

Ordinance on the Operation of Pharmacies (Apothekenbetriebsordnung – ApBetrO)

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First Chapter
General Provision

Section 1
Scope of Application

(1) This Ordinance applies to the operation and to the facilities of community pharmacies including pharmacies that supply hospitals with pharmaceuticals (hospital-supplying pharmacies), branch pharmacies and emergency pharmacies as well as hospital pharmacies. It contains provisions on how to ensure a proper supply of the population with pharmaceuticals and pharmacy-only medical devices.

(2) This Ordinance does not apply to the operation of pharmacies that were granted a license pursuant to Section 13, Section 52a or Section 72 of the German Medicines Act.

(3) The Ordinance on the Operation of Medical Devices in the version of the announcement of August 21, 2002 (Federal Gazette I p. 3396) and the Ordinance on Safety Plans for Medical Devices of June 24, 2002 (Federal Law Gazette I p. 2131), in their currently valid version respectively, shall remain unaffected.

Section 1a
Definitions

(1) Hospital-supplying pharmacies are community pharmacies that supply hospitals pursuant to Section 14 paragraph 4 of the German Pharmacies Act.

(2) Pharmaceutical staff includes pharmacists, pharmaceutical assistants, pharmacist's assistants, pharmacy technicians, pharmacy assistants as well as individuals who are training to become pharmacists or pharmaceutical assistants.

(3) Pharmaceutical activities in terms of this Ordinance include

1. Development and preparation of pharmaceuticals;
2. Testing of primary substances or pharmaceuticals;
3. Sale of pharmaceuticals;
4. Information and advice on pharmaceuticals;
5. Testing of pharmaceuticals as well as monitoring, collection and evaluation of pharmaceutical risks and medication errors in hospitals, or in institutions equivalent to hospitals pursuant to Section 14 paragraph 8 of the German Pharmacies Act with regard to pharmaceutical supply, or in institutions to be supplied in terms of Section 12a of the German Pharmacies Act;
6. Medication management in which a patient's entire medication, including self-medication, is repeatedly analyzed with the objective of improving the safety of pharmaceutical therapy and therapy compliance by recognizing and solving pharmaceutical-related problems.

(4) Patient-individual dosage provision is the patient-related manual repackaging of ready-made pharmaceuticals in a reusable container upon individual request for certain times when the patient needs to take the pharmaceutical in question.

(5) Patient-individual blistering is the patient-related manual or machine-based repackaging of ready-made pharmaceuticals in a non-reusable container upon individual request for certain times when the patient needs to take the pharmaceutical in question.

(6) A primary substance is each compound or preparation of compounds used in the production of a pharmaceutical with the exception of packaging materials.

(7) Primary packaging materials are containers or wrappings that come in contact with pharmaceuticals.

(8) Extemporaneous pharmaceuticals are any medicinal products that are individually prepared at the pharmacy based on a prescription or other order by an individual and are not produced in advance.

(9) Preparations of pharmaceuticals to be kept in stock in larger quantities describe medicinal products that are prepared as part of regular pharmacy operations in advance on a given day in quantities of up to 100 ready-for-sale packages or in the corresponding volume.

(10) Goods customarily kept at a pharmacy include:

1. Medical devices that are not restricted to pharmacies;
2. Products as well as objects and information materials that directly serve or promote the health of humans and animals;
3. Body care products;
4. Testing substances;
5. Chemicals;
6. Reagents;
7. Laboratory supplies;
8. Pesticides and plant protection products; and

9. Products for rearing animals.

(11) Services customarily rendered by a pharmacy include such services that serve or promote the health of humans and animals, specifically:

1. Advice
 - a) Regarding health or nutrition issues;
 - b) Regarding health education and information;
 - c) Regarding preventative measures;
 - d) On medical devices;
2. Implementation of simple health tests;
3. Patient-individual adjustment of medical devices; and
4. Communication of health-related information.

(12) In-process controls are tests performed during the preparation of a pharmaceutical for monitoring and, if necessary, adjustment of the process in order to ensure that the pharmaceutical has the expected quality. During the preparation of sterile pharmaceuticals, specifically parenteral products, monitoring of the environment or equipment is part of the in-process controls.

(13) Critical equipment objects or devices are items that come in contact with the primary substances or pharmaceuticals or could have another relevant influence on the quality or safety of these products.

(14) Calibration is a working step based on which the relationship is determined under exactly defined conditions between the values displayed by a measuring device or measuring system on the one hand, or the values resulting from a material measurement and the corresponding values of a reference standard on the other hand.

(15) Qualification is the provision of documented evidence which proves with high certainty that a specific piece of equipment or a specific environmental condition meets the previously determined quality requirements for the preparation or testing of a pharmaceutical.

(16) Validation is the provision of documented evidence which proves with high certainty that a pharmaceutical is prepared and tested based on a specific process or a standard operating procedure that meets the previously determined quality requirements.

(17) Preparation in a closed system describes the transfer of sterile primary substances or solutions into a presterilized closed container without the contents coming into contact with the external environment.

Second Chapter The Operation of Community Pharmacies

Section 2 Managing Pharmacist

(1) The managing pharmacist is

1. The permit holder in the event of a pharmacy operated pursuant to Section 1 paragraph 2 of the German Pharmacies Act, pursuant to Section 2 of the German Pharmacies Act, the lessee in the event of a lease;
2. The licensee in the event of a pharmacy or branch pharmacy managed pursuant to Section 13 or Section 16 of the German Pharmacies Act;

3. The pharmacist employed by the authority in charge and entrusted with the operation of the pharmacy in the event of a pharmacy operated pursuant to Section 17 of the German Pharmacies Act;
4. The permit holder pursuant to Section 2 paragraph 4 of the German Pharmacies Act in the event of a main pharmacy pursuant to Section 2 paragraph 5 no. 1 of the German Pharmacies Act;
5. The individual in charge designated by the operator for a pharmacy subsidiary pursuant to Section 2 paragraph 5 no. 2 of the German Pharmacies Act.

(2) The managing pharmacist shall personally run the pharmacy. It shall be his responsibility to ensure that the pharmacy is operated in compliance with the valid regulations. Apart from the managing pharmacist pursuant to paragraph 1 no. 5, the operator is also responsible for compliance with the valid regulations for operating a pharmacy.

(3) The managing pharmacist shall, before its commencement, report to the authority in charge any other professional or commercial activity.

(4) The managing pharmacist may, apart from pharmaceuticals, offer or sell in the pharmacy the goods listed in Section 1a paragraph 10 to an extent only that does not impair the proper operation of the pharmacy and the priority of the assignment to supply drugs. Clause 1 shall apply accordingly to the services customarily rendered by a pharmacy pursuant to Section 1a paragraph 11.

(5) A pharmacist must deputize for the managing pharmacist, if the managing pharmacist does not exercise his duty to personally run the pharmacy temporarily. Said substitution must not exceed a total of three months per year. The authority in charge may permit substitution beyond that period of time, if an important reason is given in the person of the managing pharmacist.

(6) If a managing pharmacist is unable to meet his obligation pursuant to paragraph 5 clause 1, an assistant pharmacist or a pharmaceutical engineer may deputize, provided the same is qualified in particular with respect to his knowledge and skills and provided he/she was employed full-time in a community pharmacy or hospital pharmacy for at least six months in the year preceding the commencement of such substitution. Over the course of the year, assistant pharmacists or pharmaceutical engineers may not substitute for the managing pharmacists for more than a total of four weeks. Before the substitution begins, the pharmacist must inform the authority in charge and indicate the name of the substitute. Clauses 1 to 3 do not apply to substitution of the

1. Permit holder pursuant to Section 2 paragraph 4 of the German Pharmacies Act;
2. Managing pharmacist of a hospital-supplying pharmacy; and the
3. Managing pharmacist of a pharmacy to which the special regulations in Section 34 or 35 apply.

(7) The pharmacist or assistant pharmacist or pharmaceutical engineer entrusted with such a substitution shall have to perform the duties of a managing pharmacist during the period of substitution.

Section 2a Quality Management System

(1) The managing pharmacist must operate a quality management system in accordance with the type and extent of pharmaceutical activities. The quality management system must stipulate and document the operational processes. The quality management system must specifically ensure that the pharmaceuticals are prepared, tested and stored according to state-of-the-art science and technology, that mix-ups are avoided and that sufficient advice is provided.

(2) As part of the quality management system, the managing pharmacist must ensure that regular self-inspections for controlling operational processes are performed by pharmaceutical staff and that corrections are made, if necessary. Furthermore, the pharmacy should participate in regular measures for external quality controls.

(3) The managing pharmacist is responsible for documenting the controls and self-inspections pursuant to paragraph 2 and the subsequently taken measures, if necessary.

Section 3 Pharmacy Staff

(1) The pharmacy staff may only be employed in accordance with its training and knowledge and must regularly be instructed regarding the due diligence required for the respective activities. Instruction must also extend to the theory and implementation of the quality management system as well as to specifics of the pharmaceuticals prepared, tested and stored.

(2) The required staff, especially pharmaceutical staff, must be available in sufficient numbers to ensure the proper operation of the pharmacy. Staff required additionally for supplying a hospital is determined by the kind and scope of a medically appropriate and adequate supply of the hospital with pharmaceuticals and pharmacy-only medical devices taking into account the size, the type and the services rendered by the hospital. Clause 2 applies accordingly for the supply of institutions in terms of Section 12a of the German Pharmacies Act.

(3) *deleted*

(4) Evaluation of the analysis and advice as part of medication management must be done by a pharmacist of the pharmacy.

(5) It is forbidden to have pharmaceutical activities conducted by any individuals other than pharmaceutical staff, unless otherwise provided for pursuant to paragraph 5a. The individual in question must have a command of the German language and be knowledgeable in German law to the extent required for their professional activities. Pharmaceutical activities conducted by pharmaceutical assistants, pharmacy assistants or individuals who are training to become pharmacists or pharmaceutical assistants must be supervised by the managing pharmacist or a pharmacist instructed to do so by the managing pharmacist. Pharmaceutical assistants are not permitted to dispense pharmaceuticals.

(5a) Under the supervision of a pharmacist, the repackaging including filling and packaging or labeling of pharmaceuticals may also be performed by employees other than the pharmaceutical staff, as long as these are pharmacy assistants, pharmacy technicians, pharmaceutical clerks or individuals training to become pharmaceutical clerks. Furthermore, the pharmaceutical staff is allowed to obtain support from the other employees mentioned in clause 1 for the

1. Preparation and testing of pharmaceuticals;
2. Testing of primary substances;
3. Operation, care and maintenance of the work equipment;
4. Filling and packaging or labeling of the pharmaceuticals; and the
5. Preparation of the pharmaceuticals for dispensation.

The staff employed in production pursuant to clause 1 or support pursuant to clause 2 must be qualified accordingly for these tasks and be verifiably instructed by the pharmaceutical staff about the due diligence for the tasks in question in advance as well as continuously thereafter.

(6) To supply hospitals, with the exception of deliveries, the managing pharmacist may only assign staff employed in his pharmacy. Clause 1 applies accordingly to the supply of residents of an institution to be supplied in terms of Section 12a of the German Pharmacies Act.

Section 4 State, Size and Equipment of Pharmacy Premises

(1) The type, size, number, location and equipment of the premises must be appropriate for the proper operation of the pharmacy, in particular the proper development, preparation, testing, storage, packaging and correct dispensation of the pharmaceuticals or the dispensation of pharmacy-only medical devices and information and advice on pharmaceuticals or medical devices, including via telecommunications devices. The operational facilities must be

1. Separated by walls or doors
 - a) From rooms with other commercial or professional uses, also in connection with activities for which the managing pharmacist holds a permit pursuant to Section 52a of the German Pharmacies Act; and
 - b) From public traffic areas and store aisles;
2. Protected from unauthorized access based on appropriate measures;
3. Sufficiently lit, ventilated and air-conditioned, if necessary;
4. Kept in immaculate structural and sanitary condition; and
5. Arranged in such a manner that each room is accessible without leaving the pharmacy (spatial unit).

Clause 2 no. 1 letter a does not apply to the preparation of pharmaceuticals that require a permit pursuant to Section 13 of the German Pharmacies Act.

(2) A pharmacy must consist at least of the sales area, a laboratory, sufficient storage area and a room for night duty. The laboratory must be equipped with a vent including a suction system or a corresponding system that fulfills the same function. The basic area of the operational facilities mentioned in clause 1 must be at least 110 square meters. In calculating the basic area, the separate rooms pursuant to Section 34 paragraph 3 and Section 35 paragraph 3 as well as rooms that must be separated from the operational facilities of the pharmacy pursuant to paragraph 1 clause 2 no. 1 letter a are not to be taken into account. For hospital-supplying pharmacies, Section 29 paragraph 1 and 3 apply accordingly.

(2a) The sales area must have access to the public traffic areas and should be accessible without barriers. It must be designed in such a manner that the priority of the pharmaceutical supply mandate is not negatively impacted and that there is enough room for the relevant tasks performed in the sales area, specifically the consultation of patients and customers. The sales area must be furnished in such a manner that the confidentiality of consultations, especially in the locations where pharmaceuticals are dispensed to customers, is preserved, so that it can be largely prevented that other customers overhear a consultation.

(2b) A separate workstation must be planned for the preparation of pharmaceuticals that are not designed for parenteral use. The workstation must be separated from other areas of the pharmacy up to room height on at least three sides unless this workstation is located in an operational room that simultaneously serves exclusively as a laboratory. Its walls, surfaces and floor must be easy to clean in order to minimize the environmental contamination risk for the pharmaceuticals to be prepared. The workstation can also be used for the production of medical devices or goods customarily sold at a pharmacy pursuant to Section 1a paragraph 10 no. 2, 3 or 9.

(2c) A separate workstation must be planned for the preparation of pharmaceuticals that constitute drugs or drug mixtures or for any other processing of drugs as primary substances. Paragraph 2b clause 2 and 3 do not apply.

(2d) The storage room must be sufficiently large and allow the correct storage of the products stocked or sold at the pharmacy. Storage below 25 degrees Celsius must be possible. For pharmaceuticals or primary substances that must be kept separate pursuant to Section 21 no. 7 and for falsified medicines that must be stored in a secure manner pursuant to Section 21 no. 8, a separate and correspondingly labeled storage area must be provided. If pharmaceuticals are delivered to the pharmacy outside of its opening hours, compliance with the required storage temperatures for the pharmaceuticals in question must be ensured at all times; unauthorized access must be excluded. Pharmacies that supply hospitals with pharmaceuticals must provide separate storage rooms for these pharmaceuticals or at least separate storage areas that are labeled accordingly.

(3) A branch pharmacy must consist at least of the sales area, sufficient storage area and a room for night duty. Section 4 paragraph 2 clause 1 and 3 do not apply.

(4) Paragraph 1 clause 2 no. 5 does not apply to

1. Storage rooms that are used exclusively for the pharmaceutical supply of hospitals or for the supply of residents of institutions to be supplied in terms of Section 12a of the German Pharmacies Act;
2. Rooms used for mail order business and electronic commerce and the associated consultations and information;
3. Rooms used for the production activities pursuant to Section 34 or 35; or
4. The night duty room.

These rooms must, however, be located in appropriate proximity to the other premises. The use of storage or preparation rooms within the hospital to be supplied or the institution to be supplied in terms of Section 12a of the German Pharmacies Act is not permissible.

(5) *(deleted)*

(6) Major alterations of the size and location or equipment of the premises or their use must be notified in advance to the authority in charge.

(7) The pharmacy must be equipped with such implements and devices that permit the proper preparation of pharmaceuticals, specifically in the following dosage forms:

1. Solutions, emulsions, suspensions;
2. Ointments, creams, gels, pastes;
3. Capsules, powders;
4. Drug mixtures; and
5. Suppositories and ovules.

The preparation of sterile pharmaceuticals must be possible, unless these are pharmaceuticals for parenteral use. If no device for the preparation of water for the purpose of injections is available, water for injections must be kept in stock as a ready-made pharmaceutical in sufficient quantities.

(8) At the pharmacy, devices and testing chemicals must be available for the testing of the pharmaceuticals prepared at the pharmacy and their primary substances according to the accepted pharmaceutical rules.

Section 4a Measures of Sanitation

The managing pharmacist must take appropriate measures of sanitation that ensure the microbiological quality of the pharmaceutical in question for the staff and the operational facilities

used for the preparation of pharmaceuticals. Specifically the following must be established for the measures of sanitation:

1. The frequency and type of cleaning for the production areas or rooms;
2. The frequency of disinfection of the production areas and rooms, if necessary; and
3. The products and devices to be used.

The measures must be stipulated in writing in a sanitation plan. Implementation of the measures of sanitation must be documented regularly. Irrespective of the sanitation plan, rules regarding sanitary conduct in the workplace and protective clothing for the staff must be defined.

Section 5 Scientific and other Resources

The following must be available at a pharmacy:

1. Scientific aids required within the framework of the operation of a pharmacy for the preparation and testing of drugs and primary substances in compliance with the generally accepted pharmaceutical rules, in particular the Pharmacopoeia;
2. Scientific aids required for providing information and consultation to customers on pharmaceuticals;
3. Scientific aids required for providing information and consultation on pharmaceuticals to individuals entitled to practice medicine, dentistry or veterinary medicine;
4. Texts of the relevant regulations for pharmacy operations.

The scientific and other resources must be kept up to date and can also be kept available on electronic data carriers.

Section 6 General Regulations Governing Preparation and Testing

(1) Pharmaceuticals that are prepared at the pharmacy must be of the quality required by pharmaceutical science. They are to be prepared and tested in accordance with the generally accepted pharmaceutical rules; if the Pharmacopoeia contains relevant rules, the pharmaceuticals must be prepared and tested in accordance with these rules. As far as testing is concerned, methods and devices other than those described in the German Pharmacopoeia may also be used, on the condition that the same results are obtained as with the methods and devices described. If and when required, the tests shall be repeated at adequate intervals.

(2) When pharmaceuticals are prepared, precautions must be taken to avoid drugs exerting an adverse influence on each other and to avoid confusing drugs and primary substances as well as packaging and labeling materials.

(3) Pharmaceuticals may also be tested under the responsibility of the managing pharmacist outside of the pharmacy:

1. At a facility that has been granted a license pursuant to Section 13 of the German Medicines Act;
2. At a facility in a member state of the European Union or the European Economic Area that has been granted a license in accordance with the national law pursuant to Article 40 of Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001, on the Community code relating to medicinal products for human use (Official Journal of the European Communities L 311 of November 28, 2001, p. 67), last amended by Directive 2011/62/EU (Official Journal of the European Communities L 174 of July 1, 2011, p. 74), in its current version or an authorization granted pursuant to Article 44 of Directive 2001/82/EC of the European Parliament and of the Council of November 6, 2001, on the Community code relating to veterinary medicinal products (Official Journal of the European Communities L 311 of November 28, 2001, p. 1), last amended by Directive (EC)

No. 596/2009 (Official Journal of the European Communities L 188 of July 18, 2009, p. 14) in its current version;

3. At a facility that has been granted a license pursuant to Section 1 paragraph 2 in connection with Section 2 of the German Pharmacies Act; or
4. By an expert within the meaning of Section 65 paragraph 4 of the German Medicines Act.

Indicating the batch and stating the date and results, the person in charge of testing at the facility so entrusted or the individual pursuant to clause 1 no. 4 must certify that the drug was tested in accordance with the generally accepted pharmaceutical rules and that it has the required quality (test certificate). The results in the test certificate must form the basis of the approval at the pharmacy. At least, the identity of the pharmaceutical must be established at the pharmacy; records must be kept on the tests conducted.

(4) The regulations of the German Medicines Act regarding the preparation, special preparation and production at the pharmacy of medicinal products remain unaffected.

Section 7 **Extemporaneous Preparations**

(1) If a pharmaceutical is prepared on the basis of a prescription made out by individuals entitled to practice medicine, dentistry or veterinary medicine, it must conform to the prescription. Primary substances other than those indicated in the prescription must not be used in the preparation without the consent of the prescribing individual. This does not apply to primary substances that have no medicinal effect and can not have an adverse impact on the medicinal effect. If a prescription contains a recognizable error, if it is illegible or if it gives rise to other concerns, the pharmaceutical must not be prepared before the uncertainty has been eliminated. Clause 4 shall be applied accordingly to an individual preparation without a prescription.

(1a) An extemporaneous preparation must be produced based on previously generated written preparation instructions, which must be signed by a pharmacist or – in the case of substitution pursuant to Section 2 paragraph 6 – by the individual of the pharmacy authorized to substitute. The preparation instructions must at least stipulate rules on the

1. Preparation of the dosage form in question, including the preparation technique and the equipment items;
2. Plausibility check in accordance with paragraph 1b;
3. Primary packaging materials and labeling;
4. In-process controls, if these can be implemented;
5. Preparation of the workstation; and
6. Approval and documentation.

If these are standardized and general preparation instructions by a third party, they must be adjusted to the pharmacy operation in question.

(1b) The requirements for the production of an extemporaneous preparation must be assessed by a pharmacist according to pharmaceutical criteria (plausibility check). The plausibility check must take into account the following in particular:

1. Dosage;
2. Type of application;
3. Type, quantity and compatibility of primary substances with each other as well as their consistent quality in the finished extemporaneous preparation for the time period up to its expiration date; and the
4. Shelf life of the extemporaneous preparation.

The plausibility check must be documented by a pharmacist or – in the case of substitution pursuant to Section 2 paragraph 6 – by the individual authorized to substitute.

(1c) The production of an extemporaneous preparation must be documented by the person producing it (production protocol) and must specifically include the following information:

1. Type and quantity of primary substances and their batch numbers or test numbers;
2. Preparation parameters;
3. Result of in-process controls, if planned;
4. Name of the patient and the prescribing physician or dentist;
5. Name of the animal holder and species as well as the name of the prescribing veterinarian for pharmaceuticals to be used on animals;
6. Name of the customer for extemporaneous preparations made upon customer request; and the
7. Name of the individual who made the extemporaneous preparation.

Instead of the name of the patient, animal holder or customer according to clause 1 no. 4, 5 or 6, a production reference number can also be documented. The production protocol must be updated by a pharmacist or – in the case of substitution pursuant to Section 2 paragraph 6 – by the individual authorized to substitute with the result of the organoleptic test conducted for approval and its confirmation that the prepared pharmaceutical corresponds to the requested extemporaneous preparation (approval). Approval must be made before dispensation to the patient.

(2) Analytical testing may be waived for an extemporaneous preparation, provided the quality of the pharmaceutical is guaranteed by the process of preparation, the organoleptic test of the finished pharmaceutical and the result of the in-process controls, if planned.

Section 8

Preparation of Pharmaceuticals to be Kept in Stock in Larger Quantities

(1) A pharmaceutical to be kept in stock in larger quantities must be produced in accordance with previously generated preparation instructions that must be signed by a pharmacist of the pharmacy. Specifically, the preparation instructions must stipulate rules about:

1. Primary substances to be used, primary packaging materials and equipment items;
2. Technical and organizational measures in order to avoid cross-contamination or mix-ups, including preparation of the workstation;
3. Determination of the individual working steps, including the target values, and – if implementable – in-process controls;
4. Labeling, including the date of preparation and the expiration date or the date of follow-up testing, and – if required – rules on storage conditions and cautionary measures; and
5. Approval for marketing in terms of Section 4 paragraph 17 of the German Medicines Act.

(2) In accordance with the preparation instructions, production must be documented at the time of preparation by the preparing individual (production protocol); the content of the protocol must allow the tracing of all important activities associated with preparation. The production protocol must mention the underlying preparation instructions and specifically include the following information:

1. Date of preparation and batch number;
2. Primary substances used as well as their weight, dimensions and batch numbers or test numbers;
3. Results of in-process controls;
4. Preparation parameters;
5. Overall yield and – if applicable – the number of divided dosage forms;
6. Expiration date or date for follow-up testing; and
7. Signature of the individual who prepared the pharmaceutical.

The production protocol must be updated by a pharmacist with his confirmation that the pharmaceuticals produced correspond to the preparation instructions (approval).

(3) For the testing of prepared pharmaceuticals to be kept in stock in larger quantities, testing instructions must be generated that must be signed by a pharmacist of the pharmacy. At the very least, the testing instructions must include information on sampling, the testing method and the type of tests, including the permissible target or threshold values.

(4) Testing must be conducted in accordance with the testing instructions pursuant to paragraph 3 and documented by the individual who conducted the test (test protocol). The test protocol must name the underlying testing instructions and specifically contain information about:

1. The testing date
2. The test results and their approval by the pharmacist in charge who conducted or supervised the test.

Section 9
(deleted)

Section 10
(deleted)

Section 11
Primary Substances

(1) Only primary substances whose adequate quality has been determined may be used for the preparation of pharmaceuticals. The regulations of Section 6 paragraph 1 and 3 shall apply accordingly to the testing of primary substances.

(2) If primary substances are purchased whose quality is proven by a test certificate pursuant to Section 6 paragraph 3, at least their identity must be ascertained at the pharmacy. The test certificate should also provide information on the GMP-compliant production of the primary substance, if it is an active ingredient. The responsibility of the managing pharmacist for the adequate quality of the primary substances shall remain unaffected. Records initiated by the pharmacist conducting or supervising the tests shall be kept for the tests conducted at the pharmacy.

(3) If pharmaceuticals that are not ready-made drugs are purchased for the preparation of other drugs, paragraphs 1 and 2 shall apply accordingly.

Section 11a
Contracting

(1) If the pharmacy is allowed to have pharmaceuticals prepared by other companies pursuant to Section 21 paragraph 2 no. 1b of the German Medicines Act or Section 11 paragraph 3 or 4 of the German Pharmacies Act, there must be a written contract between the pharmacy as the client and the other company as the contractor, which must be available in both companies. The contract must clearly stipulate the responsibilities of either party. Clause 1 applies accordingly for the testing of pharmaceuticals prepared at the pharmacy and for the testing of primary substances meant for pharmaceutical production at the pharmacy, if it goes beyond identity verification.

(2) The managing pharmacist may only commission the preparation of a pharmaceutical if he has a doctor's prescription for the pharmaceutical in question and if there are no concerns following the verification of the prescription. Section 7 must be applied accordingly. The responsibility for the quality of the prepared pharmaceutical and for information and advice by the prescribing physician remains with the pharmacy as the client.

Section 12

Testing of Ready-Made Pharmaceuticals and Pharmacy-Only Medical Devices not Prepared at the Pharmacy

(1) Random samples of ready-made pharmaceuticals that are not prepared at the pharmacy shall be tested. Testing beyond an organoleptic test can be waived if there are no indications giving rise to doubt about the proper quality of the pharmaceutical. Clauses 1 and 2 apply accordingly to pharmacy-only medical devices.

(2) The test protocol to be prepared must include at least the following information:

1. Name or company name of the pharmaceutical company, name of the manufacturer or his authorized representative for medical devices;
2. Description and additionally the dosage form for pharmaceuticals;
3. Batch number or production date;
4. Date and results of testing;
5. Initials of the pharmacist conducting or supervising the testing.

Section 13

Containers

For the production of pharmaceuticals, only such primary packaging materials may be used that ensure that the pharmaceuticals are protected from physical, microbiological or chemical changes and are therefore suited for the intended purposes.

Section 14

Labeling

(1) Pharmaceuticals prepared at the pharmacy must display at least the following information on the containers and, if used, the external coverings:

1. Name and address of the dispensing pharmacy and, if different, the manufacturer;
2. Contents based on weight, volume or number of pieces;
3. Mode of administration;
4. Instructions for use;
5. Type and quantity of active ingredients and other components based on type;
6. Date of preparation;
7. Expiration date with the information "Use by" and indicating the day, month, year and, if necessary, information on the shelf life after opening the container or upon production of the ready-to-use preparation;
8. If necessary, information on special precautionary measures, for the storage or removal of unused pharmaceuticals or other special precautionary measures in order to avoid risks for the environment; and
9. Name of the patient, if the extemporaneous preparation was prepared based on a prescription for human use.

The information must be affixed in legible writing and permanently and must be written in the German language except for no. 5. If a ready-made pharmaceutical is used as a primary substance for an extemporaneous preparation, indication of the ready-made pharmaceutical will suffice instead of labeling in accordance with no. 5. The information pursuant to no. 8 can also be provided in an accompanying document.

(1a) If the pharmaceuticals are partial quantities of ready-made pharmaceuticals, name and address of the pharmacy must be stated apart from the labeling information required beside the German Medicines Act.

(1b) Section 5 of the GCP Directive shall be applied to the labeling of pharmaceuticals to be used in clinical trials on humans.

(2) Section 10 of the German Medicines Act shall be applied to prepared pharmaceuticals that are kept in stock in larger quantities and in certain packages designed for dispensation to consumers and that are

1. Pharmaceuticals in terms of Section 2 paragraph 1 or paragraph 2 no. 1 of the German Medicines Act and are not meant for clinical trials on humans; or
2. Pharmaceuticals in terms of Section 2 paragraph 2 no. 2, 3 or 4 of the German Medicines Act.

If marketing authorization pursuant to Section 21 paragraph 2 no. 1 or registration pursuant to Section 38 paragraph 1 clause 3 of the German Medicines Act is not required for them, indication of the marketing authorization or registration number is waived. The information pursuant to Section 10 paragraph 1b of the German Medicines Act can be waived.

(3) Pharmaceuticals prepared at the pharmacy, which are not ready-made drugs and are designed to be administered to animals for human consumption, may be sold only if the containers and the external coverings, if used, are marked with the information pursuant to Sections 10 and 11 of the German Medicines Act.

Section 15 Stockpiling

(1) The managing pharmacist must keep in stock the pharmaceuticals and pharmacy-only medical devices required for ensuring a proper supply of pharmaceuticals for the population in a quantity that corresponds to at least the average requirement for one week. Furthermore, the following items must be kept in stock at the pharmacy:

1. Analgesic drugs;
2. Narcotic drugs, including opioids for injection and oral administration with immediate active ingredient release and with altered active ingredient release;
3. Glucocorticosteroids for injection;
4. Antihistamines for injection;
5. Glucocorticoids for inhalation for the treatment of flue gas intoxications;
6. Anti-foaming agents for the treatment of detergent intoxications;
7. Medicinal charcoal, 50 grams of powder for preparing a suspension;
8. Tetanus vaccine;
9. Tetanus hyper-immunoglobulin 250 I. E.;
10. Epinephrine for injection;
11. 0.9% sodium chloride solution for injection;
12. Dressing materials, disposable syringes and cannulas, catheters, transfusion devices for infusions and blood sugar measuring products.

(2) The managing pharmacist must ensure that the pharmaceuticals with the following active ingredients are either kept in stock at the pharmacy or can be procured in the short term:

1. Equine botulism antitoxin;
2. Equine diphtheria antitoxin;
3. Snake venom immune serum, polyvalent, Europe;
4. Rabies vaccine;
5. Rabies immunoglobulin;
6. Varicella zoster immunoglobulin;
7. C1 esterase inhibitor;
8. Hepatitis B immunoglobulin;
9. Hepatitis B vaccine;
10. Digitalis antitoxin;

11. Opioids in transdermal and transmucosal dosage forms.

(3) The managing pharmacist of a hospital-supplying pharmacy must keep in stock the pharmaceuticals required to ensure a proper supply of drugs for the patients of the hospital and medical devices, if provided in the supply agreement, in a type and quantity that corresponds to at least the average requirement of two weeks. A list of these pharmaceuticals and medical devices must be prepared.

Section 16 Storage

(1) Pharmaceuticals, primary substances, medical devices and goods customarily kept at a pharmacy and testing chemicals shall be stored clearly arranged and in such a way that there is no adverse impact on their quality and no mix-ups. If their proper quality has not been determined, they must be marked accordingly and stored separately. This also applies to containers, external coverings, labeling materials, package inserts and packing material. The regulations of the Dangerous Chemicals Ordinance as well as the German Narcotics Act and the German Medical Devices Act including associated ordinances passed regarding the storage and labeling of dangerous substances and preparations remain unaffected. The storage information contained in the Pharmacopoeia must be observed.

(2) Storage containers for pharmaceuticals must be made in such a way as to not impair the quality of their contents. They must bear legible and indelible labels that clearly specify the contents. A customary scientific designation must be used. The contents must be labeled with additional information to the extent necessary to determine the quality and avoid confusion. The expiration date or a subsequent testing date, if applicable, must be indicated on the storage containers.

Section 17 Purchase and Sale of Pharmaceuticals and Medical Devices

(1) Pharmaceuticals may only be purchased from companies authorized to sell pharmaceuticals.

(1a) With the exception of Section 11a of the German Pharmacies Act and paragraph 2a, pharmaceuticals may only be sold on pharmacy premises and may only be dispensed by pharmaceutical staff. Clause 1 shall apply to pharmacy-only medical devices accordingly.

(2) In individual cases, pharmaceuticals may be delivered without permission by a messenger of the pharmacy pursuant to Section 11a of the German Pharmacies Act; the pharmaceuticals must be packed separately for each recipient and labeled with their names and addresses. Paragraph 2a clause 1 no. 1 and 2 and clause 2 apply accordingly; paragraph 2a clause 1 no. 5 to 7 and 9 also apply, if required. If pharmaceuticals are delivered by messenger, it must be ensured that the pharmaceuticals are reliably delivered to the recipient. If no advice has already been given at the pharmacy, advice through the pharmaceutical staff of the pharmacy must be provided directly in connection with the delivery. The regulations of Section 43 paragraph 5 of the German Medicines Act concerning the dispensation of pharmaceuticals to be used for animals shall remain unaffected.

(2a) For shipping permitted pursuant to Section 11a of the German Pharmacies Act, the managing pharmacist must ensure that

1. The pharmaceutical is packed, transported and delivered in such a manner as to preserve its quality and efficacy;
2. The pharmaceutical is delivered in compliance with the information of the customer and delivery is confirmed in writing, if necessary. In justified cases, especially due to the nature of

- the pharmaceutical, the pharmacist can order – against the instructions of the customer – that the pharmaceutical be delivered only in return for a written confirmation of receipt;
3. The individual placing the order is informed in an appropriate manner when it becomes apparent that the ordered pharmaceutical can not be shipped within the deadline stated in Section 11a no. 3 letter a of the German Pharmacies Act;
 4. All ordered pharmaceuticals will be delivered, if they may be sold in the region covered by the German Medicines Act and are available;
 5. For the case of publicized pharmaceutical risks, customers have the opportunity to report such risks, that customers are informed of risks that concern them and that internal countermeasures are taken to avert pharmaceutical risks;
 6. The individual receiving treatment be informed that he/she should contact the treating physician, if he/she experiences problems while using the pharmaceutical;
 7. The individual receiving treatment be informed that, as a prerequisite for the pharmaceutical delivery, he or she must indicate a telephone number together with the order through which he or she will receive a consultation, also by means of telecommunications and without additional fees, by the pharmaceutical staff of the pharmacy that is permitted to ship pharmacy-only pharmaceuticals pursuant to Section 11a of the German Pharmacies Act; the possibilities and consultation times must be communicated to him or her;
 8. A second delivery free of charge will be arranged; and
 9. A system for tracking shipments is maintained.

Pharmaceuticals may not be shipped, if there is a need for information or consultation regarding the safe application, which can not be met in any other way than through personal information or consultation by a pharmacist.

(2b) Pharmaceuticals containing the active ingredients lenalidomide, pomalidomide or thalidomide or drugs authorized for emergency contraception containing the active ingredient levonorgestrel or ulipristalacetate must not be shipped pursuant to Section 43 paragraph 1 clause 1 of the German Medicines Act.

(3) The managing pharmacist must not sell pharmacy-only drugs as self-service pharmaceuticals.

(4) Prescriptions by individuals, who are entitled to practice medicine, dentistry or veterinary medicine, must be dealt with in an appropriate time period for the prescription at hand.

(5) The dispensed pharmaceuticals must be in compliance with the prescriptions and the associated regulations of the Social Security Code V on the supply of pharmaceuticals. If a prescription contains an error recognizable to the dispensing individual, if it is not readable or gives rise to other reservations, the pharmaceutical must not be dispensed before the uncertainty has been eliminated. The pharmacist must make a note of each change on the prescription and sign it or in the case of an electronic prescription append the note to the prescription and sign the document in total with a qualified signature pursuant to the Signature Act. The regulations of the Narcotics Prescription Ordinance shall remain unaffected.

(5a) Deviating from paragraph 5 clause 1, the pharmacist, when on standby duty during the times pursuant to Section 23 paragraph 1 clause 2, may dispense a different pharmaceutical identical to the prescribed drug with regard to area of application, type and quantity of active ingredients and comparable with regard to dosage form and pharmaceutical quality, if the prescribed drug is not available and if the case at hand is urgent and requires immediate administration of the pharmaceutical.

(6) When dispensing pharmaceuticals, the following must be indicated on the prescription or in case of a prescription pursuant to Section 3a paragraph 1 clause 1 of the Prescription Ordinance on the copy of the prescription, or appended to an electronic prescription:

1. Name or name of the company of the owner of the pharmacy and its address;
2. Initials of the pharmacist, of the assistant pharmacist, of the pharmaceutical engineer or the pharmacy assistant who dispensed the pharmaceutical, or of the pharmacist who supervised the dispensation; on an electronic prescription the initials must be replaced by an electronic signature pursuant to the Signature Act, while the retraceability to the relevant signee and the documentation must be ensured by the managing pharmacist;
3. Date of dispensation;
4. Price of the pharmaceutical;
5. The nationally standardized mark as described in Section 300 paragraph 3 no. 1 of the Social Security Code V for prescribed ready-made pharmaceuticals, as long as they are intended for human application.

Deviating from no. 2 and pursuant to Section 3 paragraph 5, the managing pharmacist may confer to pharmaceutical technical assistants the authority to initial prescriptions. In the cases indicated in paragraph 5 clause 2 and in the case of prescriptions that do not remain in the pharmacy, the pharmaceutical technical assistant must submit the prescription to a pharmacist before dispensing the pharmaceuticals and in all other cases immediately after their dispensation.

(6a) For tracing purposes, the following data must be recorded when blood preparations, sera from human blood and preparation of other substances of human origin as well as plasma proteins obtained by genetic engineering are bought and dispensed for the treatment of haemostatic disorders:

1. Name of the pharmaceutical;
2. Batch number and the quantity of the pharmaceutical;
3. Date of purchase and dispensation;
4. Name and address of the prescribing physician as well as name or company name of the supplier; and
5. Last name, first name, date of birth and address of the patient or, if dispensed for a physician's practice, name and address of the prescribing physician.

(6b) In case of the purchase and dispensation of pharmaceuticals with the active ingredients lenalidomide, pomalidomide or thalidomide and the purchase of these active ingredients the following data must be recorded:

1. Name and batch number of the pharmaceutical or the active ingredient;
2. Amount of the pharmaceutical or active ingredient;
3. Date of purchase;
4. Date of dispensation;
5. Name or commercial firm name and the address of the distributor;
6. Name and address of the prescribing physician; and
7. Name and address of the person for whom the pharmaceutical is to be meant.

Following the forwarding of the copies of the forms to the Federal Institute for Drugs and Medical Devices pursuant to Section 3a paragraph 7 of the Prescription Ordinance the date of the forwarding is to be appended to the indication pursuant to clause 1.

(6c) Pharmacies may not purchase pharmaceuticals from other pharmacies. Clause 1 shall not be applied to pharmaceuticals that

1. Are purchased by pharmacies as part of the usual pharmacy operations pursuant to Section 52a paragraph 7 of the German Medicines Act;
2. Are purchased by pharmacies to which the same license was granted pursuant to Section 1 paragraph 2 in connection with Section 2 paragraph 4 of the German Pharmacies Act;
3. May be purchased by pharmacies pursuant to Section 11 paragraph 3 or 4 of the German Pharmacies Act;
4. Are transferred to a subsequent license holder in accordance with the German Pharmacies Act following the closing of a pharmacy; or

5. Are procured from a pharmacy in urgent cases; a case is urgent when the immediate application of a pharmaceutical is required and the pharmaceutical cannot be procured or prepared on time.

If pharmaceuticals are purchased by pharmacies or transferred by them to other pharmacies, the batch number of the pharmaceutical in question must be documented additionally and also be communicated to the recipient.

(7) The regulations of Section 31 paragraphs 1 to 3 and Section 32 shall apply accordingly to community pharmacies that supply hospitals with pharmaceuticals. Clause 1 applies accordingly for pharmacy-only medical devices.

(8) The pharmaceutical staff must take appropriate action against obvious drug abuse. In cases of justifiable suspicion of abuse, the dispensation of pharmaceuticals shall be refused.

Section 18 **Importation of Pharmaceuticals**

(1) If ready-made pharmaceuticals pursuant to Section 73 paragraph 3 or 3a of the German Medicines Act are introduced into the territory covered by the present Ordinance, the following information must be recorded:

1. Name of the imported pharmaceutical;
2. Name or company name and address of the pharmaceutical company;
3. Batch number, quantity and dosage form of the pharmaceutical;
4. Name or company name and address of the supplier;
5. Name and address of the person who shall receive the pharmaceutical;
6. Name and address of the prescribing physician or the prescribing veterinarian;
7. Date of order placement and dispensation;
8. Initials of the pharmacist who dispensed the pharmaceutical or supervised the dispensation.

If special instructions must be given for drug safety reasons, they shall be given when the pharmaceutical is dispensed. This information has to be recorded.

(2) Ready-made pharmaceuticals that are introduced into the territory covered by the present Ordinance from a member state of the European Communities beyond the scope of Section 73 paragraph 3 of the German Medicines Act may only be sold for the first time by a pharmacy, if such pharmaceuticals were tested in compliance with Section 10 in conjunction with Section 6 paragraph 3 clause 1 through 3, and if the required quality has been confirmed. Testing can be waived, if the pharmaceuticals were tested in the member state pursuant to the local legal regulations and if supporting documents corresponding to the test protocol are available.

Section 19 **Purchase and Dispensation of Veterinary Prescription Drugs**

(1) Chronological records must be kept on the purchase and the delivery of prescription drugs to be administered to animals. Sufficient evidence is considered:

1. Regarding the purchase, properly ordered delivery notes, invoices or documents accompanying goods, which must indicate:
 - a) Name or firm and address of the supplier;
 - b) Designation and quantity of the pharmaceutical including the batch designation;
 - c) Date of purchase;
2. Regarding the delivery a duplicate or copy of the prescription with notes concerning
 - a) Name and address of the recipient;
 - b) Name and address of the prescribing veterinarian;

- c) Designation and quantity of the pharmaceutical including the batch designation;
- d) Date of dispensation.

If a prescription is not provided in written or electronic form pursuant to Section 4 paragraph 2 of the Prescription Ordinance delivery data must be kept pursuant to clause 2 no. 2, also in conjunction with clause 4. If in the case of clause 2 no. 1 letter b and no. 2 the pharmaceutical is not to be marketed in batches and bears a date of preparation, this is to be indicated.

(2) Prescription drugs to be administered to animals destined for human consumption may only be dispensed against a prescription that must be submitted in duplicate. The original prescription must be given to the owner of the animal, the copy shall remain at the pharmacy. The batch preparation is to be indicated on the original; if it is not to be marketed in batches and bears a date of preparation this is to be indicated.

(3) The managing pharmacist shall check arrivals and outgoings of prescription drugs to be administered to animals against the present stock at least once per year and shall note discrepancies.

Section 20 Information and Advice

(1) As part of the quality management system, the managing pharmacist must ensure that patients and other customers as well as individuals entitled to practice medicine, dentistry or veterinary medicine be sufficiently informed and advised about pharmaceuticals and pharmacy-only medical devices. The obligation to provide information and advice must be met by pharmacists of the pharmacy; it can be met by other members of the pharmaceutical staff of the pharmacy, if the managing pharmacist has stipulated this in writing beforehand. In doing so, he must also define in what cases a pharmacist of the pharmacy must be involved in principle.

(1a) The information and consultation provided to patients and other customers must not impair therapy as directed by individuals entitled to practice medicine, dentistry or veterinary medicine. If pharmaceuticals are dispensed without prescription, the pharmacist must provide the patients and other customers with the necessary information for their proper application.

(2) The information and consultation on pharmaceuticals must specifically take into account aspects of pharmaceutical safety. If required, the consultation must include the necessary information on the appropriate application of the pharmaceutical, including potential side effects or drug interactions resulting from the information in the prescription or information from the patient or customer, as well as information on appropriate storage or disposal of the pharmaceutical. When dispensing pharmaceuticals to a patient or other customer, it must also be inquired to what extent this individual has an additional need for information and consultation and the corresponding consultation must be offered. In the case of self-medication, it must also be ascertained whether the desired pharmaceutical appears appropriate for the person in question or in what cases it is advisable to see a physician. Clauses 1 through 4 shall be applied accordingly to pharmacy-only medical devices.

(3) The managing pharmacist must make available relevant information in order to help patients and other customers in making an informed decision, also with regard to treatment options, availability, quality and safety of the services rendered by him; furthermore, he issues clear invoices and clear pricing information as well as information regarding the license and permit status of the pharmacy, its insurance coverage or other forms of personal and collective protection in terms of his professional liability.

(4) The managing pharmacist of a hospital-supplying pharmacy or the pharmacist authorized by him/her must inform and advise the physicians of the hospital on pharmaceuticals and pharmacy-only medical devices. He/she is a member of the Hospital Drug Commission.

Section 21 **Pharmaceutical Risks, Handling of Non-marketable Pharmaceuticals**

The managing pharmacist must ensure that the following measures be taken with regard to pharmaceutical risks and non-marketable pharmaceuticals:

1. All information on complaints regarding pharmaceuticals, in particular pharmaceutical risks such as defects in quality and packaging, defects regarding labeling and package inserts, side effects, interactions with other pharmaceuticals, contra-indications and abuse must be communicated to him or to the pharmacist authorized by him without delay.
2. The managing pharmacist or the pharmacist authorized by him shall check the information and ensure that the measures required for warding off risks be taken.
3. If it is justified to assume that pharmaceuticals or primary substances purchased by the pharmacy are of defective quality attributable to the manufacturer, the authority in charge shall be notified immediately.
4. If pharmaceuticals prepared at the pharmacy are recalled, the authority in charge shall be notified immediately and the reason must be stated.
5. Records must be kept of pharmaceutical risks ascertained at the pharmacy as well as on the relevant checks performed, on measures taken and notifications given thereupon.
6. Without prejudice to nos. 1 to 5, the managing pharmacist of a hospital-supplying pharmacy must immediately notify the senior physicians and the Hospital Drug Commission of the pharmaceutical risks that come to his knowledge.
7. Pharmaceuticals or primary substances that are not marketable or for which a return has been ordered must be reworked, returned or destroyed; if they are not immediately reworked, returned or destroyed, they must be marked accordingly and isolated. Records must be kept on the measures taken.
8. Until a decision is made on how to proceed, falsified pharmaceuticals placed into the distribution network must be stored separately from marketable pharmaceuticals and secure in order to avoid mix-ups and prevent unauthorized access. They must be clearly labeled as pharmaceuticals not meant for sale. The authority in charge must immediately be informed about the discovery of a falsified pharmaceutical. The measures taken must be documented.

For medical devices, the Ordinance on Safety Plans for Medical Devices shall apply.

Section 22 **General Documentation**

(1) All records on the preparation, testing, checking of the pharmaceuticals at the hospital and institutions to be supplied in terms of Section 12a of the German Pharmacies Act, storage, importation, sale, recall, return of the pharmaceuticals due to a recall, the certificates pursuant to Section 6 paragraph 3 clause 2 and Section 11 paragraph 2 clause 1 as well as the evidence pursuant to Section 19 must be retained in their entirety and at least for up to one year from the date of expiration but not for a period of less than three years. The original content of an entry must not be obliterated. No changes must be made that do not show whether they were made at the time of the original entry or thereafter.

(1a) *(deleted)*

(1b) Records pursuant to Section 17 paragraph 6 clause 1 no. 2 sub-clause 2 must be retained for three years after the last recording.

(2) Records may also be kept on picture or data carriers. It must be ensured that the data are available during the retention period and that they can be made readable within a reasonable period of time. If records are made and kept exclusively on data carriers, an initial required pursuant to this ordinance must be replaced by an electronic signature pursuant to the Signature Act and a personal signature must be replaced by a qualified electronic signature pursuant to the Signature Act.

(3) The records and evidence are to be submitted to the authority in charge upon its request.

(4) Deviating from paragraph 1, the records pursuant to Section 17 paragraph 6a must be retained or stored for a period of at least 30 years and destroyed or deleted once their retention or storage is no longer required. If the records are retained or stored for longer than 30 years, they are to be rendered anonymous.

Section 23 Standby Duty

(1) Pharmacies are obligated to be on permanent standby duty. The authority in charge waives the obligation for standby duty fully or in part for some pharmacies during the following times:

1. Monday through Saturday from 12:00 a.m. to 8:00 a.m.;
2. Monday through Friday from 6:30 p.m. to 12:00 a.m.;
3. Saturday from 2:00 p.m. to 12:00 a.m.;
4. December 24 and 31 from 2:00 p.m. to 12:00 a.m.;
5. On Sundays and official holidays.

(2) The authority in charge may exempt the pharmacy from the obligation of standby duty for the duration of the customary local closing times, Wednesday afternoons, Saturdays or vacation closedowns and, in the presence of a justified reason, also outside of these times, if the pharmaceutical supply is ensured during these hours by another pharmacy, which may also be located in another municipality.

(3) During the times pursuant to paragraph 1 clause 2, it shall suffice for the maintenance of standby duty if the managing pharmacist or an individual authorized to substitute for him stays in the immediate vicinity of the pharmacy's premises and can be reached at any time. The authority in charge may in justified individual cases exempt a managing pharmacist upon application from the obligation under clause 1, if the managing pharmacist or an individual authorized to substitute for him can be reached at any time and if the pharmaceutical supply is ensured in a manner acceptable to the customers.

(4) *(deleted)*²

(5) At pharmacies, which are not on standby duty, a clearly legible note must be affixed for patients or other customers in a conspicuous location indicating the nearest pharmacies on standby duty.

(6) Without prejudice to the regulations of paragraphs 1 to 4, pharmacies that supply hospitals with pharmaceuticals and pharmacy-only medical devices must make a standby duty arrangement with the hospital carrier that ensures the proper supply of the hospital with pharmaceuticals and consultations by a pharmacist of the pharmacy.

Section 24 Prescription Collection Containers

² *Editorial annotation:* Based on the 4th Amendment Regulation, paragraph 3 was deleted and the previous paragraph 4 became paragraph 3. Paragraphs 5 and 6 were not adjusted.

(1) Containers for the collection of prescriptions (Prescription Collection Containers) may only be kept with the permission of the authority in charge. Permission shall be granted to the owner of a pharmacy upon his request, if a Prescription Collection Container is required for the proper supply of pharmaceuticals to remote villages or parts thereof where no pharmacy exists. Permission shall be limited in time and must not exceed a period of three years. Permission may be granted repeatedly.

(2) Prescription Collection Containers must not be kept in business enterprises or with members of the medical professions.

(3) The prescriptions must be collected in a closed container, which is protected from access by unauthorized individuals. The name and the address of the pharmacy as well as the collection times must be clearly indicated on the containers. Furthermore, it must be indicated on the container or in its immediate vicinity that the prescription must state the last name, first name, place of residence, street and house number of the recipient and the information as to whether the order is to be picked up at the pharmacy or delivered to the recipient. The container must be emptied or collected at the times specified thereon by a messenger who must be a member of the pharmacy's staff.

(4) The pharmaceuticals must be packed at the pharmacy separately for each addressee and marked in each case with the addressee's name and address. Unless collected, they must be delivered to the addressee in a reliable manner by a messenger pursuant to Section 17 paragraph 2.

Section 25 (deleted)

Section 25a Defense Against Menacing Communicable Diseases

In the case of a menacing communicable disease spreading in a manner that demands an instant provision of specific drugs significantly exceeding the usual extent, Section 11 paragraph 2 does not apply to primary substances used for the preparation of drugs as defined in Section 21 paragraph 2 no. 1c of the German Medicines Act, if

1. Their quality is proven by a test certificate pursuant to section 6 paragraph 3;
2. The container is locked in a way an interim opening would be obvious; and
3. Neither the container nor the seal are damaged.

If the container was opened by a company in a member state of the European Union or the European Economic Area that holds a permit pursuant to Article 77 of Directive 2001/83/EC in accordance with the respective national law, in order to decant or pack the primary substance without altering it, Section 11 paragraph 2 does not apply if a copy of the test certificate pursuant to Section 6 paragraph 3 and a written confirmation of the company that at the time of opening of the container the preconditions of clause 1 no. 1 through 3 were met and the primary substances were decanted and packaged in adequate containers, are at hand to the pharmacy. In the case of a menacing communicable disease spreading in a manner that demands an instant provision of specific drugs significantly exceeding the usual extent, Section 17 paragraph 1 does not apply to pharmaceuticals that are provided by the federal or state authorities in charge.

Third Chapter Operation of Hospital Pharmacies

Section 26 Applicable Regulations

(1) The hospital pharmacy is a functional unit of a hospital, which is responsible for ensuring the proper supply of one or several hospitals with pharmaceuticals and pharmacy-only medical devices as well as information and consultation on these products, especially for physicians, nursing staff and patients.

(2) The regulations of Sections 1a and 2a as well as Sections 4a, 5 through 8 and 11 through 14, 16, 17 paragraph 1 and paragraph 6c, Sections 18, 20 paragraph 1 and Sections 21, 22 and 25a shall apply accordingly to the operation of hospital pharmacies.

Section 27

Managing Pharmacist of the Hospital Pharmacy

(1) The managing pharmacist is the pharmacist employed by the sponsoring institution of the hospital and entrusted with the management of the pharmacy.

(2) The managing pharmacist of the hospital pharmacy is responsible for the management of the pharmacy in compliance with the applicable regulations. Specifically, he must ensure that

1. The ordered pharmaceuticals and pharmacy-only medical devices be provided as needed and that pharmaceuticals that are particularly urgently required for acute medical care be made available without delay;
2. The pharmaceuticals and pharmacy-only medical devices stored at the hospital be regularly tested and that these tests be documented;
3. A pharmacist of the pharmacy advises
 - a) The hospital staff in terms of safe, appropriate and economical pharmaceutical therapy and application of the pharmaceuticals or pharmacy-only medical devices; and
 - b) The patients, if necessary, in terms of safe pharmaceutical application, especially in connection with their discharge from the hospital.

The managing pharmacist of the hospital pharmacy is a member of the Hospital Drug Commission.

(3) The managing pharmacist of the hospital pharmacy may only be substituted by another pharmacist, who shall assume the duties of the managing pharmacist for the period of substitution.

(4) The regulations of Section 2 paragraphs 3 and 5 shall apply accordingly.

Section 28

Staff of the Hospital Pharmacy

(1) The pharmaceutical staff required for the proper operation of the hospital pharmacy, especially also the pharmaceutical staff, must be available in adequate numbers. The staff requirement is based on the type and scope of a medically appropriate and adequate supply of the hospital with pharmaceuticals and pharmacy-only medical devices, taking into account the size, type and service structure of the hospital. Clause 2 shall apply accordingly if the hospital pharmacy supplies other hospitals, too.

(2) The managing pharmacist of the hospital pharmacy is responsible for the assignment of tasks to the pharmacy staff.

(3) The regulations of Section 3 paragraphs 1, 5 and 6 shall apply accordingly.

Section 29

Rooms and Facilities of the Hospital Pharmacy

(1) The rooms required for the proper operation of the hospital pharmacy must be available. The type, state, size and number of rooms as well as the furniture and fixtures of the hospital pharmacy shall be guided by the criteria of Section 28 paragraph 1 clause 2.

(2) The hospital pharmacy shall consist of at least a sales area, two laboratories, an office and a backroom and must have sufficient storage space; there must be a vent with a suction device in the laboratory. Storage below a temperature of 25° Centigrade must be possible. The total floor space of these premises must be at least 200 square meters. The regulations of Section 4 paragraph 1 clauses 1, 2 no. 1 through 4, clause 3, paragraph 2 clause 4, paragraph 2b, 2c, 2d, 4 clause 3 and paragraph 6 shall apply accordingly.

(3) Type and number of tools and devices for preparing, testing and determining primary substances and pharmaceuticals as well the type and number of testing chemicals shall be guided by the size, type and service structure of the hospital. The regulations of Section 4 paragraphs 7 and 8 shall apply.

Section 30

Stockpiling of Pharmaceuticals at the Hospital Pharmacy

The pharmaceuticals and pharmacy-only medical devices required to ensure a proper supply of the patients of a hospital with drugs must be stored in an adequate quantity, which has to correspond to at least the average requirement of two weeks. A list of these pharmaceuticals and pharmacy-only medical devices has to be prepared.

Section 31

Dispensation of Pharmaceuticals at the Hospital Pharmacy

(1) Pharmaceuticals and pharmacy-only medical devices may only be given to wards or other subunits of the hospital on the basis of a prescription in individual cases or on the basis of a written request. This applies accordingly to prescriptions or requests in electronic format.

(2) When pharmaceuticals and pharmacy-only medical devices are dispensed to wards and other subunits of the hospital, it must be ensured that unauthorized individuals have no access to them. They must be dispensed in a suitable, closed container on which the name of the pharmacy and the recipient must be indicated. Partial quantities of ready-made pharmaceuticals that are to be handed over to patients for administration outside the hospital in connection with a treatment before or after hospitalization or surgery without hospitalization must be labeled pursuant to Section 14 paragraph 1 clause 2, and a package insert must be enclosed.

(3) Pharmaceuticals taken from packages to be dispensed to users may only be dispensed without the external cover, if the name of the pharmaceutical, the batch number and, where required for the drug, the date of expiration and instructions for storage are indicated on the container and if the package insert is attached.

(4) The regulations of Section 17 paragraph 1, 1a, 4, 5, 6 clause 1 no. 1 through 3 as well as clause 2 and 3 and paragraph 6a through 6c shall apply accordingly.

Section 32

Checking of Pharmaceuticals and Pharmacy-only Medical Devices Kept in Stock at the Wards

(1) The obligation of the managing pharmacist of the hospital pharmacy or of a pharmacist of the pharmacy authorized by him to check the pharmaceuticals kept in stock pursuant to Section 14 paragraph 6 of the German Pharmacies Act extends to all pharmaceuticals kept in stock at the wards

and at other subunits of the hospital. The pharmaceuticals kept in stock must be checked at least once every six months. Clause 1 shall apply accordingly to pharmacy-only medical devices.

(2) The pharmacist running the check-up and the pharmacy staff assisting him have the authority to enter the rooms used for pharmaceutical supply. The hospital management and the other hospital staff must assist in the check-up.

(3) The managing pharmacist of the hospital pharmacy or the pharmacist of the pharmacy authorized by him must generate records in quadruplicate for each check-up. This record must include at least the following:

1. Date of check-up;
2. Name of the ward or other subunit of the hospital;
3. Name of the pharmacist and names of the other individuals participating in the check-up;
4. Type and scope of the check-up, in particular regarding
 - a) General storage and safekeeping conditions;
 - b) Storage and safekeeping of pharmaceuticals and medical devices pursuant to the generally accepted pharmaceutical rules;
 - c) State of the pharmaceuticals and medical devices including their labeling;
 - d) Expiration dates;
5. Defects noted;
6. Measures taken to eliminate the defects;
7. Deadline set for the elimination of the defects;
8. Data on the elimination of defects detected earlier;
9. Signature of the pharmacist in charge of the check-up and the date.

A copy of the record must be transmitted to the management of the hospital no later than four weeks after the check-up, for severe defects immediately after conducting the check-up, another copy each must be handed over to the physician as well as the nursing staff in charge of the supply of the ward or of the other subunit of the hospital with pharmaceuticals, and the fourth copy must be kept at the pharmacy.

Section 33 Standby Duty of the Hospital Pharmacy

A standby duty ensuring the proper supply of the hospital with pharmaceuticals must be guaranteed by the permit holder. This also includes that consultation by a pharmacist of the pharmacy must be ensured.

Fourth Chapter Special Regulations

Section 34 Patient-individual Dosage Provision or Blistering of Pharmaceuticals

(1) The following stipulations must be made specifically in the quality management system pursuant to Section 2a:

1. For the selection of pharmaceuticals that are basically eligible for dosage provision or reblistering or that are inappropriate for dosage provision or reblistering;
2. For a decision which pharmaceuticals may possibly not be kept in the same individual container for simultaneous administration or may be blistered in the same individual blister;
3. For a decision in exceptional cases a written request by a physician may be fulfilled regarding the division of tablets before dosage provision or blistering, if otherwise pharmaceutical care cannot be ensured and there is proven validation of stable quality over the shelf life of the

blister or reusable container, even though subsequent alterations of the ready-made pharmaceutical should be prevented in principle.

4. For the interim storage and labeling of the unblistered pharmaceuticals;
5. For the technical and organizational measures in order to preserve the quality of the unblistered pharmaceuticals and to specifically avoid cross-contamination and mix-ups, including the testing of their effectiveness;
6. For calibration, qualification, maintenance and cleaning of the blister equipment, if used, or other critical equipment items or devices;
7. For primary packaging materials and their quality checks;
8. For the preparation instructions and the production protocols pursuant to Section 7;
9. For the sanitation plan; and
10. For the sanitary conduct of the staff in the workplace and the type of protective clothing for pharmaceutical preparation, including the type, manner and frequency of processes for changing clothes.

(2) The staff must be sufficiently qualified for the activities and must be trained regularly; the training measures must be documented. The number of staff required in terms of Section 3 paragraph 2 clause 1 results from the scope of production.

(3) Deviating from Section 4 paragraph 2b, the patient-individual dosage provision or blistering must be performed in a separate room that may only be used for that purpose. The room must be appropriately sized in order to be able to conduct the individual working steps in specifically assigned areas. Its walls and surfaces as well as the floor must be easy to clean in order to minimize the environmental contamination risk for the pharmaceuticals. At least for machine blistering, access and addition of the materials should be made via an intermediate room (lock) to maintain an appropriate room quality in the preparation room. Section 4a shall be applied accordingly. It is permissible to deviate from clause 1 and clause 4, if the dosage provision or the manual blistering of pharmaceuticals is to be performed for one individual patient as an exception.

(4) Labeling of the newly packaged pharmaceutical must provide the following information:

1. Name of the patient;
2. The pharmaceuticals included and their batch numbers;
3. Expiration date of the newly compiled pharmaceutical and its batch number;
4. Administration instructions;
5. Storage information, if applicable; and
6. Information by the dispensing pharmacy and, if different, by the manufacturer.

The package inserts of the included ready-made pharmaceuticals must be attached to the newly packaged pharmaceutical pursuant to Section 11 paragraph 7 of the German Medicines Act.

Section 35

Preparation of Pharmaceuticals for Parenteral Use

(1) The following stipulations must be made specifically in the quality management system pursuant to Section 2a:

1. For the pharmaceuticals to be used and the primary packaging materials and their quality checks;
2. For the technical and organizational measures in order to avoid contaminations, cross-contaminations and mix-ups, including tests of their effectiveness;
3. For calibration, qualification, maintenance and cleaning of equipment and the preparation room;
4. For validation of the processes, methods and systems impacting product quality and for revalidation; for aseptic preparation processes at the end of each work day with the involvement of the affected production staff;

5. For critical equipment items or devices;
6. For preparation instructions and production protocols pursuant to Section 7 or Section 8;
7. For possible transportation of the prepared pharmaceuticals;
8. For sanitary measures, and
9. For the sanitary conduct of the staff in the workplace and the type of protective clothing for pharmaceutical preparation, including the type, manner and frequency of processes for changing clothes.

(2) The staff must be sufficiently qualified for the activities and must be trained regularly; the training measures must be documented. The number of staff required in terms of Section 3 paragraph 2 clause 1 results from the type and scope of production.

(3) The preparation of parenteral pharmaceuticals must be conducted in a separate room that must not be used for other activities, unless this concerns the production of other sterile preparations in accordance with the Pharmacopoeia. Access to this room and addition of the materials must be made via an intermediate room (lock) that is appropriate for maintaining the required clean room classes in the preparation room. The room must be used exclusively for the purpose of preparing parenteral pharmaceuticals, be appropriately sized in order to be able to perform the individual working steps in specifically assigned areas, and ventilation must occur through filters with appropriate effectiveness. Its walls and surfaces and the floor must be easy to clean in order to minimize the environmental contamination risk for the pharmaceuticals. At the time of preparation, only those employees who perform the corresponding activities are allowed to be present in the room; their protective clothing must be adjusted to the activities and must be changed each work day at least. Section 4a shall apply accordingly.

(4) If the pharmaceuticals are not subjected to a sterilization procedure in their final container and if they are not prepared in a closed system, the following rules must be observed during preparation and bottling:

1. Compliance with an air cleanliness level for the number of germs and particles in the local zone for the work processes in accordance with Class A of the definition of the EC-GMP Guideline, Annex 1, which is published by the German Federal Ministry in the Federal Gazette in the latest version; and
2. An appropriate environment is required that meets the following requirements in terms of the number of particles and germs:
 - a) Corresponds to at least Class B of the Annex to the Guideline;
 - b) Or, in deviation from Class B, corresponds to at least Class C of the Annex to the Guideline, if the pharmaceutical quality has been proven to be guaranteed by the applied procedure and has been evidenced through the corresponding validation of the procedure;
 - c) Or corresponds to Class D of the Annex to the Guideline when using an isolator.

For the preparation of pharmaceuticals that are not produced in a closed system but are subjected to a sterilization procedure in the final container, deviating from clause 1 no. 2 an environment is required that corresponds to at least Class D of the Annex to the Guideline in terms of the number of particles and germs; compliance with an air cleanliness level of Class C is required for the bottling of these pharmaceuticals.

(5) The clean room conditions must be tested through appropriate controls of the air, critical surfaces and the staff through measurements of the number of particles and germs during preparation in open systems. The pharmacist responsible for the approval procedure must stipulate the corresponding warning and action limits in this respect.

(6) Sections 6 through 8 shall be applied to the preparation of parenteral pharmaceuticals. The plausibility check of the physician's prescription must specifically also include patient-individual

factors such as the regular dosage and the potentially resulting individual dosage. The preparation instructions must also provide for a check of the calculations, the net weights and the primary substances to be used by a second person or through validated electronic procedures as well as a leak test of the filled container.

Fifth Chapter Administrative Offenses, Transitional and Final Provisions

Section 36 Administrative Offenses

An administrative offense within the meaning of Section 25 paragraph 2 of the German Pharmacies Act is committed by any person who, by intent or negligence,

1. Performs pharmaceutical activities in violation of Section 3 paragraph 5 clause 1 in conjunction with clause 2;
- 1a. Dispenses pharmaceuticals in violation of Section 17 paragraph 1a clause 1;
- 1b. Ships pharmaceuticals named there in violation of Section 17 paragraph 2b;
2. As a managing pharmacist:
 - a) Violates a regulation of Section 2 paragraph 5 or 6 clause 1, 2 or 3 on the substitution of the managing pharmacist;
 - b) Fails to operate a quality management system in violation of Section 2a paragraph 1 clause 1;
 - c) Having pharmaceutical activities performed in violation of Section 3 paragraph 5 clause 1 in conjunction with Section 2 paragraph 2 clause 2 and 3 or Section 3 paragraph 5 clause 2;
 - d) Violates Section 3 paragraph 5 clause 2 in conjunction with Section 2 paragraph 2 clause 2 by not supervising pharmaceutical activities or not having them supervised by a pharmacist;
 - e) Violates Section 15 paragraph 1 clause 2 by not keeping in stock a pharmaceutical that is named there;
 - f) Violates Section 15 paragraph 2 by failing to ensure that a pharmaceutical named there be kept in stock or can be procured in the short term;
 - g) Violates Section 17 paragraph 1a clause 1 by marketing outside the pharmacy's premises the goods mentioned in Section 25 or violates Section 17 paragraph 3 by selling ethical drugs by way of self-service;
 - h) Violates Section 17 paragraph 7 in conjunction with Section 31 paragraph 1 clause 1 or paragraph 3, in each case also in conjunction with Section 2 paragraph 2 clause 2 and 3 by dispensing pharmaceuticals or having them dispensed;
 - i) Violates Section 17 paragraph 7 in conjunction with Section 32 paragraph 1 and with Section 2 paragraph 2 clause 2 and 3 by not checking, not checking completely or in good time the pharmaceuticals kept in stock in the wards or other subunits of the hospital or by not having them checked by a pharmacist, or violates Section 17 paragraph 7 in conjunction with Section 32 paragraph 3 and with Section 2 paragraph 2 clause 2 by not preparing the required records, by not preparing them correctly or completely, by not transmitting the same to the hospital management, to the physician in charge or by not keeping the same or by not having these measures carried out by a pharmacist;
 - j) Violates Section 21 by not seeing to it that the measures laid down therein be taken in the event of pharmaceutical risks or pharmaceuticals that are not marketable;
 - k) Violates Section 23 paragraph 1 by not keeping the pharmacy on standby duty;
 - l) Violates Section 23 paragraph 5 in conjunction with Section 2 paragraph 2 clause 2 and 3 by not affixing in a conspicuous location a clearly legible note indicating the nearest pharmacies on standby duty or by failing to have it affixed;

- m) Violates Section 24 paragraph 1 clause 1 by keeping a prescription collection container without the required permit.
3. As the managing pharmacist or as a member of the pharmaceutical staff:
- a) *(deleted)*
 - b) Violates Section 7 paragraph 1 clause 1 by failing to prepare pharmaceuticals in accordance with the prescription, or violates Section 7 paragraph 1 clause 2 by using ingredients in the preparation other than those indicated on the prescription without the consent of the individual issuing the prescription;
 - c) *(deleted)*
 - d) Violates Section 14 paragraph 1 by dispensing pharmaceuticals without the required labeling;
 - e) Violates Section 16 paragraph 1 clause 1 or clause 2 by failing to store a pharmaceutical, a primary substance or a medical device, failing to store it correctly or in the manner required;
 - f) *(deleted)*
 - g) *(deleted)*
 - h) Violates Section 18 paragraph 1 clause 1 by not recording the prescribed data in the event of pharmaceutical importation;
 - i) Violates Section 19 paragraph 1 clause 1 by not keeping the records required therein, or violates Section 19 paragraph 2 clause 1 by dispensing the pharmaceuticals mentioned therein without the existence of a prescription in duplicate;
 - j) Fails to retain records, certificates or evidence in accordance with Section 22 paragraph 1 clause 1, or violates Section 22 paragraph 1 clause 2 or 3 by obliterating records, certificates or evidence or by altering them;
 - k) Violates Section 22 paragraph 4 clause 1 by not retaining records or by failing to retain them for at least thirty years and by failing to store them or by failing to store them for at least thirty years; or
4. As the managing pharmacist of a hospital pharmacy
- a) Violates Section 22 paragraph 2 in conjunction with Section 21 by not seeing to it that the measures mentioned therein with regard to drug risks or non-marketable pharmaceuticals are taken;
 - b) Violates Section 28 paragraph 3 in conjunction with Section 3 paragraph 5 clause 1 and with Section 27 paragraph 2 clause 1 by having pharmaceutical activities performed by an individual who is not a member of the pharmaceutical staff;
 - c) Violates Section 28 paragraph 3 in conjunction with Section 3 paragraph 5 clause 3 and with Section 27 paragraph 2 clause 1 by not supervising pharmaceutical activities or by not having them supervised by a pharmacist;
 - d) Violates Section 31 paragraph 1 clause 1, paragraph 3 or 4 in conjunction with Section 17 paragraph 5 clause 1, in each case in conjunction with Section 27 paragraph 2 clause 1 by dispensing pharmaceuticals or by having them dispensed; or
 - e) Violates Section 32 paragraph 1 in conjunction with Section 27 paragraph 2 clause 1 by not checking, by not fully checking or by not checking in time pharmaceuticals kept in stock in the wards or other subunits of the hospital or by not having them checked by a pharmacist, or violates Section 32 paragraph 3 in conjunction with Section 27 paragraph 2 clause 1 by not preparing, by not correctly preparing or by not fully preparing the required records, by not passing them on to the management of the hospital, by not handing it over to the physician in charge or by not retaining the same or by not having these measures taken by a pharmacist.

Section 37
Transitional Provisions

(1) Sections 2a, 4 paragraph 1 clause 2 no. 1 letter a, Section 34 paragraph 3 clause 1 and 4 as well as Section 35 paragraph 3 clause 2 shall only apply from June 1, 2014, onward to pharmacies to which a permit was granted prior to June 11, 2012, pursuant to Section 1 paragraph 2, also in conjunction with Section 2 paragraph 4 of the German Pharmacies Act; up until this time, the rooms must continue to be in compliance with the regulations effective until June 11, 2012.

(2) Section 35 paragraph 5 shall apply from June 1, 2013, onward to pharmacies for which a permit was granted before June 11, 2012, pursuant to Section 1 paragraph 2, also in conjunction with Section 2 paragraph 4 of the German Pharmacies Act; up until this time the clean room requirements must be demonstrated to be in compliance at least with the requirements of Class A for the local zone and Class C for the surrounding area.