

## **Ordinance on the Operation of Pharmacies**

### ***(Apothekenbetriebsordnung - ApBetrO)***

(last amended pursuant to Art. 2 of the Ordinance amending the Ordinance on Prescription-only drugs and the Ordinance on the Operation of Pharmacies dated 2<sup>nd</sup> December 2008 [Federal Law Gazette I p. 2338]<sup>1</sup>)

#### **First Section 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 pursuant to Section 14, paragraph 4 of the German Pharmacies Act. It contains provisions on how to ensure a proper supply of the population with pharmaceuticals.

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

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

#### **Second Section 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;

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<sup>1</sup> **Note:** This consolidated version was developed as a working aid by ABDA (Federal Union of German Associations of Pharmacists). Only the texts published in the Federal Law Gazette are legally binding.

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 the operation of any other pharmacy in another member state of the European Communities or in another signatory state of the Agreement on the European Economic Area as well as any professional activity he/she exercises apart from his work as managing pharmacist.

(4) The managing pharmacist may, apart from pharmaceuticals, offer or sell in the pharmacy the goods listed in Section 25 to an extent only that does not impair the proper operation of the pharmacy and the priority of the assignment to supply drugs.

(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 permit holder pursuant to Section 2 paragraph 4 of the German Pharmacies Act and not to the substitution of the managing pharmacist of a hospital-supplying pharmacy.

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

### Section 3 Pharmacy Staff

(1) The pharmacy staff is made up of pharmaceutical and non-pharmaceutical staff and may only be employed in accordance with their training and knowledge.

(2) The required pharmaceutical staff must be available 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 taking into account the size, the type and the services rendered by the hospital.

(3) The pharmaceutical staff comprises:

1. Pharmacists;
2. Individuals in training to become a pharmacist;
3. Pharmaceutical-technical assistants;
4. Individuals in training to become a pharmaceutical-technical assistant;
5. Assistant pharmacists;
6. Pharmaceutical engineers;
7. Individuals in training to become a pharmaceutical engineer;
8. Pharmacy assistants;
9. Pharmaceutical assistants.

Non-pharmaceutical staff includes in particular pharmacy aides, skilled pharmacy workers and pharmaceutical-commercial employees; within the framework of pharmaceutical activities, they assist the pharmaceutical staff in the preparation and testing of pharmaceuticals, by the operation, care and maintenance of the implements and tools, and with the filling, packing and preparation of pharmaceuticals for dispensation.

(4) Pharmaceutical activities for the purposes of this Ordinance are the development, preparation, testing and dispensation of pharmaceuticals, information and advice on pharmaceuticals as well as the checking of pharmaceutical inventories in hospitals.

(5) It is forbidden to have pharmaceutical activities conducted by any individuals other than pharmaceutical staff, unless otherwise provided for in this Ordinance. 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 individuals listed in paragraph 3 no. 2 to 4, 7 and 9 must be supervised by the managing pharmacist or a pharmacist instructed to do so by the managing pharmacist. The individuals mentioned in paragraph 3 no. 9 are not permitted to dispense pharmaceuticals.

(6) To supply hospitals, with the exception of deliveries, the managing pharmacist may only assign staff employed in his pharmacy.

## 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 and information and advice on pharmaceuticals. They have to be kept in an impeccable sanitary state.

(2) A pharmacy must consist at least of the sales area, a laboratory, sufficient storage area and a room for night duty. The sales area must have access to public circulation areas; it must be equipped in such a way that the confidentiality of consultation can be guaranteed. The laboratory must be equipped with a local vent with a suction device or with a corresponding device performing the same function. The preparation in the proper quality of the dosage forms mentioned in paragraph 7 and storage below a temperature of 20° Centigrade must be possible. The floor space of the pharmacy premises mentioned in clause 1 must be at least 110 m<sup>2</sup>. Section 29 paragraphs 1 and 3 apply accordingly to hospital-supplying pharmacies.

(3) A branch pharmacy must consist at least of the sales area, sufficient storage area and a room for night duty.

(4) The premises shall be arranged in such a way that each room is accessible without having to leave the pharmacy. This does not apply to the room for night duty, for rooms that are used exclusively for the pharmaceutical supply of hospitals, for rooms in which ready-to-use cytostatic preparations are made or for rooms for mail order business and electronic commerce or information and consultations in connection with mail order business including electronic commerce. These rooms must, however, be located in appropriate proximity to the other premises. Renting storage space within the hospital to be supplied is not permissible.

(5) The premises of the pharmacy must be separated by walls or doors from other areas that are used for commercial or freelance activities as well as from public circulation areas and shopping malls.

(6) Major alterations of the size and location of the premises 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 in the following dosage forms: capsules, ointments, powders, drug mixtures, solutions, suspensions, emulsions, extracts, tinctures, suppositories and ovules. The preparation of sterile drugs and of water for injection purposes must be possible.

(8) The devices and testing chemicals, in particular those listed in Annex 1, must be available at the pharmacy. They may be substituted by other devices and testing chemicals, provided the same results can be obtained with them. If the testing chemicals can be made at the pharmacy, it will suffice if the substances and preparations required for making them are available. As far as indicators are

concerned, it will suffice if the relevant preparation (e.g. solution, trituration) is kept in stock.

## 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, the German Drug Code and a directory of the customary names of pharmaceuticals and their primary substances (List of Synonyms);
2. Scientific aids required for providing information and consultation to customers on pharmaceuticals, in particular information material on the composition, areas of application, contraindications, side effects, interactions with other drugs, dosage instructions and the manufacturers of the customary ready-made pharmaceuticals as well as information on the customary dosages of drugs;
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 current regulations contained in the German pharmacies, drugs, narcotics, drug advertising and chemicals legislation.

## 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 as well as packing and labeling materials.

(3) Pharmaceuticals may also be tested under the responsibility of the managing pharmacist outside of the pharmacy at a facility that has been granted a license pursuant to Section 13 of the German Medicines Act, or pursuant to Section 1 paragraph 2 in conjunction with Section 2 of the German Pharmacies Act, or 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 must certify that the drug was tested in accordance with the generally accepted pharmaceutical rules and that it has the required quality (test certificate). At least, the identity of the pharmaceutical must be established at the pharmacy; records must be kept on the tests conducted. Section 10 paragraph 6 shall remain unaffected.

(4) The refilling, including the filling and packaging as well as the labeling of drugs, may also be carried out by non-pharmaceutical staff under the supervision of a pharmacist.

### 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. Ingredients 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 ingredients 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.

(2) Testing may be waived for an extemporaneous preparation, provided the quality of the pharmaceutical is guaranteed by the process of preparation.

### Section 8 **Preparation of pharmaceuticals to be kept in stock in larger quantities**

(1) When drugs are prepared in advance during one day within the framework of the usual operation of the pharmacy in batch sizes of up to 100 packages ready for dispensation or in an equivalent amount, a preparation protocol shall be prepared, which must include at least the following:

1. Description and dosage form;
2. Type, quantity, quality, batch number or test number of the primary substances used;
3. Preparation rules governing the preparation of the drug;
4. Date of preparation or batch no.;
5. Expiration date;
6. Initials of the pharmacist in charge of the preparation.

(2) The procedure, the scope, the results and the date of testing are to be recorded in a test protocol. The pharmacist conducting or supervising the tests must confirm in the test protocol providing the date and his handwritten signature that the drug was tested and that it is of the required quality.

(3) The testing of the pharmaceutical may be waived, if the quality is guaranteed by the process of preparation. If testing is waived, this fact must be recorded in the preparation protocol.

## Section 9 Preparation of large quantities

(1) If pharmaceuticals are prepared during ordinary pharmacy operations beyond the volume indicated in Section 8, a pharmacist shall be appointed as the individual in charge of the preparation. The same shall be responsible for ensuring that the pharmaceuticals are prepared, stored and labeled in compliance with the regulations governing the handling and dispensation of pharmaceuticals and that the prescribed package insert is enclosed. He may not simultaneously be in charge of testing unless the operation is concerned exclusively with the refilling, including filling, packaging or labeling of pharmaceuticals.

(2) Pharmaceuticals are to be prepared and stored according to the written instructions of the pharmacist in charge of the preparation (preparation instructions). The preparation instructions must be made out in writing prior to preparation and must include at least the following information for each pharmaceutical:

1. Description and dosage form;
2. Type, quantity and quality of the primary substances;
3. Process for appropriate preparation;
4. Labeling of the pharmaceutical in the individual preparation stages;
5. Devices to be used during preparation, procedures and devices used for continuous control during preparation (in-process control) as well as permissible limits for preparation;
6. Type of dispensers to be used, external covering as well as labeling and packing material;
7. Wording of the information to be listed on the dispenser, external covering and package insert;
8. Procedure and scope of sampling for in-process control;
9. Point in time after which the pharmaceutical is to be prepared in accordance with these instructions.

As far as pharmaceuticals are concerned that are approved or registered, the preparation instructions must be in compliance with the approval or registration documents. For pharmaceuticals that are exempt from approval or registration, the preparation instructions must be in accordance with the Ordinance on Standard Approvals or the Ordinance on Standard Registrations. The procedures and devices employed for preparation must be validated pursuant to the respective state of the art; the results are to be documented.

(3) If pharmaceuticals are prepared in batches, records indicating the date must be kept on the origin of the primary substances together with full information on the preparation of the pharmaceuticals (preparation protocol). The preparation protocol must include at least the following:

1. Description and dosage form;
2. Batch number or test number of the primary substances used;
3. Date of preparation and batch number;
4. Data on the amount of the pharmaceutical prepared in one preparation operation and its composition in the individual preparation steps;
5. Results of in-process control;
6. Confirmation of the proper preparation in compliance with the preparation instructions with the initials of the individuals entrusted with the individual preparation steps;
7. Special observations during preparation;
8. Information regarding the type of dispensers used, external covers and other packing materials;
9. Information regarding the type and number of batch samples.

Indicating the date and providing his personal signature, the pharmacist in charge of preparation must confirm in the preparation protocol that the pharmaceutical was prepared in compliance with the preparation instructions and that the required package insert was enclosed. In the event that the pharmacist in charge of preparation is unable to perform his duties for a short period of time, in particular due to sickness or leave, the preparation protocol may be signed in lieu of him by an authorized individual with appropriate training and knowledge. This protocol is to be submitted for confirmation to the pharmacist in charge of preparation upon his return and without any delay. If the pharmaceutical is not prepared in batches, clauses 1 to 5 shall apply accordingly.

(4) Pharmaceuticals pursuant to paragraph 1 may also be prepared by non-pharmaceutical staff on the condition that their work is supervised by a pharmacist.

(5) If it is necessary to have individual preparations steps performed outside of the pharmacy, this must be done in compliance with the preparation instructions laid down in paragraph 2 in facilities that were granted a preparation license pursuant to Section 13 of the German Medicines Act.

## Section 10

### **Testing and release when preparing large quantities**

(1) A pharmacist is to be appointed as the individual in charge of the testing of the pharmaceuticals prepared according to Section 9. The same shall be responsible for ensuring that the pharmaceuticals be tested with respect to the required quality in compliance with the regulations governing the handling and dispensation of pharmaceuticals. He shall not be allowed to be simultaneously in charge of preparation unless the operation is exclusively concerned with the refilling, including the filling, packaging or labeling of pharmaceuticals.

(2) Pharmaceuticals are to be tested according to the written instructions of the pharmacist in charge of testing (testing instructions). The testing instructions must be made out in writing prior to testing and must include at least the following information for each pharmaceutical:



1. Description and dosage form;
2. Requirements regarding the required quality of the primary substances and of the pharmaceutical in the individual preparation stages;
3. Procedure and scope of the testing of the pharmaceutical in the individual preparation stages and of the batch samples;
4. Procedure and scope of sampling;
5. Point in time after which the pharmaceutical is to be tested in accordance with these testing instructions.

For pharmaceuticals that are approved or registered, the testing instructions must be in compliance with the approval or registration documents. For pharmaceuticals that are exempt from approval or registration, the testing instructions must be in accordance with the Ordinance on Standard Approvals or the Ordinance on Standard Registrations. The procedures and devices employed for testing must be validated pursuant to the respective state of the art; the results must be documented.

(3) Paragraph 2 clause 1 and Section 6 paragraph 1 shall apply accordingly to the testing of containers, external coverings, labeling material, package inserts and packing material.

(4) If pharmaceuticals are prepared in batches, records of the process and results of testing including the date must be generated (test protocol). The test protocol must include at least the following information:

1. Description and dosage form;
2. Date of preparation and batch number;
3. Test results for the pharmaceutical in the individual preparation steps;
4. Confirmation of the proper testing in compliance with the testing instructions with the initials of the individual entrusted with the individual tests;
5. Special observations during testing.

Indicating the date and providing his personal signature, the pharmacist in charge of testing must confirm in the test protocol that the pharmaceutical was tested in compliance with the testing instructions and that it is of the required quality. In the event that the pharmacist in charge of testing is unable to perform his duties for a short period of time, in particular due to sickness or leave, the test protocol may be signed in lieu of him by an authorized person with appropriate training and knowledge. This protocol is to be submitted for confirmation to the pharmacist in charge of testing upon his return and without any delay. If the pharmaceutical is not prepared in batches, clauses 1 to 5 shall apply accordingly.

(5) Pharmaceuticals pursuant to paragraph 1 may also be tested by non-pharmaceutical staff on the condition that their work is supervised by a pharmacist.

(6) The testing of pharmaceuticals pursuant to paragraph 1 may in part also be conducted outside the pharmacy in accordance with uniform testing instructions in facilities for which a preparation license pursuant to Section 13 of the German Medicines Act has been granted.

(7) Once the required quality has been determined, the pharmaceuticals are to be labeled accordingly. The date of expiration must be indicated.

(8) Pharmaceuticals may only be labeled as released (release), when the preparation protocol and the test protocol have been properly signed. Section 32 of the German Medicines Act shall remain unaffected.

(9) Pharmaceuticals prepared in a pharmacy pursuant to Section 9 may only be marketed after their authorization pursuant to paragraph 7.

## 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 paragraphs 1 and 3 and of Section 10 shall apply accordingly to the testing of primary substances. Primary substances whose adequate quality was not determined shall be marked as such, and they shall be isolated.

(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 responsibility of the managing pharmacist for the adequate quality of the primary substances shall remain unaffected. Records initialed 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 12 Testing of ready-made pharmaceuticals 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.

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

1. Name or company name of the pharmaceutical company;
2. Description and dosage form of the pharmaceutical;
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

Pharmaceuticals prepared at the pharmacy may be sold only in containers that ensure that the quality of the pharmaceuticals is not impaired beyond the unavoidable.

### Section 14 Labeling

(1) Pharmaceuticals prepared at the pharmacy for administration to humans or animals, which are not for human consumption and are not ready-made pharmaceuticals, may be dispensed only if the following information is indicated on the containers and, if used, on the external coverings in a legible and indelible manner and, with the exception of no. 4, in the German language:

1. Name or company name of the owner of the pharmacy and its address;
2. Contents based on weight, volume or number of pieces;
3. Mode of administration and instructions for use, if stated in the prescription;
4. Type and quantity of active ingredients;
5. Date of preparation;
6. Information regarding the product's limited shelf life.

If the pharmaceuticals are partial quantities of ready-made pharmaceuticals, beside the information according to the German Drug Law name and address of the pharmacy must be stated. In addition, a copy of the package insert must be enclosed.

(2) Ready-made pharmaceuticals, which are pharmaceuticals within the meaning of Section 2 paragraph 2 no. 2 or 3 of the German Medicines Act and which are made at a pharmacy, may only be sold if the containers and the external coverings, if used, are marked pursuant to Section 10 of the German Medicines Act. Information on the dosage form, active ingredients and waiting period may be waived. For these pharmaceuticals, the following information, if known, must additionally be provided on the container or the external covering, if used, or on a package insert:

1. Areas of application;
2. Contra-indications;
3. Side effects;
4. Interaction with other pharmaceuticals.

(3) Ready-made pharmaceuticals that are drugs within the meaning of Section 2 paragraph 2 no. 4 of the German Medicines Act and are made at a pharmacy may only be sold, if the containers and external coverings, if used, are marked pursuant to Section 10 of the German Medicines Act. Information on the dosage form may be waived.

(4) 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 Section 10 and Section 11 of the German Medicines Act.

(5) Pharmaceuticals with dangerous physical properties, which are not ready-made drugs, must be marked pursuant to the Dangerous Chemicals Ordinance with a hazardous goods symbol, the description of the hazard, warnings regarding special risks and safety instructions.

## Section 15 **Stockpiling**

(1) The managing pharmacist must keep in stock the pharmaceuticals required for ensuring a proper supply of pharmaceuticals for the population, especially the pharmaceuticals listed in Annex 2 as well as dressing materials, disposable syringes and disposable cannulas in a quantity that corresponds to at least the average requirement for one week. The pharmaceuticals listed in Annex 3 must be kept in stock, the pharmaceuticals listed in Annex 3, Nos. 1 to 3, 7 and 8 in a dosage form enabling their parenteral administration.

(2) The pharmaceuticals listed in Annex 4 must either be kept in stock at the pharmacy or it must be ensured they can be procured within a short period of time.

(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 in a quantity that corresponds to at least the average requirement of two weeks. A list of these pharmaceuticals must be prepared.

## Section 16 **Storage**

(1) Pharmaceuticals, primary substances, 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 confusion. 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 regarding the storage and labeling of dangerous substances and preparations remain unaffected.

(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. If maximum single or daily doses of a pharmaceutical are stipulated by law, they must be indicated on the storage containers.

(3) The inscriptions on the storage containers for pharmaceuticals must be made in black letters on a white background unless otherwise required in the Pharmacopoeia. Inscriptions on storage containers for pharmaceuticals that are not listed in the Pharmacopoeia but are identical or similar with regard to their composition or effect to drugs listed in the Pharmacopoeia as pharmaceuticals to be stored "with care" or "with great care," especially prescription-only pharmaceuticals, are to be made in red letters on white and/or in white letters on black.

(4) Batch samples of pharmaceuticals with an expiration date required under this Ordinance must be stored for a period of at least one year after their expiration date. Batch samples of pharmaceuticals with a shelf life of less than one year must be stored for a period of at least half a year after their expiration date. Batch samples of pharmaceuticals without an expiration date must be stored for a period of at least five years after release of the batch.

## Section 17

### **Sale of pharmaceuticals and goods customarily sold by pharmacies**

(1) With the exception of Section 11a of the German Pharmacies Act and paragraph 2a, pharmaceuticals may only be sold in pharmacy premises and may only be dispensed by pharmaceutical staff.

(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. 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 consultation through pharmaceutical staff is also available via telecommunications facilities; the possibilities and consultation times must be communicated to them;
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 Thalidomide or Lenalidomide must not be shipped pursuant to Section 43 paragraph 1 clause 1 of the German Medicinal Products 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 general store closing hours, 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 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;
3. Date of dispensation;
4. Name and address of the prescribing physician; 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 Thalidomide or Lenalidomide and the purchase of these active ingredients the following data must be recorded:

1. Name 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.

(7) The regulations of Section 31 paragraphs 1 to 3 and Section 32 shall apply accordingly to community pharmacies that supply hospitals with pharmaceuticals.

(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 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. 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;
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 clauses 1 and 2, 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 dispensing 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.



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 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 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) The pharmacist must inform and advise customers and individuals entitled to practice medicine, dentistry or veterinary medicine, as far as this is required for reasons of drug safety. The information and consultation provided to 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 customer with the necessary information for their proper application.

(2) 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. 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 Drug Commission of the hospital 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.

## Section 22 Documentation

(1) All records on the preparation, testing, checking of the pharmaceuticals at the hospital, 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) If pharmaceuticals are delivered to other pharmacies or pharmaceuticals are obtained from other pharmacies, the batch designation of the pharmaceutical in question must be documented and communicated to the recipient.

(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) With the exception of the hours during which the pharmacy is closed due to a regulation under Section 4 paragraph 2 of the Store Closing Hours Act, it has to be on standby duty at all times. The pharmacy to which such regulation applies is exempt from the obligation of standby duty at the following times:

1. Monday through Saturday - from 6:00 a.m. to 8:00 a.m.
2. Monday through Friday - from 6:30 p.m. to 8:00 p.m.
3. Saturday - from 2:00 p.m. to 8:00 p.m.

(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 closings 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) The authority in charge may exempt a pharmacy that is not subject to any regulation pursuant to Section 4 paragraph 2 of the Store Closing Hours Act from standby duty for specific hours or for Sundays and holidays.

(4) During the general store closing hours, 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.

(5) At the entrance of pharmacies, which are not on standby duty, a clearly legible note must be affixed 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 must make a standby duty arrangement with the hospital carrier that ensures the proper supply of the hospital with pharmaceuticals.

### Section 24 **Prescription Collection Containers**

(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. 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. 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.

## Section 25

### **Goods customarily offered at a pharmacy**

Goods customarily offered at a pharmacy include:

1. Medicinal products;
2. Items, objects and information media that directly or indirectly aid or promote the health of people or animals;
3. Testing chemicals, chemicals, reagents and laboratory supplies;
4. Items and articles for personal hygiene and body care,
5. Pesticides and plant protectives;
6. Animal-rearing products.

## Section 25a

### **Defense of 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 Drug Law, 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,
3. neither the container nor the seal are damaged.

If the container was opened by a pharmaceutical wholesaler 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 wholesaler that at the time of opening of the container the preconditions of clause 1 no. 1 – 3 have been met and the primary substances have been decanted and packaged in adequate containers, are at hand to the pharmacy.

### **Third Section Operation of Hospital Pharmacies**

#### Section 26

#### **Definition, applicable regulations**

(1) The hospital pharmacy is the functional unit of a hospital, which is responsible for ensuring the proper supply of one or several hospitals with pharmaceuticals.

(2) The regulations of Section 4 paragraphs 1 and 6 as well as of Sections 5 to 14, 16, 18, 20 paragraph 1, 21, 22, 25 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. He or the pharmacist authorized by him shall be responsible for providing information and advice on pharmaceuticals to the physicians of the hospital. He 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 must be available. The staff requirement is based on the type and scope of a medically appropriate and adequate supply of the hospital with pharmaceuticals, 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 3 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 20° Centigrade must be possible. The total floor space of these premises must be at least 200 m<sup>2</sup>.

(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 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 has to be prepared.

### Section 31

#### **Dispensation of pharmaceuticals at the hospital pharmacy**

(1) Pharmaceuticals 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. The regulations of the Ordinance on Prescription Drugs shall remain unaffected.

(2) When pharmaceuticals are dispensed to wards and other subunits of the hospital, it must be ensured that unauthorized individuals have no access to them. The pharmaceuticals 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 clause 1, paragraphs 4, 5 and 6 clause 1 numbers 1 - 3 as well as clauses 2 and 3 and paragraph 6a and 6b shall apply accordingly.

## Section 32

### **Checking of pharmaceuticals kept in stock at the wards**

(1) The obligation of the managing pharmacist of the hospital pharmacy or of a pharmacist 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.

(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 authorized by him must generate records in triplicate 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) The general storage and safekeeping conditions;
  - b) The storage and safekeeping of pharmaceuticals pursuant to the generally accepted pharmaceutical rules;
  - c) The state of the pharmaceuticals including their labeling;
  - d) The 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, another copy must be handed over to the physician in charge of the supply of the ward or of the other subunit of the hospital with pharmaceuticals, and the third 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.

**Fourth Section**  
**Administrative offences, transitional and final provisions**

Section 34  
**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 or dispenses pharmaceuticals in violation of Section 17 paragraph 1;
  - 1a. 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 clauses 1, 2 or 4 on the substitution of the managing pharmacist;
  - b) 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;
  - c) 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;
  - d) Violates Section 15 paragraph 1 clause 1 by not keeping in stock or in the required quantity the pharmaceuticals listed in Annex 2 or dressing materials, disposable syringes or disposable cannulas, or violates Section 15 paragraph 1 clause 2 by not keeping in stock or not keeping in the required dosage form the pharmaceuticals listed in Annex 3;
  - e) Violates Section 17 paragraph 1 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;
  - f) 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;
  - g) 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;
- h) 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;
  - i) Violates Section 23 paragraph 1 by not keeping the pharmacy on standby duty;
  - j) 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;
  - k) Violates Section 24 paragraph 1 clause 1 by keeping a prescription collection container without the required permit;
  - l) Violates Section 25 in conjunction with Section 2 paragraph 2 clause 2 and 3 by selling goods at the pharmacy other than those indicated therein or by having them sold.
3. As the managing pharmacist or as a member of the pharmaceutical staff:
- a) Violates Section 6 paragraph 1 clause 2 by failing to prepare or test pharmaceuticals in accordance with the rules of the Pharmacopoeia;
  - 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) Violates Section 8 paragraphs 1, 2 or 3 clause 2, Section 9 paragraph 2 clause 2 or paragraph 3 clauses 1, 2 or 3, Section 10 paragraph 2 clause 2 or paragraph 4, clauses 1, 2 or 3, Section 11, paragraph 1, clause 2 or paragraph 3, or Section 12 paragraph 2 by failing to prepare preparation instructions, a preparation protocol, testing instructions or a test protocol, by failing to prepare them correctly, completely and in the required manner or in good time;
  - d) Violates Section 14 paragraph 1 by dispensing pharmaceuticals without the required labeling;
  - e) Violates Section 16 paragraph 1 clause 1 by failing to store pharmaceuticals or primary substances in such a manner that their quality is not adversely affected and confusion is avoided, or violates Section 16 paragraph 1 clause 2 by failing to store separately and with the relevant labeling pharmaceuticals or primary substances for which the proper quality has not been determined;
  - f) Fails to store batch samples in accordance with Section 16 paragraph 4;
  - 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 35 Transitional Provisions

(1) Pharmaceuticals that were not prepared and tested in accordance with the present Ordinance before this Ordinance became effective or which were not labeled and packed in accordance with the provisions of the present Ordinance may still be sold by the managing pharmacist until June 30, 1988.

(2) Section 4 paragraph 2 clause 2 shall not apply until January 1, 1999, to pharmacies to which a license had been granted before the present Ordinance became effective; until said date, the sales area of the pharmacy must, however,

continue to be in compliance with the provisions that are valid until the present Ordinance becomes effective. Exceptions from the provision of Section 4 paragraph 2 clause 2 may be granted for these pharmacies by the authority in charge after January 1, 1999, if an important reason is given.

(3) The provisions of the present Ordinance shall apply to pharmaceuticals within the meaning of Section 2 paragraph 2 nos. 2 to 4 of the German Medicines Act from January 1, 1988, onward.

### Section 35a

(1) Section 4 paragraphs 2 to 5 and 8 as well as Section 29 paragraph 2 do not apply until January 1, 1996, to pharmacies in the territory described in Article 3 of the Unification Treaty to which a license is deemed granted pursuant to Section 28a paragraph 3 of the German Pharmacies Act. As far as pharmacies are concerned, the number, floor space, arrangement and furniture and fittings of their offices must, however, continue to meet the provisions that applied to them until the effective date of the accession. The provisions of clauses 1 and 2 shall also apply, if the pharmacy shall continue to be operated pursuant to clause 1 under a new license.

(2) Deviating from the provisions of Section 6 paragraph 3 clause 3 and Section 11 paragraph 2 clause 1, the identity of the pharmaceutical or of the primary substances shall only be ascertained in pharmacies pursuant to paragraph 1 in cases where the identity of the contents of every container is not reliably ascertained in another way.

(3) Hospital pharmacies, for which a license has been granted pursuant to Section 28a paragraph 2 clause 2 of the German Pharmacies Act for dispensing pharmaceuticals under prescriptions of physicians of the outpatient department of the hospital, may dispense pharmaceuticals also on the basis of such prescriptions in deviation from Section 31 paragraph 1.

### Section 35b

#### **Transitional regulations**

Deviating from Section 17 paragraph 6 no. 5, the mark must only be indicated on the prescription until March 31, 2005, if the prescription is presented on a standardized form, which corresponds to the preprinted prescription form used in statutory health insurance. If such a form is not submitted, the mark must be printed on the form submitted or on a separate sheet.

### Section 36

deleted

## Section 37

**Becoming effective, cessation of validity**

The present ordinance becomes effective on July 1, 1987. At the same time, except as provided in Section 35, the Ordinance on the Operation of Pharmacies of August 7, 1968 (Federal Law Gazette I, page 939), last amended by the Ordinance of May 3, 1985 (Federal Law Gazette I, page 746) shall be invalidated.

**Annex 1**  
(to Section 4 paragraph 8)**A. Equipment**

Acetylation flask with cooling pipe

Device for the determination of the contents of essential oils in dried plant substances

Lead crucible

Burettes, 25, 50 ml

Cassia flask, 100 ml

Chromatography tubes, plain

Chromatography tubes, 15 cm long, diameter 1.5 to 2.0 cm, with G3 frit and cock

Equipment for thin-layer chromatography

Erlenmeyer flask, 50, 100, 250, 500 ml, narrow-necked and wide-necked

Device for the determination of the congealing temperature

Device for the determination of the ethanol content

Soxhlet extractor, 100 ml tubes of low-fluorescence material

Microburette with Teflon spindle, 0.02 ml graduation

Precision balance (analytical balance)

Buchner funnel

Hot-air blower

Glass filter, 52 g/m<sup>2</sup>, thickness 0.25 mm, diameter 2.4 cm

Glass tube, 30 cm long, inside diameter 1 cm, sealable with cock

Glass tube, 30 cm long, inside diameter 2 cm, sealable with cock

Glass fritting crucible G3, G4

Iodine number flask, 100, 250 ml

Liebig condenser, 400 mm jacket length

Magnifier, at least 6-fold magnification

Graduated flask, with stopper, 10, 25, 100, 250, 1,000 ml

Graduated pipettes, 1, 5, 10 ml

Graduated cylinder, with stopper, 10, 25 (in 2.0 ml), 50 ml (140 mm graduation) and 100 ml

Microscope, magnification at least 600-fold, with eyepiece micrometer, stage micrometer and polarisation attachment

Nessler cylinder, inside diameter 16 - 25 mm, at least 3 pieces

Nickel crucible

Platinum wire

Porcelain filter crucible, A1

Precision balance with a maximum load of up to 2 kilogram

Pycnometer

Quartz crucible with lid, abt. 20 ml

Test tubes with stopper 20 x 120 mm, 25 x 150 mm

Dimroth cooler

Round flask 100, 200, 250, 500, 1,000 ml

Filter flask

Separating funnel 100, 250, 500 ml

Device for the determination of the melting temperature

a) capillary melting point

b) instantaneous melting point

Device for the determination of the boiling range  
 Device for the determination of the boiling temperature  
 Stop watch with an accuracy of reading of at least 0.1 seconds  
 Thermometers:  
 Anschuetz thermometer, set of 7 pieces  
 Thermometer up to 360°C, graduated in 1/1 degrees  
 Rotating thermometer  
 Dropping point thermometer  
 Dry tubes  
 Drying cabinet  
 Drop plate  
 UV analyses lamp 254 and 365 nm  
 Vacuum desiccator with vacuum meter or dry pistol  
 Viscosimeters:  
 Capillary viscosimeter or  
 Hoesppler drop-ball viscosimeter  
 Volumetric pipettes 2, 5, 10, 20, 25, 50 ml  
 Weighing bottles, sealable  
 Device for the determination of water by distillation  
 Glass filter pump  
 Centrifuge and centrifuge tubes (15 ml), with stopper

## B. Testing chemicals

Acetane hydride	Ammonium carbonate
Acetone	Ammonium chloride
Aescine	Ammonium ferric (II) sulphate
Aloine	Ammonium ferric (III) sulphate
Formic acid, pure	Ammonium molybdate
Aminoazobenzene	Ammonium oxalate
4-Aminophenol	Ammonium sulphate
Ammonia solution, strong	Ammonium thiocyanate
Anisaldehyde	Citric acid
Anethole	Cobaltous (II) chloride
Arbutine	Cobaltous (II) nitrate
Arsenic (III) oxide (standard titrimetric substance)	Caffeine
Atropine sulphate	Cresol red
Barium chloride	Cyclohexane
Barium hydroxide	Di-butyl-phthalate
Benzoyl chloride	1,2-Dichloroethane
Benzylbenzoate	Diethanolamine
Benzyl cinamic acid	Diethylamine
Bismuth nitrate, alkaline	2,6-Dichloroquinone-chloroimide
Lead (II) acetate	Dichloromethane
Lead (II) nitrate	4-Dimethylaminobenzaldehyde
Lead (IV) oxide	Dimethyl yellow
Borneol	Dinitrobenzene
Bornyl acetate	3,5-Dinitrobenzoyl chloride

Boric acid	2,4-Dinitrophenylhydrazine
Catechol	Diphenylamine
Bromocresolgreen	Diphenylboryloxyethylamine
Bromocresolpurple	Diphenylcarbazide
Bromophenolblue	Diphenylcarbazone
Bromthymol blue	Dithizone
1-Butanol	Oxford blue salt B
Butyl acetate	Ferric (III) chloride
Calcium carbonate	Ferric (II) sulphate
Calcium chloride	Emetinum hydrochloricum
Calcium hydroxide	Emodine
Calcium sulphate hemihydrate	Eriochrome T black
Carvone	Ethanoic acid
Quinine hydrochloride	Ethanoic acid, pure
Chloroacetanilide	Ethanol, pure
Chloral hydrate	Ethanol 96% (ml/ml)
Chloramine T	Ether
Chloroform	Ethoxychrysoidine hydrochloride
Chlorogenic acid	Ethyl acetate
Chromotrop 2 B	Ethylene glykol
Chromotropic acid	Ethylmethylcetone
Cineole	Eugenol
Citral	Fluorescein sodium
Formaldehyde solution	Potassium thiocyanate
Formamide	Kationexchanger, strong acid
Furfural	Kieselguhr
Gallic acid	Congo red
Glycerol	Crystal violet
Glycerol (85%)	Copper
Glycyrrhetin acid	Cupric (II) nitrate
Glyoxal-bis(2-hydroxy anil)	Cupric (II) sulphate
Guaiac tincture	Litmus paper, blue
Guaiazulene	Litmus paper, red
Heptane	Lanthanum nitrate
Hexane	Linalool
Hydroxylamine hydrochloride	Linalyl acetate
Hyperoside	Polyethylene glycol 400
Indophenol blue	Magnesium oxide
Iodine	Magnesium powder
Potato-spirit oil	Magnesium sulphate
Isobutylmethylketone	Manganous (II) sulphate
Isopropyl alcohol	Mannitol
Caffeic acid	Menthol
Potassium bromate	Mentholum acetate
Potassium bromide	Metaniline yellow
Potassium carbonate	Methanol
Potassium chloride	Methenamine
Potassium chromate	Methoxyphenylacetic acid
Potassium dichromate	Methylene-bis-dimethylaniline
Potassium dihydrogen phosphate	Methylene blue

Potassium hexaferrocyanide (II)	Methyl-4-hydroxybenzoate
Potassium hexaferrocyanide (III)	Methyl orange
Potassium hydrogen phthalate	Methyl red
Potassium hydrogen sulphate	Molybdate phosphorous acid
Potassium hydroxide	2-Naphtol
Potassium iodate	Naphtol benzene
Potassium iodate starch paper	Naphtylethylenediamine dihydrochloride
Potassium-sodium tartrate	Sodiumacetate
Potassium nitrate	Sodium bismuthate
Potassium permanganate	Sodium carbonate
Potassium sulphate	Sodium carbonate (standard titrimetric substance)
Sodium chloride	Picric acid
Sodium diethyldithio carbamate	Piperidine
Sodium metabisulphite	Polysorbate 80
Sodium dodecyl sulphate	1-propyl alcohol
Disodic salt	Propyl-4-hydroxybenzoate
Sodium fluoride	Pyridine
Sodium hexanitrocobaltous acetate (III)	Mercuric (II) acetate
Sodium hydrogen carbonate	Mercuric (II) iodide
Sodium hydroxide	Resorcin
Sodium hypophosphite	Rhaponticine
Sodium iodide	Rheine
Sodium monohydrogen phosphate	Rutosidum
Sodium nitrite	Salicylic acid
Sodium pentacyanonitrosyl ferrate (II)	Nitric acid, strong
Sodium periodate	Hydrochloric acid, strong
Sodium sulphate, pure	Saponine
Sodium sulphide	Sulphuric acid, strong
Sodium sulphite	Scopolamine hydrobromide
Sodium tetraborate	Scopoetine
Sodium tetraphenylborate	Silver nitrate
Sodium thiosulphate	Starch, soluble
Ninhydrin	Sudan III G
3-Nitrobenzaldehyde	Sulphamic acid
Nitrobenzene	Sulphonamido
Nitrobenzene chloride	Sulphanilic acid
0.01 M-Osmium (VIII) oxide solution in 0.1N-sulphuric acid or Osmium (VIII) oxide	Tannin
Oxalic acid	Tetramethylammonia hydroxide solution
Paracetamol	Thioacetamide
Paraffin, viscous	Thioglycolic acid
Petroleum ether	Thiourea
Penanthroline hydrochloride	Thujon
Phenyldimethyl pyrazolone	Thymol
Phenolphthaleine	Thymol blue
Phenol red	Thymol phthaleine
	Titan yellow



Phloroglucinol	Toluol
Phosphorous (V) oxide	Tragacanth, powder
Phosphoric acid, strong	Trichloro-acetic acid
Triethanolamine	0,1 N-potassium bromate solution
Triphenyltetrazolium chloride	0,1 N-potassium permanganate solution
Vanillin	0,1 M-sodium edetate solution
Tartaric acid	1 N-sodium hydroxide solution
Xanthidrol	0,1 N-sodium hydroxide solution
Xylenol orange	0,1 N-sodium thiosulphate solution
Xylol	0,1 N-perchloric acid
Zinc	1 N-hydrochloric acid
Zinc (standard titrimetric substance)	0,1 N-hydrochloric acid
Zinc dust	1 N-sulphuric acid
	0,1 N-silver nitrate solution
Standard solutions:	0,1 M-zinc sulphate solution
0,1 N-ammonia thiocyanate solution	
0,1 N-iodine solution	

**Annex 2**

(to Section 15 paragraph 1 clause 1)

1. Analgesic agents/anaesthetic agents
2. Anti-arrhythmic agents
3. Antibiotics/chemotherapeutic agents
4. Antidiabetic agents
5. Anti-emetic agents
6. Antihistamines
7. Antihypertensive agents
8. Antihypotensive agents
9. Anticoagulants
10. Antipyretic agents
11. Antitussive agents/expectorants
12. Beta blockers
13. Bronchospastic agents/anti-asthmatic agents
14. Corticoids
15. Disinfectants
16. Diuretics
17. Haemostyptic agents
18. Cardiac agents
19. Coronary agents
20. Gastro-intestinal therapeutic agents
21. Ophthalmic agents/glaucoma agents
22. Rhinologic agents
23. Vaginal therapeutic agents

**Annex 3**

(to Section 15 paragraph 1 clause 2)

1. Antidotes against intoxications and overdoses with
  - 1.1 Opiates
  - 1.2 Cholinesterase inhibitors
  - 1.3 Cyanide
  - 1.4 Methaematogenic agents
2. Emetic agents
3. Corticoids, in high doses for injection
4. Agents for the treatment of flue-gas poisoning
5. Antifoam agents for the treatment of tenside intoxications
6. Activated carbon for medical use
7. Tetanus vaccine
8. Tetanus hyper-immunoglobulin 250 I.U.

**Annex 4**  
(to Section 15 paragraph 2)

1. Botulinum antitoxin from the horse
2. Diphtheria antitoxin from the horse
3. Snake poison antiserum, polyvalent, Europe
4. Rabies vaccine
5. Rabies immunoglobulin
6. Tetanus immunoglobulin 2500 I.U.
7. Prothrombin concentrate (PPSB)
8. Polyvalent immunoglobulin
9. Rubella immunoglobulin
10. Varicella-Zoster immunoglobulin
11. Hepatitis B immunoglobulin