Approved
by Decision № 108 of the
Cabinet of Ministers of
the Republic of Azerbaijan,
dated July 13, 2007

Rules
of official registration and maintaining the register of medicines

1. General provisions

1.1. These Rules have been developed on the basis of Decree № 528, Para 1.3, of the President of the Republic of Azerbaijan «On Enforcement of Law of the Republic of Azerbaijan «On Medicines», dated February 6, 2007, and shall define the rules of official registration of medicines being imported into and manufactured in the territory of the Republic of Azerbaijan, and keeping the state register thereof.

1.2. These Rules shall not apply to medical items being used for diagnostics, prevention and treatment of diseases (medical devices, products, items and materials, instruments and equipment, medical reagents and optical accessories).

1.3. With the exception of special circumstances defined by law of the Republic of Azerbaijan «On Medicines», medicines shall be entered on the register of medicines after they are officially registered by the Health Ministry of the Republic of Azerbaijan or an entity authorized by it (hereinafter referred to as «the Health Ministry»), and, after *a control stamp* is stuck on it, their import into and production in the Republic of Azerbaijan, as well as their sale and use in medicine shall be permitted.

1.4. Following medicines shall be officially registered in accordance with Law of the Republic of Azerbaijan «On Medicines»:

1.4.1. original medicines;

1.4.2. analogues of medicines (generics);

1.4.3. new combinations of medicines that have already been officially registered;

1.4.4. medicines with expired term of state registration;

1.4.5. medical substances being used as actuating substance in production of medicines.

1.5. Should there occur any change in the information reflected in officially registered medicines' registration documents, such changes shall be officially registered.

1.6. In case of failure to apply, within the term and in order as provided for in item 3.7 of these Rules, for the state registration of changes made to the information contained in registration documents of previously registered medicines, state registration of such medicines shall be deemed to be void.

2. Basic definitions

Following definitions have been used in these Rules:

2.1. **official registration of medicines** — a system of actions providing for expert examination of medicines to be used in the medical practice based on relevant documents and/ or permitting their industrial production in, import into and application in the Republic of Azerbaijan, and registration thereof as specified;

2.2. **medicines** — natural, synthetic and biotechnological substances or a mix of several substances - with special pharmacological and biological activity and certain form of medicine - to be used in diagnosis, prevention, treatment of human-inherent diseases, prevention of pregnancy, rehabilitation of patients or changing the condition and function of a human organism;

2.3. **medical substances** — substances of natural (vegetal, animal, mineral etc. origin), synthetic and biotechnological origin being capable to change the condition and biological functions of a human organism, and being used in production of medicines;

2.4. **original medicines** — patented medicines put on sale with its unique name;

2.5. **analogues of medicines (generics)** — medicines that are produced -after the term of original medicines' exclusive patent rights expire - by other producers with the same content, dosage and form of active substances;

2.6. **article of pharmacopoeia** — a standard document defining requirements for medicines' quality, packing, storage term and conditions, and quality control;

2.7. **registration certificate** — a document certifying approval of a state body for medicines' import into, production, sale and application in treatment in the territory of the Republic of Azerbaijan;

2.8. **registration number**— a coded mark given to a medicine;

2.9. **The Register of Medicines Officially Registered in the Republic of Azerbaijan** — a data bank of medicines, of which import into, production, sale and application in treatment in the Republic of Azerbaijan have been permitted;

2.10. **medicines of OTC (over-the-counter) category** — medicines being sold without a prescription;

2.11. **actuating substance** — main medical substance used in the production of medicines;

2.12. **a registration document** — a collection of documents submitted by an applicant for official registration of medicines, approving medicines' safety, efficiency and quality.

3. Rules of applying for official registration

3.1. In order to get medicines with expired term of registration, and also the changes occurred in the information contained in the registration documents of previously registered medicines officially registered, a person authorized by a producer (hereinafter referred to as «Applicant») shall apply to the Health Ministry in writing (by a letter).

3.2. An applicant shall submit a power of attorney certifying his/her authorities to the Health Ministry.

3.3. An applicant applying for the official registration of medicines in the cases provided for in items 1.4.1 to 1.4.3 hereof shall attach the following documents to his/her letter:

3.3.1. An application for official registration of a medicine in the Republic of Azerbaijan (Schedule №1);

3.3.2. An application for official registration of a medical substance in the Republic of Azerbaijan (Schedule №2);

3.3.3. A collection of documents to be submitted for official registration of a medicine produced in a foreign country in the Republic of Azerbaijan (Schedule №3);

3.3.4. A collection of documents to be submitted for official registration of a medical substance in the Republic of Azerbaijan (Schedule №4);

3.3.5. A collection of documents to be submitted for official registration of a medicine produced within the country in the Republic of Azerbaijan (Schedule №5);

3.4. In case provided in item 1.4.4 hereof, an applicant shall apply, in writing, to the Health Ministry for reregistration of the medicine 120 days, at the most, prior to the date, on which the term of the previous state registration expires. Should the applicant fail to apply within the aforementioned term for the reregistration of the medicine, official registration of the same medicine shall be carried out in a general order.

Following documents should be attached to a letter submitted for official reregistration of medicines:

3.4.1. an application for official registration of a medicine in the Republic of Azerbaijan (Schedule №1);

3.4.2. collection of documents to be submitted for official reregistration of a medicine produced in a foreign country in the Republic of Azerbaijan (Schedule №6);

3.4.3. a collection of documents to be submitted for official reregistration of a medicine produced within the country in the Republic of Azerbaijan (Schedule №7).

3.5. If an applicant applied for official reregistration of a medicine on time, but he/she had not been issued a certificate of official reregistration until the previous registration term expired due to reasons not depending on such person, the previous certificate of official registration shall retain its force until one of the decisions provided in Para 7 hereof is made by the Health Ministry.

3.6. If an applicant timely applied for official registration of the changes occurred in registration documents of an officially registered medicine before its registration term had expired, but no decision was taken with regard to the registration of such changes or refusal of registration due to reasons not depending on such person, the previous certificate of official registration shall retain its force until one of the decisions provided in Para 7 hereof is made by the Health Ministry.

3.7. In cases provided in item 1.5 hereof, an applicant shall immediately (at the latest, within 3 months of the date, on which a decision was taken by the producer to make such a change) apply to the Health Ministry, in writing, for the official registration of the changes occurred in the registration documents of the previously registered medicine, and following documents shall be attached to the letter:

3.7.1. an application for state registration of a medicine in the Republic of Azerbaijan (Schedule №1);

3.7.2. In case of a change in the dosage of the medicine, and when each following dosage of the medicine is introduced:

3.7.2.1. a notarized copy of a document on official registration of a medicine with the new dosage in a country of its production;

3.7.2.2. a report on preclinical studies and clinical tests of the medicine in a new dosage (signed by a party which had carried out the studies and tests, and approved by the head of the relevant institution). For foreign countries, photo copies shall be certified by the head of the institution which had carried out the studies and tests, and the client;

3.7.2.3. an article of pharmacopeia for a medicine’s quality control, or draft of the normative documents;

3.7.2.4. a quality certificate issued by the producer for the medicine produced in a new dosage;

3.7.2.5. instruction for the use of the medicine;

3.7.2.6. samples of packing and its sketches, instructions for use, as well as their electronic versions;

3.7.3. In case of a change in packing (number of dosages in the container) and when registering each following packing:

3.7.3.1. new instructions for the use of a medicine;

3.7.3.2. samples of packing for the medicine, and its sketches, instructions for use, as well as their electronic versions.

3.7.3.3. a quality certificate issued by the producer for the medicine produced in a new packing;

3.7.3.4. draft of changes made to normative documents on the medicine's quality control.

3.7.4. in case of a change in a medicine's name:

3.7.4.1. a notarized copy of a document of official registration of the medicine's name in a country of its production;

3.7.4.2. a certificate substantiating the reason for the change of the medicine's name;

3.7.4.3. new instructions for the medicine's use;

3.7.4.4. samples of packing for the medicine and its sketch, instructions for use, as well as electronic version thereof. In case the name of the medicine does not correspond to the name of the same registered in the country of its registration, an application for the registration of the medicine shall be accepted only after the name of the medicine is agreed upon with the Health Ministry;

3.7.5. in case new instructions and new methods of application are added to the instruction for the medicine's use:

3.7.5.1. the new instruction for the medicine's use;

3.7.5.2. samples of packing for the medicine, and its sketches, instructions for use, as well as their electronic versions;

3.7.5.3. reports on clinical tests on the medicine's new indications (signed by a party which had carried out the test, and approved by the head of the relevant institution). Photo copies for foreign countries shall be approved by the head of the institution which had carried out the tests, and the client;

3.7.6. in case of removing previous indications and methods of application from the instruction for the medicine's use:

3.7.6.1. the new instruction for the medicine’s use;

3.7.6.2. samples of packing for the medicine, and its sketches, instructions for use, as well as their electronic versions;

3.7.6.3. data defining the necessity of removing indications and methods of application (additional effects disclosed, results of application, clinical data, a decision of competent national authorities on removing indications and methods of application);

3.7.7. In case of additions and changes in the colouring, stabilizing agents, aromatizers contained in the medicine, and covering components of the pill and capsule:

3.7.7.1. comparative information about the bio-digestion of the previously registered medicine and the newly introduced medicine;

3.7.7.2. data certifying the stability of the medicine;

3.7.7.3. article of pharmacopeia of the previously registered medicine forms’ content and comparative table of quality indications defined in regulatory documents;

3.7.7.4. quality certificate for one series of the medicine;

3.7.7.5. new instructions for the medicine’s use;

3.7.7.6. samples of packing for the medicine, and its sketches, instructions for use, as well as their electronic versions;

3.7.8. in case of changes in regulatory documents on quality control of the active substance, secondary substance or ready medicine:

3.7.8.1. new regulatory documents;

3.7.8.2. a comparative table of previous and new tests;

3.7.8.3. quality certificate for the active substance, secondary substance or ready medicine;

3.7.9. in case of a change in the primary packing material, and when registering each following type of packing:

3.7.9.1. regulatory documents related to new packing material;

3.7.9.2. comparative table of quality indications confirming stability of the medicine in a packing changed during the term of effectiveness, and defined in regulatory documents;

3.7.9.3. instructions for the medicine’s use;

3.7.9.4. samples of the medicine's packing, and its sketches, instructions for use, as well as their electronic versions;

3.7.10. in case of additions and changes to the medicine's production process:

3.7.10.1. summary of the previous production process;

3.7.10.2. summary of the new production process, by indicating the change made;

3.7.10.3. the draft of regulatory documents (if the mixture's content has changed);

3.7.10.4. quality certificate for the ready medicine;

3.7.11in case of a change in the medicine's effectiveness term:

3.7.11.1. all information confirming stability of the medicine according to the indications of regulatory documents;

3.7.11.2. new instructions for the medicine's use;

3.7.11.3. samples of packing for the medicine, and its sketches, instructions for use, as well as their electronic versions;

3.7.12. in case of a change in the medicine's storage conditions:

3.7.12.1. a comparative table of quality indications confirming stability of the medicine in the new storage conditions and during the term of fitness, and defined in regulatory documents;

3.7.12.2. new instructions for the medicine's use;

3.7.12.3. samples of packing for the medicine, and its sketches, instructions for use, as well as their electronic versions;

3.7.13. in case of a change in the medicine's (or medical substance's) or ready medicine's quality control method, the results of the new method's validation, confirming the new method's being equivalent to or better than the previous one by its preciseness;

3.7.14. in case of a change in the producer's name or address, and each time when a new production site is registered:

3.7.14.1. a letter of explanation;

3.7.14.2. a production license;

3.7.14.3. a certificate conforming reliable production experience;

3.7.14.4. samples of packing for the medicine, and its sketches, instructions for use, as well as their electronic versions.

3.8. Documents shall be drawn up in two copies: one copy — documents being drawn up by a producer (along with notarized copies of official documents) and one copy — Azerbaijani or Russian translation of these documents certified by the applicant.

3.9. A report on the results of the tests conducted shall be signed by the executor of these tests, and shall be approved by the head of the organization conducting these tests, and sealed. Copy of such a report for medicines made abroad shall be certified by the applicant.

3.10. In addition to the documents specified in these Rules, the applicant shall also submit to the Health Ministry samples of the medicine and the medical substance used in production of the same medicine. The sample of the medicine should comprise of 5 boxes in a form provided for sale, and the sample of the medical substance being used in the production of the same medicine should be submitted in a volume sufficient for conducting of three analyses. Samples of drugs (narcotics) and expensive (costing over 30 Manats a sample) medicines, including medical substance being used in the production of the same medicine should be submitted in an amount sufficient for a single laboratory analysis.

3.11. Marking (primary and final packing) of a medicine shall meet the requirements provided in Schedule №8 hereof.

3.12. Instructions related to the medicine's use (for professionals) shall meet the requirements provided in Schedule №9 hereof.

3.13. Instructions related to the medicine's use (for users) shall meet the requirements provided in Schedule №10 hereof.

3.14. The applicant shall bear responsibility for the accuracy of the documents being submitted, as well as of the information contained in such documents.

3.15. Regardless of whether or not the medicine is officially registered, documents and samples submitted for official registration shall not be returned back.

3.16. The Health Ministry shall bear responsibility for keeping confidentiality of the information submitted by the applicant and related to his commercial secret, as provided by the relevant legislation of the Republic of Azerbaijan.

3.17. The applicant may withdraw registration at any stage of the official registration. In this case, documents and samples submitted for registration shall not be returned.

4. Preliminary expert examination of documents submitted for official registration

4.1. In case of no shortages in the application, documents and samples provided for in these Rules, they shall be accepted for preliminary expert examination, by

being registered by the Health Ministry in a special log, and the applicant shall be provided a notice thereof.

4.2. Within 5 days of the receipt of the notice referred to in item 5.1 hereof with regard to carrying out an expert examination, the applicant should sign an agreement with the Health Ministry on conducting of such expert examination. Scope and term of the expert examination to be conducted, as well as cost of the service and other conditions shall be included in the agreement. Within 15 banking days of signing the agreement, the Applicant shall pay the cost of the preliminary expert examination to the Health Ministry's relevant bank account.

4.3. The Health Ministry shall, within 15 calendar days of the date, on which the cost of the preliminary examination was paid, carry out preliminary examination of the documents and samples submitted for the official registration. During the preliminary expert examination, reasonability of the medicine's official registration and completeness of the information contained in the documents submitted shall be looked into.

4.4. In case of discovering any non-conformity or error in the documents submitted by the applicant during their examination, and if the information contained in such documents were not sufficient to confirm the quality, safety and effectiveness of the medicine submitted for registration, the Health Ministry may require that the applicant submit additional documents and remove the non-conformity and errors.

4.5. The Applicant shall be granted 90 calendar days to submit additional documents and remove the errors and non-conformity. This term shall not include the time provided in Para 4.3 hereof for conducting the preliminary examination. Should the applicant fail to submit additional documents and remove the errors and nonconformity within the abovementioned term, the preliminary examination shall be stopped and documents and samples returned to the applicant. In case the documents and samples are returned back, the cost of the preliminary examination paid by the applicant shall not be returned.

4.6. The medicine, of which documents and samples were returned, may in future be again submitted by the Applicant for official registration.

4.7. Based on the results of the preliminary expert examination, the Health Ministry shall take one of the following decisions on:

4.7.1. sending the documents and samples to the Specialized Expert Examination Institution of the Health Ministry of the Republic of Azerbaijan for examination;

4.7.2. refusing to officially register the medicine.

4.8. In case of taking a decision on sending the documents and samples for the official registration purpose to the Specialized Expert Examination Institution, the applicant shall be given a notice thereof.

4.9. In the following cases, the Health Ministry shall refuse to officially register the medicine based on the results of the preliminary expert examination:

4.9.1. in case of submitting an application for registration of a medicine with a new name, provided that the previous name of this officially registered medicine is maintained. At the same time, if the producer of the original medicine produces another medicine under a different name, but with the same content, form and dosage as that of the original medicine, then both the medicines may be officially registered;

4.9.2. in case another medicine is submitted for official registration under the trade name, which has already been officially registered in the Republic of Azerbaijan;

4.9.3. in case a medicine is submitted for official registration by another person under the same name, without a consent of the owner of the original medicine, which has already been officially registered (with the exclusion of cases of using an international unpatented name recommended by the World Health Organization);

4.9.4. in case documents and samples submitted failed to meet the requirements of Law of the Republic of Azerbaijan «On Medicines» and these Rules.

5. Specialized expert examination of documents submitted for official registration

5.1. Within 5 days of receiving a notice referred to in item 4.8 hereof with regard to the official registration of medicines, the applicant shall sign an agreement with the Specialized Analytical and Expert Examination Institution of the Health Ministry of the Republic of Azerbaijan on carrying out the expert examination.

The agreement shall include the scope and term of the specialized expert examination, as well as cost of the service, and other conditions. Within 60 banking days of signing the agreement, the applicant shall pay the cost of the specialized examination to the relevant bank account of the Health Ministry.

5.2. Specialized expert examination shall consist of the laboratory analysis of the medicine and appraisal of technical documents, and the results of the clinical and pharmacological tests.

5.3. Specialized examination shall be carried out within maximum 180 calendar days since the date, on which the cost of the specialized expert examination was paid by the applicant.

5.4. Specialized expert examination of documents submitted for official registration of medicines in cases provided for in item 1.4.4 hereof, and of documents submitted for official registration of changes occurred in the information contained in registration documents provided for in item 1.5 hereof shall be carried out within maximum 90 calendar days of the date, on which the applicant paid the cost of the specialized expert examination.

5.5. In necessary cases, the Health Ministry may require additional information and reagents on the subject of the specialized expert examination being conducted.

5.6. Time spent by the applicant for the submission of such additional information and reagents shall not be included in the time period provided for conducting a specialized examination as specified in items 5.3 and 5.4 hereof. Should the applicant fail to submit additional information within 90 calendar days of the date, on which a notice was served, the specialized expert examination shall be stopped.

In case of ceasing the specialized expert examination, documents and samples submitted, as well as the cost of the examination paid by the applicant shall not be returned.

5.7. The medicine, for which a specialized expert examination was stopped, may be re-submitted in future for official registration.

5.8. A report on the results of the specialized expert examination shall be made up by the Specialized Expert Examination Institution of the Health Ministry and submitted to the Health Ministry.

6. Additional specialized expert examination of documents submitted for official registration

6.1. In cases when the results of the specialized expert examination was not sufficient to permit production of a medicine submitted for official registration, import thereof into the Republic of Azerbaijan and application in the medical practice, and in cases when the quality, safety and effectiveness of the medicine was not completely proved, the Health Ministry shall, within 10 calendar days of the date, on which a report on the results of the specialized expert examination was submitted, take a decision on sending the said medicine to the Pharmacology and Pharmacopeia Experts Council of the Health Ministry of the Republic of Azerbaijan for additional specialized expert examination. A copy of such a decision shall be provided to the applicant.

6.2. Additional specialized expert examination shall consist of examination of the documents submitted by the applicant, expert examination carried out on the findings of the report drawn up as a result of the specialized expert examination and/ or laboratory analysis of the medicines.

6.3. Additional specialized expert examination shall be carried out during maximum 30 calendar days.

6.4. In necessary cases, the Pharmacology and Pharmacopeia Experts Council of the Health Ministry may require additional information from the applicant on the subject of the expert examination being carried out.

6.5. The term referred to in item 6.3 hereof for conducting additional specialized expert examination shall not include the time spent by the applicant for providing additional information. Should the applicant fail to submit additional information within 90 days of the date, on which an inquiry was made, additional specialized expert examination shall be stopped.

6.6. In case of ceasing the additional specialized expert examination, documents and samples submitted by the applicant shall not be returned.

6.7. The medicine, for which additional specialized expert examination was stopped, may in future be re-submitted by the Applicant for official registration.

6.8. A report on the results of the additional specialized expert examination shall be submitted to the Health Ministry by the Pharmacology and Pharmacopeia Experts Council of the Health Ministry.

7. Taking a decision on the results of additional specialized expert examination

7.1. The Health Ministry shall, based on the report on the results of the specialized expert examination and, in cases provided in Section 6 hereof, and the report drawn up by the Pharmacology and Pharmacopeia Experts Council of the Health Ministry, take one of the following decisions within 15 calendar days of the date, on which the report was made up, on:

7.1.1. official registration of the medicine;

7.1.2. refusing to carry out official registration of the medicine.

8. Grounds for refusing to carry out official registration

8.1. In the following cases, the Health Ministry shall refuse to carry out official registration of medicines:

8.1.1. in case of discovering untrue information in the documents submitted for registration;

8.1.2. if the medicine contained a substance prohibited in the territory of the Republic of Azerbaijan;

8.1.3. if quality and quantity indices shown in the documents submitted for registration were not true;

8.1.4. if therapeutic efficiency was not proved;

8.1.5. if clinical tests and other research works carried out to appraise the medicine’s safety, efficiency and quality resulted in negative outcome;

8.1.6. if serious side effects are discovered during the registration process;

8.1.7. if a negative opinion was given on the results of the producing company’s audit;

8.1.8. if a negative opinion was given on the results of the specialized expert examination and/or additional specialized expert examination carried out by the Pharmacology and Pharmacopeia Experts Council of the Health Ministry;

8.2. In case of taking a decision to turn down official registration of the medicine, the applicant shall be given a written substantiated response.

9. Issue of a certificate of official registration

9.1. In case of taking a decision on official registration of a medicine, within 15 calendar days, the Applicant shall be issued a registration certificate in a form indicated in Schedule 11 hereof.
9.2. In case several forms of one medicine are officially registered at a time, each form of medicine shall be issued an individual certificate.
9.3. In case of official registration of a medicine produced in a few factories being located in different countries, the medicine being produced in each factory shall be issued a separate certificate.
9.4. In case of changing a dosage of a previously registered medicine and upon officially registering each following dosage, in case of changing a packing (number of dosages in each container) and upon registering each following packing, in case of a change in the name and/ or a legal person-producer (change of a producer-legal person's name or address) and upon registering each following production site, in case of a change in preliminary packing and upon registering each following packing, in case of additions and changes in colouring and stabilizing substances, aromatizers contained in the medicine, as well as in covering components of pills and capsules, and in case of registering a change in additional substances in the medicine, a new form of a registration certificate shall be developed. The previous registration number and date of the official registration of the change shall be indicated on the form. In these cases, term of effectiveness of the registration certificate shall be defined by the previous registration date.

In case of other types of changes in registration documents, official registration shall be carried out without developing a new registration certificate.

10. Validity of official registration

Official registration of medicines shall be valid during 5(five) years. Upon expiry of this term, medicines shall be officially reregistered.

11. Approving instructions on a medicine's use and relating the medicine to the «List of over-the-counter drugs»

11.1. Instructions on the use of a medicine shall be approved by the Pharmacology and Pharmacopeia Experts Council of the Health Ministry after the relevant specialized expert examination.

11.2. Relation of a medicine to the «List of over-the-counter drugs» shall be defined by Pharmacology and Pharmacopeia Experts Council of the Health Ministry.

12. Maintaining the register of medicines

12.1. Medicines officially registered in the Republic of Azerbaijan shall be entered by the Health Ministry on the «Register of Medicines of the Republic of Azerbaijan».

12.2. Following information about the medicine shall be included in the register:

12.2.1. a trade name;

12.2.2. internationally patented name;

12.2.3. form of production;

12.2.4. producer;

12.2.5. date, number and term of the official registration.

12.3. In case of cancellation of an official registration, such medicine shall be withdrawn from the register.
12.4. Registration data shall be written in a registration book (register) of medicines. The registration bock of medicines shall be made up both in hard and electronic formats.
12.5. A registration book in a paper medium shall be firmly bound, laced and sealed. Each registration book shall be compiled at the beginning of a year and renewed each following year with a new one.
12.6. Electronic format of a registration book for medicines shall not differ from a paper medium by form and content.

12.7. Any person may acquaint himself with information contained in a registration book and related to him.

13. Grounds for cancellation of official registration

13.1. The Health Ministry shall cancel official registration of a medicine in the following cases:

13.1.1. if no application was submitted for the registration of changes occurred in information contained in the registration documents;

13.1.2. in case of discovering non-conformities in the documents submitted for official registration;

13.1.3. in case of discovering untrue information in documents submitted for official registration;

13.1.4. in case competent bodies' taking a decision on the registered medicine's posing a threat to human life and health;

13.1.5. in case of discovering nonconformities in quality standards of three series of the registered medicine imported into the republic or produced within the country during its validity term;

13.1.6. if side effects are discovered during the period after the official registration;

13.2. In case of cancellation of an official registration and withdrawing the medicine from the «Register of Medicines of the Republic of Azerbaijan», the Health Ministry shall, within 5 working days of the date, on which a relevant decision was made, send a written notice to the applicant.