

German Pharmacies Act

(Gesetz über das Apothekenwesen)

(last amended by the Act for the Structural Development of Nursing Care Insurance
(Nursing Care Development Act) of May 28, 2008
[Federal Law Gazette I p. 874 ff.]¹)

FIRST CHAPTER

Permit

Section 1

(1) The pharmacies are responsible for ensuring a proper supply of medicinal products to the population as required by public interest.

(2) Individuals intending to operate a pharmacy and up to three (3) subsidiary pharmacies require a permit by the relevant authority.

(3) The permit applies only to the pharmacist to whom it was awarded and to the rooms designated in the permit certificate.

Section 2

(1) The permit is to be awarded upon application, if the applicant

1. Is a German national in the sense of Article 116 of the German Constitution, a national of one of the other member states of the European Union or another signatory state of the Agreement on the European Economic Area, or a signatory state to which Germany and the European Union have contractually granted a corresponding legal claim, or a displaced alien in the sense of the Act on the Legal Status of Displaced Aliens;
 2. Has full legal capacity;
 3. Holds the German license as pharmacist;
 4. Has the reliability that is required for operating a pharmacy; this is not the case if facts exist that show that the applicant is unreliable with respect to operating a pharmacy, particularly if criminal offenses or severe moral offenses prevail that make him/her appear unsuitable to manage a pharmacy, or if he/she has proven to be unreliable by severely and consistently violating this legislation, the Ordinance on the Operation of Pharmacies that was enacted based on this legislation, or the legal regulations for the production of medicinal products and their handling and dispensation;
- 4a. *(Canceled)*

¹ **Note:** This consolidated version was generated by ABDA – Bundesvereinigung Deutscher Apothekerverbände (Federal Union of German Associations of Pharmacists) as a working aid. Only the texts published in the Federal Law Gazette are legally binding.

5. Makes the affirmation in lieu of an oath that he/she did not conclude any agreements that violate Section 8 clause 2, Section 9 paragraph 1, Section 10 or Section 11 and will present the purchase agreement or lease for the pharmacy as well as other contracts related to the establishment and operation of the pharmacy upon request of the relevant government authority.
6. Proves that he/she will have the rooms required by the Ordinance on the Operation of Pharmacies (Section 21), if he/she is awarded the permit;
7. Is not unfit to correctly manage a pharmacy with regard to his/her health;
8. Provides information on whether and, if applicable, at which location he/she operates one or several pharmacies in a member state of the European Union or another signatory state of the Agreement on the European Economic Area, or a signatory state to which Germany and the European Union have contractually granted a corresponding legal claim.

(2) Deviating from paragraph 1, the permit is to be awarded to a licensed applicant, who – pursuant to Section 4 paragraph 1 no. 4 of the Federal Pharmacists Regulation – has not passed the pharmaceutical examination within the territory covered by this legislation, only if the application is made for a pharmacy that has been in operation for at least three years.

(2a) Supplementary to paragraph 1 no. 1, an applicant who is a national of another country must be awarded a permit to operate a pharmacy located in the area defined in Article 3 of the Unification Treaty, if the applicant had his/her permanent residence in the area defined in Article 3 of the Unification Treaty on January 1, 1990, and fulfills the other requirements listed in paragraph 1.

(3) If the pharmacist has not worked in a pharmaceutical profession for a period of more than two years continuously after receiving his/her license or after being awarded a diploma, examination certificate or other proof of qualification equivalent to the pharmaceutical examination pursuant to Section 4 paragraph 1a to d, 2 or 3 of the Federal Pharmacists Regulation, he/she will be granted a permit only if he/she worked again in such a profession at a pharmacy or hospital pharmacy located in a member state of the European Union, or another signatory state of the Agreement on the European Economic Area, or a signatory state to which Germany and the European Union have contractually granted a corresponding legal claim, for at least six months during the last year prior to submitting the application.

(4) The permit to operate several community pharmacies must be granted upon application, if

1. The applicant meets the requirements pursuant to paragraphs 1 to 3 for each of the pharmacies listed in the application; and

2. The pharmacy to be operated as well as the pharmacy subsidiaries are located within the same district or the same autonomous city or in

neighboring districts or neighboring autonomous cities.

(5) To operate several community pharmacies, the regulations of this legislation shall apply with the following requirements:

1. The operator must personally manage one of the pharmacies (main pharmacy).

2. For each additional pharmacy (pharmacy subsidiary), the operator must designate an accountable pharmacist, who must fulfill the obligations as stipulated for pharmacy managers in this legislation and in the Ordinance on the Operation of Pharmacies. If a different individual is to be designated as accountable pharmacist, the authorities must be notified by the operator one week prior to the change.

Section 3

The permit expires

1. Upon death;
2. By waiver;
3. By withdrawal or revocation of the license to practice as a pharmacist, by waiver of the license or revocation of the permit pursuant to Section 2 paragraph 2 of the Federal Pharmacists Regulation;
4. If the permit has not been used for one year; the authorities in charge may extend this period, if there is an important reason;
5. *(Canceled)*

Section 4

(1) The permit must be revoked, if one of the prerequisites pursuant to Section 2 was not met when it was awarded.

(2) The permit must be revoked, if one of the prerequisites pursuant to Section 2 paragraph 1 nos. 1, 2, 4, 6 or 7 ceased to exist. The permit may be revoked, if the permit holder later concluded agreements in violation of Section 8 clause 2, also in connection with clause 4, Section 9 paragraph 1, Section 10 or Section 11.

Section 5

If a pharmacy is operated without a permit, the authority in charge must close said pharmacy.

Section 6

A pharmacy may only be opened after the authority in charge has certified that the pharmacy meets the legal requirements (approval).

Section 7

The permit obliges the holder to manage the pharmacy personally in his/her own responsibility. In the case of Section 2 paragraph 4, the duties in clause 1 are incumbent upon the pharmacist designated by the operator pursuant to Section 2 paragraph 5 no. 2; this does not affect the obligations of the operator. The personal management of a hospital pharmacy is the responsibility of the employed pharmacist.

Section 8

Several persons may jointly manage a pharmacy only with the legal status of a partnership under the Civil Code or a general partnership; in these cases, all partners must hold a permit. Shareholdings in a pharmacy in the form of a silent partnership and agreements in which the remuneration for loans that were granted to the permit holder or for other assets the permit holder was allowed to use depends upon the turnover or profit of the pharmacy, or lease contracts that are oriented at the turnover or profit of the pharmacy, are not permitted. Lease agreements for pharmacies pursuant to Section 9 in which the rent depends upon the turnover or profit are not considered agreements in the sense of clause 2. Clauses 1 to 3 apply to pharmacies pursuant to Section 2 paragraph 4 accordingly.

Section 9

(1) Leasing a pharmacy or several pharmacies pursuant to Section 2 paragraph 4 is permitted only in the following cases:

1. If and as long as the lessor holds a permit and is unable to operate the pharmacy him-/herself due to an important personal reason, or if the permit was revoked, because one of the prerequisites pursuant to Section 2 paragraph 1 no. 7 ceased to exist, or if the license was revoked, because one of the prerequisites pursuant to Section 4 paragraph 1 clause 1 no. 3 of the Federal Pharmacists Regulation ceased to exist;
2. After the death of the permit holder by his children who are entitled to inherit up until the time when the youngest child reaches the age of 23. If one of these children takes the profession of pharmacist before attaining the age of 23 years, the period may be extended upon application until said child him- or herself is able to meet the prerequisites for receiving a permit;

3. By the surviving spouse or common-law spouse, who is entitled to inherit until the time he or she remarries or enters a common-law relationship, unless he or she is awarded his/her own permit pursuant to Section 1.

The permissibility of the lease is not affected by transferring the pharmacy within the same community or in cities within the same district or to a neighboring district or altering its premises after any of the cases mentioned in clause 1 occurred. If the pharmacy that is transferred or whose premises are altered is leased pursuant to clause 1 no. 1, the lessor does not require a new permit. Section 3 no. 5 remains unaffected.

- (1a) If the lessor dies before the lease has expired, the authority in charge may allow that the lease between the lessee and the heirs be continued for a maximum period of twelve (12) months to prevent unreasonable hardship for the lessee.
- (2) The lessee requires a permit pursuant to Section 1. The lease agreement may not impair the professional responsibility and decision-making freedom of the leasing pharmacist.
- (3) For the duration of the lease period, Section 3 no. 4; Section 4 no. 2, as far as this regulation refers to Section 2 paragraph 1 no. 6; and Section 7 clause 1 shall not apply to the permit of the lessor.
- (4) The permit awarded pursuant to paragraph 2 must be revoked, if one of the prerequisites according to subparagraph 1 was not met at the time it was awarded; it must be revoked, if one of these prerequisites is no longer met after the fact. Section 4 remains unaffected.

Section 10

The permit holder may not undertake to exclusively or preferentially offer or dispense certain medicinal products or to limit the choice of medicinal products to be dispensed by him/her to the offerings of certain manufacturers or traders or groups thereof.

Section 11

- (1) Permit holders and pharmacy staff may not execute legal transactions or enter into agreements with physicians or other individuals concerned with the treatment of health disorders involving the preferential supply of certain pharmaceuticals, the referral of patients, the assignment of prescriptions or the production of medicinal products without full indication of their composition. Section 140a of the German Social Security Code V remains unaffected.
- (2) Deviating from paragraph 1, based on an agreement, the holder of a permit to operate a community pharmacy may immediately dispense ready-to-use cytostatic preparations, which were produced during regular pharmacy operations, to the treating physician.

- (3) Upon a request by the holder of a permit to operate a community pharmacy, the holder of a permit to operate a hospital pharmacy may dispense the ready-to-use cytostatic preparations produced in his/her pharmacy to said community pharmacy, or he/she may dispense them to another hospital pharmacy upon request by the holder of a permit to operate said hospital pharmacy. This rule applies accordingly to the holder of a permit to operate a community pharmacy for the dispensation of the medicinal products listed in clause 1 to a hospital pharmacy or to another community pharmacy. An agreement pursuant to Section 14 paragraph 3 or 4 is not required.
- (4) In the case of a menacing communicable disease spreading in a manner that demands an instant provision of specific medicinal products significantly exceeding the usual extent,
- a. paragraph 1 does not apply to medicinal products that have been stored by the Health Authorities of the Federation or the German States (*Bundesländer*) or by entities entitled by them pursuant to Section 47 paragraph 1 clause 1 no. 3c) of the German Medicines Act or that have manufactured pursuant to Section 21 paragraph 1c of the German Medicines Act,
 - b. paragraph 3 clause 1 and 2 applies mutatis mutandis to preparations manufactured from active components stored by the Health Authorities of the Federation or the German States or by entities entitled by them.

Section 11a

Permission to send pharmacy-only medicinal products in the mail pursuant to Section 43 paragraph 1 clause 1 of the German Medicines Act must be granted to the permit holder pursuant to Section 2 upon application, if he assures in writing that he will meet the following requirements, if the permit is granted:

1. Shipping will be performed from the community pharmacy in addition to the conventional pharmacy operation and based on the applicable regulations, as long as there are no special regulations for the mail order business.
2. A quality assurance system will ensure that
 - a) The medicinal product to be shipped is packed, transported and delivered in such a manner as to preserve its quality and efficacy;
 - b) The shipped pharmaceutical is delivered to the individual that was indicated to the pharmacy by the individual placing the order. This designation may involve delivery to an individual designated by name or a designated group of individuals.
 - c) The patient is informed of the necessity of contacting the treating physician, if problems occur while using the medication; and
 - d) The consultation through pharmaceutical staff will be provided in German.

3. It ensures that

- a) The ordered pharmaceutical is shipped within two business days upon receipt of the order, if the medicinal product is available during that time, unless a different arrangement was made with the individual who ordered the pharmaceutical; if it becomes apparent that the ordered pharmaceutical can not be shipped within the time period specified in clause 1, the individual who placed the order must be notified appropriately.
- b) All ordered pharmaceuticals are delivered, if they may be circulated within the scope of the German Drugs Act and are available;
- c) That, in case of risks reported for pharmaceuticals, an appropriate system for customers reporting such risks, to inform customers of such risks and to implement internal countermeasures is in place;
- d) A second delivery free of charge will be arranged;
- e) A system for tracking shipments is maintained; and
- f) Transport insurance is purchased.

For electronic commerce with pharmacy-only medicinal products, clause 1 shall apply subject to the proviso that the pharmacy has the appropriate equipment and devices available.

Section 11 b

- (1) The permit pursuant to Section 11a must be withdrawn, if one of the prerequisites pursuant to Section 11a was not met.
- (2) The permit must be revoked, if later one of the prerequisites pursuant to Section 11a is not met. The permit can be revoked, if facts justify the assumption that, contrary to an executable regulation by the authority in charge, the permit holder does not operate the pharmacy pursuant to the requirements of Section 11a clause 1 no. 1 to 3, clause 2 or a legal regulation pursuant to Section 21.
- (3) If the mail order business is operated without a permit, Section 5 shall apply.

Section 12

Legal transactions that partially or entirely violate Section 8 clause 2, Section 9 paragraph 1, Section 10 or Section 11 are null and void.

Section 12a

- (1) To supply the residents of nursing homes with pharmaceuticals and pharmacy-only medicinal products in the sense of Section 1 of the Care Facilities Act, the holder of a permit to operate a community pharmacy is obligated to conclude a written agreement with the sponsor of the nursing homes. To become legally effective, the agreement is subject to authorization through the authority in charge. Authorization must be granted, if
1. The community pharmacy and the nursing homes to be supplied are located within the same district or the same autonomous city or in neighboring districts or autonomous cities;
 2. The correct pharmaceutical supply is ensured and if especially the kind and extent of supply, the right of access to the nursing facility and the responsibilities to verify the correct, occupant-oriented storage of the products delivered by him/her through the pharmacy's pharmaceutical staff and the documentation of said supply are contractually stipulated;
 3. The responsibilities of the pharmacist regarding information and consultation of the care facility's residents and those of the individual in charge of dispensing or administering the supplied products are stipulated, if information and consultation of the care facility's residents or staff are required;
 4. The agreement does not restrict the free choice of pharmacy of the care facility's residents; and
 5. The agreement does not contain an exclusivity clause in favor of a given pharmacy and clearly defines the responsibilities of multiple pharmacies involved in the pharmaceutical supply activities.

Subsequent amendments or addenda must be reported to the authority in charge immediately.

- (2) Before starting the supply process, such activities must be reported to the authority in charge.
- (3) If care facility residents procure their own supply of pharmaceuticals and pharmacy-only medicinal products from community pharmacies, no agreement pursuant to paragraph 1 is needed.

Section 13

- (1) After the death of a permit holder, the heirs are allowed to have the pharmacy managed by a pharmacist for a maximum period of twelve (12) months.

- (2) (1a) If the lessee of a pharmacy dies before the contractual lease has expired, the authority in charge may allow the lessor to have the pharmacy managed by a pharmacist for a maximum period of twelve (12) months to avoid unreasonable hardship to the lessor.
- (3) (1b) The manager requires a permit for the managing period. The permit must be awarded, if he/she meets the prerequisites pursuant to Section 2 paragraph 1 nos. 1 to 4, 7 and 8.
- (3) The permit expires, if the manager no longer holds a license to practice as a pharmacist. Section 4 must be applied accordingly.
- (4) The manager is responsible for compliance with the Ordinance on the Operation of Pharmacies and the regulations regarding the production of pharmaceuticals and their handling and dispensation.

SECOND CHAPTER

Hospital pharmacies, military pharmacies, branch pharmacies, emergency pharmacies

Section 14

- (1) Upon application, the sponsoring institution for a hospital must be granted a permit to operate a hospital pharmacy, if
 - 1. It hires a pharmacist who meets the prerequisites pursuant to Section 2 paragraph 1 nos. 1 to 4, 7 and 8 as well as paragraph 3, also in connection with paragraph 2 or 2a; and
 - 2. Proves that the premises required by the Ordinance on the Operation of Pharmacies for hospital pharmacies are available.

The manager of the hospital pharmacy or a pharmacist commissioned by him/her must inform and consult the hospital's physicians on pharmaceuticals, especially with regard to purposeful and economical pharmaceutical therapy. This also applies to outpatient pharmaceutical care.

- (2) The permit must be rescinded, if it becomes apparent at a later date that one of the required prerequisites pursuant to paragraph 1 clause 1 was not met. It must be revoked, if one of the prerequisites pursuant to paragraph 1 was eliminated or if the permit holder or an individual commissioned by him/her severely or consistently violates the provisions contained in this regulation, the regulation passed based on Section 21 or the regulations addressing the production or dispensation of pharmaceuticals. The same applies to the permit pursuant to paragraph 5 clauses 1 and 3, if the prerequisites pursuant to paragraph 5 clause 2 did not apply or were eliminated.

- (3) If the holder of a permit to operate a hospital pharmacy pursuant to paragraph 1 intends to supply another hospital not supported by him/her with pharmaceuticals, he/she must conclude a written agreement with the sponsor of said hospital.
- (4) If the sponsor of a hospital intends to have the hospital supplied by the holder of a permit to operate a pharmacy pursuant to Section 1 paragraph 2 or pursuant to the laws of another member state of the European Union or another signatory state of the Agreement on the European Economic Area, he/she needs to conclude a written agreement with the holder of said permit. The place of fulfillment for the contractual services is the hospital's place of business. German law shall apply.
- (5) To become effective, the agreement concluded pursuant to paragraph 3 or 4 requires the approval of the authority in charge. This approval must be given, if it is ensured that the hospital has concluded an agreement with a pharmacy in accordance with paragraph 3 or 4 for the pharmaceutical supply of the hospital through this pharmacy and that said agreement meets the following prerequisites:
 1. The correct pharmaceutical supply is guaranteed, and the necessary rooms, facilities and staff in particular are available that are required pursuant to the Ordinance on the Operation of Pharmacies or, for pharmacies that are located in another member state of the European Union or another signatory state of the Agreement on the European Economic Area, pursuant to the legislation applicable in that state.
 2. The pharmacy supplies the hospital with the medicinal products it ordered either directly or, if it is a mail order, in accordance with the requirements pursuant to Section 11a;
 3. The pharmacy provides pharmaceuticals required urgently by the hospital for acute medical care immediately and as needed;
 4. Personal consultations for the hospital staff by the manager of the pharmacy pursuant to paragraph 3 or 4 or the pharmacist of the supply pharmacy he commissioned are made as needed or provided immediately during an emergency;
 5. The supply pharmacy guarantees that the hospital staff is provided with continuous consultation with respect to a purposeful and economical pharmaceutical therapy.
 6. Pursuant to paragraph 3 or 4, the manager of the pharmacy is a member of the hospital's pharmaceutical commission.

Approval from the authority in charge is also necessary for the supply of another hospital with a pharmacy sponsored by the same institution. For granting said approval, clause 2 shall apply accordingly.

- (6) The manager of a hospital pharmacy pursuant to paragraph 1 or a pharmacy pursuant to paragraph 4 or a pharmacist commissioned by him must inspect the pharmaceutical supplies of the hospital to be provided based on the requirements of the Ordinance on the Operation of Pharmacies and must ensure in particular that the pharmaceuticals are of impeccable quality and are stored properly. To eliminate any defects that were discovered, he must set an appropriate deadline and report any non-compliance with this deadline to the supervisory authority for pharmacies.
- (7) The manager of the hospital pharmacy pursuant to paragraph 1 or a pharmacist commissioned by him, or the manager of a pharmacy pursuant to paragraph 4 may supply pharmaceuticals only to those hospitals with which legally effective agreements have been concluded or for whose supply a permit pursuant to paragraph 5 clause 3 was granted. The individuals mentioned in clause 1 may only dispense pharmaceuticals to the individual wards and subunits of the hospital for the supply of patients, who are undergoing full or partial inpatient treatment, pre- or post-treatment (Section 115a of the Social Security Code V), who receive outpatient surgery or receive pharmaceutical care during other non-inpatient procedures (Section 115b of the Social Security Code V), furthermore for immediate patient application to authorized outpatient centers of the hospital, especially to outpatient centers at university clinics (Section 117 of the Social Security Code V), outpatient centers at psychiatric institutes (Section 118 of the Social Security Code V), social pediatric centers (Section 119 of the Social Security Code V) and authorized hospital physicians (Section 116 of the Social Security Code V) as well as patients during outpatient treatment at the hospital, if the hospital is authorized (Section 116a of the Social Security Code V) or has the right (Sections 116b and 140b paragraph 4 clause 3 of the Social Security Code V). Upon discharge of a patient following inpatient or outpatient treatment at the hospital, the required quantity of pharmaceuticals to bridge several days may only be dispensed, if a weekend or official holiday follows immediately. Irrespective of clause 3, the pharmaceuticals required for temporary assistance may be dispensed for no longer than three days to patients, for whom a prescription for at-home nursing care is available pursuant to Section 92 paragraph 7 no. 3 of the Social Security Code V. Pharmaceuticals may only be dispensed to hospital employees for their own immediate needs.
- (8) Hospitals in the sense of this legislation are institutions pursuant to Section 2 no. 1 of the Hospital Financing Act. With regard to pharmaceutical supply, the following are equivalent to hospitals:
1. The providers and implementers of ambulance service based on national law;
 2. Health resorts and special facilities that serve the purpose of preventive health care or medical or occupational rehabilitation, as long as they

- a) Provide treatment or nursing care as well as accommodations and boarding;
- b) Are permanently managed by a physician on a full-time basis; and
- c) Bill at least 40 percent of the annual services to patients of public service providers or self-pay patients who do not pay higher rates than those paid by the public service providers.

The designated providers and implementers of ambulance services as well as health resort and special facilities are to be considered wards in the sense of paragraph 7 clause 2, unless they are subdivided into wards and other subunits with different service purposes. A permit pursuant to paragraph 1 must not be awarded to an institution responsible for a facility listed in clause 2.

- (9) Paragraphs 3, 4, 5 clause 3 and paragraph 7 clause 1 to 3 do not apply as far as medicinal products are concerned which are intended for the treatment of a menacing communicable disease spreading in a manner which demands an instant provision of specific medicinal products significantly exceeding the usual extent and that have been stored by Health Authorities of the Federation or the German States (*Bundesländer*) or by entities entitled by them pursuant to Section 47 paragraph 1 clause 1 no. 3c) of the German Medicines Act or that have been manufactured pursuant to Section 21 paragraph 1c of the German Medicines Act.

Section 15

- (1) Within the scope of responsibility of the Federal Ministry of Defense, the supply of pharmaceuticals is the task of the military pharmacies.
- (2) Taking into account the special military conditions, the Federal Ministry of Defense stipulates the construction of military pharmacies and their establishment and operation in official regulations. In doing so, it ensures that the members of the German armed forces are equal to civilians with respect to pharmaceutical supply and drug safety.
- (3) *(canceled)*

Section 16

- (1) If an emergency arises with regard to the supply of pharmaceuticals due to the absence of a pharmacy, the authority in charge may award a permit to operate a branch pharmacy to the owner of a nearby pharmacy upon application, if he/she proves that the required premises are available.
- (2) Branch pharmacies must be managed. Section 13 applies accordingly.

- (3) A permit pursuant to paragraph 1 should not be awarded to a pharmacist for more than one branch pharmacy.
- (4) The permit is awarded for a period of five years; it may be renewed.

Section 17

If it is found that six months after a pharmaceutical supply shortage for the population was publicly announced that no application was submitted either for the operation of a pharmacy or for the operation of a branch pharmacy, the authority in charge may award a community or association of local governments the permit to operate a pharmacy to be managed by a pharmacist in their employ, if they prove the availability of the required premises and facilities. The pharmacist must meet the prerequisites of Section 2 paragraph 1 nos. 1 to 4 and 7.

THIRD CHAPTER

Ordinance on the Operation of Pharmacies and Exemption for the Federal Police and Riot Police

Sections 18 to 20

(canceled)

Section 21

- (1) By decree and with the consent of the Federal Council, the Federal Ministry of Health is authorized to enact an Ordinance on the Operation of Pharmacies to ensure the proper operation of pharmacies, branch pharmacies and hospital pharmacies and to guarantee the quality of pharmaceuticals to be manufactured and dispensed there. The fundamental rules established by the World Health Organization for the production and quality assurance of pharmaceuticals, the regulations of the pharmacopoeia and the generally accepted rules of pharmaceutical science must be taken into account. With the approval of the Federal Council, regulations regarding the organization, equipment and participation of pharmacies in the implementation of supply forms stipulated in accordance with the Social Security Code V can be decreed through the Ordinance on the Operation of Pharmacies pursuant to clause 1. In addition, by decree and with the consent of the Federal Council, the Federal Ministry of Health and Social Security is authorized to enact regulations especially regarding the design, operation and quality assurance of information in electronic media used in conjunction with the electronic commerce involving pharmaceuticals.
- (2) The Ordinance on the Operation of Pharmacies pursuant to paragraph 1 clause 1 may stipulate regulations regarding

1. The development, production, acquisition, testing, filling and refilling, packaging and packing, storage, marketing, dispensation and labeling of pharmaceuticals as well as the separation and destruction of pharmaceuticals that are not marketable and on other operating activities;
- 1a. The requirements for the mail order business, electronic commerce including shipping, consultation and information in connection with this pharmaceutical commerce and the assurance of proper dispensation of these pharmaceuticals to the end consumer, documentation requirements and the identification of pharmaceuticals or groups of pharmaceuticals for which dispensation by mail order is not permitted for reasons of pharmaceutical safety or consumer protection, unless pharmaceutical safety and consumer protection can be ensured with appropriate means and the assumption of risks is justified and these risks are disproportionate;
2. The maintenance and storage of proof regarding the operating activities listed in no. 1;
3. The special experimental conditions and the control of animals used in the development, production and testing of drugs as well as the maintenance and storage of proof thereof; the regulations of the Animal Welfare Act and the legal regulations enacted based on the Animal Welfare Act shall remain unaffected;
4. The requirements toward pharmacy staff and their activities;
5. The deputy for the managing pharmacist;
6. The size, quality, equipment and furnishings of the pharmacy premises as well as the other rooms concerned with the mail order business and electronic commerce including the shipping of pharmaceuticals and the consultation and information provision in connection with this business;
7. The quality and labeling of containers in the pharmacy;
8. The merchandise usually found in pharmacies, ancillary business, duty turns and the stockroom of the pharmacies as well as pharmaceutical dispensation inside and outside of pharmacy premises;
9. The prerequisites for awarding a permit to establish prescription collection centers and the procedure to be followed in this respect as well as the prerequisites for closing prescription collection centers and the requirements for operating them;
10. The designation and area of responsibility of pharmacy controllers;
11. The reservation of batch samples and their extent and storage period;

12. The requirements with respect to sanitation in the pharmacies; and
 13. The inspection of pharmaceutical inventories in hospitals and the maintenance and storage of proofs thereof.
- (3) Especially the following provisions regarding the design including the operation and quality assurance of information in electronic media that are used in conjunction with electronic commerce with pharmaceuticals can be incorporated in the regulation pursuant to paragraph 1 clause 4:
1. Presentation and safety of application;
 2. Order form and information listed on the order form;
 3. Questionnaire on information relevant for the pharmaceutical therapy, if these are required for reasons of pharmaceutical safety;
 4. Information on pharmaceutical safety;
 5. Communication mode and quality of the information;
 6. Quality assurance, quality control and quality confirmation;
 7. Target group orientation;
 8. Transparency;
 9. Authorship of the website and information;
 10. Confidentiality and data privacy;
 11. Updating of information;
 12. Responsibility and contacts for feedback;
 13. Accessibility of health- or pharmaceutical-related data or content;
 14. Links to other websites or other information sources;
 15. Installations for the identification and verification of the monitoring or inspection of the pharmacy and the website as well as its basics.
- (4) If pharmacies have a permit to produce pharmaceuticals in accordance with the regulations of the German Medicines Act, the regulations of the Ordinance on the Operation of Pharmacies shall apply to the operation of the pharmacy and the corresponding regulations of the German Medicines Act shall apply to the production of pharmaceuticals.

Section 22

Facilities used to provide pharmaceuticals to the members of the Federal Police and the riot police of the German states as well as their livestock under the free medical care framework are not subject to the regulations of this legislation.

FOURTH CHAPTER

Regulations on penalties and fines

Section 23

Individuals who intentionally or by neglect operate or manage a pharmacy, hospital pharmacy or branch pharmacy without the required permit or authorization shall be punished by imprisonment of up to six months a fine of up to one hundred eighty daily rates.

Section 24

(canceled)

Section 25

- (1) Individuals commit an administrative offense, if they commit the following acts intentionally or by neglect:
 1. Failure to designate an individual in charge or failure to do so properly and in a timely manner in violation of Section 2 paragraph 5 clause 2.
 2. Providing or accepting services on the basis of an agreement that is inadmissible pursuant to Section 8 clause 2, Section 9 paragraph 1, Section 10 or Section 11 paragraph 1, or if they conduct such an agreement in any other way,
 3. Having a pharmacy managed by an individual who was not awarded a permit pursuant to Section 13 paragraph 1b clause 1; or
 4. Supplying a hospital with pharmaceuticals in violation of Section 14 paragraph 7 clause 1; or
 5. Dispensing pharmaceuticals in violation of Section 14 paragraph 7 clause 2, 3 or 4.
- (2) An administrative offense is also committed by individuals who violate a statutory order intentionally or by neglect that was enacted on the basis of Section 21, if said statutory order refers to this regulation on fines and penalties for certain offenses.
- (3) The administrative offense can be punished with a fine of up to twenty thousand Euros for the cases described in paragraph 1 no. 2 and with a fine of up to five thousand Euros for the cases described in paragraph 1 nos. 1, 3 and 4 and paragraph 2.

FIFTH CHAPTER

Final and transitional regulations

Section 26

- (1) Personal licenses, real licenses and other personal operating permits, which were awarded before this legislation became effective, are considered permits in the sense of Section 1. This also applies to permits that are held by local or regional authorities; the pharmacies may be let; Section 9 does not apply.
- (2) The permits for operating a hospital pharmacy remain in force to the extent they had to date. The permits for operating a branch pharmacy are considered permits in the sense of Section 16.

Section 27

- (1) Holders of permits to operate a pharmacy other than those described in Section 26 require a permit for operating a pharmacy pursuant to Section 1. Provided they operate a pharmacy on the basis of such a permit, the permit is considered to have been awarded.
- (2) If, according to the stipulations of the award certificate and based on the national regulations prior to the effective date of this legislation, the use of such a permit was allowed to an individual who did not meet one of the prerequisites of Section 2 paragraph 1 no. 3, this shall not change. Pharmacy use must be based on a lease; Section 9 does not apply; Section 13 remains unaffected.
- (3) Holders of such a permit will only be awarded a permit to operate a branch pharmacy, if they waive their prior permit.

Section 28

- (1) For leased pharmacies, the operating permit awarded to the lessee or the acknowledgment as the lessee shall be considered permits pursuant to Section 1.
- (2) Pharmacy lease or management agreements that were effective on May 1, 1960, and are not in compliance with Sections 9 and 13 shall remain effective until the stipulated expiration date, unless they become ineffective at an earlier date.

Section 28 a

- (1) The government and community pharmacies, the pharmaceutical centers and other institutions of the government pharmacy system in the region described in Article 3 of the Unification Treaty are transferred to the trusteeship of the Treuhandanstalt for the purpose of privatization.

- (2) Pharmacies located in the region described in Article 3 of the Unification Treaty that primarily supply one or several hospitals with pharmaceuticals and share the premises of a hospital shall become hospital pharmacies and be transferred to the ownership of the corresponding institution, which is responsible for the hospital in question. In the region described in Article 3 of the Unification Treaty, and deviating from Section 14 paragraph 7 clause 2, in the interest of a proper pharmaceutical supply, the authority in charge may –upon application by the hospital's sponsoring institution – award to a hospital pharmacy the permit to provide drugs on prescriptions issued by physicians working in the outpatient department affiliated with the hospital. The permit must be revoked, if a pharmacy opens at a reasonable distance from the hospital. The permit expires no later than December 31, 1993.
- (3) For existing pharmacies in the region described in Article 3 of the Unification Treaty at the effective time of accession, the permit is considered awarded - for state pharmacies, it is considered awarded to the sponsoring institution. If there is a change in the sponsoring institution, a new permit application must be submitted. For the Treuhandanstalt and the sponsoring institution of a hospital, the permit is considered awarded.
- (4) The regional pharmacy inspections and the regional pharmacy administrations in the region described in Article 3 of the Unification Treaty shall be dissolved upon the formation of federal states. The dissolution of the pharmaceutical centers must be completed by June 30, 1991.
- (5) Upon application by entitled individuals pursuant to paragraph 6, the Treuhandanstalt is obligated to
 1. Sell pharmacies to them by December 31, 1991, or
 2. Assign the management of pharmacies to these individuals, if the pharmacies can not be sold immediately due to the legal situation or if the applicant's age is less than five years below the age of early retirement.

Pharmacy management must be limited to a maximum period of five years. It must be designed in such a way as to end no later than December 31, 1996. In the interest of ensuring the pharmaceutical supply, the management term may be extended until the individual in question has reached retirement age. Section 13 paragraphs 2 and 3 apply accordingly.

- (6) Prerequisites for the purchase and management of a pharmacy are as follows:
 1. The buyer must hold a permit pursuant to Section 1 paragraph 2;
 2. The manager must hold a permit pursuant to Section 13 paragraph 1b;
 3. An option pursuant to subparagraph 7.

The permit or authorization and the option must be enclosed with the application pursuant to paragraph 5.

- (7) The authority in charge must issue tenders for the sale or management of the pharmacies that are to be transferred into trusteeship. Upon application, this authority will issue an option for the purchase or management of a pharmacy. The decision will be made through majority vote by a commission consisting of
1. One representative from the authority in charge as chairperson;
 2. One representative from the Treuhandanstalt;
 3. Three pharmacists, of whom at least one must be a managing pharmacist and one an employee. These pharmacists are designated by the state chamber of pharmacists. As long as there is no state chamber of pharmacists yet, they shall be designated by the regional chapter of the national pharmacists association.
- (8) A pharmaceutical engineer, who manages a pharmacy in the region described in Article 3 of the Unification Treaty based on an exceptional permit, may upon application be awarded a permit to manage the pharmacy he/she has been managing, if the applicant
- a) Has been reliably managing this pharmacy for at least 10 years; and
 - b) Meets the requirements in Section 2 paragraph 1 nos. 4 and 7.

For a permit to be awarded, it is further required that the pharmacy managed by the pharmaceutical engineer become a branch pharmacy of a community pharmacy. Decisions on such applications shall be made in accordance with paragraph 7. The management permit shall be valid until the applicant has reached retirement age, however, for a maximum duration of five years.

- (9) Until December 31, 1992, the sale or management assignment of state pharmacies that existed at the effective time of accession in the region described in Article 3 of the Unification Treaty, is allowed only to applicants who were citizens of said region when the Treaty became effective, or who were former citizens of this region, had their permanent residence outside of this region after 1972 and re-established permanent residence in this region after January 1, 1990.

Section 29

(canceled)

Section 30

The provisions of this legislation do not apply to medical and veterinary centers for dispensing drugs (in-house pharmacies).

Section 31

(Cessation of validity)

Section 32

(canceled)

Section 33

(Becoming effective)