



# **Procedural principles for conducting knowledge tests in accordance with Section 4 (3) sentence 3 of the Federal Pharmacists' Code in the state of Berlin**

## **I. Fundamentals**

The Berlin State Office for Health and Social Affairs is the competent authority in the state of Berlin for decisions on the granting of a licence to practise in accordance with Section 4 of the Federal Pharmacists' Code (BApO) and the granting or extension of a permit to temporarily practise as a pharmacist in accordance with Section 11 BApO.

The granting of a licence to practise in accordance with Section 4 (3) sentence 3 BApO requires applicants who hold a certificate of training as a pharmacist issued in a third country to have an equivalent level of training. The state office is responsible for checking the equivalence of the level of training in the state of Berlin. If the equivalence of the level of training is not given or can only be determined with an unreasonable amount of time or effort, proof of the required knowledge and skills is provided in accordance with Section 4 (3) sentence 3 BApO by passing an examination that relates to the content of the state final examination. The relevant regulations can be found in the "Ordinance on the Implementation and Content of Adaptation Measures and on the Issuing and Extension of Professional Licences in the Federal Healthcare Professions".

The State Office may also make the granting or extension of a professional licence dependent on proof of the required knowledge and skills by means of an examination. The provisions of these procedural principles apply accordingly to this examination.

## **II Examination board**

The knowledge test is taken in the form of a state examination before a state examination board appointed by the state office. The examination board has the task of assessing the performance in the subjects listed under No. 3 in an overall assessment. Passing the examination requires at least that the performance still fulfils the requirements despite its deficiencies.

The examination board consists of the chairperson and at least two, but no more than four other members. Deputies must be appointed for the chairperson and the other members. Professors or other teaching staff of the subjects that are the subject of the examination are appointed as chairpersons, other members and deputies. Instead, pharmacists who are not members of the teaching staff of a university may also be appointed as members of the examination board.

The chairperson of the examination board leads the examination and must conduct the examination themselves. He or she must ensure that the candidates are questioned in an appropriate manner. He or she is responsible for maintaining order. § Section 11 (3), (5) sentence 1 and (6) and Section 14 of the Licensing Regulations for Pharmacists (AAppO) apply accordingly.

The regulations on the exclusion or concern of bias of persons in Sections 20 and 21 of the Administrative Procedure Act are to be applied accordingly to the examiners.

### III Knowledge test

#### 1. Exam date

The examinations usually take place in January, April, July and October. The state office determines the place and time of the examination and informs the commission members. The summons is sent to the candidate at least 7 days before the examination date. In the summons, the state office informs the applicant about the examination procedure, including the examination requirements in accordance with No. 3, as well as the consequences of missing the examination (Section 13 AAppO).

#### 2. Examination procedure

The knowledge examination in accordance with Section 4 (3) sentence 3 BApO is an oral examination that takes place on one day in German. The examination is generally conducted as an individual examination. If the subjects to be examined permit, up to four applicants may be examined at the same time. The duration of the examination depends on the extent of the significant differences identified. It lasts **a minimum of 30 minutes** and **a maximum of 60 minutes** for each applicant.

The examination board must be present during the entire examination. They are obliged to maintain confidentiality. The examination is not public. The State Office may send observers to the oral examinations.

#### 3. Examination requirements

The content of the examination is based on the content of the state final examination in accordance with the licensing regulations for pharmacists. The knowledge examination relates to the subjects

- **Pharmaceutical practice** and
- **Special areas of law for pharmacists** and
- to **one of the subjects** in which the State Office has identified **significant differences** in accordance with Section 4 (2) sentence 8 of the Federal Pharmacists' Code and which is determined by the State Office.

In the area of "**Pharmaceutical Practice**", the examination questions relate to the basic principles of formulation and defectology; incompatibility; basic principles of the development, manufacture and authorisation of finished medicinal products; conformity assessment of medical devices; possibilities of influencing the shelf life of medicinal products; procurement, documentation, evaluation, assessment and dissemination of information on medicinal products and medical devices;

Information and counselling of patients, physicians and members of other healthcare professions on medicinal products and medical devices placed on the market in pharmacies, in particular on proper storage and use, side effects and interactions; dangers of long-term use and misuse of medicinal products; aspects of quality assurance; applied pharmacotherapy; drug counselling and selection in self-medication; interpretation of medical, dental and veterinary prescriptions and their terminology; practical aspects of pharmaceutical care; standard pharmacy services; Blood and blood products; hospital hygiene; economic aspects of the use of medicinal products and medical devices; products for infant and child nutrition and for nutritional measures for illnesses; dietary supplements; products for enteral and parenteral nutrition; products and articles for personal hygiene, pesticides and pest control; health promotion; accident prevention, occupational safety and first aid measures; business management principles of pharmacy operations, in particular accounting, annual financial statements, profitability, rationalisation and taxes.

In the area of "**Special areas of law for pharmacists**", the examination questions must be based on an overview of the delimitation of the following areas of law: Constitutional law, administrative law, criminal law, civil law, commercial law; distinction between law, statutory instrument, administrative regulation, sta-

tutes; professional law for pharmacists; training and tasks of other professions in pharmacies, legal foundations; chamber laws including professional jurisdiction; pharmacy law, in particular the Pharmacy Act and Pharmacy Operating Regulations; other regulations from other areas of law that are important for pharmacy operations; basic outline of the history of pharmacy; Pharmaceutical and narcotics law, in particular the Medicinal Products Act, the Therapeutic Products Advertising Act and the Narcotics Act as well as related ordinances; medical product law; special features of the national and international pharmaceutical market, in particular supply, advertising and price structures; regulations on the handling and circulation of hazardous substances; tasks and organisation of the health administration at federal, state and local level as well as at international level; legal basis for the business aspects of pharmacy management, social insurance law.

In addition, the applicant must demonstrate in the examination that he or she has the knowledge and skills, including in **pharmacy communication skills**, required to practise the profession of pharmacist.

#### 4. Assessment

On the basis of the oral examination, the examination board assesses the performance in the subjects listed under 3. in an overall assessment. The examination is successfully completed if the performance still fulfils the requirements despite the deficiencies. The examination board makes its decision by majority vote.

In the event of a tie, the chairperson has the casting vote. The chairperson shall inform the candidate of the result of the oral examination and, if requested by the candidate, provide reasons.

#### 5. Documentation of the test

A transcript of the examination of each applicant must be drawn up and signed by all members of the examination committee in accordance with the model in Annex 19 of the Ordinance on the Implementation and Content of Adaptation Measures and on the Issuing and Renewal of Professional Licences in the Federal Healthcare Professions, from which the subject of the examination, the passing or failing grade and the reasons for this as well as any serious irregularities that may have occurred are evident. It must be sent to the state office immediately after the examination.

#### 6. Withdrawal, default and cancellation

If the candidate withdraws from the examination after being admitted, he/she must inform the State Office immediately of the reasons for his/her withdrawal. If the State Office authorises the withdrawal, the examination shall be deemed not to have been taken. Authorisation shall only be granted if there is good cause. In the event of illness, the State Office may require the submission of a medical certificate from a doctor or public health officer. If authorisation for withdrawal is not granted or if the candidate fails to notify the reasons for withdrawal without delay, the examination shall be deemed to have been failed.

If the candidate misses an examination date or interrupts the examination, they have failed the examination. If there is an important reason for the candidate's behaviour, the examination is deemed not to have been taken. The state office shall decide whether there is good cause.

#### 7. Repeating the exam

The knowledge test can be repeated twice. Failed knowledge examinations in other federal states are counted towards the number of retakes. A further repetition is not permitted.

Imprint: Berlin

State Office for Health and Social Affairs

Responsible for the content: Department IV A

Turmstraße 21, 10559 Berlin

E-mail: [bqfg@lageso.berlin.de](mailto:bqfg@lageso.berlin.de)

V.i.S.d.P. Silvia Kostner - Z Press - Status: January 2020

Internet address: [www.berlin.de/lageso](http://www.berlin.de/lageso)