

Section 1
Purpose of the law

It is the purpose of the present Law to guarantee, in the interest of furnishing both human beings and animals with a proper supply of drugs, safety in respect of the trade in drugs, ensuring in particular the quality, efficacy and safety of drugs in accordance with the following provisions.

Section 2
Definition of drugs

(1) Drugs are substances and preparations made from substances which, by application on or in the human or animal body, are intended

1. to cure, alleviate, prevent or diagnose diseases, suffering, bodily injury or disease symptoms,

2. to diagnose the nature, the state or the functions of the body or the mental health conditions,

3. to substitute active principles or body fluids produced in the human or animal body,

4. to ward off pathogens, parasites or substances alien to the body or to destroy them or render them harmless,

5. to influence either the nature, the state or the functions of the body or mental health conditions.

(2) The following shall be considered as drugs:

1. objects which contain a drug as specified in sub-section 1 or to the surface of which a drug specified in sub-section 1 is applied and which are intended to come into either temporary or permanent contact with the human or animal body,
1a. veterinary instruments in so far as they are intended for single use and the labelling of which indicates that they have been subjected to a procedure for microbe reduction,

2. objects which, without being objects as specified in No. 1 or 1a, are intended for the purposes indicated in sub-section 1 No. 2 or 5, to be introduced either temporarily or permanently into the human or animal body, with the exception of veterinary instruments,

3. (deleted)

4. substances and preparations made from substances which, also in combination with other substances or preparations made from substances, without being applied on or in the human or animal body, are intended
   a) to diagnose the nature, state or functions of the body or to identify pathogens,
   b) to combat pathogens or parasites, with the exception of those which are intended to combat micro-organisms, including viruses, in commodities as defined by section 5 sub-section 1 No. 1 of the Law on Foodstuffs and Commodities or in medical devices as defined in section 3 Nos. 1, 2, 6, 7 and 8 of the Act on Medical Devices.

(3) For the purposes of the present Law, drugs shall not mean

1. foodstuffs as defined in section 1 of the Law on Foodstuffs and Commodities,

2. tobacco products as defined in section 3 of the Law on Foodstuffs and Commodities,

3. cosmetic products as defined in section 4 of the Law on Foodstuffs and Commodities,

4. substances or preparations made from substances, which are exclusively intended for the external cleaning or hygiene or for influencing the appearance or the body odour of an animal, provided that no substances or preparations made from substances are added, which are excluded from trade outside of pharmacies,

5. (deleted)

6. feeding stuffs, additives and premixes as defined in sections 2 to 2b sub-section 1 No. 1 of the Law on Feeding Stuffs.
7. medical devices and accessories for medical devices within the meaning of § 3 of the Medical Devices Act unless they are drugs within the meaning of section 2 sub-section 1 No. 2,

8. the organs and corneas specified in section 9 sentence 1 of the Transplantation Act if they are intended for transplanting to other persons.

(4) As long as a product is authorized or registered as a drug pursuant to the present Law, or is exempted from the need for authorization or registration by ordinance, such product shall be considered as a drug. A product shall not be considered as a drug if its authorization or registration has been rejected by the competent higher federal authority, on the grounds that it is not a drug.

Section 3
Definition of substances

For the purpose of the present Law, 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, whether in the processed or crude state,

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

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

(1) Finished drugs are drugs which are manufactured beforehand and then marketed in packages ready for distribution to the consumer.

(2) Blood preparations are drugs which are or which contain, as medically active constituents, blood, plasma or serum conserves obtained from blood, blood components or preparations made from blood components.

(3) Sera are drugs as defined in section 2 sub-section 1 which are obtained from blood, organs, parts of organs or secretions from organs of the healthy or the sick, or from beings who have been sick or previously immunized, which contain specific antibodies and which are intended for use on account of these antibodies. Sera shall not be considered as blood preparations as defined in sub-section 2.

(4) Vaccines are drugs as defined in section 2 sub-section 1, containing antigens and intended for use in human beings or animals for the production of specific antitoxins and protective agents.

(5) Test allergens are drugs as defined in section 2 sub-section 1, containing antigens or haptens and intended for use on human beings or animals for the diagnosis of specific antitoxins or protective agents.

(6) Test sera are drugs as defined in section 2 sub-section 2 No. 4 letter a), which are obtained from blood, organs, parts of organs or secretions from organs of the healthy or the sick, or from beings who have been sick or previously immunized, which contain specific antibodies and which are intended to be used on account of these antibodies, as well as the control sera appertaining to these drugs.

(7) Test antigens are drugs as defined in section 2 sub-section 2 No. 4 letter a), which contain antigens or haptens and which are intended to be used as such.

(8) Radiopharmaceuticals are drugs which are or contain radioactive substances and spontaneously emit ionizing radiation and which are intended to be used on account of these properties; radionuclides (precursors) which have been manufactured for the radiolabelling of other substances prior to administration as well as systems with a fixed mother radionuclide
which forms a daughter radionuclide (generators) shall also be regarded as radio-pharmaceuticals.

(9) (deleted)

(10) Medicated feeding stuffs are drugs in the form of ready feeding stuff, manufactured from premix drugs and mixed feed and intended to be marketed for administration to animals.

(11) Premix drugs are drugs intended for use in the manufacture of medicated feeding stuffs.

(12) Withdrawal period is the time during which, if a drug is administered to animals in keeping with its intended purpose, residues of a type and quantity not innocuous to health, especially in quantities which exceed established maximum levels, must be anticipated in the foodstuffs to be obtained from the animals undergoing treatment, and includes an appropriate safety margin.

(13) Side effects are those undesired concomitant effects which occur when a drug is administered in keeping with its intended purpose.

(14) Manufacturing is the producing, preparing, formulating, treating or processing, filling as well as decanting, packaging and labelling of drugs.

(15) Quality is the nature of a drug, 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 drug produced in a standard manufacturing process.

(17) Marketing is the keeping in stock for sale or for other forms of supply, the keeping and offering for sale and the distribution to others.

(18) A pharmaceutical entrepreneur is any person placing drugs on the market under his own name.

(19) Active principles are substances which are intended for use as medically active constituents in the manufacture of drugs.
SECOND CHAPTER  
DRUG REQUIREMENTS

Section 5  
Prohibition in respect of unsafe drugs

(1) The placing on the market of unsafe drugs shall be prohibited.

(2) Drugs shall be considered unsafe if, according to the current level of scientific knowledge, there is reason to suspect that, when used in accordance with their intended purpose, they have harmful effects which exceed the limits considered tolerable in the light of current medical knowledge.

Section 6  
Empowerment in respect of health protection

(1) The Federal Ministry for Health (the Federal Ministry) shall be empowered to specify, restrict or prohibit, by ordinance subject to the approval of the Bundesrat, the use of certain substances, preparations made from substances or objects in the manufacture of drugs and to forbid the marketing of drugs which have not been manufactured in compliance with these regulations in so far as this is deemed necessary in order to prevent drugs from posing a direct or indirect hazard to human or animal health.

(2) The ordinance referred to in sub-section 1 shall be promulgated in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used, and in agreement with the Federal Ministry for Food, Agriculture and Forestry as far as drugs intended for administration to animals are concerned.
Section 6a
Prohibition of the use of drugs for doping purposes in sport

(1) The placing on the market, prescribing or administering of drugs to others for the purpose of doping in sport, is prohibited.

(2) Paragraph 1 shall apply only to drugs which contain substances belonging to the classes of doping agents contained in the Appendix to the Anti-Doping Convention (Act of 2nd March 1994 on the Anti-Doping Convention of 16th November 1989, Federal Law Gazette 1994 II, p. 334) in so far as

1. the placing on the market, prescribing or administering serves purposes other than the treatment of disease and

2. human beings are subjected to or intended to be subjected to doping.

(3) The Federal Ministry for Health shall be empowered to specify, in agreement with the Federal Ministry of the Interior, by ordinance subject to the approval of the Bundesrat, additional substances or preparations made from substances to which paragraph 1 shall apply, in so far as this is deemed necessary in order to prevent drugs from posing a direct or indirect hazard to human health through doping in sport.

Section 7
Radiopharmaceuticals and drugs treated with ionizing radiation

(1) It shall be forbidden for radiopharmaceuticals or drugs in the manufacture of which ionizing radiation has been used to be placed on the market unless the authorization to do so has been given by ordinance according to sub-section 2.

(2) The Federal Ministry shall be empowered to authorize, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and, as far as drugs intended for administration to animals are involved, in agreement with the Federal Ministry for Food, Agriculture and Forestry, by ordinance subject to the approval of the Bundesrat, the placing of radiopharmaceuticals on the market or the use of ionizing radiation in the manufacture of drugs in so far as this is deemed, according to the current level of scientific knowledge, to be justified for medical purposes and in so far as it does not compromise hu-
man or animal health. The ordinance may prescribe the channel of distribution for the drugs and specify that certain data concerning their radioactivity are to appear on the container, the outer package and the package leaflet.

Section 8
Prohibitions to prevent deception

(1) It shall be prohibited for drugs

1. which, by deviating from recognized pharmaceutical principles, are of considerably reduced quality, or

2. which bear misleading designations, specifications or presentations,

to be manufactured or placed on the market. Deception shall be said to exist, in particular, in cases where

a) claims are made to the effect that certain drugs have a therapeutic efficacy or effects which they do not possess,

b) the erroneous impression is given that success can be expected with certainty or that no harmful effects can be expected to occur when the drug is used in accordance with its intended purpose or over a prolonged period,

c) designations, specifications or presentations having an influence on the assessment of the drug are employed to mislead others with regard to its quality.

(2) It shall be prohibited for drugs whose expiry date has elapsed to be marketed.

Section 9
The party responsible for the marketing of a drug

(1) Drugs which are placed on the market within the purview of the present Law shall bear the name or the company and the address of the pharmaceutical entrepreneur.
(2) Within the purview of the present Law, drugs may only be placed on the market by a pharmaceutical entrepreneur whose registered place of business is situated within the purview of the present Law, in another Member State of the European Communities or another State Party to the Agreement on the European Economic Area.

Section 10
Labelling of finished drugs

(1) Finished drugs which are drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1, may only be marketed within the purview of the present Law provided that the following particulars are displayed on the containers and, where used, on the outer wrappings in easily legible and indelible characters and in easily comprehensible German:

1. the name or the company and the address of the pharmaceutical entrepreneur,

2. the name of the drug; if the drug is placed on the market with the same name in several pharmaceutical forms or strengths, the name must be followed by the information regarding the pharmaceutical form, strength or the group of persons for which the drug is intended, unless this information is already contained in the name,

3. the marketing authorization number with the abbreviation "Zul.-Nr."

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

5. the pharmaceutical form,

6. the content by weight, volume or number of units,

7. the method of administration,

8. the medically active constituents by type and quantity and other constituents by type in so far as this is imposed as a condition by the competent higher federal authorities pursuant to section 28 sub-section 2 No. 1 or provided for by an ordinance having the force of law pursuant to section 12 sub-section 1 No. 4 or pursuant to section 36 sub-section 1;
in the case of drugs intended for parenteral or topical use, including application to the eye, all constituents by type,

8a. in the case of drugs produced using genetic engineering, the active principle and the name of the genetically modified micro-organism or cell line used in its manufacture,

9. the expiry date with the instruction "verwendbar bis" (to be used by),

10. in the case of drugs which may only be dispensed upon prescription by a physician, dentist or veterinarian, the indication "Verschreibungspflichtig" (prescription-only), in the case of other drugs which may only be sold to consumers 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 drugs 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 drugs or other special precautions to avoid hazards to the environment.

In so far as the information pursuant to sentence 1 is also provided in another language, the data provided in that language shall be identical. Additional information is admissible in so far as it is connected with the use of the drug, is important for health education and is not inconsistent with the information pursuant to section 11a.

(1a) In the case of drugs containing only one medically active constituent, the information pursuant to sub-section 1 No. 2 shall be followed by the name of this constituent and the indication "Wirkstoff" (active principle); this shall not apply in cases where the name of the medically active constituent pursuant to sub-section 1 No. 8 is contained in the information pursuant to sub-section 1 No. 2.

(2) Moreover, warnings, specific storage instructions for the consumer as well as storage instructions for experts shall be given in so far 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 sub-section 2 No. 1 or provided for by an ordinance having the force of law.

(3) In respect of sera, particulars on the type of living organism from which the sera were obtained, in respect of virus vaccines, particulars of the host system which was used for the multiplication of the virus shall be indicated.

(4) In respect of drugs entered in the Register for Homeopathic Drugs, the indication "Homöopathisches Arzneimittel" (homeopathic drug) shall be given with the name of the drug pursuant to sub-section 1 sentence 1 No. 2. Instead of the particulars specified in sub-section 1 sentence 1 No. 3, the registration number with the abbreviation "Reg.-Nr." shall be given. Particulars on the fields of application may not be given with these drugs. The indication "Registriertes homöopathisches Arzneimittel, daher ohne Angabe einer therapeutischen Indikation" (registered homeopathic drug and therefore devoid of any reference to a therapeutic indication) and, in the case of drugs which are intended for administration to human beings, the indication that the user should consult a physician if the symptoms persist while using the drug shall be included. The information pursuant to sub-section 1 sentence 1 Nos. 12 and 13 may be dispensed with. Sentences 1 and 3 to 5 shall apply mutatis mutandis to drugs which are exempted from registration pursuant to section 38 sub-section 1 sentence 3. Drugs which have been manufactured according to homeopathic manufacturing procedures and authorized for marketing pursuant to section 25, shall be specially labelled with an indication of their homeopathic nature.

(5) In respect of drugs which are intended for administration to animals, the following additional particulars shall be given:

1. the indication "Für Tiere" (for animals) or the animal species to which the drug is meant to be administered,

2. the withdrawal period, if the drugs are intended for administration to food-producing animals; should a withdrawal period not be necessary, this shall be indicated,

3. the indication "Nicht bei Tieren anwenden, die der Gewinnung von Lebensmitteln dienen" (not to be administered to food-producing animals), in so far as such drugs are intended exclusively for administration to animals whose meat or products are not intended for human consumption,
3a. the indication "Nur durch den Tierarzt selbst anzuwenden" (for administration by a veterinarian only) in so far as this has been provided for in an ordinance pursuant to section 56a sub-section 3 No. 2.

4. in the case of premix drugs, the indication "Arzneimittel-Vormischung" (premix drug).

In the information pursuant to sub-section 1 sentence 1 No. 2, the animal species shall be indicated instead of the group of persons. By way of derogation from sub-section 1 sentence 1 No. 8, the active ingredients shall be indicated by type and quantity.

(6) For the designation of the ingredients, the following shall apply:

1. for the designation of the type, the international non-proprietary names fixed by the World Health Organization or, if such names do not exist, other common scientific names shall be given. The Federal Ministry shall be empowered to stipulate the individual names by ordinance, without the approval of the Bundesrat;

2. for the indication of quantity, units of measure shall be used; if biological units or other specifications regarding valence are customarily in scientific use, then these shall be used.

(7) The month and the year shall be given as the expiry date.

(8) Aluminium foil strips are to be affixed with the name or the firm of the pharmaceutical entrepreneur, the name of the drug, the batch number and the expiry date. It shall not be necessary to state the name and firm of a parallel importer. In the case of containers with a volume of not more than ten millilitres and single-dosage ampoules, the particulars specified in sub-sections 1 to 5 need only be displayed on the outer packages; the containers and the ampoules must, however, at least bear the particulars specified in sub-section 1 Nos. 2, 4, 6, 7, 9 as well as sub-section 3 and sub-section 5 No. 1; adequate abbreviations may be used. In the case of fresh plasma preparations and preparations derived from blood cells, at least the particulars specified in sub-section 1, Nos. 1 to 4, 6, 7 and 9 must be displayed as well as the blood group and, in the case of preparations made from red blood cells, the rhesus formula as well.
(9) Abbreviations customary in the drug trade may be used in the indications given in compliance with sub-sections 1 to 5. The company to be indicated under sub-section 1 No. 1 may be abbreviated, provided that the firm is generally recognizable from the abbreviation.

(10) For drugs which are to be submitted to clinical investigation or to residue testing, sub-section 1 Nos. 1, 2 and 4 to 7 as well as sub-sections 8 and 9 shall be applicable, in so far as they are relevant. Drugs intended for clinical investigation shall be labelled "Zur klinischen Prüfung bestimmt" (for clinical investigation) and drugs intended for residue testing shall be labelled "Zur Rückstandsprüfung bestimmt" (for residue testing). In cases where drugs which are authorized for marketing pursuant to sentence 2 must bear the indication "Zur klinischen Prüfung bestimmt" (for clinical investigation), they shall refrain from bearing the authorized name and shall carry a name which deviates from it. Aluminium fail strips shall bear the name and the batch identification number; sentences 2 and 3 shall apply.

Section 11
Package leaflet

(1) Finished drugs which are drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1 and are intended neither for clinical investigation nor residue testing may only be marketed within the purview of the present Law with a package leaflet bearing the heading "Gebrauchs-information" (instructions for use) and containing, in the following order in an easily legible and readily comprehensible form, the following information written in the German language:

1. the name of the drug; section 10 sub-section 1 No. 2, sub-section 1a and sub-section 10 sentence 3 shall apply mutatis mutandis,

2. the medically active constituents by type and quantity and other constituents by type; section 10 sub-section 6 shall apply,

3. the pharmaceutical form and the contents by weight, volume or number of units,

4. the substance or indication group or the mode of action,

5. the name or the company and the address of the pharmaceutical entrepreneur as well as of the manufacturer who released the finished product for placing on the market,
6. the fields of application,

7. the contra-indications,

8. safety precautions for use in so far as these are necessary in the light of the current level of scientific knowledge,

9. the interactions with other products in so far as these are able to influence the efficacy of the drug,

10. warnings, in particular where these have been imposed by the competent higher federal authority pursuant to section 28, sub-section 2, No. 2 or are provided for by ordinance,

11. the dosage instructions including the method of administration, single or daily doses and, in the case of drugs which should only be administered for a limited period of time, the duration of the administration,

12. directions to be followed in the event of an overdose, the failure to take the drug or references to the risk of undesirable sequelae resulting from the failure to continue taking the drug where necessary,

13. the side-effects; where considered necessary in the light of the current level of scientific knowledge, the counter-measures to be taken; the indication that the patient is to be called upon to report all side-effects which are not listed in the package leaflet to his/her physician or pharmacist,

14. the indication that the drug should not be used once the expiry date printed on the container and outer package has elapsed and, in so far as necessary, information on the shelf life after the user has opened the container or made the preparation ready for use and warnings regarding specific visible signs indicating that the drug is no longer suitable for use,

14a. in the case of drugs derived from human blood plasma for the purpose of fractionation, the country in which the blood plasma originated,

15. the date on which the package leaflet was worded.
Explanatory information on the terms listed in sentence 1 is admissible. In so far as information referred to in sentence 1 is also rendered on the package leaflet in another language, the information provided in this language shall be identical. Sentence 1 shall not apply to drugs which do not require a marketing authorization pursuant to section 21 sub-section 2 No. 1. Additional information is admissible in so far as it deals with the use of the drug, is important for the purpose of health education and is not in contradiction to the information referred to in section 11a. With regard to the information referred to in sentence 1 Nos. 7 to 9, 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, in so far as this is deemed necessary in the light of the current level of scientific knowledge; furthermore, where necessary, the effects which the use of the drug could have on a person’s ability to drive or to operate specific machines should also be indicated. Information pursuant to sentence 1 Nos. 8 and 10 may be combined.

(1a) A sample of the package leaflet and modified versions shall be sent to the competent higher federal authority unless the drug is exempted from the obligation to obtain a marketing authorization or registration.

(2) Furthermore, the package leaflet shall contain references to ingredients, the knowledge of which is necessary for the safe and effective use of the drug, as well as specific storage instructions for the consumer in so far 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 sub-section 2 No. 2, or provided for by ordinance.

(2a) In the case of radio-pharmaceuticals, such precautions as are to be taken by the user and the patient in the preparation and administration of the drug, as well as special precautionary measures for the disposal of the containers used for transport and for the disposal of drugs which are not used, shall also be indicated.

(3) With regard to drugs listed in the Register for Homeopathic Drugs, the indication "Homöopathisches Arzneimittel" (homeopathic drug) shall be given with the name of the drug in compliance with sub-section 1 sentence 1 No. 1. Particulars regarding fields of application may not be given; instead the package leaflet shall contain the indication "Registriertes homöopathisches Arzneimittel, daher ohne Angabe einer therapeutischen Indikation" (registered homeopathic drug, therefore devoid of any reference to a therapeutic indication) and in the case of drugs intended for human beings, the indication to the user that a physician should be consulted if symptoms persist while the drug is being used. The information referred
to in sub-section 1 sentence 1 Nos. 4, 7, 9, 12, 13 and 15 may be omitted. Sentences 1 to 3 apply *mutatis mutandis* to drugs which are exempted from registration pursuant to section 38 sub-section 1 sentence 3.

(3a) In the case of sera, particulars shall be given regarding the species of living organism from which they were obtained and, in the case of virus vaccines, information on the host system which was used for the multiplication of the virus.

(4) In the case of drugs which are intended for administration to animals, the following particulars must also be given:

1. details as stipulated in section 10 sub-section 5,

2. in respect of premix drugs, indications for the correct manufacture of medicated feeding stuffs, the types of mixed feed and manufacturing procedures suitable for this purpose, interactions with additives authorized by legislation governing feeding stuffs as well as information on the shelf life of the medicated feeding stuffs,

3. in so far as required in the light of the current level of scientific knowledge, special precautions for the disposal of unused drugs or other special precautions to avoid hazards to the environment.

By way of derogation from sub-section 1 sentence 1 No. 2, the nature and quantity of the active ingredients shall be indicated. The information referred to under sub-section 1 sentence 1 No. 4 and the manufacturer's information referred to under sub-section 1 sentence 1 No. 5 may be omitted. The information to be provided under sub-section 1 sentence 1 No. 13 shall be accompanied by the proviso that the animal owner shall be required to notify the veterinarian or pharmacist of any occurrence of the side-effects specified.

(5) Should it not be possible to provide the information stipulated in sub-section 1 Nos. 7, 9 and 13, the indication *"keine bekannt"* (none known) shall be given. Should additional particulars be given on the package leaflet, they shall be clearly set out and well separated from those particulars specified in sub-sections 1 to 4.

(6) The package leaflet may be omitted provided that the information specified in sub-sections 1 to 4 is to be found either on the container or on the outer package. Sub-section 5 shall apply *mutatis mutandis.*
(1) The pharmaceutical entrepreneur shall be obliged to make available upon request to physicians, dentists, veterinarians, pharmacists and, if the drugs concerned are not subject to prescription, to other persons practising medicine or dentistry professionally, instructions for use by experts (expert information) for finished drugs which are subject to or exempted from the obligation to obtain a marketing authorization, are drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1 and are not released for trade outside of pharmacies. These instructions for use shall bear the heading "Fachinformation" (expert information) and include the following details written in clearly legible type:

1. the name of the drug; section 10 sub-section 1a shall apply mutatis mutandis,

2. in the case of drugs which may only be dispensed upon prescription by a physician, dentist or veterinarian, the indication "Verschreibungspflichtig" (prescription-only), in the case of narcotic drugs the indication "Betäubungsmittel" (narcotic drug), in the case of other drugs which may only be dispensed to the consumer in pharmacies, the indication "Apotheken-pflichtig" (pharmacy-only) in the case of drugs containing a substance or preparation pursuant to section 49, the indication that this drug contains a substance whose action is not yet widely known in medical science and for which the pharmaceutical entrepreneur has to submit a report on experiences with its use to the competent higher federal authority pursuant to section 49 sub-section 6, in so far as this is stipulated pursuant to section 49 sub-section 6 sentence 1,

3. the group of substances or indications, the constituents by nature and the medically active constituents by nature and quantity; section 10 sub-section 6 shall apply mutatis

   mutandis,

4. the fields of application,

5. the contra-indications,

6. the side effects,

7. the interactions with other products,
8. the warnings, in so far as this is stipulated for containers, outer packages, the package leaflet or the expert information by virtue of a condition imposed by the competent higher federal authority pursuant to section 28 sub-section 2 No. 1 letter a or stipulated by ordinance pursuant to section 12 sub-section 1 No. 3 or pursuant to section 36 sub-section 1,

9. the most important incompatibilities,

10. the dosage, including single and daily doses,

11. the method of administration and, in the case of drugs which should only be administered for a limited period of time, the duration of administration,

12. measures in the case of an emergency, symptoms and antidotes,

13. the pharmacological and toxicological properties and information on pharmacokinetics and bioavailability in so far as this information is necessary for therapeutic use,

14. in so far as necessary, other indications, particularly indications for the administration to certain groups of patients,

15. the duration of the shelf-life and, if necessary, the period of stability after the user has opened the container or made the preparation ready for use,

16. the particular instructions for storage and retention,

16a. where necessary, special precautions for the disposal of drugs which have not been used, or other special precautions to avoid hazards to the environment,

17. pharmaceutical forms and package sizes,

17a. in the case of drugs manufactured from human blood plasma for the purpose of fractionation, the country in which the blood plasma originated,

18. the date on which the expert information is issued,
19. the name or the company and the address of the pharmaceutical entrepreneur.

Additional information is admissible if it has to do with the use of the drug and is not in contradiction to the information required under sentence 2; it must be clearly separated from the information provided for under sentence 2 and set off against the latter. Sentence 1 shall not apply to drugs which, according to section 21 sub-section 2, do not require a marketing authorization or have been manufactured according to homeopathic manufacturing procedures.

(1a) In the case of sera, particulars on the type of living organism from which the sera were obtained and, in the case of virus vaccines, particulars regarding the host system which was used for the multiplication of the virus shall 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 shall also be given and, where necessary, the maximum storage time shall also be indicated during which an intermediate preparation, such as an eluate or the drug when ready for use, corresponds to its specifications.

(1c) In the case of drugs intended for administration to animals, the information specified in section 11 sub-section 4, must also be provided.

(2) The pharmaceutical entrepreneur shall be obliged to make all modifications to the expert information, which are relevant for therapy, accessible to the experts in an appropriate form. In so far as 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 shall be sent immediately to the competent higher federal authority unless the drug is exempted from the obligation to obtain a marketing authorization.

(4) The obligations referred to in sub-section 1 sentence 1 can also be fulfilled in the case of drugs which are administered exclusively by members of the health professions by including the information referred to in sub-section 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 drug labelling, package leaflets and package sizes

(1) The Federal Ministry shall be empowered, in agreement with the Federal Ministry for Economics by ordinance subject to the approval of the Bundesrat:

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

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

3. to stipulate that, for certain drugs or certain groups of drugs, warnings, warning symbols or recognition marks shall be contained in or affixed to
   a) the containers, the outer packages or the package leaflet or
   b) the expert information

4. to stipulate that specific constituents are to be listed by nature on the containers and outer packages 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 drugs within the purview of the present Law and in order to prevent any direct or indirect risk to human or animal health, which 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 summarizing names for substances or preparations from substances in the information provided on containers and outer packages or in package leaflets or in expert information, as long as active ingredients are not involved and no direct or indirect hazard to human or animal health arising from a lack of information is to be feared.

(2) The ordinance shall be promulgated in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used, and in agreement with the Federal Ministry for Food, Agriculture and Forestry where drugs intended for administration to animals are concerned. Furthermore, the ordinance shall be promulgated in the cases pro-
vided for in sub-section 1 No. 3 in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in so far as warnings, warning symbols or recognition marks with regard to the particulars stipulated in section 10 sub-section 1 sentence 1 No. 13, section 11 sub-section 4 sentence 1 No. 3 or section 11a sub-section 1 sentence 2 No. 16a are required.

(3) Furthermore, the Federal Ministry is hereby empowered to stipulate, by ordinance not subject to the approval of the Bundesrat, that drugs may only be placed on the market in specific package sizes and that they shall be labelled accordingly by the pharmaceutical entrepreneur on the container or, if used, on the outer package. The fixing of these package sizes shall be done for specific medically active constituents and shall take into account the fields of application, the duration of application and the pharmaceutical form. In fixing the package size, the following sub-division shall, in principle, 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 prolonged duration of application.

THIRD CHAPTER
MANUFACTURE OF DRUGS

Section 13
Manufacturing authorization

(1) Any person intending to manufacture drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1, test sera, test antigens or active principles which are of human or animal origin or are produced using genetic engineering on a commercial or professional basis and for distribution to others shall require authorization by the competent authority. The same shall also apply to artificial persons, non-incorporated associations and companies established under civil law which manufacture drugs for distribution to their members. Distribution to others, in the meaning of the first sentence, shall exist if the person manufacturing the drug is not the same as the person using it.

(2) The following shall not require an authorization as defined in sub-section 1:
1. the owner of a pharmacy manufacturing drugs within the scope of the normal operation of a pharmacy,

2. the body responsible for a hospital, in so far as it is authorized to distribute drugs pursuant to the Law on Pharmacies,

3. the veterinarian manufacturing drugs which he dispenses for animals he treats himself; if, in individual cases, he has medicated feeding stuffs intended for the animals under his care manufactured by a third party, under his supervision, using premix drugs and mixed feeds, this third party shall not require an authorization in this respect either,

4. the wholesaler decanting, packaging or labelling drugs 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 drugs without altering them for direct distribution to the consumer.

The exceptions specified in sentence 1 shall not apply to the manufacture of blood preparations, sera, vaccines, test allergens, test sera, test antigens and radiopharmaceuticals. The exceptions pursuant to sentence 1 No. 3, shall apply to the manufacture of medicated feeding stuffs only if manufacture takes place in factories which are in possession of an authorization under sub-section 1 or a licence to manufacture mixed feeds using specific additives or premixes containing such additives granted by the competent authority under provisions governing feeding stuffs.

(3) (deleted)

(4) The decision on the granting of the authorization shall be reached by the competent authority of the federal Land where the factory site is situated or is to be situated. As far as blood products, sera, vaccines, test allergens, test sera and test antigens are concerned, the decision on the authorization shall be reached in consultation with the competent higher federal authority.
Section 14
Decision on the manufacturing authorization

(1) An authorization may only be refused if

1. the person under whose direction the drug is to be manufactured (production manager) does not possess the expert knowledge required,

2. the person under whose direction the drug is to be tested (control manager) does not possess the expert knowledge required,

3. the person under whose direction the drug is to be sold (sales manager) has not been named,

4. the production manager, control manager or sales manager do not possess the reliability required for carrying out their work,

5. the production manager, control manager or sales manager cannot permanently fulfil the obligations incumbent on them, or

5a. in factories which manufacture medicated feeding stuffs from premix drugs, the person responsible for supervising the technical side of the manufacturing procedure does not possess sufficient knowledge and experience in the field of mixing technology, or

5b. the physician under whose responsibility pre-treatment of the donor is carried out for the purpose of separating blood stem cells or other blood components, does not possess the expert knowledge required,

5c. contrary to section 4 sentence 1 No. 2 of the Transfusion Act, no physician in charge has been appointed, said person is not licensed to practise medicine or does not possess the necessary professional knowledge according to the state of the medical art, or

6. suitable premises and equipment for the intended manufacture, testing and storage of the drugs are not available, or
6a. the manufacturer is not in a position to ensure that the manufacture or the testing of the drugs is carried out according to the latest standards prevailing in science and technology.

(2) The sales manager may at the same time be the production manager. In companies applying exclusively for an authorization for the decanting, packaging or labelling of drugs or for the manufacture of medicated feeding stuffs made from premix drugs, the production manager may be both control and sales manager at the same time. The physician in charge pursuant to section 4 sentence 1 No. 2 of the Transfusion Act may be production or control manager at the same time. Where autologous blood preparations are manufactured and tested exclusively and in cases where the manufacture, testing and use is carried out under the responsibility of a hospital department or another medical facility, the production manager may be control manager at the same time.

(2a) In enterprises or facilities which exclusively manufacture radioactive drugs, transplants, drugs for use in somatic gene therapy and for in-vivo diagnosis by means of marker genes for use within the confines of such facilities or active principles, the production manager may also be control and sales manager at the same time.

(3) In companies exclusively producing, filling or labelling natural curative waters, bathing muds, other peloids and gases for medicinal purposes as well as plants or parts of plants, the production manager may be both control and sales manager at the same time.

(4) In some cases, the testing of drugs can be carried out outside of the factory site in appropriately commissioned companies, on condition that they have the premises and equipment suitable for this purpose.

(5) Should the documentation presented be deemed defective, the applicant shall be given the opportunity to remedy the defects within an appropriate period of time. If the defects are not remedied, the manufacturing authorization shall be refused.
Section 15
Expert knowledge

(1) Proof of the required expert knowledge on the part of the production manager or control manager shall be furnished by

1. the licence to practise as a pharmacist, or

2. the diploma in pharmacy, chemistry, biology, human or veterinary medicine attained upon completion of university studies

and a period of at least two years' practical experience in the manufacture or testing of drugs.

(2) In the cases specified in sub-section 1 No. 2, proof shall 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 sub-section 1 No. 2 and may be proved by examination.

(3) Sub-section 2 shall not apply to the manufacture and testing of blood preparations, sera, vaccines, test allergens, test sera and test antigens. In place of the evidence of practical experience required in sub-section 1, proof shall be furnished of at least three years' experi-
ence in the field of medical serology or medical microbiology. By way of derogation from sentence 2, in place of the practical experience required in sub-section 1, proof shall be furnished of

1. at least three years' experience in manufacture or testing in plasma processing enterprises with a manufacturing authorization 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 or, in the case of a control manager who is a qualified doctor for laboratory medicine or a specialist in microbiology and infection epidemiology, at least six months' experience in transfusion medicine in the case of blood preparations made from blood cells, preparations made from fresh plasma and active principles used in 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. in the case of preparations made from blood stem cells, in addition to sufficient knowledge, at least one 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 blood stem cells or other blood components, the responsible physician shall provide evidence of sufficient knowledge in addition to at least two years' experience in this field of activity. The prerequisites contained in sub-section 1 remain valid for packaging and labelling.

(3a) Sub-section 2 shall not apply to the manufacture and testing of drugs for use in gene therapy and for use in in-vivo diagnosis by means of marker genes, transplants, radioactive drugs and active principles. In place of the practical experience required in sub-section 1, proof can be furnished of at least 2 years' experience in a medically relevant field of genetic engineering in particular microbiology, cell biology, virology or molecular biology in the case of drugs for use in gene therapy and for use in in-vivo diagnosis by means of marker genes; at
least three years' experience in the field of tissue transplantation in the case of transplants; at least three years' experience in the field of nuclear medicine or that of radiopharmaceutical chemistry in the case of radioactive drugs; and at least two years' experience in the manufacture and testing of active principles in the case of active principles.

(4) The period of practical experience specified in sub-section 1 shall be spent at a firm which has been granted a manufacturing authorization by a Member State of the European Communities, 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) The period of practical experience shall not be required for the manufacture of medicated feeding stuffs from premix drugs; sub-section 2 shall not apply.

Section 16
Limitation of the manufacturing authorization

The authorization shall be issued to the manufacturer for a specific factory site and for particular drugs and forms of drugs and, in cases as defined in section 14 sub-section 4, also for a specific factory site of the commissioned company.

Section 17
Deadlines for the granting of an authorization

(1) The competent authority shall reach a decision on the application for an authorization within three months.

(2) If the holder of the authorization makes an application for the authorization to be modified in respect of the drugs to be manufactured or the premises and equipment as defined by section 14 sub-section 1 No. 6, the authority shall reach a decision within one month. In exceptional cases, the deadline shall be extended by a further two months. The applicant shall be notified thereof prior to the expiry of the deadline and shall be informed of the grounds.

(3) If the authority gives the applicant the opportunity to remedy defects in accordance with section 14 sub-section 5, the deadlines shall be interrupted until such defects have been
corrected or until the expiry of the deadline set in accordance with section 14 sub-section 5. The interruption of the deadline shall begin on the day the applicant receives the request to remedy the defects.

**Section 18**

Withdrawal, revocation, suspension

(1) The authorization shall be withdrawn if it becomes known subsequently that one of the grounds for refusal, as specified in section 14 sub-section 1, existed at the time the authorization was granted. The authorization shall be revoked, if one of the grounds for refusal has subsequently developed; the suspension of the authorization may be ordered instead of its revocation. Section 13 sub-section 4 shall apply *mutatis mutandis.*

(2) The competent authority may issue a provisional order mandating that the manufacture of a drug 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

(1) The production manager shall be responsible for ensuring that the drugs are manufactured, stored and labelled in compliance with the regulations applicable to the trade in drugs, as well as ensuring that they are accompanied by the prescribed package leaflet.

(2) The control manager shall be responsible for drugs being tested for required quality, in compliance with the regulations applicable to the trade in drugs.

(3) In so far as responsibility does not rest either with the production manager or the control manager in accordance with sub-sections 1 and 2, or with the information officer pursuant to section 74a, the sales manager shall be responsible for ensuring that the drugs are marketed in compliance with the regulations applicable to the trade in drugs and that the regulations governing advertising in the field of curative medicine are observed.

(4) In the cases defined in section 14 sub-section 4, the control manager shall continue to be responsible.
Section 20
Obligations to notify

The holder of an authorization shall notify the competent authority prior to any change in person of the production, control or sales manager, furnishing proof of the requirements specified in section 14 sub-section 1 Nos. 1 to 5, as well as prior to any substantial change in the premises or the equipment of the factory site specified in the authorization. In the event of an unexpected change in person of the production, control or sales manager, due notification shall be made forthwith.

Section 20a
Applicability to active principles

Section 13 sub-sections 2 and 4 and sections 14 to 20 shall apply mutatis mutandis to active principles in so far as their manufacture pursuant to section 13 sub-section 1 requires an authorization.

FOURTH CHAPTER
MARKETING AUTHORIZATION FOR DRUGS

Section 21
Obligation to obtain a marketing authorization

(1) Finished drugs which are drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1, may only be placed on the market within the purview of the present Law, if they have been authorized by the competent higher federal authority or if the Commission of the European Communities or the Council of the European Union has granted an authorization for them to be placed on the market pursuant to Article 3 paragraph 1 or 2 of Council Regulation (EEC) No. 2309/93 of 22nd July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ EC No. L 214, p. 1). The same shall apply to drugs which are not finished drugs and which are intended for administration to animals, provided they are not intended for distribution to pharmaceutical entrepreneurs holding an authorization for the manufacture of drugs.

(2) A marketing authorization (Zulassung) shall not be required for drugs which
1. are intended for administration to human beings and 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 as part of normal pharmacy operations and are intended for distribution in the same pharmacy,

2. are intended for use in clinical investigations on human beings,

3. are medicated feeding stuffs, manufactured in keeping with their designated purpose from premix drugs for which a marketing authorization has been issued in accordance with section 25,

4. are manufactured for individual animals belonging to a specific stock in pharmacies or in veterinarians' house dispensaries,

5. are intended for use in clinical investigations on animals or in residue tests.

(2a) Drugs which contain substances and preparations from substances which have not been released for trade outside of pharmacies, may only be manufactured pursuant to sub-section 2 No. 4 if a drug authorized for the treatment of the animal species in question or for the specific field of application is not available, if the necessary medicinal treatment of the animals would otherwise be seriously jeopardized and if no direct or indirect danger to the health of human beings and animals is to be feared. Drugs intended for administration to food-producing animals may, however, contain only substances or preparations from substances which are contained in drugs which are authorized for the treatment of food-producing animals and must be intended for use by a veterinarian or for administration under his or her supervision; the decanting, packaging or labelling of drugs in their unaltered form shall not be considered manufacturing within the meaning of sentence 1. Sentences 1 and 2 shall not apply to homeopathic remedies which are either registered or exempt from registration, the degree of dilution of which does not lie below the sixth decimal potency in so far as they are intended for application to food-producing animals.

(3) Application for a marketing authorization shall be made by the pharmaceutical entrepreneur. For a finished drug manufactured in pharmacies or at other retail dealers using standardized procedures and distributed to the consumer under a standardized name, application for marketing authorization shall be made by the party responsible for the issue of the master formula. If a finished drug is manufactured for several pharmacies or other retail deal-
ers and is to be distributed to the consumer under their name and under a standardized
name, then the manufacturer shall apply for marketing authorization.

(4) Furthermore, upon request by the competent authority of the Land the competent
higher federal authority shall decide on the obligation to obtain a marketing authorization for a
specific drug irrespective of an application for a marketing authorization pursuant to sub-
section 3.

Section 22
Documents required for marketing authorization

(1) The applicant shall attach the following particulars, written in German, to his appli-
cation for a marketing authorization:

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

2. the name of the drug,

3. the constituents of the drug by type and quantity; section 10 sub-section 6 shall apply,

4. the pharmaceutical form,

5. the effects,

6. the fields of application,

7. the contra-indications,

8. the side effects,

9. the interactions with other products,

10. the dosage,

11. a brief summary of the drug's manufacture,

12. the method of administration and, in the case of drugs which should only be administered
   for a limited period of time, the duration of the administration,
13. the package sizes,

14. the method of preservation, the shelf-life, the storage conditions, the results of stability tests,

15. the methods of quality control (test methods).

(2) Furthermore, the following information shall 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 examinations (pharmacological-toxicological test),

3. the results of the clinical or other medical, dental or veterinarian test (clinical investigation).

The results shall 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 authorization shall be accompanied by all of the relevant particulars and documents necessary for the assessment of the drug, whether favourable or unfavourable. This shall also apply to incomplete or discontinued toxicological or pharmacological experiments or clinical investigations carried out using the drug in question.

(3) Instead of the results specified in sub-section 2 Nos. 2 and 3, other scientific documents may be presented

1. in the case of a drug, the effects and side effects of which are already known and which are evident from the scientific documents,

2. in the case of a drug which, in its composition, is comparable to a drug as specified in No. 1,

3. for the constituents of the drug, in the case of a drug which is a new combination of constituents which are already known; however, other documents containing scientific find-
ings may also be presented for the combination as such, if the efficacy and safety of the
drug according to its composition, dosage, pharmaceutical form and fields of application
can be determined by these documents.

Furthermore, the medical experience gained by the specific schools of therapy must
also be taken into consideration.

(3a) If the drug contains more than one medically active constituent, evidence shall be
provided to prove that every medically active constituent contributes to the positive assess-
ment of the drug.

(3b) In the case of radiopharmaceuticals which are generators, a general description of
the system including a detailed description of those components of the system which 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.

(3c) In cases where the storage of the drug, its use or the disposal of its waste pro-
ducts require special safety precautions or security measures to avoid endangering the envi-
ronment or impairing the health of human beings, animals or plants, this shall also be stated.
Information on how to reduce these dangers shall also be submitted and substantiated.

(4) If an application is made for a marketing authorization in respect of a drug manu-
factured within the purview of the present Law, proof shall be furnished that the manufacturer
is entitled to manufacture the drug. This shall not apply in the case of an application as speci-
fied in section 21 sub-section 3 sentence 2.

(5) If an application is made for a marketing authorization in respect of a drug manu-
factured outside the purview of the present Law, proof shall be furnished that the manufac-
turer is entitled to manufacture drugs in accordance with the legal regulations laid down by the
country of manufacture and, in the event that the drug is imported from a country which is not
a member state of the European Communities or a State Party to the Agreement on the Euro-
pean Economic Area, that the importer is in possession of an authorization to import the drug
into the territory governed by the present Law.

(6) If the drug has already been granted a marketing authorization in another state or
in several other states, a copy of such authorization shall be included. Where an application
for a marketing authorization has been denied in whole or in part, the details of that decision
shall be furnished and the grounds for it explained. Where an application for a marketing authorization is currently being examined in one or several Member States of the European Union, this shall be stated. Copies of the summaries of the product characteristics and package leaflets authorized 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, shall also be included. Furthermore, where an application for the recognition of the marketing authorization of another Member State is submitted, the declarations required under Article 9 of Council Directive 75/319/EEC in the version valid at the time or in Article 17 of Council Directive 81/851/EEC in the version valid at the time shall be submitted along with the other particulars stipulated therein. Sentence 5 shall not apply to drugs which have been manufactured according to homeopathic manufacturing procedures.

(7) The application for a marketing authorization shall be accompanied by the text of the particulars which are meant to appear on the container, the outer package and the package leaflet as well as by the draft of the expert information pursuant to section 11a subsection 1 sentence 2. The competent higher federal authority may require the submission of one or more samples or mock-ups of the sales presentation of the drug including the package leaflets as well as starting materials, intermediate products and substances which are used in the manufacture or testing of the drugs, in a quantity sufficient to conduct the test and in a state suitable to the conduct of said test.

Section 23

Particular documents required for drugs intended for administration to animals

(1) In respect of drugs intended for administration to food-producing animals, the following particulars shall be given in addition to those specified in section 22:

1. particulars of the withdrawal period shall be given and shall be substantiated by documents on the results of the residue tests and particularly on the fate of the active ingredients and their metabolic products in the animal body and on the influence had on food-stuffs of animal origin, in so far as these results are necessary for the assessment of withdrawal periods taking stipulated maximum levels into account,

2. the description of a routine procedure by means of which the type and quantity of residues from substances which are harmful to health can be detected reliably, especially in such quantities as exceed the stipulated maximum levels, or from which reliable conclu-
sions can be drawn regarding such residues (residue test procedures), as well as docu-
ments containing proof thereof,

3. in the case of a drug the active ingredient of which is not listed in Annexes I, II or III of
Council Regulation (EEC) No. 2377/90 of 26th June 1990 laying down a Community pro-
cedure for the establishment of maximum residue limits of veterinary medicinal products
in foods of animal origin (OJ EC No. L 224, p. 1), a duplicate of the documents submitted
to the Commission of the European Communities pursuant to Annex V of this Regulation.

The obligation to submit documents regarding the residue test procedure pursuant to
sentence 1 No. 2 can be met by making reference to the procedure pursuant to Annex V of

(2) In the case of premix drugs, the particulars of the mixed feed intended as carrier
shall be given with the designation of the type of feeding stuff. Furthermore, it shall be justified
and proved by documents that the premix drugs are suited for the intended manufacture of
the medicated feeding stuff, and particularly that they allow a homogeneous and stable distri-
bution of the active ingredients in the medicated feeding stuffs taking into consideration the
manufacturing methods applied in the production of mixed feed; furthermore, the shelf-life of
medicated feeding stuffs shall be indicated, grounds provided and proved by documents.
Moreover, a routine test method suitable for the quantitative and qualitative analysis of the ac-
tive ingredients in the medicated feeding stuffs, shall be described and documents on test re-
results submitted as proof.

(3) The nature and scope of as well as the date on which the tests were carried out
shall be inferable from the documents containing the results of the residue tests and the resi-
due test procedures pursuant to sub-section 1, as well as from the evidence regarding the
suitability of the premix drugs for the intended manufacture of the medicated feeding stuff and
the test results of the test methods pursuant to sub-section 2. Instead of the documents, the
evidence and test results referred to in sentence 1, other scientific findings may be submitted.

(3a) (deleted)

(4) (deleted)

Section 24
Expertises
(1) Expertises in which the test methods, test results and residue test procedures are summarized and assessed, shall be included with the required documents as specified in section 22 sub-section 1 No. 15, sub-sections 2 and 3 and section 23. In particular, the following information shall be included in detail in the expertises presented:

1. the analytical expert opinion shall state whether the drug is of appropriate quality in accordance with recognized pharmaceutical practice, whether the proposed test methods comply with the prevailing standard of scientific knowledge and are suitable for quality assessment,

2. the pharmacological-toxicological expert opinion shall state the drug's toxic effects and pharmacological properties,

3. the clinical expert opinion shall state whether the drug has the required effect in the specified fields of application, whether it is tolerated, whether the prescribed dosage is appropriate and which contra-indications and side effects exist,

4. the expert opinion on the residue test shall state whether and, if so, how long after the administration of the drug, residues occur in the foodstuffs obtained from the animals which have undergone treatment, how these residues are to be assessed, whether the prescribed withdrawal period is sufficient and whether the residue test procedure can reliably detect the presence of residues of substances which may be detrimental to health, as well as their type and quantity, and whether it lends itself to routine use.

Moreover, the expert opinion must state whether the type and quantity of residue present after the prescribed withdrawal period has elapsed are below the maximum levels stipulated by Council Regulation (EEC) No. 2377/90.

(2) In so far as scientific documentation is presented pursuant to section 22 sub-section 3 and section 23 sub-section 3 sentence 2, it must be evident from the expert opinion, that the documents on scientific findings were elaborated under analogous application of the Guidelines for the Testing of Drugs.

(3) The expert opinion shall be accompanied by particulars regarding the name, training and professional practice of the expert as well as his professional relationship with the ap-
applicant. The experts shall sign their statements personally, stating the place and the date of issue of the expert opinion.

Section 24a
Use of documentation from a previous applicant

(1) In the case of a drug which is or was subject to prescription pursuant to section 49, the applicant may refer to documents pursuant to section 22 sub-section 2 Nos. 2 and 3, sub-section 3c, and section 23 sub-section 1 including an expertise pursuant to section 24 sub-section 1 sentence 2 Nos. 2 to 4 from a preceding applicant (previous applicant) if the previous applicant has granted permission in writing and confirmed, also in writing, that the documents to which reference is being made fulfil the requirements of the general administrative provision pursuant to section 26. The previous applicant shall respond to a request for permission within a period of three months. The permission of the previous applicant and his or her confirmation shall not be necessary in cases where the applicant can prove that more than ten years have elapsed since the first marketing authorization was granted for the drug in one of the Member States of the European Communities.

(2) Deleted

Section 24b
Request for additional documents

If several holders of a marketing authorization have to be requested to submit additional documents, the competent higher federal authority shall notify every holder of a marketing authorization of the documents necessary for the further assessment as well as of the names and addresses of the other holders of a marketing authorization who are involved. The competent higher federal authority shall give those holders of the marketing authorization who are involved the opportunity to decide among themselves as to who shall 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 shall decide and immediately notify all persons concerned. Unless the other holders of a marketing authorization choose to forgo the marketing authorization granted for their own pharmaceutical product, they shall be obliged to contribute proportionally to the expenditure incurred in the preparation of the documents calculated according to the number of holders of a marketing authorization involved: they are jointly and severally liable. Sentences 1 to 4 shall apply mutatis mutandis for persons using
standard marketing authorizations as well as in cases where documents with the same contents are requested from several applicants in ongoing marketing authorization procedures.

Section 24c
General right of exploitation

The competent higher federal authority is empowered to utilize the documents submitted to it, with the exception of those referred to under section 22 sub-section 1 Nos. 11, 14 and 15 as well as sub-section 2 No. 1 and the expert opinion pursuant to section 24 sub-section 1 sentence 2 No. 1, in fulfilling its tasks under the present Law, provided that at least 10 years have elapsed since the drug first received a marketing authorization in one of the Member States of the European Communities or a procedure pursuant to section 24b has not yet been terminated.

Section 25
Decision on marketing authorization

(1) The marketing authorization, together with a marketing authorization number, shall be issued in writing by the competent higher federal authority. The marketing authorization shall only be applicable to the drug specified in the marketing authorization notice and, in the case of drugs manufactured according to homeopathic manufacturing procedures it shall also apply to the degree of dilution mentioned in results published in accordance with section 25 sub-section 7 sentence 1 of the version in force prior to 17th August 1994 and specified in the marketing authorization notice.

(2) The competent higher federal authority may only refuse to grant the marketing authorization if

1. the documents submitted are incomplete,

2. the drug has not been sufficiently tested in accordance with the current state of scientific knowledge,

3. the drug does not display the appropriate quality in accordance with recognized pharmaceutical practice,
4. the therapeutic efficacy attributed to the drug by the applicant is lacking or is insufficiently substantiated by the applicant according to the current state of scientific knowledge,

5. there is a reason to suspect that, when used in a manner which is in keeping with its intended purpose, the drug has harmful effects which exceed the bounds considered justifiable in the light of the current state of medical knowledge,

5a. inadequate evidence is provided to prove that each medically active constituent makes a contribution to the positive assessment of the drug in the case of a drug which contains more than one active constituent, whereby the special characteristics of the drug in question are to be taken into account in a risk-graduated assessment,

6. the withdrawal period given is insufficient,

6a. the proposed residue test procedure cannot reliably detect the type and quantity of substances which are detrimental to health or cannot be carried out in a routine manner,

6b. in the case of premix drugs, the test methods used to prove the quality and quantity of the active ingredients in the medicated feeding stuffs cannot be carried out in a routine manner,

6c. the drug is intended for administration to food-producing animals and contains a pharmaceutically active ingredient which is not listed in Annexes I, II or III of Council Regulation (EEC) No. 2377/90,

7. the marketing of the drug or its administration to animals would violate legal regulations or a regulation or directive issued or a decision adopted by the Council or the Commission of the European Communities,

8. the drug has been exempted from the obligation to obtain a marketing authorization by virtue of an ordinance pursuant to section 36, sub-section 1, or is identical with such a drug as far as its medically active constituents are concerned and comparable in respect of the quantity of its medically active constituents, in so far as no legitimate interest in a marketing authorization pursuant to sub-section 1 for export purposes can be demonstrated.
The marketing authorization 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 currently recognized state of scientific knowledge, that a therapeutic effect can be produced with the drug.

(3) The marketing authorization shall be refused for a drug which differs from a drug bearing the same name which has been authorized for marketing or is already on the market, in the nature of the quantity of its active ingredients. Deviating from sentence 1, a difference in the quantity of active ingredients shall be harmless if the drugs differ in their pharmaceutical form.

(4) Should the documents submitted be deemed defective, the applicant shall be given the opportunity to remedy the defects contained therein, within an appropriate deadline which may, however, not exceed six months. Should these defects not be remedied within the prescribed deadline, the marketing authorization shall be refused. After the decision has been taken to refuse the marketing authorization, the submission of documents in order to remedy defects shall not be allowed.

(5) The marketing authorization shall be granted on the basis of the examination of the documents submitted as well as on the basis of the expert opinions. In the assessment of the documents, the competent higher federal authority may utilize its own scientific results, call in experts or request expert opinions. The competent higher federal authority may examine authorization-related data and documents in enterprises and facilities which develop, manufacture or test drugs. 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 authorization, the competent higher federal authority is also entitled to have the documents assessed by independent counter-experts and shall apply the results of their evaluation in deciding on the marketing authorization and, in so far as drugs which are subject to mandatory prescription under section 49 are concerned, as a basis for the draft of the marketing authorization decision which is to be submitted to the marketing authorization commission pursuant to sub-section 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 shall be permitted to peruse the expert opinions. If the applicant requires that experts be called in
which he himself selects, these persons shall also be heard. Sub-section 6 sentences 5 and 6 shall apply *mutatis mutandis* for the appointment of experts and counter-experts.

(5a) Furthermore, the competent higher federal authority shall draw up an assessment report upon request by the holder of the marketing authorization or of the applicant unless such a report has already been drawn up by the competent authority of another Member State; the assessment report shall be updated upon request if new information which has a bearing on the assessment of the quality, safety or efficacy of the drug in question becomes available.

(5b) If the drug has already been granted a marketing authorization by a Member State of the European Union said marketing authorization shall be recognized on the basis of the assessment report transmitted by that Member State unless there is reason to assume that the authorization of the drug could constitute a danger for public health, in the case of drugs intended for administration to animals, a danger to the health of human beings, animals or the environment. In this exceptional case, the competent higher federal authority shall, in compliance with Article 10 paragraph 1 of Council Directive 75/319/EEC or with Article 18 of Council Directive 81/851/EEC, refer the matter to the Commission for Proprietary Medicinal Products or for Veterinary Medicines. Sub-section 6 shall not apply.

(5c) The provisions contained in Chapter III of Council Directive 75/319/EEC, or in the case of veterinary drugs those contained in Chapter IV of Council Directive 81/851/EEC shall apply with respect to the recognition of the marketing authorization of another Member State. Where a procedure pursuant to Article 37b of Council Directive 75/319/EEC or Article 42k of Council Directive 81/851/EEC has been conducted within the framework of an application for the recognition of a marketing authorization, the decision on the authorization shall be taken in compliance with the decision taken by the Commission of the European Communities or of the Council pursuant to said articles. No preliminary procedure pursuant to section 68 of the Rules of the Administrative Courts shall be held in the event of an appeal against decisions of the competent higher federal authority pursuant to sentence 2. Furthermore, sub-section 6 shall not apply.

(5d) If an application for a marketing authorization submitted after 1st January 1995 is already being examined by another Member State of the European Union, or if that state’s evaluation report is not available, the competent higher federal authority shall be entitled to suspend the authorization procedure until such time as the assessment report of the Member
State in question becomes available. In the case of an application for a marketing authoriza-
tion made after 1\textsuperscript{st} January 1998, the suspension must be effected if the marketing authoriza-
tion has been granted by the other Member State.

(5e) Sub-sections 5a to 5d shall not apply to drugs which have been manufactured ac-
cording to homeopathic manufacturing procedures.

(6) Prior to the decision on the marketing authorization of a drug subject to prescription
pursuant to section 49, a marketing authorization commission shall be consulted. The hearing
shall cover the contents of the documents presented, the expertises, the expert opinions re-
quested, 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 authorization or the as-
essment of the counter-experts. Should the federal higher authority diverge from the result of
the hearing in deciding on the application, it shall set forth its reasons for doing so. The Fed-
eral Ministry shall appoint the members of the marketing authorization commission on the pro-
posal of the chambers of the medical professions, the professional societies of medical practi-
tioners, dentists, veterinarians, pharmacists, alternative medical practitioners as well as those
of pharmaceutical entrepreneurs. In appointing the commission's members, consideration
shall be given to the individual peculiarities of the drugs. The experts to be appointed to the
marketing authorization commission shall be persons who possess scientific knowledge and
have gained practical experience in the specific fields of application as well as in the school of
therapy in question (phytotherapy, homeopathy, anthroposophy).

(7) For drugs not subject to prescription pursuant to section 49, commissions shall be
set up for specific fields of application or schools of therapy at the competent higher federal
authority. Sub-section 6 sentences 4 to 6 shall apply \textit{mutatis mutandis}. In preparing the deci-
sion regarding the extension of marketing authorizations pursuant to section 105 sub-section
3 sentence 1, the competent higher federal authority may involve the competent commission.
If the decision pursuant to sentence 3 affects drugs from a specific school of therapy (phyto-
therapy, homeopathy, anthroposophy), the competent commission shall be involved if the in-
tention is to refuse the extension pursuant to section 105 sub-section 3 sentence 1 totally, or if
the decision is of fundamental importance; the competent commission shall be afforded a pe-
riod of two months in which to respond. In cases where the competent higher federal authority
does not take the opinion of the commission into account in making its decision under sen-
tence 4, it shall set forth its reasons for not doing so.
(8) In the case of sera, vaccines, blood products and test allergens, the competent higher federal authority shall grant the marketing authorization either on the basis of an examination of the documents submitted or based on its own tests or on the basis of the 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 an inspection both of the said premises and of the company's transport facilities. At the request of the competent higher federal authority, the applicant shall give particulars of the manufacturing process. Sub-sections 6 and 7 shall not apply to these drugs.

(8a) Sub-section 8 sentences 1 to 3 shall apply mutatis mutandis to the examination of the residue test procedures pursuant to section 23 sub-section 1 No. 2 and to test methods pursuant to section 23 sub-section 2 sentence 3.

(9) If various pharmaceutical forms of a drug are authorized for marketing under an identical name or if various concentrations of a drug of the same pharmaceutical form are authorized for marketing, then a uniform marketing authorization number shall be used, to which additional marks shall be added to differentiate between the pharmaceutical forms or concentrations.

(10) The marketing authorization shall be without prejudice to the pharmaceutical entrepreneur's penal or civil liability.

**Section 25a**

**Prior examination**

(1) The competent higher federal authority shall have the application for a marketing authorization examined by independent experts to determine whether it is complete and whether the drug has been sufficiently tested according to the current recognized state of scientific knowledge. Section 25 sub-section 6 sentence 5 shall apply mutatis mutandis.

(2) Should defects within the meaning of sub-section 1 be identified, the expert shall grant the applicant an opportunity to remedy such defects within a period of three months.

(3) If, on the basis of the final opinion delivered by the expert, the application for a marketing authorization continues to be incomplete or defective within the meaning of section
25 sub-section 2 No. 2 after the deadline has passed, the marketing authorization shall not be granted. Section 25 sub-sections 4 and 6 shall not apply to the prior examination.

Section 26
Guidelines for the testing of drugs

(1) After consultation with experts from the fields of medical and pharmaceutical science and practice and with the approval of the Bundesrat, the Federal Ministry shall issue general administrative regulations on the requirements set by the competent higher federal authority for the analytical and pharmacological-toxicological test and for the clinical investigation as well as for the residue test, the test method which can be applied in a routine manner as well as the residue test procedures and shall promulgate them as guidelines for the testing of drugs in the Federal Journal of Official Publications (Bundesanzeiger). The regulations have to comply with the prevailing state of scientific knowledge and are to be continually adjusted to it; animal experiments, in particular, shall 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. They shall be issued, in so far as radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used are concerned and, in so far as tests for ecotoxicity are concerned, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and, in so far as drugs intended for administration to animals are concerned, in agreement with the Federal Ministry for Food, Agriculture and Forestry. Section 25 sub-section 6 sentences 4 and 5 shall apply accordingly in respect of the appointment of the experts.

(2) The competent higher federal authority and the commissions specified in section 25 sub-section 7 shall apply the Guidelines for the Testing of Drugs analogously to the documents on scientific findings specified in section 22 sub-section 3 and section 23 sub-section 3 sentence 2, whereby consideration shall be given to the peculiarities of the individual drug. Documents on empirical medical findings prepared in accordance with scientific methods shall also be deemed to be documents on scientific findings.

(3) The competent higher federal authority shall publish, in the Federal Journal of Official Publications, a list of those drugs for which bioavailability tests are deemed necessary. The list shall be updated to bring it in line with the prevailing state of scientific knowledge.

Section 27
Deadlines for the granting of marketing authorizations

(1) The competent higher federal authority shall reach its decision on the application for marketing authorization within a period of seven months. The decision on the recognition of a marketing authorization shall 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 remedy the defects pursuant to section 25 sub-section 4, then the deadline shall be interrupted until the defects are remedied or until the deadline set pursuant to section 25 sub-section 4 has expired. The interruption shall commence on the day on which the applicant is served with the request to remedy the defects. The same shall apply to the deadline granted to the applicant, at his request, for the purpose of giving his opinion, including the calling in of experts as well as in the case of a suspension pursuant to section 25 sub-section 5d.

Section 28
Authority to impose conditions

(1) The competent higher federal authority may combine the marketing authorization with the imposition of conditions. In the case of conditions imposed pursuant to sub-sections 2 to 3c for the protection of the environment, the competent higher federal authority shall decide in agreement with the Federal Environmental Agency when the impact on the environment needs to be evaluated. For this purpose, the competent higher federal authority shall transmit 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 sub-section 1 may be imposed in order to ensure that:

1. the labelling of the containers and outer packages complies with the regulations laid down in section 10; in this connection it may be prescribed that the following details shall be given:
   a) instructions or warnings, in so far as they are necessary to prevent a direct or indirect health hazard to human beings or animals by administration of the drug,
b) keeping instructions for the consumer and storage instructions for experts, in so far as they are deemed necessary in order to maintain the required drug 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 shall be given:

a) the instructions or warnings mentioned in No. 1 letter a) and

b) keeping instructions for the consumer, in so far as they are deemed necessary in order to maintain the required drug quality,

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

a) the instructions or warnings mentioned in No. 1 letter a),

b) particular storage and keeping instructions, in so far as they are deemed necessary to maintain the required drug quality,

c) references to conditions pursuant to sub-section 3,

3. the details given pursuant to sections 10, 11 and 11a comply with the documents submitted for the marketing authorization and that, in this connection, standardized and generally comprehensible terms as well as a standardized wording are used whereby the provision of information regarding additional contra-indications, side-effects and interactions remains admissible; the competent higher federal authorities may generally make use of this authority for reasons of drug safety, transparency or to ensure a rational method of working; in this connection, provisions may be imposed prescribing that certain fields of application be omitted in respect of prescription-only drugs, if there is reason to fear that by giving such details, the therapeutic aim will be jeopardized,

4. the drug is marketed in package sizes appropriate to the fields of application and the envisaged duration of administration,

5. the drug is marketed in a container of a particular form with a specific seal or some other kind of safety measure, in so far 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 sub-section 2 can also be stipulated so as to ensure that the drug 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 drug appears to be completely safe only in the presence of special knowledge or special therapeutic facilities.

(3) Furthermore, the competent higher federal authority may impose conditions prescribing that additional analytical and pharmaceutical-toxicological tests or clinical investigations are to be carried out and a report be submitted on the results, if there is sufficient indication that the drug can have a high therapeutic value and that, therefore, it is in the public interest to have the drug introduced onto the market forthwith, even though further important details are still required to facilitate a comprehensive assessment of the same. Sentence 1 shall apply mutatis mutandis to documents on the residue test procedure pursuant to section 23 sub-section 1 No. 2.

(3a) The competent higher federal authority may, if it is deemed to be necessary in the interest of drug safety, impose conditions prescribing, in addition, that findings resulting from the administration of the drug be systematically collected, documented and evaluated subsequent to the granting of the marketing authorization and that a report be submitted to it on the results of this investigation within a specific period of time.

(3b) In the case of conditions pursuant to sub-sections 3 and 3a, the competent higher federal authority may specify the nature and scope of the investigation or tests to be conducted. The results are to be proven by means of documents in such a way that the latter clearly show the nature, scope and date of the investigation or tests.

(3c) Furthermore, the competent higher federal authority may impose conditions prescribing that in the manufacture and control of such drugs and their starting materials which 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, in so far as this is deemed necessary to ensure adequate quality or to prevent risks. The conditions imposed shall be immediately enforceable. The lodging of an objection or action to rescind shall have no suspensive effect.

(3d) Furthermore, the competent higher federal authority may, in the case of drugs intended for administration to food-producing animals and containing a pharmacologically active constituent listed in Annex III of Council Regulation (EEC) No. 2377/90, impose conditions prescribing that documents pursuant to § 23 paragraph 1 No. 2 be submitted within the period for which the preliminary maximum residue limit has been fixed as long as there is no indication that residues from the substance in question pose a danger to human health.

(4) Should the marketing authorization be subject to a condition, the deadline envisaged in section 27 sub-section 1 shall be interrupted until the deadline granted to the applicant for comment has expired. Section 27 sub-section 2 shall apply mutatis mutandis.

Section 29
Obligation to notify, renewal of the marketing authorization

(1) Submitting supporting documents, the applicant shall notify the competent higher federal authority forthwith of any changes occurring in the particulars and documents supplied pursuant to sections 22 to 24. He shall furthermore inform the competent higher federal authority immediately, or at the latest within 15 days of it coming to his knowledge, of any case of serious suspected side effects or interactions with other products which have become known to him, as well as frequent abuse or individual cases of substantial abuse, if this can directly jeopardize human or animal health. He shall keep a record of all suspicious cases other than serious side effects or interactions with other substances of which he is informed by a member of a health profession. In so far as no condition has been imposed to the contrary, he shall transmit these records to the competent higher federal authority forthwith upon request or at least every six months during the first two years following the granting of the marketing authorization, and once a year in the following three years. Thereafter, he shall submit the documents every five years along with the application for an extension of the marketing authorization or immediately upon request by the competent higher federal authority. All existing documents which are necessary to be able to assess suspect cases or cases of ob-
served abuse as well as a scientific evaluation thereof shall be submitted to the competent higher federal authority. Once the marketing authorization has been granted, the pharmaceutical entrepreneur shall be responsible for meeting the obligation contained in sentences 2 to 5; this obligation shall continue to exist regardless of whether the drug is still on the market. Sentences 2 to 6 apply correspondingly to any person who conducts a clinical investigation of drugs or has such an investigation conducted.

(2) In the case of a change in the name of the drug, the marketing authorization notice shall be amended accordingly. A pharmaceutical entrepreneur may place the drug 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 1st January or 1st July after the promulgation of the change in the Federal Journal of Official Publications.

(2a) A change

1. in the information pursuant to sections 10, 11 and 11a bearing on the dosage, nature and duration of the administration, the fields of application, if it does not concern an addition or modification of an indication which is to be classified under another area of therapy, a limitation of the contra-indications, side-effects or interactions with other substances, in so far as drugs which are excluded from trade outside of pharmacies are concerned,

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

3. in a pharmaceutical form which is comparable with the one authorized for marketing,

3a. in treatment with ionizing radiation,

4. in the manufacturing and test procedures or the indication of longer shelf-life for sera, vaccines, preparations derived from blood, test allergens, test sera and test antigens as well as any change in manufacturing procedures using genetic engineering technology, and

5. in the package size,

may only be made if the competent higher federal authority has granted its approval. The approval shall be deemed to be granted if no objection has been filed to the change within a period of three months.
(3) In the following cases an application shall be made for renewal of the marketing authorization for a drug:

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

2. in the case of a change in the pharmaceutical form unless a change pursuant to sub-section 2a No. 3 is concerned,

3. in the case of an extension of the fields of application, as long as this does not constitute a change pursuant to sub-section 2a No. 1,

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

4. (deleted)

5. in the case of a reduction of the withdrawal period.

The competent higher federal authority shall decide on the obligation to obtain a marketing authorization pursuant to sentence 1.

(4) Sub-sections 1, 2, 2a and 3 shall not be applicable to drugs which have been granted a marketing authorization by the Commission of the European Communities or the Council of the European Union. For such drugs the obligations of the pharmaceutical entrepreneur shall be those stipulated in Council Regulation (EEC) No. 2309/93 as well as his obligations pursuant to Regulation (EC) No. 540/95 of the Commission of the European Communities or of the Council of the European Union laying down the arrangements for reporting suspected unexpected adverse reactions which are not serious, whether arising in the Community or in a third country, to medicinal products for human or veterinary use authorized in accordance with the provisions of Council Regulation (EEC) No. 2309/93 (OJ EC No. L 55, p. 5) on condition that, within the purview of the present Law, an obligation on the part of the relevant competent higher federal authority to notify or to inform the Member States exists.

(5) Sub-sections 2a and 3 shall not apply as long as Commission Regulation (EC) No. 541/95 of 10th March 1995 concerning the examination of variations to the terms of a market-
Section 30
Withdrawal, revocation, suspension

(1) A marketing authorization shall be withdrawn if it becomes subsequently known that one of the grounds for refusal of marketing authorizations as defined in section 25 sub-section 2 Nos. 2, 3, 5, 5a, 6 or 7 existed at the time of issuance; the marketing authorization shall be revoked, if one of the grounds for refusal as specified in section 25 sub-section 2 Nos. 3, 5, 5a, 6 or 7 has subsequently developed. The marketing authorization shall furthermore be withdrawn or revoked, if

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

2. in the cases referred to in section 28 sub-section 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 drug. In the cases referred to in sentence 1, the suspension of the marketing authorization may also be ordered for a limited period of time.

(1a) Furthermore, the authorization may be partially or completely withdrawn or revoked if necessary to comply with a decision adopted by the Commission of the European Communities or the Council of the European Union pursuant to Article 37b of Directive 75/319/EEC or pursuant to Article 42k of Directive 81/851/EEC. No preliminary procedure pursuant to section 68 of the Rules of the Administrative Courts shall be held in the event of an appeal against decisions by the competent higher federal authority pursuant to sentence 1. In the cases covered by sentence 1, the suspension of the authorization may also be ordered on a temporary basis.

(2) The competent higher federal authority may

1. withdraw the marketing authorization if incorrect or incomplete information is given in the documents specified in sections 22, 23 or 24 or if one of the grounds for the refusal of a marketing authorization, as defined in section 25 sub-section 2 Nos. 6a, 6b or 6c existed at the time when it was granted,
2. revoke the marketing authorization, if one of the grounds for refusal as defined in section 25 sub-section 2 Nos. 2, 6a, 6b or 6c has subsequently developed or if one of the conditions imposed pursuant to section 28 has not been met and the defect has not been remedied within a reasonable period of time which is to be specified by the competent higher federal authority,

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

In these cases, the suspension of the marketing authorization may also be ordered for a limited period of time.

(3) Before a decision is reached pursuant to sub-sections 1 and 2, the holder of the marketing authorization shall be heard, unless danger is imminent. In the cases set forth in section 25 sub-section 2 No. 5, the decision can be implemented immediately. The lodging of an objection or action to rescind shall have no suspensive effect.

(4) If the marketing authorization of a drug has been withdrawn or revoked or if the marketing authorization has been suspended, the drug

1. shall not be placed on the market and

2. shall not be introduced into the purview of the present Law.

It shall be permitted to return the drug, appropriately marked, to the pharmaceutical entrepreneur. The competent authority may order the return of a drug.
Section 31

Expiry

(1) The marketing authorization shall expire

1. (deleted)

2. by written renouncement,

3. after the completion of a period of five years as from the date of its granting, unless an application for prolongation is filed at the latest three months prior to the expiry of the period.

3a. in the case of a drug intended for administration to food-producing animals, and which contains an active ingredient which is listed in Annex IV of Council Regulation (EEC) No. 2377/90, at the end of a period of 60 days following its publication in the Official Journal of the European Communities unless, within this deadline, the areas of application with respect to food-producing animals have been waived pursuant to section 29 sub-section 1; in the case of a notification of changes pursuant to section 29 sub-section 2a, the aim of which is to remove the active ingredient in question, the 60-day deadline shall be interrupted until the decision by the competent higher federal authority or until the expiry of the deadline pursuant to section 29 sub-section 2a sentence 2 and the authorization shall be suspended for this period of time after the 60-day deadline has expired; the half-sentences 1 and 2 shall apply mutatis mutandis in so far as Regulation (EC) No. 541/95 is applicable as regards the alteration of the drug,

4. if the prolongation of the marketing authorization is refused.

(2) The application for prolongation shall be supplemented by a report giving details of whether and to what extent the criteria by which the drug is assessed, have altered within the previous five years. In respect of drugs intended for administration to food-producing animals, the competent higher federal authority may furthermore demand that the report comprise details of experience gained in the residue test procedure.

(3) Upon application as specified in sub-section 2 sentence 1, the marketing authorization shall be prolonged for a further five years within the three months prior to its expiry on
condition that none of the grounds for refusal as specified in section 25 sub-section 2 Nos. 3, 5, 5a, 6, 6a, 6b, 6c, 7 or 8 exist, that the marketing authorization is not to be withdrawn or revoked pursuant to section 30 sub-section 1 sentence 2 and that no use is to be made of the possibility of withdrawal pursuant to section 30 sub-section 2 No. 1 or of revocation pursuant to section 30 sub-section 2 No. 2. Section 25 sub-section 5a shall apply *mutatis mutandis*. In respect of the decision regarding prolongation, it shall be verified whether findings exist which could influence the subordination of the drug to the prescription requirement.

(4) If the marketing authorization expires pursuant to sub-section 1 Nos. 2 or 3, the drug may be marketed for a further two years, commencing on the 1\textsuperscript{st} January or 1\textsuperscript{st} July following the promulgation of the expiry pursuant to section 34. This shall not apply if the competent higher federal authority ascertains that a condition for the withdrawal or the revocation of the marketing authorization as defined in section 30 existed; section 30 sub-section 4 shall apply.

**Section 32**

**Official batch testing**

(1) A batch of a serum, a vaccine or a test allergen may only be marketed, without prejudice to the marketing authorization, if it has been released by the competent higher federal authority. The batch shall 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 shall also be released if the competent authority of another Member State of the European Communities has decided, on the basis of an experimental investigation, that the prerequisites stated in sentence 2 are met.

(1a) The competent higher federal authority shall reach a decision pursuant to sub-section 1 within two months of receipt of the batch sample to be tested. Section 27 sub-section 2 shall apply *mutatis mutandis*.

(2) The Federal Ministry shall issue general administrative regulations on the requirements to be set by the federal higher authority for methods of manufacture and control, as defined in sub-section 1, following consultation with experts from the fields of medical and pharmaceutical science and practice and shall promulgate them as Guidelines for the Testing
of Drugs in the Federal Journal of Official Publications. The regulations must comply with the prevailing standard of scientific knowledge and are to be continually adjusted to it.

(3) Section 25 sub-section 8 and section 22 sub-section 7 sentence 2 shall apply mutatis mutandis to the execution of the official batch testing.

(4) Release, pursuant to sub-section 1 sentence 1, shall not be necessary if the drugs specified therein are exempted by ordinance according to section 35 sub-section 1 No. 4 or by the competent higher federal authority; the competent higher federal authority shall grant an exemption if the manufacturing and test methods of the manufacturer have reached a level of development which guarantees the quality, efficacy and safety required.

(5) The release as defined in sub-section 1 or the exemption by the competent higher federal authority as defined in sub-section 4 shall be withdrawn if one of their conditions has not been fulfilled; it shall be revoked if one of the conditions is subsequently no longer fulfilled.

Section 33
Costs

(1) The competent higher federal authority shall levy charges (fees and expenses) for the decisions reached on marketing authorizations, batch releases, as well as other official acts including independent consulting and information services in so far as these do not consist of oral information and simple written information within the meaning of section 7 sub-section 1 of the Administrative Costs Act, in compliance with the present Law and pursuant to Commission Regulation (EC) No. 541/95 of 10th March 1995.

(2) The Federal Ministry shall be empowered to determine, in agreement with the Federal Ministry for Economics, by ordinance not subject to the approval of the Bundesrat, which elements are liable to a fee and to establish fixed rates or rate schedules in the process. The amount of fees payable for the decisions on the marketing authorizations, batch releases, as well as other official acts shall be determined in each case according to the expenditure for personnel and material, including in particular the costs for the marketing authorization procedure in the case of sera, vaccines and test allergens and also the expenditure for the tests and for the development of appropriate testing procedures. The amount of fee payable for the decision in respect of a batch release shall be determined by the average costs for personnel and material, whereby the expenditure for tests made previously shall not be taken into ac-
count; in addition, appropriate consideration shall be given to the significance, the economic value or other benefit derived from the release by the party liable to pay the fee.

(3) The Law on Administration Costs shall apply.

(4) Costs shall not be payable for the protest procedure with respect to any administrative act performed by the competent higher federal authority on the basis of the present Law. The expenses of the persons involved shall not be reimbursed.

Section 34
Promulgation

(1) The competent higher federal authority shall promulgate the following in the Federal Journal of Official Publications:

1. the granting and prolongation of a marketing authorization,

2. the withdrawal of a marketing authorization,

3. the revocation of a marketing authorization,

4. the suspension of a marketing authorization,

5. the expiry of a marketing authorization,

6. the ascertainment pursuant to section 31 sub-section 4 sentence 2,

7. the change in the name pursuant to section 29 sub-section 2,

8. the withdrawal or revocation of the release of a batch pursuant to section 32 sub-section 5.

Sentence 1 Nos. 1 to 5 and No. 7 shall apply mutatis mutandis to decisions adopted by the Commission of the European Communities or by the Council of the European Union.
(2) The competent higher federal authority may promulgate an administrative act executed on the basis of the present Law in the Federal Journal of Official Publications if more than 50 addressees are affected. Two weeks after publication of the administrative act in the Federal Journal of Official Publications, the act shall be 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 sub-section 1 of the Law on Administrative Procedures may also be published in the Federal Journal of Official Publications if more than 50 addressees are affected. Sentence 2 shall apply mutatis mutandis.

Section 35

Empowerments in respect of marketing authorization and exemptions

(1) The Federal Ministry shall be empowered by ordinance having the force of law, subject to the approval of the Bundesrat:

1. to settle further details regarding the procedures in respect of the marketing authorization, official batch testing and release of a batch, as well as the alteration of marketing authorization documents; in the process, it may decide on the number of copies of documents to be submitted, in addition to determining whether copies are to be forwarded to the competent authorities, and may stipulate that documents be submitted on electronic or optical storage media or permit this to be done,

2. to extend the provisions on the marketing authorization to other drugs, in so far as it is deemed necessary to prevent direct or indirect hazards to human or animal health,

3. to extend the provisions on the release of a batch and on official batch testing to other drugs which are subject to variation in their composition or in their content of active principles, in so far as it is deemed necessary to prevent direct or indirect hazards to human or animal health,

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

(2) The ordinances, as specified in sub-section 1 Nos. 2 to 4, shall be issued in agreement with the Federal Ministry for Economics and, in the case of radiopharmaceuticals and
drugs in the manufacture of which ionizing radiation is used, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and, in the case of drugs intended for administration to animals, in consultation with the Federal Ministry for Food, Agriculture and Forestry.
Section 36
Empowerment in respect of standard marketing authorizations

(1) The Federal Ministry shall be empowered to exempt by ordinance, subject to the approval of the Bundesrat and subsequent to consultation with experts, certain drugs or groups of drugs or drugs presented in particular pharmaceutical forms from the obligation to obtain a marketing authorization, in so far as no direct or indirect danger to human or animal health is to be feared, since it is evident that the requirements with regard to the necessary quality, efficacy and safety have been met. For the sake of the protection of human or animal 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, fields or ranges of application. It is admissible for the pharmaceutical entrepreneur to provide information regarding additional contraindications, side-effects and interactions.

(2) In selecting the drugs to be exempted from the obligation to apply for a marketing authorization, account must be taken of the legitimate interests of the drug consumer, the health professions and the pharmaceutical industry. The pharmaceutical entrepreneur is free to choose the name of the drug.

(3) The ordinance as specified in sub-section 1 shall be promulgated in agreement with the Federal Ministry for Economics and, in the case of radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used, in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and, in the case of drugs intended for administration to animals, in agreement with the Federal Ministry for Food, Agriculture and Forestry.

(4) In cases where it is necessary to make immediate changes to information regarding contra-indications, side-effects and interactions and, on condition that the validity of the ordinance having the force of law does not exceed a maximum period of one year, the hearing of experts and the approval of the Bundesrat shall not be necessary prior to the promulgation of an ordinance pursuant to sub-section 1. The deadline may be prolonged once for a further year if the procedure pursuant to sub-section 1 cannot be completed within the one-year period.
Section 37
Authorization from the Commission of the European Communities or the Council of the European Union for the placing of drugs on the market and marketing authorizations for drugs from other countries

(1) The marketing authorization issued by the Commission of the European Communities or the Council of the European Union pursuant to Council Regulation (EEC) 2309/93 shall rank equally with a marketing authorization issued pursuant to section 25 in so far as the provisions of sections 11a, 21 paragraph 2a, sections 42, 56, 56a, 58, 59, 67, 69, 73, 84 or 94 are geared to a marketing authorization. The marketing authorization issued for a drug by another country shall be considered a valid marketing authorization as defined in section 21, in so far as this is stipulated by ordinance from the Federal Ministry.

(2) The Federal Ministry shall be empowered to issue an ordinance pursuant to subsection 1, which shall not be subject to the approval of the Bundesrat, in order to implement a directive of the Council of the European Communities or in so far as the marketing authorization of drugs is mutually recognized in international treaties as being of equivalent value.

FIFTH CHAPTER
REGISTRATION OF HOMEOPATHIC DRUGS

Section 38
Obligation to have a drug registered and documents required for registration

(1) Finished drugs which are drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1 may only be placed on the market as homeopathic drugs within the purview of the present Law, if they have been entered into the Register for Homeopathic Drugs kept by the competent higher federal authority (registration). A marketing authorization shall not be necessary; section 21 sub-section 1 sentence 2 and sub-section 3 shall apply accordingly. A registration is not required for drugs which are marketed by a pharmaceutical entrepreneur in amounts of up to 1,000 packages per year, unless these are drugs:

1. which contain preparations made from substances pursuant to section 3 Nos. 3 or 4,
2. which contain more than the one-hundredth part of the smallest dose used in non-
homeopathic drugs which are subject to prescription pursuant to section 48 or section 49
or,

3. in which the conditions contained in section 39 paragraph 2 Nos. 3, 4, 5, 6, 7 or 9 are
   present.

(2) The particulars, documents and expert opinions specified in sections 22 to 24 shall
be enclosed with the application for registration. This shall not apply to the particulars on the
effects and fields of application nor to the documents and expert opinions on the pharmaceu-
tical-toxicological tests and clinical investigations.

Section 39
Decision on the drug registration

(1) The competent higher federal authority shall register the homeopathic drug and in-
form the applicant in writing as to the registration number. Section 25 sub-section 5 sentence
5 shall apply mutatis mutandis. The registration shall only be valid for the homeopathic drug
and its degrees of dilution as specified in the notice of registration. The competent higher fed-
eral authority may connect the registration notice with the imposition of conditions. Conditions
may also be imposed subsequently. Section 28 sub-sections 2 and 4 shall apply.

(2) The competent higher federal authority shall refuse registration if

1. the documents submitted are incomplete,

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

3. the drug does not possess the appropriate quality according to acknowledged pharma-
ceutical principles,

4. there is good reason to suspect that, if used in keeping with its designated purpose, the
drug has harmful effects which exceed the bounds considered justifiable in the light of the
knowledge available to medical science,
4a. the drug is intended for administration to food-producing animals,

5. the withdrawal period given is insufficient,

5a. the drug, in so far as it is intended for administration to human beings, is intended neither for oral administration nor for external use,

6. the drug is subject to prescription,

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

7a. the use of the drug as a homeopathic or anthroposophic drug is not generally known,

8. a marketing authorization has been granted for the drug,

9. the marketing of the drug or its use on animals would violate legal regulations or the provisions contained in Council Regulation (EEC) No. 2377/90.

(2a) If the drug has already been registered in a Member State of the European Communities 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 sub-section 2 is present.

(2b) The registration shall expire five years after it has been issued unless an application for prolongation is submitted three to six months before the deadline expires. Section 31 sub-sections 2 to 4 shall apply mutatis mutandis to the prolongation of the registration provided that the grounds for refusal pursuant to sub-section 2 Nos. 3 to 9 apply.

(3) The Federal Ministry shall be empowered to issue provisions by ordinance, subject to the approval of the Bundesrat, on the obligation to notify, on renewed registration, cancellation, costs, promulgation and exemption from registration of homeopathic drugs in compliance with the provisions on marketing authorization. The ordinance shall be issued in agreement with the Federal Ministry for Food, Agriculture and Forestry in so far as drugs intended for administration to animals are concerned. Section 36 paragraph 4 shall apply mutatis mutandis to the amendment of an ordinance on the exemption from registration.

SIXTH CHAPTER
PROTECTION OF HUMAN BEINGS DURING CLINICAL INVESTIGATIONS

Section 40
General preconditions

(1) The clinical investigation of a drug shall only be performed on human beings if and as long as

1. the risks, which are involved for the person on whom the investigation is to be carried out, are medically justifiable when compared with the anticipated significance of the drug for medical science,

2. the person, on whom the clinical investigation is to be carried out, has given his or her consent, having been informed by a physician of the nature, significance and scope of the clinical investigation and with this consent has, at the same time, declared that he or she consents to the recording of disease-related data which takes place within the framework of the clinical investigation, to the transmission of such data for verification to the person commissioning the clinical investigation (sponsor), to the competent control authority, to the competent higher federal authority and, in so far as personal data is involved, to the examination of such data by persons commissioned by the sponsor or by the authorities concerned,

3. the person, on whom the investigation is to be carried out, has not been committed to an institution by virtue of an order issued either by judicial or administrative authorities,

4. it is run under the supervision of a physician who can prove at least two years’ experience in the field of the clinical investigation of drugs,

5. an appropriate pharmacological-toxicological test has been carried out which is in compliance with the prevailing standard of scientific knowledge,

6. the documents on the pharmacological-toxicological test, the investigation protocol reflecting the prevailing standard of scientific knowledge and indicating the names of the investigators and the investigation sites as well as the opinion of the ethics committee responsible for the principal investigator, have been submitted to the competent higher federal authority,
7. the person directing the clinical investigation has been informed by a scientist responsible for the pharmacological-toxicological test about the findings of said test and the risks to be anticipated with the clinical investigation, and

8. in the event that a person is killed or a person's body or health is injured or impaired in the course of the clinical investigation, an insurance policy which also provides benefits when no one else accepts liability for the damage, exists in accordance with the provisions contained in sub-section 3.

The clinical investigation of a drug on human beings may only be commenced subject to sentence 3, if an independent ethics committee established under Land legislation has issued a favourable opinion; the prerequisite for a favourable opinion is the observance of the regulations contained in sentence 1 Nos. 1 to 5, No. 6, in so far as the documents regarding the pharmacological and toxicological tests and the investigational protocol are concerned, as well as those contained in Nos. 7 and 8. Where no favourable opinion has been delivered by the ethics committee, the clinical investigation may be commenced only if the competent higher federal authority has not delivered a decision to the contrary within 60 days following receipt of the documents referred to in sentence 1 No. 6. The ethics committee shall be informed of all serious or unexpected undesirable events which occur during the clinical investigation and which could compromise the safety of the participants or the conduct of the investigation itself.

(2) A declaration of consent as specified in sub-section 1 No. 2 shall only be valid if the person granting it

1. has legal capacity and is in a position to comprehend the nature, significance and scope of the clinical investigation and to form a rational intention in the light of these facts,

2. has granted consent in person and in writing.

The declaration of consent may be revoked at any time.

(3) The insurance specified in sub-section 1 No. 8 must be taken out in favour of the person undergoing the clinical investigation with an insurance carrier authorized to conduct business within the purview of the present Law. Its size must be commensurate with the risks involved in the clinical investigation and must amount to a minimum of one million deutsche
marks to cover the risk of death or permanent disability. In so far as benefits are paid by the insurance, all claims to damages shall be extinguished.

(4) In respect of a clinical investigation carried out on minors, sub-sections 1 to 3 shall apply with the following proviso:

1. The drugs must be intended to diagnose or prevent diseases in minors.

2. The administration of the drug must be indicated in accordance with medical knowledge for the purpose of diagnosing or preventing diseases in the minor.

3. Clinical investigations performed on adults cannot be expected to produce satisfactory test results according to medical knowledge.

4. The consent shall be granted by the minor’s legal representative. It shall only be valid if this person has been informed by a physician on the nature, significance and scope of the clinical investigation. If the minor is in a position to comprehend the nature, significance and scope of the clinical investigation and to form a rational intention in the light of these facts, then his written consent shall also be required.

(5) The Federal Ministry is hereby empowered to stipulate by ordinance, with the approval of the Bundesrat, provisions to guarantee the proper conduct of clinical investigations and the production of documents which comply with the prevailing standard of scientific knowledge. The ordinance may cover, in particular, further details regarding the tasks and areas of responsibility of the persons commissioning, conducting or supervising the clinical investigation, as well as requirements regarding the keeping and preservation of records. Furthermore, the ordinance may also authorize the compilation, processing and use of personal data in so far as this is necessary for the conduct and supervision of the clinical investigation. This also applies to the processing of data which are not processed or used in the form of computer files.
Section 41
Special preconditions

The conduct of clinical investigations on persons suffering from a disease in the cure of which the drug under investigation is intended to be used is subject to section 40 sub-sections 1 to 3 under the following proviso:

1. The clinical investigation may only be conducted if the use of the drug under investigation is indicated according to the findings of medical science in order to save the patient's life, to restore him or her to health or to alleviate his or her suffering.

2. The clinical investigation may also be performed on a person who is legally incapacitated or whose legal capacity is limited.

3. Should a legally incapacitated person or a person of limited legal capacity be in the position to comprehend the nature, significance and scope of the clinical investigation and to determine his/her will in the light of these facts, the clinical investigation shall necessitate, in addition to the consent of this person, the consent of his/her legal representative.

4. Should the sick person be incapable of comprehending the nature, significance and scope of the clinical investigation and of determining his/her will accordingly, then the consent of his legal representative shall suffice.

5. The consent of the legal representative or guardian shall only be valid if this person has been informed by a physician about the nature, significance and scope of the clinical investigation. In the event that consent is revoked, section 40 sub-section 2 sentence 2 shall apply. The consent of the legal representative shall not be required as long as immediate treatment is necessary in order to save the patient's life, to restore his health or to alleviate his suffering and a declaration of consent cannot be produced.

6. If the sick person is not able to give his or her consent in writing, the declaration of consent shall also be valid if it is delivered orally to the physician in charge of the treatment in the presence of a witness.

7. The informed consent of the patient may be dispensed with in very serious cases where informing him or her might jeopardize the success of the treatment referred to in number 1 and where it cannot be ascertained that this would be contrary to the patient's will.
Section 42

Exceptions

Sections 40 and 41 shall not apply to drugs within the meaning of section 2 sub-section 2 No. 4. Section 40 sub-section 1 Nos. 5 and 6 shall not apply to clinical investigations involving drugs for which a marketing authorization has been granted or drugs which are exempted from the obligation to obtain a marketing authorization.

SEVENTH CHAPTER

DRUG SUPPLY

Section 43

Obligation to dispense drugs in pharmacies only, marketing of drugs by veterinarians

(1) Drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1, which 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 sub-section 1 may, except for the cases provided for in section 47, be marketed professionally or commercially to the consumer exclusively in pharmacies and not by mail-order. With the exception of the cases provided for in sub-section 4 and section 47 sub-section 1, no trade may be conducted outside of pharmacies with those drugs reserved exclusively for sale in pharmacies pursuant to sentence 1.

(2) Drugs reserved, in compliance with sub-section 1 sentence 1, for trade in pharmacies, may not be dispensed by artificial persons, non-incorporated associations and companies established under civil law and under commercial law to their members, unless these members are either pharmacies themselves or are persons and establishments as defined in section 47 sub-section 1 and the dispensing of drugs is carried out under the conditions specified therein.

(3) Drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1 may only be dispensed in pharmacies upon prescription. This shall be without prejudice to section 56 sub-section 1.

(4) Drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1 may furthermore be dispensed by veterinarians to the keepers of animals undergoing treatment
and may be held in stock for this purpose. This shall also apply to the dispensing of drugs, deemed advisable by veterinarians and supervised by them, for the purpose of implementing measures to prevent illness in animals whereby the amount dispensed may not exceed the amount needed according to veterinarian indication.

(5) Drugs intended for administration to animals and which are not released for trade outside of pharmacies, may only be dispensed to the animal owner or to other persons not mentioned in section 47 sub-section 1 in pharmacies or in the veterinarian's house dispensary or by the veterinarian. This shall not apply to medicated feeding stuffs.

Section 44

Exceptions to the obligation to dispense drugs in pharmacies only

(1) Drugs which 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 shall be released for trade outside of pharmacies.

(2) Furthermore, the following shall be released for trade outside of pharmacies:

1. a) natural curative waters as well as their salts, also as tablets or pastilles,

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

2. therapeutic clays, mud for mud baths and other peloids, preparations for the manufacture 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 drugs,

   c) distillates made from plants and parts of plants,

   d) juices pressed from fresh plants and parts of plants in so far as they are prepared without the use of any solvents other than water,
4. (deleted)

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

(3) Sub-sections 1 and 2 shall not apply to drugs which

1. may only be dispensed upon a medical, dental or veterinarian prescription or

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

Section 45
Empowerment in respect of further exceptions to the obligation to dispense drugs in pharmacies only

(1) The Federal Ministry shall be empowered to release, in agreement with the Federal Ministry of Economics and upon consultation with experts, by ordinance, subject to the approval of the Bundesrat, preparations made from substances or objects which 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. in so far as they may not only be dispensed upon a medical, dental or veterinarian prescription,

2. in so far 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. in so far as a direct or indirect hazard to human or animal health need not be feared as a result of their release or in particular as a result of inappropriate handling or

4. in so far as the proper supply of drugs is not jeopardized by their release.

(2) The release may be limited to finished drugs, certain dosages, fields of application or pharmaceutical forms.
(3) The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used are concerned, and in agreement with the Federal Ministry for Food, Agriculture and Forestry, as far as drugs intended for administration to animals are concerned.

Section 46
Empowerment in respect of extension of the obligation

to dispense drugs in pharmacies only

(1) The Federal Ministry shall be empowered to exclude, in agreement with the Federal Ministry for Economics and upon consultation with experts, by ordinance subject to the approval of the Bundesrat, drugs as defined in section 44 from trade outside of pharmacies, if a direct or indirect hazard to human or animal health is to be feared even when such drugs are used in keeping with their designated purpose or in the customary manner.

(2) The ordinance in compliance with sub-section 1 may be limited to certain dosages, fields of application or pharmaceutical forms.

(3) The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used are concerned, and in agreement with the Federal Ministry for Food, Agriculture and Forestry, as far as drugs intended for administration to animals are concerned.

Section 47
Channel of distribution

(1) Pharmaceutical entrepreneurs and wholesalers may only supply drugs 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 or blood components manufactured using gene technology which, in so far as clotting factor preparations are concerned, are authorized for dispensing by the haemostaseologically qualified physician to his or her patients within the framework of the medically supervised self-treatment of haemophiliacs,

b) human or animal tissue,

c) infusion solutions in containers of at least 500 ml intended for the replacement or the correction of body fluid, as well as solutions for haemodialysis and transperitoneal dialysis,

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

e) medical gasses which are licensed for distribution to alternative medical practitioners,

f) radiopharmaceuticals or

g) drugs which are labelled "Zur klinischen Prüfung bestimmt" (for clinical investigation), in so far as they are furnished free of charge,

3. hospitals, public health offices and physicians, as far as vaccines intended for administration free of charge within the framework of a vaccination campaign pursuant to section 20 sub-sections 5, 6 or 7 of the Federal Protection against Infection Act of 20th July 2000 (Federal Law Gazette I, p. 1045) are concerned or in so far as a supply of vaccines is necessitated to prevent the spread of a communicable disease or to protect lives,

3a. recognized vaccination centres as far as yellow fever vaccines are concerned,

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

5. central drug purchasing agencies, established on a statutory basis or approved by the competent authority in consultation with the Federal Ministry,
6. veterinarians, for administration to animals undergoing treatment by them and for dispensing to the keepers of those animals,

7. persons entitled to practise dentistry, as far as finished drugs are concerned, which are used exclusively in the field of dentistry and in the treatment of patients,

8. research and scientific institutions which have been granted an authorization pursuant to section 3 of the German Law on Narcotic Drugs (Betäubungsmittelgesetz) entitling them to purchase the drug in question,

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

(1a) Pharmaceutical entrepreneurs and wholesalers may only supply drugs intended for administration to animals to the recipients specified in sub-section 1 No. 1 or 6 if the latter have submitted a certification by the competent authority stating that they have fulfilled their obligation to notify according to section 67.

(1b) Pharmaceutical entrepreneurs and wholesalers shall keep records on the purchase and distribution of prescription-only drugs intended for administration to animals and which are not exclusively intended for administration to animals other than those whose products and meat are intended for human consumption, from which the amount of the purchase with indication of the supplier(s) and the amounts supplied with indication of the recipient(s) can be demonstrated for each of these drugs separately and in chronological order, and shall have to submit these records to the competent authority upon request.

(2) The recipients specified in sub-section 1 Nos. 5 to 9 may only obtain drugs for their own use within the framework of the fulfilment of their duties. The central purchasing agencies specified in sub-section 1 No. 5 shall only be officially recognized if evidence is produced that they are run under the professional supervision of a pharmacist or, in so far as drugs intended for administration to animals are concerned, under the professional supervision of a veterinarian, and provided that suitable premises and equipment are available for the testing, control and storing of the drugs.

(3) Pharmaceutical entrepreneurs may supply samples of finished drugs or have samples of finished drugs supplied to

1. physicians, dentists or veterinarians or
other persons practising medicine or dentistry as a profession, provided no prescriptiononly drugs are involved,

3. training centres for health professions.

Pharmaceutical entrepreneurs may supply samples of a finished drug or have samples of a finished drug supplied to training centres for health professions only in the amounts required for the purpose of training. Samples may not contain any of the substances or preparations referred to in section 2 of the German Law on Narcotic Drugs or listed as such in Annexes II or III of the German Law on Narcotic Drugs.

(4) Pharmaceutical entrepreneurs may supply samples of a finished drug or have samples of a finished drug supplied to persons pursuant to sub-section 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 drug. Samples shall be accompanied by the relevant expert information in so far as such information is provided for in section 11a. The sample shall particularly serve the purpose of informing the physician about the drug itself. Records shall be kept on the recipients of samples, the kind and extent as well as on the date on which the samples were supplied, under separate cover for each recipient and they shall be submitted to the competent authority upon request.

Section 47a

Special distribution channels, obligation to keep records

(1) Pharmaceutical entrepreneurs may supply drugs which are authorized for the conduct of abortions only to facilities within the meaning of section 13 of the Act on the Assistance to Cope with Conflicts in Pregnancy of 27th July 1992 (Federal Law Gazette I, p. 1398) amended by Article 1 of the Act of 21st August 1995 (Federal Law Gazette I, p. 1050) and only on the prescription of one of the doctors administering treatment in said facility. Other persons are not authorized to place the drugs mentioned in sentence 1 on the market.

(2) Pharmaceutical entrepreneurs shall give serial numbers to the packages of the drugs mentioned in paragraph 1 sentence 1 which are intended for delivery; the drugs may not be delivered without this labelling. The pharmaceutical entrepreneur shall keep records of the delivery and both the facility and the attending physician shall keep records of the receipt
and use of said drugs and shall submit them for inspection to the competent authority upon request.

(2a) Both the pharmaceutical entrepreneur and the facility shall store the drugs mentioned in paragraph 1 sentence 1 which are in their possession in a separate place and secure them against unauthorized removal.

(3) Sections 43 and 47 shall not apply to the drugs mentioned in paragraph 1 sentence 1.

Section 48
Prescription requirement

(1) Drugs which, by ordinance issued in compliance with sub-section 2 No. 1, constitute certain substances, preparations made from substances or objects or to which such substances or preparations made from substances have been added, may only be dispensed to the consumer upon presentation of a medical, veterinarian or dental prescription. This shall not apply to dispensing by pharmacies for the equipping of merchant vessels in accordance with the relevant legal regulations in force.

(2) The Federal Ministry shall be empowered, in agreement with the Federal Ministry for Economics and upon consultation with experts, by ordinance subject to the approval of the Bundesrat

1. to identify substances, preparations made from substances or objects

   a) which even when used in keeping with their designated purpose can directly or indirectly jeopardize human or, where they are intended for administration to animals, animal health or the environment, if they are administered without medical, dental or veterinarian supervision or

   b) which are frequently administered in considerable quantity, in a manner which is not in keeping with their designated purpose, if they may thus constitute a source of direct or indirect danger to human or animal health,

2. to stipulate that substances or preparations made from substances may only be distributed if specific maximum quantities are not exceeded in the prescription for the single and
daily dosage or if the fact that such maximum quantities are being exceeded has been explicitly indicated by the prescribing person,

3. to determine that a drug may not be dispensed more than once on one medical prescription or to determine the conditions under which repeated dispensing on one prescription shall be permissible,

3a. to stipulate that a drug may be dispensed only on prescription from physicians with a specific medical speciality for use in facilities authorized to provide treatment using said drug and that records must be kept of the prescription, dispensing and use of the drug,

4. to issue provisions on the form and content of the medical prescription.

(3) The ordinance specified in sub-section 2 No. 1 may be limited to specific dosages, potencies, pharmaceutical forms or fields of application. Similarly, an exception to the prescription requirement may be envisaged for dispensing to midwives and obstetric nurses where this is deemed necessary for the proper exercise of their profession.

(4) The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, in so far as radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used are concerned, and in agreement with the Federal Ministry for Food, Agriculture and Forestry, as far as drugs intended for administration to animals are concerned.

Section 49
Automatic prescription requirement

(1) Drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1 containing substances or preparations made from substances the effects of which are not generally known in the field of medical science shall only be dispensed to the consumer upon presentation of a medical, dental or veterinarian prescription. The same shall apply to drugs which are preparations made from substances, the effects of which are generally known, if the effects of these preparations as a whole are not generally known in the field of medical science, unless the effects can be determined according to the composition, dosage, pharmaceutical form or application field of the preparation.
(2) Sub-section 1 shall not apply to drugs which are preparations from substances, the
effects of which are known, in so far as these substances may be distributed outside of phar-
macies.

(3) The prescription requirement as specified in sub-section 1 shall end on the 1\textsuperscript{st}
January or 1\textsuperscript{st} July following the termination of a five-year-period after the ordinance pursuant
to sub-section 4 has entered into force.

(4) The Federal Ministry shall be empowered, by ordinance not subject to the approval
of the Bundesrat:

1. to specify the substances or preparations referred to in sub-section 1,

2. to make use of the empowerments defined in section 48 sub-section 2 Nos. 2 to 4 and
sub-section 3 for the substances or preparations determined by ordinance pursuant to
No. 1,

3. to cancel the prescription requirement if, after the termination of a period of three years
following the coming into force of an ordinance pursuant to No. 1, by virtue of the experi-
ence made with the administration of the drug, it is clear that the conditions stipulated in
section 48 sub-section 2 No. 1 do not exist.

The ordinance pursuant to sentence 1 shall be issued in agreement with the Federal
Ministry for Food, Agriculture and Forestry, in so far as drugs intended for administration to
animals are concerned.

(5) A renewed specification of substances or preparations pursuant to sub-section 4
No. 1 shall be permissible after expiry of the period of time mentioned in sub-section 3 if their
effects are still not generally known in the field of medical science or if the data available do
not enable an assessment of the preconditions for specifying the substances or preparations
pursuant to section 48 sub-section 2 No. 1.

(6) The pharmaceutical entrepreneur shall be obliged to present a report to the com-
petent higher federal authority on the experience gained with any drug containing a substance
or preparation as specified in sub-section 4 No. 1, and for which a marketing authorization has
been granted by the competent higher federal authority, two years after the drug received its
marketing authorization and, in the case of sub-section 5, two years after the specification of
the substance or the preparation in the ordinance pursuant to sub-section 4 No. 1. This report
shall give details of the quantities distributed during the period under review; furthermore, new findings on effects, type and frequency of side effects, contraindications, interaction with other products, habituation, dependence or a use of the drug not complying with the intended purpose shall be given. In the case of drugs intended for administration to food-producing animals, a report shall also be submitted on the experience gained for example on whether and how often residues have been found in foodstuffs produced from treated animals after administration of the drug, where appropriate, to what it is ascribed and how successful the described residue test procedures have proved to be. In the case of premix drugs, reports must also be submitted on the experience gained, saying how successful the described test method has proved to be for the qualitative and quantitative detection of the active ingredients in medicated feeding stuffs.

Section 50
Retail trade in over-the-counter drugs

(1) The retailing, outside of pharmacies, of drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1 which 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 shall require a person having the necessary expert knowledge for each of the branch premises.

(2) To be considered as possessing the necessary expert knowledge, the person in question shall furnish proof of experience and skill in respect of proper filling, packaging, labelling, storing and marketing of drugs which are released for trade outside of pharmacies as well as knowledge of the existing regulations applicable to these drugs. The Federal Ministry shall be empowered to issue, with the agreement of the Federal Ministry for Economics and the Federal Ministry for Education, Science, Research and Technology and, as far as drugs intended for administration to animals are concerned, in agreement with the Federal Ministry for Food, Agriculture and Forestry, 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 drugs. It may hereby recognize certificates of professional training or of attendance at further education courses. Furthermore, it may stipulate that proof of the expert knowledge shall be 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 as specified in sub-section 1 shall not be required by a person retailing finished drugs which

1. may be distributed in itinerant trading,

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

3. (deleted)

4. are disinfectants intended exclusively for external use, or

5. are oxygen.

6. (deleted)

Section 51
Drug supply in itinerant trading

(1) Itinerant traders shall be prohibited from offering drugs for sale or seeking to procure orders for drugs; exempted from the prohibition shall be finished drugs released for trade outside of pharmacies which

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 specified in the first half-sentence of sub-section 1 shall not apply in so far as the trader visits other persons in the framework of their business activities, unless the trader offers for sale drugs which are intended for administration to animals in agricultural and forestry undertakings, commercial livestock enterprises as well as for use in vegetable, fruit growing and horticultural undertakings, or in wine-growing, bee-keeping and fishery, or seeks to procure, in such undertakings, orders for drugs, the dispensing of which is reserved
solely for pharmacies. The same shall also apply to commercial travellers and other persons
active on behalf of and in the name of a trader.

Section 52
Prohibition of self-service

(1) Drugs as defined in section 2 sub-section 1 or sub-section 2 No. 1 may

1. not be placed on the market by means of vending machines and

2. not be placed on the market using other forms of self-service.

(2) Sub-section 1 shall not apply to finished drugs which

1. may be supplied in itinerant trading,

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

3. (deleted)

4. are disinfectants intended exclusively for external use, or

5. are oxygen.

6. (deleted)

(3) Furthermore, sub-section 1 No. 2 shall not be applicable to drugs released for mar-
teting outside of pharmacies in cases where a person in possession of the expert knowledge
required under section 50 is available.

Section 53
Expert consultation

(1) In so far as expert opinions need to be heard in accordance with section 36 sub-
section 1, section 45 sub-section 1 and section 46 sub-section 1 prior to the issue of ordi-
nances, the Federal Ministry shall establish an expert committee by ordinance not subject to
the approval of the Bundesrat. The committee shall 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) In so far as the opinion of experts needs to be heard in accordance with section 48 sub-section 2 prior to the issue of an ordinance, sub-section 1 shall apply mutatis mutandis, subject to the provision that the committee shall comprise experts from the fields of medical and pharmaceutical science and practice as well as from the pharmaceutical industry.

EIGHTH CHAPTER
QUALITY ASSURANCE AND CONTROL

Section 54
Internal regulations

(1) The Federal Ministry shall be empowered to issue in agreement with the Federal Ministry for Economics, by ordinance subject to the approval of the Bundesrat, internal regulations for companies or establishments which bring drugs or active principles into the purview of the present Law or in which drugs or active principles are developed, manufactured, tested, stored, packaged or marketed, in so far as it is deemed necessary in order to ensure the proper running of the company in question and the required quality of the drugs or active principles. The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety if radiopharmaceuticals or drugs in the manufacture of which ionizing radiation is used are concerned and in agreement with the Federal Ministry for Food, Agriculture and Forestry, if drugs intended for administration to animals are concerned.

(2) In the ordinance pursuant to sub-section 1, regulations may be laid down in particular concerning

1. the development, manufacture, testing, storage, packaging, acquisition and marketing,

2. the maintaining and keeping of records on the company operations mentioned in No. 1,
3. keeping and control of the animals used in the manufacture and testing of drugs and the records kept on them,

4. staffing requirements,

5. nature, size and equipment of the premises,

6. sanitation requirements,

7. nature of the containers,

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

9. stand-by obligation for drug wholesalers,

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

11. labelling, separation or destruction of drugs which are unfit for marketing,

12. exercise of the veterinarian dispensing right (veterinarian's house dispensary), especially on the requirements made in respect of the treatment of animals.

(2a) It can furthermore be stipulated in the ordinance pursuant to sub-section 1, that drug wholesalers shall only be allowed to start the operation of their business after they have been officially recognized; in this connection, it can be envisaged that the official recognition shall only be required for the wholesale trade in certain drugs or groups of drugs. Furthermore, the preconditions for the official recognition may be stipulated in the ordinance; the refusal of recognition can only be envisaged in a case where the facts justify the assumption that the proprietor of the company does not have the required reliability or expert knowledge.

(3) The regulations under sub-sections 1, 2 and 2a shall also apply to persons practising the activities indicated in sub-section 1 professionally.

(4) Sub-sections 1 and 2 shall apply to pharmacies as defined in the Law on Pharmacies, in so far as these shall require an authorization under section 13.
(1) The Pharmacopoeia is a collection of recognized pharmaceutical practice regarding the quality, testing, storage, dispensing and designation of drugs and the substances used in their manufacture, published by the Federal Ministry. The Pharmacopoeia also contains requirements regarding the nature of containers and outer packages.

(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 Federal Ministry with its work within the framework of the Convention on the Elaboration of a European Pharmacopoeia.

(4) The German Pharmacopoeia Commission shall be set up at the Federal Institute for Drugs and Medical Devices. The Federal Ministry shall appoint the members of the German Pharmacopoeia Commission from among experts in the fields of medical and pharmaceutical science, the health professions, the affected business circles and the field of pharmacovigilance proportionally. The Federal Ministry shall appoint the chairperson of the Commission and his or her deputies and shall issue rules of procedure after hearing the Commission.

(5) In principle, the German Pharmacopoeia Commission shall take decisions regarding the rules contained in the Pharmacopoeia unanimously. Decisions taken by three-quarters of the members of the Commission or less shall not be valid. Further details are settled in the rules of procedure.

(6) Sub-sections 2 to 5 shall apply *mutatis mutandis* to the work of the German Homeopathic Pharmacopoeia Commission.

(7) Publication shall take place in the Federal Journal of Official Publications. It can be limited to indicating the source of supply of the version of the Pharmacopoeia in question and the date on which the revised version becomes valid.

(8) Drugs may only be manufactured and placed on the market for distribution to consumers within the purview of the present Law if the substances they contain and their pharmaceutical forms comply with recognized pharmaceutical practice. Furthermore, drugs may be placed on the market for distribution to consumers within the purview of the present Law if the
containers and outer packaging comply with recognized pharmaceutical practice in cases where they come into contact with the drugs. Sentences 1 and 2 shall not apply to drugs within the meaning of section 2 sub-section 2 No. 4 letter a).

Section 55a
Official compilation of test procedures

The competent higher federal authority shall publish an official compilation of test procedures for the sampling and testing of drugs and their starting materials. The procedures shall be established in consultation with experts from the field of pharmacovigilance, scientists and pharmaceutical entrepreneurs. The compilation of procedures shall be kept up to date.

NINTH CHAPTER
SPECIAL REGULATIONS FOR DRUGS INTENDED FOR ADMINISTRATION TO ANIMALS

Section 56
Medicated feeding stuffs

(1) Medicated feeding stuffs may be supplied by the manufacturer directly to the animal owner, by way of derogation from section 47 sub-section 1, but only upon prescription issued by a veterinarian; this shall also apply in cases where the medicated feeding stuffs are manufactured in another Member State of the European Communities or another State Party to the Agreement on the European Economic Area using premix drugs authorized for marketing within the purview of the present Law or such premix drugs as possess the same qualitative and a comparable quantitative composition as premix drugs authorized for marketing within the purview of the present Law, where the other drug-related provisions valid within the purview of the present Law are observed and the medicated feeding stuffs carry an accompanying certificate based on the sample certificate published by the Federal Ministry. Repeated dispensing upon presentation of a single prescription shall not be admissible; section 48 sub-section 2 No. 4 shall apply accordingly.

(2) For the manufacture of medicated feeding stuffs, only premix drugs, authorized for marketing pursuant to section 25 or section 36 sub-section 1 may be used; it is admissible to manufacture medicated feeding stuffs using several premix drugs if an authorized premix drug is not available for the specific field of application. If a veterinarian has medicated feeding stuffs manufactured pursuant to section 13 sub-section 2 No. 3 by another person holding a
licence for manufacturing mixed feed as required by ordinance pursuant to section 9 subsection 1 No. 3 of the Feeding Stuffs Act, he may assign the supervision of the technical aspect of the manufacturing process to this person.

(3) If medicated feeding stuffs are manufactured, the mixed feed used for this purpose shall have to comply with the provisions of the Feeding Stuffs Act before and after the mixing procedure and it may not contain any antibiotic or coccidiostatic agent as a feeding stuff additive which is contained in the premix drug.

(4) Only mixed feed complying with an ordinance in accordance with section 4 subsection 1 of the Feeding Stuffs Act may be used for medicated feeding stuffs. The daily dose of the drug shall be contained in a quantity of mixed feed which covers at least half of the daily feed ration of the animals under treatment and, in the case of cattle and sheep, at least half of the daily supplementary feed requirement with the exception of mineral feed. The mixtures ready for feeding shall be clearly and visibly labelled "Fütterungsarzneimittel" (medicated feeding stuff), and shall comprise particulars about the percentage of the feed requirement, as defined in sentence 2, they are intended to cover.

(5) A veterinarian may only manufacture or have medicated feeding stuffs manufactured

1. if they are intended for administration to animals treated by him,

2. for the fields of application indicated in the package leaflets of premix drugs and

3. in a quantity which, from the point of view of veterinary medicine, is justified in order to achieve the purpose of the treatment.

Section 56a sub-section 2 shall apply accordingly.

Section 56a

Prescription, dispensing and administration of drugs by veterinarians

(1) The veterinarian may only prescribe or dispense drugs intended for administration to animals, which are not released for trade outside of pharmacies, to the animal owner if

1. they are intended for animals treated by him,
2. they have been authorized for marketing or may be marketed without a marketing authorization,

3. according to the marketing authorization, they are intended for administration to the animal species under treatment, and

4. their application, with regard to the field of administration and the quantity, is justified from the point of view of veterinary medicine to achieve the purpose of the treatment.

Sentence 1 Nos. 2 to 4 shall apply accordingly to the administration by the veterinarian.

(2) In the case of individual animals or animals belonging to a specific stock the veterinarian may, by way of derogation from sub-section 1 sentence 1 No. 3, administer drugs which, according to their marketing authorization are not authorized for administration to the specific animal species being treated or the field of application or for administration to animals or have such drugs administered, if a drug authorized for marketing is not available for the treatment of the specific animal species or for the specific field of application, if the medicinal care required by the animals would otherwise be seriously jeopardized, and if there are no grounds to fear direct or indirect risk to human or animal health. However, in the case of food-producing animals, the drug may only be administered by the veterinarian or under his or her supervision and may only contain substances or preparations from substances which are contained in drugs which are authorized for administration to food-producing animals. The veterinarian shall specify the length of the withdrawal period; all further details are regulated in the Veterinarian House Dispensary Ordinance. Sentences 1 to 3 shall apply mutatis mutandis to drugs which are manufactured according to section 21 sub-section 2 No. 4 in conjunction with sub-section 2a. Registered homeopathic medicines or such homeopathic medicines as are exempted from registration, may be prescribed, dispensed and administered, by way of derogation from sub-section 1 sentence 1 No. 3; this shall apply to drugs which are intended for administration to food-producing animals if their degree of dilution does not lie below the sixth decimal potency.

(3) The Federal Ministry shall be empowered to stipulate, in agreement with the Federal Ministry for Food, Agriculture and Forestry, by ordinance subject to the approval of the Bundesrat, that
1. Veterinarians have to keep records on the prescription and administration of drugs not released for trade outside of pharmacies.

2. Specific drugs may only be used by the veterinarian himself if such drugs

   a) are capable of posing a danger to human and animal health, directly or indirectly, even when used in keeping with the intended purpose, if they are used in an unprofessional manner, or

   b) are frequently used in considerable quantities in a manner which is not in keeping with the intended purpose and can therefore constitute a direct or indirect threat to human or animal health.

The ordinance may contain provisions regulating the type, form and content of these records as well as the period for which they must be kept. The obligation to keep records may be restricted to certain drugs, fields of application or forms of administration.

(4) The veterinarian is prohibited, by ordinance pursuant to sub-section 3 sentence 1 No. 2, from prescribing or dispensing certain drugs to animal owners.

Section 57

Acquisition and possession by animal owners, records

(1) The animal owner may only acquire drugs which are not released for trade outside of pharmacies for administration to animals, either in pharmacies or from the veterinarian treating the animals or, in those cases defined in section 56 sub-section 1, from manufacturers. Other persons not defined in section 47 sub-section 1 may acquire such drugs in pharmacies only.

(1a) Animal owners may not have in their possession any drugs which are reserved by ordinance for administration exclusively by the veterinarian himself. This shall not apply if the drug is intended for another purpose other than the administration to animals or if possession is allowed pursuant to Council Directive 96/22/EC of 29th April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of β-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC (OJ EC, No. L 125, p. 3).
(2) The Federal Ministry shall be empowered to stipulate, in agreement with the Federal Ministry for Food, Agriculture and Forestry, by ordinance subject to the approval of the Bundesrat, that

1. enterprises which keep food-producing animals and market these animals or products manufactured from them, and

2. other persons who may acquire drugs, pursuant to sub-section 1, in pharmacies only

shall be required to keep records on the acquisition, the storage and the whereabouts of the drugs as well as a register or records of the application of the drug in so far as this is deemed necessary in order to guarantee the proper utilization of drugs and in so far as enterprises pursuant to No. 1 are concerned, and this is necessary for the implementation of legal acts of the European Communities. The ordinance may contain provisions regulating the type, form and content of these registers and records as well as the period for which they must be kept.

Section 58
Administration to food-producing animals

(1) Animal owners and other persons who are not veterinarians may only administer prescription-only drugs or other drugs prescribed by or purchased from a veterinarian to food-producing animals according to treatment instructions from a veterinarian for the specific case. Drugs not subject to a prescription which are not released for trade outside of pharmacies and which are not administered on the basis of treatment instructions from a veterinarian, may only be administered:

1. if they are authorized for marketing or may be marketed without a marketing authorization,

2. to the animal species and in the fields of application specified in the labelling or package leaflet and

3. in a quantity corresponding to the labelling of the drug as to dosage and duration of administration.
(2) The Federal Ministry shall be empowered, in agreement with the Federal Ministry for Food, Agriculture and Forestry, to prohibit by ordinance subject to the approval of the Bundesrat, drugs intended for administration to food-producing animals from being marketed for particular fields or areas of application or used for these purposes, as long as this is deemed necessary in order to prevent an indirect hazard to human health.

Section 59
Clinical investigation and residue test on food-producing animals

(1) A drug within the meaning of section 2 sub-section 1 or sub-section 2 No. 1 may be administered by the manufacturer or on his behalf, by way of derogation from section 56a sub-section 1, for the purposes of clinical investigations and residue tests, if the application is limited to a test which, in accordance with the currently prevailing level of scientific knowledge is necessary in both type and extent.

(2) No foodstuffs may be obtained from the animals undergoing these tests unless, on the basis of the test findings, neither residues of the drugs administered nor of their metabolic products are expected to be present in the foodstuffs. The manufacturer shall submit, to the competent authority, test results regarding the residues from the drugs used and their metabolic products in foodstuffs, stating the residue test procedures employed.

(3) Where a clinical investigation or residue test is conducted on food-producing animals, the notification required under section 67 sub-section 1 sentence 1 must contain, in addition, the following particulars:

1. name and address of the manufacturer and of the person who is conducting the tests on his behalf,

2. the type and purpose of the test,

3. the species and number of animals envisaged for the tests,

4. the location, date of commencement and envisaged duration of the tests, and

5. particulars on the envisaged use of the animal products which are obtained either during or upon completion of the tests.
(4) Records shall be kept on the tests carried out and shall be presented to the com-
petent authority upon request.

Section 59a
Trade in substances and preparations from substances

(1) Persons, enterprises and establishments mentioned in section 47 sub-section 1
shall not acquire substances or preparations from substances, the use of which in the manu-
facture of drugs for animals is prohibited by ordinance pursuant to section 6, for the purpose
of manufacturing such drugs or for administration to animals, nor shall they offer for sale,
store, package, carry with them or place these substances or preparations made from such
substances on the market for the purpose of such a manufacturing activity or administration.
Animal owners as well as other persons, enterprises and establishments not mentioned in
section 47 sub-section 1 shall not acquire, store, package or carry with them such substances
or preparations, unless they are intended for a manufacturing activity or use not prohibited by
ordinance pursuant to section 6.

(2) Veterinarians may only obtain substances or preparations from substances speci-
fied by ordinance pursuant to section 48 or section 49, and such substances and preparations
may only be distributed to veterinarians, if they have been authorized for marketing as drugs
or if they may be traded without a marketing authorization on the basis of section 21 sub-
section 2 No. 3 or 5 or on the basis of an ordinance pursuant to section 36. Animal owners
may only acquire or store them for administration to animals, if they have been prescribed as
drugs or distributed by a veterinarian. Other persons, enterprises and establishments not
specified in section 47 sub-section 1, shall, by virtue of ordinance pursuant to section 48 or
section 49, not acquire, store, package, carry with them or place certain substances or prepa-
rations from substances on the market, unless the substances or preparations are intended
for a purpose other than the administration to animals.

(3) The foregoing shall be without prejudice to the provisions of the Feeding Stuffs Act.

Section 59b
Residue test procedure

With respect to drugs which are intended for administration to food-producing animals,
the pharmaceutical entrepreneur shall keep stocks of such substances as are to be tested for
by means of the residue test procedure pursuant to section 23 sub-section 1 No. 2 as well as such substances as are necessary for the execution of the residue test procedure if they are not available through normal commercial channels, and shall place these substances at the disposal of the competent authority pursuant to section 64 in sufficient quantities in exchange for an appropriate compensation. In the case of drugs which are no longer being marketed by the pharmaceutical entrepreneur, the provisions contained in sentence 1 shall be valid for a period of three years starting from the last date on which the pharmaceutical entrepreneur markets the drug, but ending at the latest on the expiry date, indicated pursuant to section 10 sub-section 7, of the last batch marketed.

Section 59c

Obligation to keep records for substances which could be used as veterinary drugs

Enterprises and facilities which manufacture, store, import or market substances or preparations from substances which can be used as veterinary drugs or in the manufacture of veterinary drugs and which display anabolic, infection-inhibiting, parasite-repelling, anti-inflammatory, hormonal or psychotropic characteristics, shall keep records on the acquisition or sale of these substances or preparations from substances which indicate the name of the previous supplier or the recipient as well as the amounts received or delivered in each case, shall preserve these records for at least three years and shall submit them, upon request, to the competent authority. Sentence 1 shall also apply to persons who carry out these activities on a professional basis. In the case of substances or preparations from substances with a thy-reostatic, oestrogenic, androgenic or gestagenic effect or ß-agonists with an anabolic effect, these records shall take the form of a register in which the amounts manufactured or purchased as well as the amounts sold or used in the manufacture of drugs are documented in chronological order along with the name of the previous supplier and the recipient.
Section 60

Pet animals

(1) The provisions in section 21 to section 39 and section 50 shall not apply to drugs intended exclusively for administration to aquarium fish, cage or singing birds, carrier-pigeons, animals kept in terrariums or small rodents, and authorized for marketing outside of pharmacies.

(2) The provisions on the manufacture of drugs shall apply on condition that the production manager can at the same time be both control and sales manager and the evidence pertaining to two years' practical experience according to section 15 sub-section 1 is not required.

(3) The Federal Ministry shall be empowered to extend, in agreement with the Federal Ministry for Economics and the Federal Ministry for Food, Agriculture and Forestry, by ordinance subject to the approval of the Bundesrat, the regulations governing marketing authorizations, to drugs used for the animals specified in sub-section 1, in so far as it is deemed advisable in order to prevent either a direct or indirect hazard to human or animal health.

(4) The competent authority may authorize exceptions to section 43 sub-section 5 sentence 1, in so far as the supply of drugs for the animals mentioned in sub-section 1 is concerned.

Section 61

Authority of veterinary schools

Facilities belonging to veterinary schools at university level, which are directed by a veterinarian or pharmacist and involved in dispensing drugs for animals under treatment there, shall have the same rights and obligations as a veterinarian under the regulations of the present Law.
TENTH CHAPTER
OBSERVATION, COMPILATION AND EVALUATION OF DRUG RISKS

Section 62
Organization

In the interests of preventing direct or indirect hazards to human or animal health, it shall be the responsibility of the competent higher federal authority to record centrally and evaluate those risks occurring during the administration of drugs, in particular side effects, interactions with other products, contraindications and adulterations and to co-ordinate the measures to be adopted in accordance with the present Law. For this purpose, the higher federal authority shall act in co-operation with the agencies of the World Health Organization, the drug authorities of other countries, the health and veterinary authorities of the federal Laender, the drug commissions of the chambers of the health professions as well as with others who, in the execution of their work, keep records on drug risks. The competent higher federal authority may inform the public about drug-related risks and envisaged measures.

Section 63
Graduated plan

By means of general administrative regulations subject to the approval of the Bundesrat, the Federal Ministry shall draw up a graduated plan detailing the execution of the tasks indicated in section 62. This plan shall specify the details of the co-operation to take place between the authorities and the services involved at the various danger levels as well as the intervention of the pharmaceutical entrepreneurs and shall stipulate the various measures to be taken in compliance with the provisions of the present Law. In the graduated plan, information means and channels may also be specified.

Section 63a
Commissioner for the graduated plan

(1) Anyone who, in his capacity as a pharmaceutical entrepreneur, markets finished drugs which are drugs under the terms of section 2 sub-section 1 or sub-section 2 No. 1, shall commission a person having the required expert knowledge and the reliability necessary for exercising his/her function (commissioner for the graduated plan), to collect and evaluate notifications on drug risks that have become known and co-ordinate the necessary measures.
Sentence 1 shall not apply to persons who do not require a manufacturing authorization pursuant to section 13 sub-section 2 sentence 1 Nos. 1, 2, 3 or 5. The commissioner for the graduated plan shall be responsible for meeting the obligations to notify in so far as they concern drug risks. Further particulars shall be settled by the Ordinance on Internal Regulations for Pharmaceutical Entrepreneurs. Persons other than those specified in sentence 1 shall not be authorized to perform the duties of the commissioner for the graduated plan.

(2) Proof of the required expert knowledge on the part of the commissioner for the graduated plan shall be furnished either by a certificate proving the successful completion of an examination taken at the end of university studies in human medicine, human biology, veterinary medicine or pharmacy in addition to professional experience of at least two years, or by the proof provided for in section 15. The commissioner for the graduated plan may be production manager, control manager or sales manager at the same time.

(3) The pharmaceutical entrepreneur shall have to inform the competent authority about the identity the commissioner for the graduated plan and present the proof that the requirements pursuant to sub-section 2 have been met and shall give notice of any change beforehand. In the case of an unforeseen change in the person of the commissioner for the graduated plan, notice shall be given immediately.

ELEVENTH CHAPTER
SUPERVISION

Section 64
Execution of supervision

(1) Companies and establishments in which drugs are manufactured, tested, stored, packaged or marketed or in which any other form of trade with them takes place shall be subject to supervision by the competent authority; the same shall apply to companies and establishments which develop drugs, subject them to clinical investigations, residue tests or acquire or administer drugs pursuant to section 47a paragraph 1 sentence 1 or drugs intended for administration to animals. The development, manufacture, testing, storage, packaging or the marketing of active principles shall be subject to supervision in so far as they are regulated by an ordinance pursuant to section 54. Sentence 1 shall also apply to persons carrying out these activities professionally or carrying with them drugs not exclusively intended for personal use as well as to persons or associations collecting drugs for others.
(2) Persons in charge of supervision shall carry out this activity as their main profession. The competent authority may call in experts. In so far as blood preparations, radiopharmaceuticals, drugs produced using genetic engineering, sera, vaccines, test allergens, test sera and test antigens are concerned, the competent authority shall summon members of the competent higher federal authority to participate as experts. With regard to pharmacies which are not hospital pharmacies or which do not require an authorization in compliance with section 13, the competent authority may commission experts to carry out the supervision.

(3) The competent authority shall satisfy itself that the provisions on the trade in drugs, on advertising in the field of medicine and on pharmacies are observed. As a rule, the competent authority shall carry out inspections every two years and have drug samples tested officially.

(4) The persons in charge of the supervision shall be authorized

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 in which the activities referred to in sub-section 1 are carried out; the fundamental right to the inviolability of the home (Article 13 of the Basic Law) shall be limited in this regard,

2. to review documentation on the development, manufacture, testing, clinical investigation or residue testing, acquisition, storing, packaging, marketing and other whereabouts of the drugs as well as on the advertising material currently in circulation and on the liability coverage required in accordance with section 94 and, in so far as personal data from patients are not concerned, to make copies or photocopies of such documentation,

3. to demand from natural and artificial persons and associations without legal capacity all the necessary information, in particular on the company operations mentioned in No. 2,

4. to issue provisional orders also on the closing of the company or establishment, in so far 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 the present Law or of ordinances issued on the basis of the present Law or Council Regulation (EEC) No. 2309/93, experts from the
Member States of the European Union may exercise the powers contained in sub-section 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 sub-section 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 shall be empowered, to issue, by ordinance subject to the approval of the Bundesrat, regulations governing the fulfilment of supervising tasks in cases where drugs are imported into the territory governed by the present Law, by a pharmaceutical entrepreneur who has no registered place of business in the territory governed by the present Law, in so far as necessary for the implementation of the provisions governing the trade in drugs as well as advertising in the field of medicine. In the process, the main responsibility for supervisory tasks which arise out of the introduction of a drug 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 drugs, on advertising in the field of medicine and on pharmacies, those persons in charge of supervision shall be authorized to demand or to take samples of their own selection, against receipt, for the purposes of testing them. This authorization shall also extend to the taking of samples from living animals including the necessary interventions on these animals for this purpose. In so far as the pharmaceutical entrepreneur does not explicitly waive his 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 shall be left behind.

(2) The samples left behind shall be officially closed or sealed. They shall be marked with the date on which the sample was taken and the date after which the closing or sealing of the sample may be considered as cancelled.
(3) For samples which are not drawn from the pharmaceutical enterprise, an appropriate compensation shall be paid if this right is not explicitly waived.

(4) Eligible for appointment as a private expert for the testing of samples left behind pursuant to sub-section 1 sentence 2 shall only be a person who

1. has the expert knowledge pursuant to section 15. The practical experience pursuant to section 15 sub-sections 1 and 4 can be replaced by practical experience in the control and assessment of drugs in drug control laboratories or in other similar drug 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 drugs.

Section 66
Obligation to tolerate and collaborate

The party subject to supervision in compliance with section 64 sub-section 1 shall be 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 obligation shall apply to the production manager, control manager, sales manager, commissioner for the graduated plan, information officer and the person responsible for the clinical investigation as well as to their deputies.

Section 67
General obligation to notify

(1) Companies and establishments which develop or manufacture drugs, subject drugs to clinical investigations or to residue tests, test, store, package, market them or are otherwise engaged in the trade with drugs shall accordingly notify the competent authorities before taking up these activities. The development of drugs shall be notified in so far as it is settled by a regulation pursuant to section 54. The same shall apply to persons practising these activities
on a self-employed and professional basis as well as to persons or associations who collect drugs for others. The notification shall state the type of activity and the factory site; if drugs are collected, details shall be given on the type of collection made and the place of storage. If, according to sentence 1, notification is to be given of a clinical investigation, the person responsible shall also be designated by name. Sentences 1 to 4 shall apply mutatis mutandis to factories and facilities which manufacture, market or otherwise trade in active principles, in so far as these activities are regulated by an ordinance pursuant to section 54.

(2) If drug manufacture is envisaged, for which an authorization defined in section 13 is not necessary, the drugs shall be specified by name and composition.

(3) Notification shall likewise be given of subsequent changes.

(4) Except for the obligation to notify clinical investigations, sub-sections 1 to 3 shall not apply to those persons holding an authorization under section 13 or section 72 nor to pharmacists in accordance with the Law on Pharmacies. Sub-section 2 shall not apply to veterinarians’ house dispensaries.

(5) A person who, in his/her capacity as a pharmaceutical entrepreneur, markets a drug which, pursuant to section 36 sub-section 1, is exempted from the obligation to obtain a marketing authorization and not authorized for trade outside pharmacies, shall notify the competent higher federal authority of this immediately. The notification shall include the name used for the drug and the non-active ingredients used in so far as they are not specified in the ordinance pursuant to section 36 sub-section 1.

(6) The pharmaceutical entrepreneur shall immediately give notice to the federal panel doctors’ association as well as to the competent higher federal authority of tests which serve the purpose of gathering knowledge on the application of authorized or registered drugs.

Section 67a
Database-supported information system

(1) The federal and Land authorities responsible for the implementation of the present Law shall collaborate with the German Institute for Medical Documentation and Information (DIMDI) to set up a central drug information system which can be used jointly. This information system shall collate all of the important data necessary for the fulfilment of the specific tasks
affecting more than one authority. DIMDI shall set up this information system on the basis of the data supplied to it by the competent higher federal authorities pursuant to the ordinance issued in accordance with sub-section 3 and shall be responsible for its operation. Data from the information system shall be transmitted to the competent higher federal authority for the fulfilment of the tasks assigned to them by law. Transmission to other agencies shall be permissible in so far as this is provided for in the ordinance issued pursuant to sub-section 3. DIMDI shall charge fees for its services in accordance with the ordinance issued pursuant to sub-section 3.

(2) DIMDI may also provide access to generally available databases which have some connection with drugs.

(3) The Federal Ministry shall be empowered to grant, in agreement with the Federal Ministry of the Interior and the Federal Ministry of Economics, by ordinance subject to the approval of the Bundesrat, the power to process and utilize data for the purposes defined in sub-sections 1 and 2 and to collect data for the purposes contained in sub-section 2, and to issue regulations governing the transmission of data by federal and Land authorities to DIMDI, including personal data, for the purposes regulated by the present Law, as well as the type and scope of such data and the requirements to be placed thereon. The ordinance in question may also contain provisions stipulating that notifications may or must be made on electronic or optical storage media, in so far as required for the proper implementation of the regulations governing the trade in drugs. Furthermore, this ordinance may also contain provisions specifying the fees for services rendered by DIMDI.

(4) The ordinance pursuant to sub-section 3 shall be promulgated in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety in the case of radiopharmaceuticals or drugs in the manufacture of which ionizing radiation is used, and in agreement with the Federal Ministry for Food, Agriculture and Forestry where drugs intended for administration to animals are concerned.

(5) DIMDI shall take the necessary measures to ensure that the data are transmitted only to authorized persons and that only such persons receive access to them.
Section 68
Obligation to inform and to report

(1) The federal and Land authorities and agencies responsible for the implementation of the present Law shall

1. inform each other of the authorities, agencies and experts responsible for the enforcement of the law and,

2. in instances of contravention and suspected contravention of the provisions of the drug legislation for the individual sphere of responsibility, report to each other immediately and support each other in the investigative activities.

(2) The authorities specified in sub-section 1

1. shall furnish the competent authority of another Member State of the European Union, upon reasonable request, with information and shall transmit to it the necessary certificates and documents in so far as necessary to monitor compliance with the drug-related regulations in force,

2. shall investigate all of the facts of which it is informed by the requesting authority of another Member State and shall inform said authority of the results of the investigation.

(3) The authorities specified in sub-section 1 shall provide the competent authorities of another Member State with all of the information which is necessary to monitor compliance with the drug-related regulations in force in that Member State. In cases of infringement or suspected infringement, the competent authorities of other Member States, the Federal Ministry and the Commission of the European Communities may also be informed.

(4) The authorities specified in sub-section 1 may, if required for the implementation of requirements stipulated in drug-related legislation, also inform the competent authorities of other states. States Parties to the Agreement on the European Economic Area which are not Member States of the European Union shall be informed through the Commission of the European Communities.

(5) Communication with the competent authorities of other Member States and with the Commission of the European Union shall be the prerogative of the Federal Ministry. It may
transfer this power to the competent higher federal authority or, by means of an ordinance with the consent of the Bundesrat, to the competent higher authorities of the Laender. Furthermore, in individual cases, it 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 authorized to transfer the powers specified in sentences 2 and 3 to other authorities.

(6) In the cases provided for in sub-section 3 sentence 2 and sub-section 4, personal data shall not be transmitted if so doing will have an adverse effect on interests of the affected person which are worthy of protection especially if, on the side of the recipient, an adequate standard of data protection is not guaranteed. Personal data may be transmitted, even if the recipient cannot guarantee an adequate standard of data protection, if necessary for reasons of health protection.

Section 69
Measures to be taken by the competent authorities

(1) The competent authorities shall issue the necessary directives to rectify any offences which have been identified and to prevent offences in the future. They may, in particular, prohibit the marketing of drugs and order their withdrawal from the market and seize them if

1. the required marketing authorization or registration of the drug has not been submitted or if their suspension has been ordered,

2. the drug does not possess the appropriate quality in keeping with acknowledged pharmaceutical principles,

3. the drug is lacking in therapeutic efficacy,

4. there is reason to suspect that, when used in keeping with its designated purpose, the drug has harmful effects which 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 authorization required for the manufacture of the drug or the introduction into the pur-
view of the present Law has not been granted or a reason for the complete withdrawal or
the revocation of the permit in accordance with section 18 sub-section 1 exists.

In the case described in sentence 2 No. 4, the competent higher federal authority may
order a drug to be recalled from the market if its actions are in connection with measures pur-
suant to section 28, section 30, section 31 sub-section 4 sentence 2 or section 32 sub-section
5 to prevent risks posed by drugs to human and animal health.

(1a) In the case of drugs for which a marketing authorization or an authorization has
been issued

1. pursuant to Council Regulation (EEC) No. 2309/93, or

2. within the framework of the recognition procedure pursuant to Chapter III of Directive
75/319/EEC or Chapter IV of Directive 81/851/EEC, or

3. on the basis of an expert opinion of the Committee provided for in Article 4 of Directive
87/22/EEC of 22nd December 1986 prior to 1st January 1995,

the competent higher federal authority shall inform the Committee on Proprietary Medicinal
Products or the Committee on Veterinary Medicinal Products about any observed violation of
the drug-related regulations, in accordance with the procedures envisaged by the above-
mentioned legal acts, submitting at the same time detailed grounds and details of the pro-
posed procedure. In the case of these drugs, the competent authorities may take the meas-
ures necessary to eliminate observed violations and to prevent future violations before in-
forming the Committee, in so far as these are urgently needed to guarantee the protection of
human or animal health or the protection of the environment. The competent authorities shall
inform the Commission of the European Communities and the other Member States 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 sub-section 1 sentence 2 No. 4, the
competent higher federal authority can also order the recall of a drug if such action is urgently
needed to ensure the protection of the legal rights mentioned in sentence 2; in such a case
sentence 3 shall apply mutatis mutandis.

(2) The competent authorities may prohibit the collection of drugs if suitable storage of
the drugs is not guaranteed or if there is reason to suspect that the drugs collected will be
used improperly. Collected drugs may be seized if, as a result of inappropriate storage or through their distribution, human and animal health will be endangered.

(2a) The competent authorities may furthermore seize drugs intended for administration to animals as well as substances and preparations from substances within the meaning of section 59a if facts justify the assumption that provisions on the trade with drugs have not been observed.

(3) The competent authorities may seize advertising material which fails to comply with the regulations governing the trade in drugs and advertising in the field of medicine.

(4) In the case of sub-section 1 sentence 3, the competent higher federal authority may also issue a public warning.

Section 69a
The monitoring of substances which can be used as veterinary medicines

Sections 64 to 69 shall apply mutatis mutandis to the enterprises, facilities and persons specified in section 59c as well as to the enterprises, facilities and persons who manufacture, store, import or market substances listed in Annex IV of Council Regulation (EEC) No. 2377/90.

TWELFTH CHAPTER
SPECIAL PROVISIONS WITH REGARD TO THE FEDERAL ARMED FORCES, THE FEDERAL BORDER GUARD, THE RIOT POLICE AND CIVIL PROTECTION

Section 70
Application and enforcement of the law

(1) The provisions of the present Law shall apply mutatis mutandis to the establishments which serve to meet the drug supply of the Federal Armed Forces, the Federal Border Guard and the Riot Police of the Laender as well as to the storage of drugs for civil protection purposes.

(2) In the sphere of the Federal Armed Forces, the execution of the present Law in respect of the supervision of the trade in drugs shall be incumbent upon the competent agen-
cies and experts of the Federal Armed Forces. In the sphere of the Federal Border Guard, it shall be incumbent upon the competent agencies and experts of the Federal Border Guard. With regard to the stock-keeping of drugs for civil protection, it shall be incumbent on the agencies designated by the Federal Ministry of the Interior; in so far as offices of the individual Laender are designated, the approval of the Bundesrat shall be required.

Section 71
Exceptions

(1) The indication of the expiry date stipulated in section 10 sub-section 1 No. 9 is not necessary in the case of drugs which are supplied to the Federal Armed Forces, the Federal Border Guard, as well as to the Federal Government and the Laender for the purpose of civil protection and disaster control. The competent Federal Ministries or, in cases where drugs are supplied to the Laender, the competent Land authorities shall ensure that quality, efficacy and safety are also guaranteed with respect to these drugs.

(2) The Federal Ministry shall be empowered to permit, by means of ordinance, exceptions from the regulations contained in the present Law and the ordinances issued by virtue of the present Law for the sphere of the Federal Armed Forces, the Federal Border Guard, the Riot Police of the Laender and the Civil Protection and Disaster Control Service, in so far as this is justified in the execution of the specific duties in these areas and in so far as the protection of human or animal health continues to be guaranteed.

(3) The ordinance shall be issued, in so far as it concerns the Federal Armed Forces, in agreement with the Federal Ministry of Defence and, in so far as it concerns the Federal Border Guard and civil protection, in agreement with the Federal Ministry of the Interior without, in either instance, the approval of the Bundesrat; in so far as the ordinance concerns the Riot Police of the individual federal Laender or the Disaster Control Service, it shall be issued in agreement with the Federal Ministry of the Interior and subject to the approval of the Bundesrat.
THIRTEENTH CHAPTER
IMPORT AND EXPORT

Section 72
Import authorization

A party wishing to bring finished drugs within the meaning of section 2 sub-section 1 or
sub-section 2 No. 1, test sera, test antigens or active principles which are of human or animal
origin or are produced using genetic engineering on a commercial or professional basis into
the purview of the present Law from countries which are not Member States of the European
Communities or other States Parties to the Agreement on the European Economic Area for
the purpose of supplying others, shall require an authorization by the competent authorities.
Section 13 sub-section 1 sentence 2 and sub-section 4 and sections 14 to 20 shall apply muta-
tatis mutandis, it being understood that the control manager can at the same time be the pro-
duction manager.

Section 72a
Certificates

(1) The importer may only introduce drugs within the meaning of section 2 sub-sections
1 and 2 Nos. 1, 1a, 2 and 4 letter a), or active principles, from countries which are not Member
States of the European Communities or other States Parties to the Agreement on the Euro-
pean Economic Area into the purview of the present Law, if

1. the competent authority of the manufacturing country has confirmed by certificate that the
drugs or active principles are being manufactured in compliance with the requirements of
the recognized Good Practices in the Manufacture and Quality Control of Drugs espe-
cially those adopted by the European Communities, the World Health Organization or the
Pharmaceutical Inspection Convention, and on condition that such certificates as refer to
drugs within the meaning of section 2 sub-sections 1 and 2 No. 1, which are intended for
administration to human beings, and active principles which are of human or animal origin
or are manufactured using gene technology are mutually recognized,

2. the competent authority has certified that the afore-mentioned requirements have been
adhered to in manufacturing the drugs and the active principles used in their manufacture
in so far as they are of human or animal origin or are manufactured using gene technology, or in the manufacture of the active principles, or

3. the competent authority has certified that the import is in the interests of the general public.

The competent authority may only issue a document of certification as specified in No. 2 if no certificate pursuant to No. 1 exists and the competent authority has satisfied itself regularly in the country of manufacture that the above-mentioned requirements are being observed in manufacturing the drugs or the active principles. The document of certification as specified in No. 3 may only be issued if no certificate pursuant to No. 1 exists and the granting of a certification as specified in No. 2 is not envisaged or not possible. Drugs and active principles which are or contain blood preparations, shall not be imported on the basis of sentence 1 No. 3. Sentence 1 shall be applicable to the import of active principles in so far as their supervision is regulated by means of an ordinance having the force of law pursuant to section 54.

(2) The Federal Ministry shall be empowered by ordinance subject to the approval of the Bundesrat to mandate that active principles or drugs which are blood or blood preparations, may not be imported from certain countries which are not Member States of the European Communities or other States Parties to the Agreement on the European Economic Area, in so far as this is necessary to prevent hazards to human health or for the purpose of taking precautions against risks.

Section 73
Prohibition of introduction

(1) Drugs which are subject to compulsory marketing authorization or registration may only be introduced into the purview of the present Law, with the exception of duty-free zones other than the island of Helgoland, if they are authorized for marketing or registered within the purview of the present Law or if they have been exempted from the obligation to obtain the marketing authorization or registration and if

1. in the case of introduction from a member country of the European Communities 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
2. in the case of introduction from a country which is not a Member State of the European Communities or another State Party to the Agreement on the European Economic Area, the recipient is the holder of an authorization as specified in section 72.

The drugs specified in section 47a sub-section 1 sentence 1 shall only be introduced into the purview of the present Law if the recipient is one of the facilities mentioned there.

(1a) Medicated feeding stuffs may only be introduced into the purview of the present Law if

1. they comply with the drug-related provisions in force within the purview of the present Law, and

2. the recipient belongs to the group of persons mentioned in sub-section 1, or is an animal owner in the case of section 56 sub-section 1 sentence 1.

(2) Sub-section 1 sentence 1 shall not apply to drugs which

1. are intended, in individual cases and in small amounts, for the supply of particular animals with drugs at animal shows, tournaments or similar events,

2. are intended for scientific and research establishments' own requirements and needed for scientific purposes,

2a. are needed in small quantities by a pharmaceutical entrepreneur as samples for inspection or for analysis purposes,

3. are conveyed under customs control through the purview of the present Law or are re-exported after transit storage in customs depots or bonded warehouses,

4. are introduced for the head of state of a foreign country or for his escort and are intended for use during his stay within the purview of the present Law,

5. are intended for the personal use or consumption of members of diplomatic missions or consular representations within the purview of the present Law or of officials of international organizations located there or of their family members, in so far as these persons
are neither German nor have their permanent residence within the purview of the present Law,

6. are introduced when entering into the purview of the present Law in an amount corresponding to the normal personal requirement,

6a. may be marketed in the country of origin and are purchased, without a commercial or professional intermediary, in a quantity which corresponds to the amount needed for normal personal use in a Member State of the European Communities 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 authorization or for official batch testing,

10. are procured by federal or Land authorities in interstate commerce.

(3) By way of derogation from sub-section 1 sentence 1, finished drugs which are not authorized for marketing or registered for trade within the purview of the present Law or which are not exempted from the obligation to obtain a marketing authorization or registration, may be introduced into the purview of the present Law if they are authorized for marketing in the State from which they are being introduced into the purview of the present law and have been ordered by pharmacies. Pharmacies may only obtain such drugs in small quantities and upon the specific order of individual persons and may only distribute them within the scope of the normal operation of the pharmacy and, in so far as the drugs are not from Member States of the European Communities or other States Parties to the Agreement on the European Economic Area, only on the basis of a prescription from a doctor, dentist or veterinarian; more detailed particulars shall be settled by the Pharmacies’ Operation Regulations. Sentence 1 shall not apply to drugs intended for administration to food-producing animals; the competent authority may authorize exceptions to this provision if a drug authorized for marketing is not available for the treatment of the specific animal species or for the specific field of application, if the necessary medical care required by the animals would otherwise be seriously jeopard-
ized, and if no direct or indirect risk to human or animal health need be feared, and if the drug has been authorized for marketing in a Member State of the European Communities or in another State Party to the Agreement on the European Economic Area for the treatment of food-producing animals. Sentences 1 to 3 shall apply mutatis mutandis to the ordering of drugs by veterinarians for animals being treated by them.

(4) The provisions of the present Law shall not be applicable to drugs pursuant to sub-sections 2 and 3 sentences 1 and 2, with the exception of sections 5 and 8 and furthermore in the cases referred to in sub-section 2 No. 2 and sub-section 3 sentences 1 and 2 and also with the exception of sections 40, 41, 48, 49, 95 sub-section 1 No. 1 sub-sections 2 to 4 section 96 Nos. 2, 3, 10 and 11 and section 97 sub-section 1 sub-section 2 Nos. 1 and 9 and sub-section 3.

(5) When exercising their profession in local border traffic, physicians and veterinarians may only carry drugs with them which have been authorized for marketing or registered within the purview of the present Law or which are exempted from the obligation to obtain a marketing authorization or registration. By way of derogation from sentence 1, veterinarians who render services as nationals of a Member State of the European Communities or of another State Party to the Agreement on the European Economic Area, may carry with them small amounts of drugs which are authorized for marketing in the place where they are established in a quantity which is necessary for the performance of the services and in their original packaging if and in so far as drugs with the same composition and intended for the same fields of application are also authorized for marketing within the purview of the present Law; the veterinarian may only administer these drugs himself and shall inform the animal owner of the withdrawal period specified for the corresponding drug authorized for marketing within the purview of the present Law.

(6) In the case of sub-section 1 No. 2, as well as sub-section 1a No. 2, in conjunction with sub-section 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 drug and confirming that the requirements specified in sub-section 1 or sub-section 1a have been met, shall be necessary for customs clearance for free circulation. The customs office shall forward the certificate to the authorities which issued it, at the expense of the party paying the customs duties.

(7) In the case of sub-section 1 No. 1, a recipient who is a wholesaler or who runs a pharmacy shall prove the existence of the coverage provision pursuant to section 94.
Section 73a

Export

(1) By way of derogation from sections 5 and 8 sub-section 1, the drugs referred to there may be exported if the competent authority of the country of destination has authorized the import of such drugs. The import authorization must state that the competent authority of the country of destination is cognisant of the grounds for refusal which prevent the marketing of said drugs within the purview of the present Law.

(2) At the request of the pharmaceutical entrepreneur or the competent authority of the country of destination, the competent authority shall issue a certificate corresponding to the World Health Organization's Certification Scheme. 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 him shall participate in the control of the introduction of drugs and active principles into the purview of the present Law 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. inform the competent administrative authorities of suspected violations of prohibitions and restrictions of the present Law or of the ordinances issued in accordance with the present Law, if this suspicion becomes evident during customs clearance,

3. issue instructions to the effect that, in instances defined in No. 2, consignments of the type named in sentence 1 be presented to a competent drug supervision authority at the cost and at the risk of the person holding the right of disposal of the consignment.

(2) The Federal Ministry for Finance shall settle the details of the procedure indicated in sub-section 1, in agreement with the Federal Ministry, by ordinance not subject to the ap-
proval of the Bundesrat. In particular, it may thereby envisage obligations to notify, register, submit information and provide assistance services, as well as to tolerate the inspection of business papers and other documents and to tolerate the inspection of premises and the taking of samples free of charge. The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, as far as radiopharmaceuticals and active principles or drugs and active principles in the manufacture of which ionizing radiation is used are concerned and in agreement with the Federal Ministry for Food, Agriculture and Forestry as far as drugs intended for administration to animals are involved.

FOURTEENTH CHAPTER
INFORMATION OFFICER,
PHARMACEUTICAL CONSULTANT

Section 74a
Information Officer

(1) Any person who, as a pharmaceutical entrepreneur, places drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1 on the market, shall commission a person with the necessary expert knowledge and the reliability required to perform his or her activities, to responsibly fulfil the tasks of providing scientific information on the drugs (information officer). The information officer shall, in particular, be responsible for ensuring compliance with the prohibition contained in section 8 sub-section 1 No. 2 and that the labelling, the package leaflets, the professional information and advertisements correspond with the content of the marketing authorization or registration or, in so far as the drug is exempted from the need for a marketing authorization or registration, with the content of the ordinances governing the exemption from marketing authorizations or registrations pursuant to section 36 or section 39 sub-section 3. Sentence 1 shall not apply to persons who pursuant to section 13 sub-section 2 sentence 1 Nos. 1, 2, 3 or 5 do not require a manufacturing authorization. Persons other than those specified in sentence 1 shall not be allowed to exercise the functions of an information officer.

(2) Proof of the necessary expert knowledge for the post of information officer shall be furnished in the form of a certificate proving the successful completion of an examination taken at the end of university studies in the field of human medicine, human biology, veterinary medicine, pharmacy, biology or chemistry in addition to professional experience of at least two years, or by the proof provided for in section 15. The information officer may exer-
cise the functions of commissioner for the graduated plan, production manager, control manager or sales manager at the same time.

(3) The pharmaceutical entrepreneur shall inform the competent authority about the identity the information officer and present the proof that the requirements pursuant to sub-section 2 have been met and shall give notice of any change beforehand. In the case of an unforeseen change in the person of the information officer, notice shall be given immediately.

Section 75
Expert knowledge

(1) Pharmaceutical entrepreneurs may only appoint persons in possession of expert knowledge, as defined in sub-section 2, to visit members of the medical professions on a full-time basis, in order to give technical information on drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1 (pharmaceutical consultant). Sentence 1 shall also apply 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 shall be deemed to 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,

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. persons with professional further training qualifying them as pharmaceutical sales representatives (Pharmareferent).

(3) The competent authority shall be empowered to recognize 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 sub-section 2.
Section 76
Obligations

(1) The pharmaceutical consultant shall have to make the expert information pursuant to section 11a available, in so far as he provides expert information on individual drugs to members of the medical professions. He shall record in writing any information given to him by members of the medical professions on side effects and contraindications or other risks associated with the drugs and notify his contract-giver thereof in writing.

(2) In so far as the pharmaceutical consultant is commissioned by the pharmaceutical entrepreneur to distribute samples of finished drugs to those persons entitled to receive them in accordance with section 47 sub-section 3, he shall 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, on request, to the competent authorities.

FIFTEENTH CHAPTER
DESIGNATION OF THE COMPETENT HIGHER FEDERAL AUTHORITIES
AND OTHER PROVISIONS

Section 77
Competent higher federal authority

(1) The competent higher federal authority shall be the Federal Institute for Drugs and Medical Devices unless either the Paul Ehrlich Institute (the Federal Agency for Sera and Vaccines) or the Federal Institute for Health Protection of Consumers and Veterinary Medicine is competent.

(2) The Paul Ehrlich Institute shall be competent for sera, vaccines, blood preparations, test allergens, test sera and test antigens.

(3) The Federal Institute for Health Protection of Consumers and Veterinary Medicine shall be responsible for drugs which are intended for administration to animals.

(4) The Federal Ministry shall be empowered, by means of ordinance not subject to the approval of the Bundesrat, to modify the competences of the authorities specified in sub-sections 1 to 3, in so far as this is deemed necessary to take account of new scientific devel-
opments or if such a change is required for reasons of a more uniform distribution of the workload.

Section 78

Prices

(1) The Federal Ministry for Economics shall be empowered to fix, in agreement with the Federal Ministry for Health and, as far as drugs intended for administration to animals are concerned, in agreement with the Federal Ministry for Food, Agriculture and Forestry, by ordinance subject to the approval of the Bundesrat

1. price margins for drugs which are distributed in wholesale commerce or in pharmacies or which are re-sold by veterinarians,

2. prices for drugs which are manufactured and distributed in pharmacies or by veterinarians, as well as for the containers in which they are sold,

3. prices for particular services rendered by pharmacies in connection with the dispensing of drugs.

(2) The prices and price margins shall take into account the legitimate interests of the drug consumers, the veterinarians, the pharmacies and the wholesale trade. A uniform pharmacy retail price shall be guaranteed for drugs which are to be sold exclusively in pharmacies.

Section 79

Exceptional empowerments in times of crises

(1) The Federal Ministry shall be empowered to permit exceptions to the regulations laid down by the present Law and by the ordinances issued by virtue of the present Law, in agreement with the Federal Ministry for Economics, by ordinance not subject to the approval of the Bundesrat, if the necessary supply of drugs to the population or to livestock would otherwise be seriously jeopardized and if an indirect or direct hazard by drugs to human or animal health is not to be feared.

(2) The ordinance shall be issued in agreement with the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, as far as radiopharmaceuticals and drugs
in the manufacture of which ionizing radiation is used are concerned, and in agreement with
the Federal Ministry for Food, Agriculture and Forestry as far as drugs intended for adminis-
tration to animals are involved.

(3) The term of validity of the ordinance shall be limited to six months.

Section 80
Exceptions regarding the field of application of the present Law

The present Law shall not apply to

1. drugs which are produced by using pathogens or using biotechnology procedures and
   which are intended for the prevention, diagnosis or curing of epizootics,

2. the obtaining and marketing of sperm for artificial insemination,

3. (deleted)

4. human organs, parts of organs and tissue which are removed under the professional su-
   pervision of a physician for transplanting to other human beings if these persons are be-
   ing treated under said physician's professional supervision.

Sentence 1 No. 1 shall not apply to section 55. Sentence 1 No. 4 shall not apply to
blood preparations.

Section 81
Relation to other laws

The regulations contained in the legislation on narcotic drugs and on nuclear energy
and those contained in the Law on the Protection of Animals shall not be affected.

Section 82
General administrative regulations

The Federal Ministry shall issue, with the approval of the Bundesrat, the general ad-
ministrative regulations required for the implementation of the present Law. In so far as these
apply to the competent higher federal authority, the general administrative regulations shall be issued by the Federal Government.

Section 83
Approximation to community legislation

(1) Ordinances or general administrative regulations issued in compliance with the present Law may also be issued for the purpose of approximation to the legal and administrative regulations of the Member States of the European Economic Community, in so far as this is necessary for the implementation of regulations, directives or decisions adopted by the Council or the Commission of the European Communities, which affect fields covered by the present Law.

(2) Ordinances covering exclusively the incorporation of directives or decisions adopted by the Council or the Commission of the European Communities into national law shall not be subject to the approval of the Bundesrat.

SIXTEENTH CHAPTER
LIABILITY FOR DAMAGES CAUSED BY DRUGS

Section 84
Absolute liability

If, as a result of the administration of a drug intended for human use, which was distributed to the consumer within the purview of the present Law and which is subject to compulsory marketing authorization or is exempted by ordinance from the need for a marketing authorization, a person is killed or the body or the health of a person is substantially injured, the pharmaceutical entrepreneur who placed the drug on the market within the purview of the present Law shall be obliged to compensate the injured party for the harm caused. The liability to compensate shall only exist if

1. when used in accordance with its intended purpose, the drug has harmful effects which exceed the limits considered tolerable in the light of current medical knowledge and which have their origin in the development or manufacturing process, or
2. the harm has occurred as a result of labelling, expert information or instructions for use which do not comply with current medical knowledge.

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 shall apply.

Section 86
Extent of liability for damages in the case of death

(1) In the case of death, compensation shall 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 earning capacity or the resultant increase in his needs during his disease. The party liable for damages shall 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 was or could 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 shall indemnify the third party, guaranteeing maintenance to the extent to which the deceased party would have been liable for the length of lifespan he would probably have had. Liability for damages shall also be enforced if, at the time of injury, the third party had been conceived but not yet born.

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 health, compensation shall 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 earning capacity or the resultant increase in his needs.
Section 88
Maximum amounts

The party liable for damages shall be liable

1. in the case of the death of or injury to a person only up to a capital amount of one million deutsche marks or an annuity of up to sixty thousand deutsche marks per year,

2. in the case of the death of or injury to several persons by the same drug, notwithstanding the limits stipulated in No. 1, up to a capital amount of two hundred million deutsche marks or an annuity of up to twelve million deutsche marks 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 shall 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 in accordance with section 86 sub-section 2, shall be paid in the future by means of an annuity.

(2) The provisions of section 843 sub-sections 2 to 4 of the Civil Code and of section 708 No. 8 of the Code of Civil Procedure shall apply mutatis mutandis.

(3) If a security bond is not awarded when the party liable is sentenced to pay the annuity, the entitled party may nevertheless demand a security bond if the pecuniary circumstances of the party liable have deteriorated considerably; under the same circumstances, he/she may demand an increase in the security bond specified in the verdict.
Section 90
Limitation of action

(1) The claim specified in section 84 shall be limited to three years as from the date on which the party entitled to damages actually becomes aware of the injury, of the circumstances leading to his right to file a claim and of the identity of the party liable for damages; this stipulation notwithstanding, the claim shall cease to be valid after a period of thirty years following the occurrence of the damage.

(2) If negotiations are in progress between the party liable for damages and the party entitled to damages to determine the level of indemnification to be paid, the limitation period shall be suspended until either one of the parties involved refuses to continue negotiations.

(3) In other respects, the regulations of the Civil Code with regard to the limitation of action shall apply.

Section 91
Extended liability

This shall be without prejudice to legal provisions according to which the party liable for damages under section 84 shall be liable to a greater extent than stipulated by the provisions in this chapter, or according to which another party is responsible for the damage incurred.

Section 92
Mandatory provision

The liability for damages pursuant to this chapter may neither be excluded nor restricted beforehand. All agreements to the contrary shall be void.

Section 93
Several parties liable for damages

If several parties are liable for damages, they shall be jointly and severally liable. With regard to the relationship of the liable parties to each other, the obligation to pay compensation as well as the extent of the compensation to be paid shall depend on the extent to which the damage has been predominantly caused by one or the other party.
Section 94
Coverage provision

(1) The pharmaceutical entrepreneur shall ensure that he is able to meet his legal commitments in respect of compensation for the damages incurred as a result of the administration of a drug intended for human use, placed by him on the market, and subject to a compulsory marketing authorization or exempted by ordinance from a marketing authorization (provision for coverage). The provision for coverage must be made available in the amounts specified in section 88 sentence 1. It can only be made available by means of:

1. a third party insurance taken out with an insurance company authorized to conduct business within the purview of the present Law,

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 Communities 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, sections 158 c to 158 k of the Law on Insurance Contracts of 30th May 1908 (Reich Law Gazette, p. 263), last amended by the Law of 30th June 1967 (Federal Law Gazette (Bundesgesetzblatt) I, p. 609), shall apply analogously.

(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. Sections 158 c to 158 k of the Law on Insurance Contracts shall apply analogously with respect to exemption or warranty obligations.

(4) The competent office within the meaning of section 158 c sub-section 2 of the Law on Insurance Contracts shall be the authority competent for the execution of supervision pursuant to section 64.

(5) The Federal Republic of Germany and the federal Laender are not obliged to provide coverage in compliance with sub-section 1.
Section 94a
Local jurisdiction

(1) In the case of legal actions initiated on the basis of section 84, the court in whose district the plaintiff has his domicile or, failing this, has his usual place of abode at the time of filing the action shall have jurisdiction.

(2) No account shall be taken of sub-section 1 when determining the international jurisdiction of the courts of a foreign nation pursuant to section 328 sub-section 1 No. 1 of the Code of Civil Procedure.

SEVENTEENTH CHAPTER
PENAL PROVISIONS AND PROVISIONS ON ADMINISTRATIVE FINES

Section 95
Penal provisions

(1) Any person who

1. contrary to section 5, also in conjunction with section 73 sub-section 4 or section 73a, markets drugs for which there is reasonable suspicion that it can cause harmful effects,

2. contravenes an ordinance issued in compliance with section 6, which forbids the marketing of drugs, in so far as it refers to the present penal provision for specific cases,

2a. contrary to section 6a sub-section 1, markets or prescribes drugs for doping purposes in the field of sport, or administers such drugs to others,

3. markets radiopharmaceuticals and drugs in the manufacture of which ionizing radiation is used in breach of section 7 sub-section 1,

4. contrary to section 43 sub-section 1 sentence 2, sub-section 2 or 3 sentence 1, trades in or dispenses drugs which may be dispensed to the consumer on prescription only,

5. dispenses drugs which may be dispensed to the consumer on prescription only, in breach of section 47 sub-section 1, to persons or bodies other than those specified therein, or
dispenses them in breach of section 47 sub-section 1a or obtains them in breach of section 47 sub-section 2 sentence 1,

5a. in breach of section 47a sub-section 1, dispenses one of the drugs specified therein to any facility other than those specified therein or places such a drug on the market,

6. in breach of section 48 sub-section 1 or of section 49 sub-section 1 also in conjunction with an ordinance pursuant to section 49 sub-section 4 and without presentation of the required prescription, dispenses drugs which are intended for administration to food-producing animals and which may be dispensed to the consumer on prescription only,

7. in breach of section 56 sub-section 1, dispenses medicated feeding stuffs to animal owners without the required prescription,

8. in breach of section 56a sub-section 1, prescribes, dispenses or administers drugs which may be dispensed to consumers on prescription only, or

9. in breach of section 57 sub-section 1, acquires drugs which may be dispensed to consumers on prescription only,

10. in breach of section 58 sub-section 1 sentence 1, administers drugs, which may only be dispensed to consumers on prescription, to food-producing animals, or

11. in breach of article 5 paragraph 2 of Council Regulation (EEC) No. 2377/90, administers a substance to one of the animals specified therein

shall be liable to imprisonment for a term not exceeding three years or to a fine.

(2) The attempt to commit such acts shall be punishable.

(3) In particularly serious instances, the penalty shall be imprisonment from one to ten years. As a rule, a particularly serious instance shall be said to exist if, by means of one of the actions indicated in sub-section 1, the perpetrator

1. endangers the health of a large number of persons,
2. exposes another person to the risk of death or the risk of serious injury to that person's body or health,

3. acquires a considerable pecuniary gain for himself/herself or another person out of gross self-interest, or

4. in the case of sub-section 1 No. 2a, dispenses drugs for doping purposes in the field of sport to persons under the age of 18 years or administers such drugs to these persons.

(4) If the perpetrator has acted negligently in the instances cited in sub-section 1, the penalty shall be imprisonment for a period of not more than one year or a fine.

Section 96
Penal provisions

Any person who

1. contravenes an ordinance pursuant to section 6, which prescribes, restricts or prohibits the use of certain substances, preparations made from substances or materials in the manufacture of drugs, in so far as it refers to the present penal provision for specific cases,

2. in breach of section 8 sub-section 1 No. 1, also in conjunction with section 73 sub-section 4 or section 73a, manufactures or markets drugs which considerably deviate in their quality from recognized pharmaceutical principles,

3. in breach of section 8 sub-section 1 No. 2, also in conjunction with section 73 sub-section 4 or section 73a, manufactures or markets drugs which bear misleading names, specifications or are presented in a misleading way,

4. in breach of section 13 sub-section 1, manufactures drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1, test sera, test antigens or active principles which are of human or animal origin or are manufactured using genetic engineering, without an authorization, or introduces them into the purview of the present Law from countries other than Member States of the European Communities or States Parties to the Agreement on the European Economic Area without either the authorization required by section 72 or the necessary confirmation or certification as specified in section 72a,
5. in breach of section 21 sub-section 1, markets finished drugs or drugs intended for administration to animals or drugs specified in an ordinance pursuant to section 35 sub-section 1 No. 2 or section 60 sub-section 3 without a marketing authorization or without an authorization from the Commission of the European Communities or the Council of the European Union,

6. fails to submit completely or correctly the data required in accordance with section 22 sub-section 1 Nos. 3, 5 to 9, 11, 12, 14 or 15, sub-section 3b or 3c sentence 1 or section 23 sub-section 2 sentence 2 or 3 or fails to submit a document required according to section 22 sub-section 2 or 3, section 23 sub-section 1, sub-section 2 sentence 2 or 3, sub-section 3, also in conjunction with section 38 sub-section 2, or a document required according to an enforceable order pursuant to section 28 sub-section 3, 3a, 3c sentence 1 No. 2 or sub-section 3d completely or with the correct contents,

7. markets a drug in breach of section 30 sub-section 4 sentence 1 No. 1, also in conjunction with an ordinance pursuant to section 35 sub-section 1 No. 2,

8. markets a batch which has not been released for marketing, in breach of section 32 sub-section 1 sentence 1, also in conjunction with an ordinance pursuant to section 35 sub-section 1 No. 3,

9. markets finished drugs as homeopathic drugs without registration, in breach of section 38 sub-section 1 sentence 1,

10. carries out the clinical investigation of a drug in breach of a provision contained in section 40 sub-section 1 Nos. 1, 2, 3, 4, 5 or 8, sub-section 4 or in section 41 No. 1, in each case also in conjunction with section 73 sub-section 4,

10a. in breach of section 47a sub-section 1 sentence 1, dispenses without a prescription one of the drugs specified therein if the act is not punishable pursuant to section 95 sub-section 1 No.5a,

11. in breach of section 48 sub-section 1 or in breach of section 49 sub-section 1, in conjunction with an ordinance pursuant to section 49 sub-section 4, in each case also in conjunction with section 73 sub-section 4, dispenses drugs without the necessary prescription having been presented, unless the offence is subject to a penalty according to section 95 sub-section 1 No. 6,
11a. prescribes or dispenses a drug in breach of section 56a sub-section 4,

11b. in breach of section 57 sub-section 1a sentence 1, in conjunction with an ordinance pursuant to section 56a sub-section 3 sentence 1 No. 2 is in possession of a drug specified therein,

12. in breach of section 59 sub-section 2, produces food in which residues of the drugs administered or their metabolic products are to be expected,

13. in breach of section 59a sub-section 1 or 2 acquires, offers, stores, packages, carries on his/her person or markets substances or preparations from substances,

14. markets a drug intended for administration to human beings although the third party insurance or the exemption or warranty obligation required in compliance with section 94 does not or no longer exists,


shall be liable to imprisonment for a period of not more than one year or to a fine.

Section 97
Administrative fines

(1) Any person who commits one of the acts indicated in section 96 by negligence shall be deemed to have committed an administrative offence.

(2) An administrative offence shall also be deemed to have been committed by any person who wilfully or negligently

1. markets drugs whose expiry date has elapsed, in breach of section 8 sub-section 2, also in conjunction with section 73 sub-section 4,

2. markets drugs which do not bear the name or the company name of the pharmaceutical entrepreneur, in breach of section 9 sub-section 1,

3. markets drugs in breach of section 9 sub-section 2 without having his place of business within the purview of the present Law or in another Member State of the European Communities or another State Party to the Agreement on the European Economic Area,

4. markets drugs without the prescribed labelling, in breach of section 10, also in conjunction with section 109 sub-section 1 sentence 1 or an ordinance pursuant to section 12 sub-section 1 No. 1,

5. markets drugs without the prescribed package leaflet, in breach of section 11 sub-section 1 sentence 1 or 3, sub-sections 2, 2a, 3 sentence 1, 2 or 4, sub-sections 3a, 4 sentence 1, 2 or 4, sub-section 5 sentence 2 or sub-section 6 sentence 2, in each case also in conjunction with an ordinance pursuant to section 12 sub-section 1 No. 1,

6. contravenes an enforceable order pursuant to section 18 sub-section 2,

7. fails to notify to the competent authority pursuant to section 20, section 29 sub-section 1, also in conjunction with section 63a sub-section 1 sentence 3 or pursuant to section 67 sub-section 1, also in conjunction with section 69a sub-sections 2, 3, 5 or 6 or fails to do so either correctly, completely or in due time,

8. introduces drugs within the purview of the present Law in breach of section 30 sub-section 4 sentence 1 No. 2 or section 73 sub-section 1 or sub-section 1a,
9. carries out a clinical investigation of a drug, in breach of a provision contained in section 40 sub-section 1 No. 6 or 7, also in conjunction with section 73 sub-section 4,

10. in breach of section 43 sub-sections 1, 2 or 3 sentence 1, places drugs on the market professionally or commercially or trades in or dispenses any drugs which may be dispensed to consumers without prescription,

11. in breach of section 43 sub-section 5 sentence 1, dispenses drugs intended for administration to animals and not released for trade outside of pharmacies in a manner which is in breach of the relevant provisions,

12. in breach of section 47 sub-section 1, dispenses drugs which may be dispensed to consumers without prescription to persons or bodies other than those specified therein or dispenses them in breach of section 47 sub-section 1a or obtains the same in breach of section 47 sub-section 2 sentence 1,

12a. in breach of section 47 sub-section 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 sub-section 1b or section 47 sub-section 4 sentence 3 or in section 47a sub-section 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 sub-section 2 sentence 1, dispenses any drug specified therein without the prescribed labelling,

14. retails drugs in breach of section 50 sub-section 1,

15. in breach of section 51 sub-section 1, offers drugs for sale within the framework of itinerant trading or seeks to procure orders for drugs,

16. in breach of section 52 sub-section 1, markets drugs on a self-service basis,

17. in breach of section 55 sub-section 8 sentence 1 or 2, places drugs intended for dispensing to the consumer on the market within the purview of the present Law,
18. manufactures medicated feeding stuffs in breach of section 56 sub-section 2 sentence 1, sub-section 3 or 4 sentence 1 or 2,

19. fails to label medicated feeding stuffs in compliance with section 56 sub-section 4 sentence 3,

20. in breach of section 56 sub-section 5, manufactures a medicated feeding stuff or has it manufactured,

21. in breach of section 56a sub-section 1, prescribes, dispenses or administers drugs which may be dispensed to consumers without a prescription,

22. acquires drugs which may be dispensed to consumers without a prescription in breach of section 57 sub-section 1,

23. in breach of section 58 sub-section 1 sentence 2, administers drugs to food-producing animals,

24. contravenes an obligation to keep records or to submit them in compliance with section 59 sub-section 4,

24a. in breach of section 59b, fails to keep stocks of or fails to produce upon request such substances as are to be tested for by means of the residue test procedure pursuant to section 23 sub-section 1 No. 2 and such substances as are required for the execution of a residue test procedure,

24b. in breach of section 59c sentence 1, also in conjunction with sentence 2, fails to keep any of the records mentioned therein, fails to do so correctly or completely or fails to preserve them or fails to do so for a minimum of three years or fails to submit them to the competent authority or to do so in due time,

24c. in breach of section 63a sub-section 1 sentence 1, fails to appoint a commissioner for the graduated plan or, in breach of section 63a sub-section 3, fails to give notice or fails to do so completely or in due time,

24d. in breach of section 63a sub-section 1 sentence 5, works as a commissioner for the graduated plan,
25. contravenes an enforceable order pursuant to section 64 sub-section 4 No. 4, also in conjunction with section 69a,

26. contravenes the obligation to tolerate or to collaborate as defined in section 66, also in conjunction with section 69a,

27. in breach of an enforceable order pursuant to section 74 sub-section 1 sentence 2 No. 3, fails to present a consignment for clearance,

27a. in breach of section 74a sub-section 1 sentence 1, fails to appoint an information officer or, in breach of section 74a sub-section 3, fails to inform the competent authority or fails to do so completely or in due time,

27b. in breach of section 74a sub-section 1 sentence 4, works as an information officer,

28. in breach of section 75 sub-section 1 sentence 1, appoints a person as pharmaceutical consultant,

29. in breach of section 75 sub-section 1 sentence 3, works as a pharmaceutical consultant,

30. contravenes an obligation to record, to inform or to present records in compliance with section 76 sub-section 1 sentence 2 or sub-section 2,

30a. in breach of section 109 sub-section 1 sentence 2, places a finished drug on the market,

31. contravenes an ordinance pursuant to section 7 sub-section 2 sentence 2, section 12 sub-section 1 No. 3 letter a), section 40 sub-section 5, section 54 sub-section 1, section 56a sub-section 3, section 57 sub-section 2, section 58 sub-section 2 or section 74 sub-section 2, in so far as it relates to this regulation on administrative fines for specific cases,

32. in breach of Article 15 paragraph 2 or Article 37 paragraph 2 of Council Regulation (EEC) No. 2309/93, in each case in conjunction with section 29 sub-section 4 sentence 2, fails to inform the European Agency for the Evaluation of Medicinal Products or the competent higher federal authority about any new information or fails to do so accurately completely or on time,
33. in breach of Article 22 paragraph 1 sub-paragraph 1 or 2 or Article 44 paragraph 1 sub-
paragraph 1 or 2 of Council Regulation (EEC) No. 2309/93 in each case in conjunction
with section 29 sub-section 4 sentence 2, fails to ensure that the competent higher fed-
eral authority or the European Agency for the Evaluation of Medicinal Products is notified
of any of the side-effects mentioned therein,

34. in breach of Article 22 paragraph 2 sentence 1 or Article 44 paragraph 2 sentence 1 of
Council Regulation (EEC) No. 2309/93, fails to keep one of the records mentioned therein
or fails to do so accurately or completely, or

35. in breach of Article 1 of Council Resolution (EC) No. 540/95, in conjunction with section
29 sub-section 4 sentence 2, fails to ensure that the European Agency for the Evaluation
of Medicinal Products and the competent higher federal authority are notified of a side-
effect mentioned therein.

(3) The committing of an administrative offence may be liable to a fine not exceeding
fifty thousand deutsche marks.

(4) The administrative authority within the meaning of section 36 sub-section 1 No. 1 of
the Act on Administrative Offences shall be the competent higher federal authority pursuant to
section 77 in the cases provided for in sub-section 1 in conjunction with section 96 Nos. 6, 15
and 16, sub-section 2 No. 7 in conjunction with section 29 sub-section 1 and sub-section 2
Nos. 32 to 35.

Section 98
Confiscation

Materials connected with an offence as defined in section 95 or section 96 or an ad-
ministrative offence as defined in section 97 may be confiscated. Section 74a of the Penal
Code and section 23 of the Law on Administrative Offences shall apply.

EIGHTEENTH CHAPTER
TRANSITIONAL PROVISIONS

First sub-chapter
Transitional provisions arising out of the Law on the Reform of Drug Legislation
Section 99
1961 Drug Law


Section 100

(1) Any authorization which had been granted pursuant to section 12 sub-section 1 or section 19 sub-section 1 of the 1961 Drug Law and was still valid on 1st January 1978, shall continue to be valid to the previous extent as an authorization within the meaning of section 13 sub-section 1 sentence 1.

(2) Any authorization which is considered as granted pursuant to section 53 sub-section 1 or Section 56 of the 1961 Drug Law and was still valid on 1st January 1978, shall continue to be valid to the previous extent as an authorization within the meaning of section 13 sub-section 1 sentence 1.

(3) Where the manufacture of drugs did not require an authorization pursuant to the 1961 Drug Law, but requires an authorization pursuant to section 13 sub-section 1 sentence 1, such an authorization shall be deemed to be granted to any person who had been carrying out the activity of manufacturing drugs, with an authorization to do the same, for a period of at least three years on 1st January 1978, however, only in so far as manufacture is restricted to such drugs as had been manufactured previously or drugs which are similar in composition.
Section 101
(deleted)

Section 102

(1) Any person who exercises the function of production manager, with an authorization to do so, on 1st January 1978 shall continue to exercise this function to the same extent as hitherto.

(2) Any person who, on 1st January 1978, is in possession of the expert knowledge pursuant to section 14 sub-section 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 drugs can be shown. If the practical experience was obtained prior to 10th June 1965, proof shall 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 sub-section 1 prior to 10th June 1975 shall be deemed to have acquired expert knowledge as a production manager, if he/she completed his/her studies by 10th June 1985 and exercised a function pursuant to section 15 sub-sections 1 and 3 for at least two years. This shall be without prejudice to the provisions contained in sub-section 2.

(4) Sub-sections 2 and 3 shall apply *mutatis mutandis* to any person seeking to work as a quality control manager.

Section 102a
(deleted)

Section 103

(1) In the case of drugs which, pursuant to section 19a or section 19d in conjunction with section 19a of the 1961 Drug Law, are authorized for marketing on 1st January 1978 or which are deemed to have been granted a marketing authorization on 1st January 1978 pursuant to Article 4 sub-section 1 of the Law on the Establishment of a Federal Agency for Sera and Vaccines of 7th July 1972 (Federal Law Gazette I, p. 1163), a marketing authorization
pursuant to Section 25 shall be deemed to be granted. Sections 28 to 31 shall apply to the marketing authorization *mutatis mutandis*.

(2) (deleted)

Section 104
(deleted)

Section 105

(1) Finished drugs which are drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1 and are on the market on 1\(^{st}\) January 1978 are deemed to be authorized for marketing if they are on the market on 1\(^{st}\) 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 drugs pursuant to sub-section 1 must be submitted, within a period of six months from the 1\(^{st}\) January 1978, to the competent higher federal authority indicating the designation of the active ingredients according to their nature and quantity as well as their fields of application. In making a notification regarding a homeopathic drug, the particulars bearing on the fields of application may be omitted. A copy of the notification shall be sent to the competent authority indicating the stipulated particulars. The finished drugs may only be kept on the market if the deadline for notification is observed.

(3) The marketing authorization for a drug, notification of which has been submitted within the deadline pursuant to sub-section 2, shall expire by way of derogation from section 31 sub-section 1 No. 3 on 30\(^{th}\) April 1990, unless an application for a prolongation of the marketing authorization or for registration is submitted prior to the date of expiry, or unless the drug is exempted from the need for a marketing authorization or registration by ordinance. Section 31 sub-section 4 sentence 1 shall not apply to the marketing authorization pursuant to sentence 1 if the renouncement pursuant to section 31 sub-section 1 sentence 1 No. 2 is submitted by 31\(^{st}\) January 2001.

(3a) Until the first prolongation of the marketing authorization, a modification pursuant to Section 29 sub-section 2a sentence 1 No. 1 in the case of finished drugs pursuant to sub-section 1, in so far as it concerns the fields of application, and number 3 shall only be admis-
sible if it is necessary to remedy the defects bearing on the efficacy or safety of the drug indicated to the applicant by the competent higher federal authority; furthermore, section 29 subsection 2a sentence 1 Nos. 1, 2 and 5 shall not apply to finished drugs pursuant to subsection 1 until the first prolongation of the marketing authorization. By way of derogation from section 29 sub-section 3, a finished drug pursuant to sub-section 1, which has been manufactured using a manufacturing procedure described in the homeopathic section of the Pharmacopoeia, may be marketed up until the first prolongation of the marketing authorization:

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 drug 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 fields of application, with a change in indication if the drug is adjusted as a whole to the results published pursuant to section 25 sub-section 7 sentence 1 in the version in force before 17th August 1994,

3. (deleted)

4. with a change in the quantity of the medically active constituents, in so far as it is a drug with several active ingredients 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 field of application and the same school of therapy if the drug, as a whole, is adjusted to a result published pursuant to section 25 sub-section 7 sentence 1 in the version in force before 17th August 1994 or to a drug model submitted by the Federal Institute for Drugs and Medical Devices and the drug does not become subject to prescription as a result of the adjustment;

a change shall only be admissible in so far as it is necessary for the purpose of remedying the defect bearing on the efficacy or safety of the drug indicated to the applicant by the competent higher federal authority. The pharmaceutical entrepreneur shall make notification of the change and in the event of a change in the composition, shall 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 drug for a period of at least five years. Upon expiry of a period of six months following the notification, the pharmaceutical entrepreneur may market the drug
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 drugs by imposition of a condition pursuant to section 28 sub-section 2 No. 3, the drug may only be marketed when changed pursuant to sentence 2 No. 2 by way of derogation from section 109 sub-section 2, only with a package leaflet pursuant to section 11.

(4) In applying for a prolongation of the marketing authorization, documents pursuant to section 22 sub-section 1 Nos. 1 to 6 shall be submitted in derogation of section 31 sub-section 2. The competent higher federal authority shall determine on a case by case basis when the documents pursuant to section 22 sub-section 1 Nos. 7 to 15, sub-section 2 No. 1 and sub-section 3a and in the case of premixed drugs the documents pursuant to section 23 sub-section 2 sentences 1 and 2, in addition, as well as the analytical expert opinion pursuant to section 24 sub-section 1 are to be submitted. Upon request by the competent authority, documents shall also be submitted providing evidence that the drug’s medically active constituents possess sufficient bioavailability in so far as this is required according to the current state of scientific knowledge. An appraising expertise shall also be submitted. Section 22 sub-section 2 sentence 2 and sub-sections 4 to 7 and section 23 sub-section 3 shall apply mutatis mutandis. The documents referred to in sentences 2 to 5 shall be submitted within a period of four months following the request by the competent higher federal authority.

(4a) In applying for a prolongation of the marketing authorization pursuant to sub-section 3, documents pursuant to section 22 sub-section 2 Nos. 2 and 3 as well as the expert opinions pursuant to section 24 sub-section 1 sentence 2 Nos. 2 and 3 shall be submitted by 1st February 2001 in cases where these documents have not already been submitted by the applicant; section 22 sub-section 3 shall apply mutatis mutandis. Sentence 1 shall not apply to drugs which have been manufactured using a manufacturing procedure described in the homoeopathic 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 sub-section 2 No. 2 and the expert opinion pursuant to section 24 sub-section 1 sentence 2 No. 2 shall not be required unless substances are contained therein which do not exist naturally in the human body. With the exception of the cases specified in section 109a, the marketing authorization shall expire if the documents stipulated in sentences 1 to 3 are not submitted on time.

(4b) In submitting documents pursuant to section 22 sub-section 2 No. 2, in the case of veterinary drugs which contain pharmacologically active substances which have been tested pursuant to Council Regulation (EEC) No. 2377/90 and listed in one of its Annexes I to III, ref-
erence may be made to documents submitted pursuant to that Regulation’s Annex V, in so far as a veterinary drug containing this pharmacologically active constituent has already been authorized for marketing in a Member State of the European Communities and the prerequisites for referring to such documents pursuant to section 24a have been met.

(4c) If the drug pursuant to sub-section 3 has already been authorized 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 65/65/EEC or Directive 81/851/EEC, the prolongation of the marketing authorization shall be granted if:

1. the drug is on the market in the other Member State and
2. the applicant
   a) provides all of the particulars stipulated under section 22 sub-section 6 and submits the necessary copies and
   b) declares in writing that the documents submitted pursuant to sub-sections 4 and 4a match the marketing authorization documents on the basis of which the authorization was granted in the other Member States,

unless the prolongation of the marketing authorization could constitute a danger for public health, in the case of drugs intended for administration to animals a danger to the health of human beings, animals or the environment.

(4d) In applying for registration, documents pursuant to section 22 sub-section 1 Nos. 1 to 4 shall be submitted along with the application in derogation of section 38 sub-section 2. The documents pursuant to section 22 sub-section 1 Nos. 7 to 15 and sub-section 2 No. 1 as well as the analytical expert opinion pursuant to section 24 sub-section 1 shall be submitted to the competent higher federal authority upon request. Section 22 sub-sections 4 to 7, with the exception of the draft of the expert information, shall apply mutatis mutandis. The documents stipulated in sentences 2 and 3 shall be submitted within a period of two months following a request by the competent higher federal authority.

(4e) In deciding on an application for prolongation of a marketing authorization or registration pursuant to sub-section 3 sentence 1, section 25 sub-section 5 sentence 5 and section 39 sub-section 1 sentence 2 shall apply mutatis mutandis.
(4f) The manufacturing authorization pursuant to sub-section 1 shall be prolonged upon request pursuant to sub-section 3 sentence 1 for a period of five years if no reason for a refusal pursuant to section 25 sub-section 2 exists; for additional prolongations section 31 shall apply. The particularities of a specific substance group or school of therapy (phytotherapy, homeopathy, anthroposophy) shall be taken into consideration.

(4g) In the case of drugs which are blood preparations, section 25 sub-section 8 shall be applied mutatis mutandis.

(5) In the case of defects, the applicant shall remedy the defects within a reasonable deadline which may, however, not exceed twelve months following the notice of defects; the remedying of defects shall be recorded in writing. In the event that the defects are not remedied within this deadline, the marketing authorization shall be refused. After a decision has been taken to refuse the marketing authorization, the submission of documents in order to remedy defects shall not be allowed. In all appropriate cases, the competent authority shall refrain from giving notice of defects pursuant to sentence 1 first half-sentence and shall instead prolong the marketing authorization on the basis of sub-section 5a sentences 1 and 2 with a proviso requiring the applicant to remedy the defects within a deadline which it shall set according to its best judgement.

(5a) The competent higher federal authority is empowered to impose conditions on the prolongation of the marketing authorization pursuant to sub-section 3 sentence 1. Apart from ensuring the requirements stipulated in section 28 sub-section 2, the contents of conditions may also be geared towards guaranteeing the requirements of quality, safety and efficacy, unless notice must be given of defects pursuant to sub-section 5 or the prolongation of the marketing authorization refused as a result of serious deficiencies in the pharmaceutical quality, efficacy or safety. Sentence 2 shall apply mutatis mutandis to document requirements pursuant to section 23 sub-section 1 No. 1. The notice regarding the prolongation shall state whether the condition imposed shall be met immediately or by a deadline to be specified by the competent higher federal authority. Notice shall be given 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 drug corresponds to the current state of scientific knowledge. Section 25 sub-section 5 sentences 5, 6 and 8 as well as section 30 sub-section 2 sentence 1 No. 2 second alternative shall apply mutatis mutandis. Sentences 1 to 6 shall apply mutatis mutandis to the registration pursuant to sub-section 3 sentence 1.
(5b) No preliminary procedure pursuant to section 68 of the Rules of the Administrative Court shall be held in the event of an appeal against the decision regarding the prolongation of the marketing authorization pursuant to sub-section 3 sentence 1. Immediate execution shall be ordered pursuant to section 80 sub-section 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 sub-section 3 sentence 1, the marketing authorization for a drug for which a notification has been made within the specified time pursuant to sub-section 2, for which the pharmaceutical entrepreneur declares by 31st December 1999 that the application to prolong the marketing authorization pursuant to sub-section 3 sentence 1 was withdrawn, shall expire on 1st February 2001 unless the procedure to prolong the marketing authorization 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 17th August 1994 pursuant to sub-section 4 sentence 2, or if the date of submission of documents for the drug in question was subsequent to that date, or if the request for documents regarding the drug in question was issued after said date, the procedure to prolong the marketing authorization shall be resumed by the competent federal higher authority upon application by the entrepreneur; the application shall be submitted by 31st January 2001, accompanied by the documents specified in sub-section 4a sentence 1.

(5d) Sub-section 3 sentence 2 and sub-sections 3a to 5c shall apply mutatis mutandis to drugs for which an application for prolongation was submitted by 30th June 1991, in accordance with section 4 sub-section 2 of the EC Transition Ordinance of 18th December 1990 (Federal Law Gazette I, p. 2915) Annex 3 to section 2 No. 2, chapter II Nos. 1 and 2.

(6) (deleted)

(7) Sub-sections 1 to 5d shall also apply to drugs intended for administration to animals which are not finished drugs in so far as they are required to have a marketing authorization or to be registered and are on the market on 1st January 1978.

Section 105a

(1) (deleted)
(3) In the case of finished drugs, which are not subject to prescription pursuant to Section 49, 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 or her duties pursuant to section 11a and the pharmaceutical consultant from his or her duty pursuant to section 76 sub-section 1 sentence 1 until the standardized wording of the expert information for the drugs in question is stipulated by imposition of conditions pursuant to section 28 sub-section 2 No. 3.

(4) Sub-sections 1 to 3 shall not apply to drugs which are intended for administration to animals or which fall within the competence of the Paul Ehrlich Institute.

Section 105b

The right to the payment of costs which are to be levied pursuant to section 33 sub-section 1, in conjunction with an ordinance issued pursuant to section 33 sub-section 2 or section 39 sub-section 3 for the prolongation of a marketing authorization or for the registration of a finished drug within the meaning of section 105 sub-section 1, shall expire after a period of four years subsequent to informing the applicant of the final decision regarding the prolongation of the marketing authorization.

Section 106
(deleted)

Section 107
(deleted)

Section 108
(deleted)
Section 108a

Any batch of serum, vaccine, test allergen, test serum or test antigens which was 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 1st December 1986 (Law Gazette I No. 37, p. 483) shall be deemed to be released within the meaning of section 32 sub-section 1 sentence 1 in the territory stipulated in Article 3 of the Unification Treaty. Section 32 sub-section 5 shall apply to the release mutatis mutandis.

Section 108b

(deleted)

Section 109

(1) Finished drugs which are drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1 and were on the market on 1st January 1978, shall be governed by section 10 with the proviso that the marketing authorization number stipulated in section 10 sub-section 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.". Finished drugs pursuant to sentence 1 and pursuant to section 105 sub-section 5d may be placed on the market only if the following indication is included in the package leaflet pursuant to section 11: "This drug has been placed on the market under the statutory transitional regulations. Official testing to determine pharmaceutical quality, efficacy and safety has not yet been concluded". The indication pursuant to sentence 2 shall also be included in the expert information pursuant to section 11a where it is provided. Sentences 1 to 4 shall be valid until the first prolongation of the marketing authorization or registration.

(2) The text for labels and package leaflets shall be submitted by 31st July 2001 at the latest. Until that date, drugs pursuant to sub-section 1 sentence 1 may be placed on the market by the pharmaceutical entrepreneur, thereafter by wholesalers and retailers with labels and package leaflets which are in keeping with the regulations in force up to the date specified in sentence 1.

(3) Finished drugs which are drugs within the meaning of section 105 sub-section 1, and are released for trade outside of pharmacies pursuant to section 44 sub-section 1 or sub-section 2 Nos. 1 to 3 or section 45 and fall under letters a to e may, without prejudice to the
provisions contained in sub-sections 1 and 2, be placed on the market from 1st 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:

"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 drug."

Sentence 1 shall not apply in cases where the fields of application are restricted to the results published within the framework of a marketing authorization pursuant to section 25 sub-section 1 or a marketing authorization pursuant to the version in force before 17th August 1994.

Section 109a

(1) In the case of drugs specified in section 109 sub-section 3, as well as drugs which 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 section 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 prolongation of the marketing authorization can be granted pursuant to section 105 sub-section 3 and furthermore, pursuant to section 31 in accordance with sub-sections 2 and 3.

(2) The requirements in respect of the necessary quality are deemed to be met when the documents pursuant to section 22 sub-section 2 No. 1, as well as the analytical expert opinions pursuant to section 24 sub-section 1 have been submitted and the pharmaceutical entrepreneur has made a statutory declaration that the drug 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 shall be stipulated by the competent higher federal authority.

(3) The requirements in respect of the efficacy are deemed to be met when the drug claims efficacy in fields of application which are recognized in a list of the fields of application
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 sub-section 6 sentences 4 to 6 shall apply mutatis mutandis. These fields of application shall be stipulated taking into account the peculiarities of the particular drug and the experience which has been handed down and documented and shall be accompanied by the additional remark: "Traditionally used". Such fields of application 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 drug for use in ...". Fields of application which would result in the drug being excluded from trade outside of pharmacies may not be recognized.

(4) Sub-sections 1 to 3 shall apply only in cases where the documents pursuant to section 105 sub-section 4a have not been submitted and the applicant declares in writing that he or she is pursuing a prolongation of the marketing authorization pursuant to section 105 sub-section 3 in accordance with sub-sections 2 and 3.

Section 110

In the case of drugs which are subject to a marketing authorization pursuant to Section 21 or to registration pursuant to section 38, and which are on the market on 1st January 1978, the competent higher federal authority can stipulate, by imposing conditions, the affixing of warnings in so far as they are necessary to prevent a direct or indirect health hazard to human beings or animals by administration of the drug. This shall be without prejudice to the provisions contained in section 38a of the 1961 Drug Law in conjunction with Article 9 No. 1 of the Law on the Reform of Drug Legislation.

Section 111

(deleted)

Section 112

Any person who, on 1st January 1978, places drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1, which are released for trade outside of pharmacies, on the market on a retail basis outside of pharmacies, may continue to pursue this activity in so far 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 5th August 1957 (Federal

Section 113

By way of derogation from section 58 sub-section 1, drugs may be administered if it can be inferred from the labelling or accompanying documents that the drugs may continue to be placed on the market pursuant to section 105 sub-section 1.

Section 114

(deleted)

Section 115

Any person who exercises the function of a pharmaceutical consultant pursuant to section 75 on 1st January 1978, shall not need to provide the proof of training stipulated therein.

Section 116

Physicians who are entitled, on 1st January 1978, under provisions contained in the legislation of the individual Land to manufacture and dispense drugs to persons being treated by them, may continue to pursue this activity to the same extent as hitherto. Section 78 shall be applicable.

Section 117

(deleted)

Section 118

Section 84 shall not apply to damage caused by drugs which were dispensed prior to 1st January 1978.

Section 119
Finished drugs which are drugs within the meaning of section 2 sub-section 1 or sub-section 2 No. 1 and which 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 marketed by wholesalers and retailers without the package leaflet required under section 11, in so far 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, in so far as this is deemed necessary for the prevention of direct or indirect danger to human beings or animals as a result of the application of the drug.

Section 120

In the case of a clinical investigation which is being carried out in the territory mentioned in Article 3 of the Unification Treaty at the time when accession takes effect, the insurance policy required under section 40 sub-section 1 No. 8 shall be taken out.

Section 121

(deleted)

Section 122

The obligation to notify pursuant to section 67 shall not apply to undertakings, facilities and persons in the territory mentioned 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 shall also be deemed to possess the necessary expert knowledge as a pharmaceutical consultant pursuant to section 75 sub-section 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 mentioned in Article 3 of the Unification Treaty.

Section 124
Sections 84 to 94a shall not be applicable to drugs which were dispensed to consumers in the territory mentioned in Article 3 of the Unification Treaty before accession took effect.
Second sub-chapter

Transitory provisions arising out of the First Law amending the Drug Law

Section 125

(1) After hearing the commissions pursuant to section 25 sub-sections 6 and 7, the competent higher federal authority shall lay down, in the case of drugs which were authorized for marketing on 2\textsuperscript{nd} March 1983, the deadline by which the documents regarding the test method pursuant to section 23 sub-section 2 sentence 3 are to be submitted.

(2) In the case of drugs for which a marketing authorization was applied after 1\textsuperscript{st} March 1983, and before 4\textsuperscript{th} March 1998, the provisions contained in section 23 shall apply with the proviso that the documents regarding the test methods do not have to be submitted prior to the deadline referred to in sub-section 1.

(3) In cases where a deadline for the submission of documents regarding the test method pursuant to sub-section 1 has been set, the marketing authorization may be withdrawn if the documents are not submitted or if they fail to meet the requirements stipulated in section 23 sub-section 2 sentence 3.

Section 126

In the case of drugs intended for administration to animals, and which are authorized for marketing in the territory mentioned in Article 3 of the Unification Treaty at the time when accession takes effect, section 125 sub-sections 1 and 3 shall apply mutatis mutandis.

Third sub-chapter

Transitional provisions arising out of the Second Law amending the Drug Law

Section 127

(1) Drugs which are on the market on 1\textsuperscript{st} February 1987 and are subject to the labelling provisions contained in section 10, must be placed on the market by the pharmaceutical entrepreneur in accordance with the provision contained in section 10 sub-section 1 No. 9 within a period of one year after the first prolongation of the marketing authorization on 1\textsuperscript{st} February 1987, or after the exemption from the marketing authorization or, in the case of homeopathic
drugs, five years after the 1\textsuperscript{st} February 1987. Up to this point in time, drugs 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 drug’s shelf-life is more than three years or, in the case of drugs governed by the provisions contained in section 109, more than two years. This shall be without prejudice to the provisions contained in section 109.

(2) Drugs which are on the market on 1\textsuperscript{st} February 1987 and are subject to the labelling regulations of section 10 sub-section 1a, may be placed on the market until 31\textsuperscript{st} December 1988 by the pharmaceutical entrepreneur, and even after this deadline by wholesalers and retailers without the particulars stipulated in section 10 sub-section 1a.

\textbf{Section 128}

(1) In the case of finished drugs which are on the market on 1\textsuperscript{st} February 1987, the pharmaceutical entrepreneur shall submit the wording of the expert information to the competent higher federal authority along with the first application for the prolongation of the marketing authorization or registration filed on 1\textsuperscript{st} February 1987. Sentence 1 shall not apply in so far as the competent higher federal authority has exempted drugs which are not subjected 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 sub-section 1 sections 11a, 47 sub-section 3 sentence 2 and section 76 sub-section 1 shall apply from the date of the prolongation of the marketing authorization or the registration or the stipulation of a specific expert information by means of section 36 sub-section 1, or in the cases described in sub-section 1 sentence 2, six months after the decision of the competent higher federal authorities on the contents of the expert information. Finished drugs, the package leaflet of which fails to comply with the provisions contained in section 11 sub-section 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 sub-section 1a shall apply to drugs which are on the market on 1st February 1987 subject to the proviso that their package leaflet must be forwarded to the competent authority after the next prolongation of the authorization or registration.

Section 130

Any person who is appointed as a private expert by 1st February 1987 to test samples pursuant to section 65 sub-section 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 shall apply mutatis mutandis to drugs which 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.

Fourth sub-chapter

Transitory provisions arising out of the Fifth Law amending the Drug Law

Section 132

(1) Drugs which are on the market on 17th August 1994 and are subject to the provisions contained in sections 10 and 11, must be placed on the market by the pharmaceutical entrepreneur in accordance with the provisions contained in sections 10 and 11 within a period of one year after the first prolongation of the marketing authorization granted on 17th August 1994, or in so far as they are exempt from the need for a marketing authorization, from the time stipulated in the ordinance pursuant to section 36 or, in so far as homeopathic drugs are concerned, five years after 17th August 1994. Until such time, drugs referred to in sentence 1 may continue to be placed on the market by the pharmaceutical entrepreneur, and thereafter such drugs may continue to be placed on the market by wholesalers and retailers with labelling and package leaflets which comply with the provisions in force up to 17th August 1994. The foregoing shall be without prejudice to the provisions contained in section 109.
(2) In the case of finished drugs which are on the market on 17th August 1994, the pharmaceutical entrepreneur shall submit the wording of the expert information in compliance with section 11a of this version of the present Law to the competent higher federal authority along with the first application for the prolongation of the marketing authorization filed on 17th August 1994. This shall be without prejudice to the provisions contained in section 128 sub-section 1 sentence 2.

(2a) Marketing authorizations which are not in compliance with section 16 shall be adapted to section 16 by 17th August 1996. Sentence 1 shall apply to section 72 mutatis mutandis.

(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 17th August 1994 and fulfils the prerequisites of section 15 sub-section 3 as contained in the version in force up until 17th August 1994, may continue to exercise this function.

(3) Until the date specified in Article 14 of EEC Council Regulation No. 2377/90, section 23 sub-section 1 Nos. 2 and 3 and section 25 sub-section 2 sentence 1 No. 6c shall not apply to drugs the pharmaceutically active constituent of which was authorized for marketing on 1st January 1992 within the purview of the present Law in a drug which is intended for administration to food-producing animals.

(4) Section 39 sub-section 2 Nos. 4a and 5a shall not apply to drugs which were registered by 31st 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 sub-section 2 and which were placed on the market pursuant to section 38 sub-section 1 sentence 3 in the version valid before 11th September 1998. Furthermore, section 39 sub-section 2 No. 4a shall not apply to drugs pursuant to sentence 1 in respect of which a re-registration is being applied for because an ingredient is to be removed or several ingredients are to be removed or the degree of dilution of ingredients is to be increased. Furthermore, section 39 sub-section 2 Nos. 4a and 5a shall not apply, in the case of decisions bearing on the registration or on its prolongation, to drugs which are identical, in the nature and quantity of their components as well as with regard to their pharmaceutical forms, with drugs specified in sentence 1. Section 21 sub-section 2a sentence 3 and section 56a sub-section 2 sentence 5 shall also apply to drugs intended for administration to animals whose degree of dilution is below the sixth decimal potency, in so far as they have been registered pursuant to sentence 1 or 2 or have been exempted from registration.
Fifth sub-chapter
Transitory provisions arising out of the Seventh Law Amending the Drug Law

Section 133

The obligation to notify pursuant to section 67 in conjunction with section 69a shall apply to the enterprises, facilities and persons specified in section 59c who were already exercising one of the functions provided for in section 59c on 4th March 1998 with the proviso that the notification must be made at the latest by 1st April 1998.

Sixth sub-chapter
Transitory 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 1st July 1998 (Federal Law Gazette I, p. 1752), exercises the function of production manager in the manufacture of or as control manager for the testing of blood preparations or sera from human blood and meets the requirements stipulated by section 15 sub-section 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 technological and scientific state-of-the-art, may continue to exercise this function.

Seventh sub-chapter
Transitory provisions arising out of the Eighth Act Amending the Drug Law

Section 135

(1) Drugs which are on the market on 11th September 1998 and are subject to the provisions contained in sections 10 and 11, must be placed on the market one year after the first prolongation of the marketing authorization on 11th September 1998 or, in so far as they are exempt from the marketing authorization, on the date specified in the ordinance pursuant to section 36 or, in so far as they are homeopathic drugs, on 1st October 2003, by the pharmaceutical entrepreneur pursuant to the provisions contained in sections 10 and 11. Until this
date, drugs pursuant to sentence 1 may be placed on the market by the pharmaceutical entrepreneur; after this date such drugs may continue to be placed on the market by wholesalers and retailers with labelling and package leaflets which are in accordance with the provisions in force up to 11th September 1998. This shall be without prejudice to section 109.

(2) Any person who on 11th September 1998 exercises the function of production manager or control manager for the drugs or active principles named in section 15 sub-section 3a and is authorized to do so, may continue to exercise this function to the same extent as hitherto. Until 1st October 2001 section 15 sub-section 4 shall not apply to the practical activities involved in the manufacture of drugs and active principles pursuant to section 15 sub-section 3a.

(3) Homeopathic remedies which are on the market on 11th September 1998 and for which an application for registration was submitted by 1st October 1999 may, by way of derogation from section 38 sub-section 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 11th September 1998.

(4) In the amended version, section 41 No. 6 shall not apply to declarations of consent which were made prior to 11th September 1998.

Eighth sub-chapter

Transitional provisions arising out of the Tenth Act Amending the Drug Law

Section 136

(1) In the case of drugs for which the prolongation applied for under Section 105 sub-section 3 sentence 1 has already been granted, the documents specified in section 105 sub-section 4a sentence 1 shall be submitted, at the latest, with the application pursuant to section 31 sub-section 1 No. 3. In the case of such drugs, the marketing authorization shall be prolonged if no reason for refusal pursuant to section 25 sub-section 2 exists; section 31 shall apply to further prolongations.

(1a) With regard to drugs pursuant to section 105 sub-section 3 sentence 1 which are manufactured according to a procedure which is not described in the homeopathic section of the Pharmacopoeia, section 105 sub-section 3 sentence 2 in the version in force up to 12th
July 2000 shall apply until such time as a decision is made by the Commission pursuant to section 55 sub-section 6 on the inclusion of this manufacturing procedure insofar as an application has been submitted by 1st October 2000 regarding its inclusion in the homeopathic section of the Pharmacopoeia.

(2) In the case of drugs with respect to which the applicant has been informed prior to 12th July 2000 of defects regarding their efficacy or safety, section 105 sub-section 3a in the version in force up to 12th July 2000 shall apply.

(2a) Section 105 sub-section 3a sentence 2, in the version in force up to 12th July 2000 shall apply up to 31st January 2001 with the proviso that a notice of defects is not necessary and that a notification is admissible only if it is restricted to the fact that one or several medically active constituents contained up to that point in the drug are no longer present after the notification.

(3) In the case of drugs which have been manufactured according to a manufacturing procedure described in the homeopathic section of the Pharmacopoeia, section 105 sub-section 5c shall continue to apply in the version in force prior to 12th July 2000.