

Azerbaijan

➤ REGULATIONS OF STATE REGISTRATION AND REGISTER

COMPILATION OF MEDICINAL PRODUCTS

➤ MEDICINES REGULATION - Pharmaceutical Regulatory framework

REGULATIONS

OF STATE REGISTRATION AND REGISTER COMPILATION OF MEDICINAL PRODUCTS

1. GENERAL PROVISIONS

1.1 Present Regulations are prepared on the basis of section 1.3 of the Decree of the President of the Azerbaijan Republic № 528 dated February 6, 2007 “About application of the Law of the Azerbaijan Republic “About medicinal products” and determine regulations of the state registration and state register compilation of medicinal products imported to the Azerbaijan Republic and manufactured in the Azerbaijan Republic.

1.2 Present Regulations do not concern medicinal products used for diagnostics, prophylaxis and treatment of diseases (such as medical devices, products, goods and materials, instruments and equipments, medical reagents and optical devices).

1.3 Except the cases provided for by the Law of the Azerbaijan Republic “About medicinal products” the Ministry of Health of the Azerbaijan Republic or its authorized organ (after the Ministry of Health) includes medicinal products after state registration into the register of medicinal products of the Azerbaijan Republic and issues the permission for their import to the Azerbaijan Republic, manufacturing, selling, and use for medical purposes on the territory of the Azerbaijan Republic.

1.4 According to the Law of the Azerbaijan Republic “About medicinal products” the following medicinal products are to be registered:

1.4.1 original medicinal products

1.4.2 analogues (generics) of medicinal products

1.4.3 new combinations of early registered medicinal products

1.4.4 medicinal products with the expired period of state registration

1.4.5 pharmaceutical substances used as active ingredients in the medicinal products manufacturing

1.5 If there are changes to the information reflected in the medicinal products registration documents passed the state registration, given amendments are to pass the state registration.

1.6 Under non-applying for the state registration of amendments made to the registration documents of early registered medicinal products within the time and established procedure indicated in the section 3.7 of the present Regulations, the state registration of the medicinal products is declared invalid.

2. BASIC CONCEPTS

The following terms are used in the present regulations:

2.1 Medicinal products state registration is the system of measures, providing for the permission for the industrial manufacturing in the Azerbaijan Republic, import, application and also register of medicinal products used for medical practice purposes, by the results of the conducted expertise and (or) experiments based on correspondent documents.

2.2 Medicinal products are substances or mixture of several substances of natural, synthetic, biotechnological origin possessing special pharmacological, biological activity and in some pharmaceutical form used for diagnostics, prophylaxis, and treatment of human diseases, pregnancy prevention, patients' rehabilitation or change of human organism state and functions.

2.3 Pharmaceutical substances are substances of natural (vegetative, animal, mineral, etc.), synthetic, biotechnological origin that can change the state and biological functions of human organism and can be used in medicinal products manufacturing.

2.4 Original medicinal products are patented medicinal products gone into turnover under peculiar name.

2.5 Medicinal products analogues (generics) are medicinal products manufactured with the combination, dosage and active ingredients form by other manufacturers after valid period of exclusive patent rights is over for original medicinal products.

2.6 Pharmacopeia article is the normative document that determines quality, package, storage conditions and shelf life of medicinal products, and also requirement for medicinal products quality control.

2.7 Registration certificate is the document approving state permission for manufacturing, selling and using medicinal products for medical purposes on the territory of the Azerbaijan Republic and also for import to the Azerbaijan Republic.

2.8 Registration number is the code symbol issued for the medicinal product.

2.9 Register of registered medicinal products of the Azerbaijan Republic is the data bank of medicinal products, which manufacturing, selling and medical use on the territory of the Azerbaijan Republic and also importing to the territory of the Azerbaijan Republic.

2.10 Medicinal products of OTC category (over the counter) are medicinal products sold without doctors' prescription.

2.11 Active ingredient is the basic pharmaceutical substance used for medicinal products manufacturing.

2.12 Registration document is a set of documents confirming safety, efficacy and quality of medicinal products the applicant submits for the state registration of medicinal products.

3. PROCEDURE OF SUBMITTING FOR STATE REGISTRATION

3.1 Manufacturer's authorized person (hereinafter the applicant) addresses the Ministry of Health with a letter with the aim of state registration of medicinal products with the expired state registration or amendments made to the state registration documents of medicinal products.

3.2 Applicant presents the letter confirming his/her authorities to the Ministry of Health.

3.3 In the cases provided for by the sections 1.4.1 – 1.4.3 and 1.4.5 of the present Regulations the applicant applied for state registration of the medicinal products presents the following documents:

3.3.1 Application for the state registration of medicinal product in the Azerbaijan Republic (enclosure № 1)

3.3.2 Application for the state registration of pharmaceutical product (pharmaceutical substance) in the Azerbaijan Republic (enclosure № 2)

3.3.3 Set of documents submitted for the state registration of medicinal product in the Azerbaijan Republic manufactured in a foreign state (enclosure № 3)

3.3.4 Set of documents submitted for the state registration of pharmaceutical product (pharmaceutical substance) in the Azerbaijan Republic (enclosure № 4)

3.3.5 Set of documents for the state registration of medicinal product in the Azerbaijan Republic produced in the country (enclosure № 5)

3.4 In the case provided by the section 1.4.4 of the present regulations within 120 calendar days before the expiration of previous state registration term the applicant should address the Ministry of Health with a letter for the re-registration of medicinal product. If the applicant fails to submit the application for re-registration within the fixed terms, state registration of such medicinal product is to be conducted on common basis.

Under re-registration of medicinal product the applicant should present the following documents:

3.4.1 Application for the state registration of the medicinal product in the Azerbaijan Republic (enclosure № 1)

3.4.2 Set of documents for the re-registration of medicinal product in the Azerbaijan Republic manufactured in a foreign state (enclosure № 6)

3.4.3 Set of documents for the state registration of medicinal product manufactured in the country (enclosure № 7)

3.5 If the applicant has timely submitted the application for the re-registration of medicinal product, but due to circumstances beyond his/her control the certificate about state re-registration is not issued before the previous state registration is expired, the previous state registration certificate is to remain in force till one of the decisions is made by the Ministry of Health provided for by the section 7 of the present Regulations.

3.6 If the applicant has timely applied for the registration of amendments made to the registration documents of early registered medicinal products with valid term, but due to circumstances beyond his/her control the decision on amendments registration or refusal from amendments registration is not accepted yet, the certificate about previous state registration is to remain in force till one of decisions is made by the Ministry of Health provided by the section 7 of present Regulations.

3.7 In the cases indicated in section 1.5 of the present Regulations the applicant should urgently address the Ministry of Health (not later than 3 months since the date after the decision was taken about amendments made by the manufacturer) with the letter for state registration of amendments made to the medicinal product state registration documents, passed the registration earlier and should add the following documents to the letter:

3.7.1 Application for the state registration of medicinal product in the Azerbaijan Republic (enclosure № 1)

3.7.2 In case of making amendments to the medicinal product dosage and submission of another dosage for the registration:

3.7.2.1 Copy of document about the registration of medicinal product new dosage in the manufacturing country certified notarially

3.7.2.2 Report about pre-clinical tests and clinical trials of medicinal product in the new dosage (signed by tests and trials executor and approved by the head of agency). Copies for foreign countries are to be approved by the head of agency conducting the trials and the customer

3.7.2.3 Pharmacopeia article on quality control over medicinal product or normative document project

3.7.2.4 Quality certificate issued by the manufacturer for the new dosage of medicinal product

3.7.2.5 Indications for use of medicinal product

3.7.2.6 Samples of package and its drafts, indications for use and their electronic versions

3.7.3 At the registration of changes in the package (dosage quantity per pack) and at registration of another package:

3.7.3.1 New indications for use of medicinal product

3.7.3.2 Samples of package and its drafts, indications for use and their electronic versions

3.7.3.3 Quality certificate issued by the manufacturer for the new dosage of medicinal product

3.7.3.4 Project of amendments to the normative documents on the quality control over the medicinal product

3.7.4 In case medicinal product name is changed:

3.7.4.1 Copy of document about registration of the medicinal product name in manufacturing country certified notarially

3.7.4.2 Reference grounding change in medicinal product name

3.7.4.3 New indications for use of medicinal product

3.7.5 In case of introducing new indication for use, i.e. how to use medicinal product:

3.7.5.1 New indication for use of medicinal product

3.7.5.2 Samples of package and its drafts, indications for use and their electronic versions

3.7.5.3 Report about medicinal product clinical trials on the new indication (signed by the tests and trials executor and approved by the head of agency). Copies for foreign countries are to be approved by the head of agency conducting the trials and the customer

3.7.6 In case the previous indications for use of medicinal product are excluded:

3.7.6.1 New indications for use of the medicinal product

3.7.6.2 Samples of package and its drafts, indications for use and their electronic versions

3.7.6.3 Information approving necessity to exclude previous indications and methods of use (revealed additional side effects, results of use, clinical indications, decision accepted by the competent organ concerning exclusion of previously provided indications and methods of use)

3.7.7 In case of making changes concerning coloring, stabilizing substances, aromatizers included into the medicinal product or changes in tablets and capsules covering:

3.7.7.1 Comparative information on biological availability of early registered and being registered medicinal product

3.7.7.2 Information confirming medicinal product stability

3.7.7.3 Pharmacopeia article on composition of early registered medicinal products and comparative table of quality indices determined in normative documents

3.7.7.4 Quality certificate for one series of medicinal product

3.7.7.5 New indication for use of medicinal product

3.7.7.6 Samples of package and its drafts, indications for use and their electronic versions

3.7.8 In case of making changes to the normative documents on quality control over active ingredient, auxiliary ingredient or ready medicinal product:

3.7.8.1 New normative documents

3.7.8.2 Comparative table of previous and following trials

3.7.8.3 Quality certificate of pharmaceutical substance, auxiliary ingredient and ready medicinal product

3.7.9 In case of changes to the preliminary package and at the registration of another kind of package:

3.7.9.1 Normative documents concerning new packaging material

3.7.9.2 Comparative table of quality indices proving medicinal product stability in the package changed within the shelf life and determined in the normative documents

3.7.9.3 Indications for use of medicinal product

3.7.9.4 Samples of package and its drafts, indications for use and their electronic versions

3.7.10 While making changes and amendments to the manufacturing process:

3.7.10.1 Brief description of the previous manufacturing process

3.7.10.2 Brief description of the new manufacturing process with indication on the changes made

3.7.10.3 Normative documents project (if mixture combination is changed)

3.7.10.4 Quality certificate on ready medicinal product

3.7.11 In case of change of medicinal product shelf life:

3.7.11.1 All information proving medicinal product stability based on normative documents indices

3.7.11.2 New indications for use of medicinal product

3.7.11.3 Samples of package and its drafts, indications for use and their electronic versions

3.7.12 In case medicinal product storage conditions are changed:

3.7.12.1 Comparative table of quality indices proving medicinal product stability in the package changed within shelf life and determined in normative documents

3.7.12.2 New indications for use of medicinal product

3.7.12.3 Samples of package and its drafts, indications for use and their electronic versions

3.7.13 In case the method (way) of quality control over the pharmaceutical substance or ready medicinal product is changed the results of new method validation proving equivalence with previous method or advantage over it are to be presented.

3.7.14 In case the name of medicinal product or the address of the manufacturer are changed and at another registration of each regular manufacturing branch:

3.7.14.1 Explanatory letter

3.7.14.2 Manufacturing license

3.7.14.3 Certificate of reliable manufacturing practice

3.7.14.4 Samples of package and its drafts, indications for use and their electronic versions

3.8 Documents are to be submitted in 2 copies: one copy is the documents compiled by manufacturer (along with copies of official documents certified notariially); and the other copy is the set of the same documents translated into the Azerbaijani or Russian languages and approved by the applicant.

3.9 Report on results of conducted trials is to be signed by the testing executor and signed and sealed by the head of agency. A copy of such a report for medicinal products of foreign origin is to be certified by the applicant.

3.10 Along with the application to the Ministry of Health and documents mentioned in the present Regulations the applicant is to present the samples of medicinal product submitted for the state registration and also pharmaceutical substances used in the process of manufacturing this medicinal product. Samples of medicinal product are to be submitted 5 boxes in number and in the form acceptable for selling, and pharmaceutical substance in the quantity sufficient for conducting three analyses. Narcotic and expensive medicinal products (price for 1 sample exceeding AZN 30) and also samples of pharmaceutical substances used for the manufacturing of these medicinal products are to be submitted in the quantity sufficient for conducting a single laboratory analysis.

3.11 Labeling (preliminary and final packaging) of medicinal product is to meet the requirements provided for in enclosure № 8 of the present Regulations.

3.12 Indication for use of medicinal product (for experts) is to meet the requirements provided for in enclosure № 8.

3.13 Indication for use of medicinal product (for consumers) is to meet the requirements provided for in enclosure № 9.

3.14 Applicant is responsible for authenticity of the documents presented and the information contained in the documents.

3.15 Irrespective of presence or absence of medicinal product state registration the documents and samples presented for the state registration are not to be returned.

3.16. Ministry of Health is responsible for the confidentiality of the information presented by the applicant that concerns commercial secret the way provided for by the correspondent Legislation of the Azerbaijan Republic.

3.17 Applicant can refuse from the registration at any stage of state registration. In this case the documents and samples presented for the state registration are not to be returned.

4. Preliminary expertise of documents submitted for the state registration:

4.1 Application, documents provided for by the present Regulations and samples presented for the state registration are registered in the special book in case everything is correct, submitted for preliminary expertise and the applicant is informed about it

4.2 After the applicant receives the notification provided for by the section 4.1 of the present Regulations to conduct preliminary expertise, within 5 days the agreement is to be concluded with the Ministry of Health to conduct preliminary expertise. The agreement will reflect the volume, period of expertise along with the cost of services and other correspondent terms. After the agreement is concluded the applicant within 15 bank days makes a bank transfer to the bank account of the Ministry of Health for conducting preliminary expertise

4.3 From the day of payment of the preliminary expertise within 15 calendar days the Ministry of Health is to conduct the expertise of documents and samples presented for the state expertise with the aim of state registration. During the preliminary expertise the expediency of state registration and completeness of the information submitted are studied

4.4 In case of a mistake or discrepancy revealed in the applicant's documents while conducting the preliminary expertise and in case not all documents are submitted to prove quality, safety and efficacy of medicinal products for state registration, the Ministry of Health can demand from the applicant to submit additional documents, eliminate mistakes and discrepancy

4.5 Applicant has 90 calendar days to organize the submission of additional documents, elimination of mistakes and discrepancy. This period does not concern the period of preliminary expertise provided for in section 4.3 of the present Regulations. If additional documents are not presented and mistakes and discrepancy are not eliminated within 90 calendar days from the day of demand, the process of the preliminary expertise is suspended while documents and samples are returned to the applicant. In case of documents and samples return the cost of the preliminary expertise the applicant paid is not to be returned

4.6 Medicinal product with returned documents can be repeatedly submitted for the state registration by the applicant

4.7 Basing on the results of the preliminary expertise the Ministry of Health takes one of the following decisions:

4.7.1 To send the documents and samples for expertise from the side of specialized expertise agency of the Ministry of Health of the Azerbaijan Republic

4.7.2 To refuse from the state registration

4.8 In case the decision to send the documents and samples for the specialized expertise is taken the applicant is to be notified.

4.9 The Ministry of Health refuses from the state registration of the medicinal products basing on the results of the preliminary expertise in the following cases:

4.9.1 Provided keeping the previous name of early registered medicinal product while submitting the application for the registration under the new name. At the same time, if the manufacturer of the original medicinal product manufactures the medicinal product under the new name, but with analogous combination, form and dosage, both medicinal products can undergo the procedure of state registration

4.9.2 While submitting another medicinal product for the state registration under the trade mark that has already undergone the procedure of the state registration in the Azerbaijan Republic

4.9.3 While submitting the early registered original medicinal product for the state registration under the same name and from the third person side without agreement of the license holder (excluding the cases when the international nonproprietary name recommended by the World Health Organization is used)

4.9.4 In case the documents and samples presented do not meet the requirements of the Law of the Azerbaijan Republic "About medicinal products" and present Regulations

5. Specialized expertise of the documents presented for the state registration:

5.1 After the applicant receives the notification indicated in section 4.8 of the Regulations about state registration of medicinal products, within 5 working days the applicant is to conclude an agreement with specialized analytical expertise agency of the Ministry of Health of the Azerbaijan Republic concerning conduction of expertise.

The agreement reflects the volume, period of expertise and also cost of services and other correspondent conditions. Once the agreement is concluded the applicant within 60 bank days is to make payment for conducting specialized expertise to the bank account of the Ministry of Health.

5.2 Specialized expertise consists of laboratory tests of medicinal product, evaluation of normative-technical documents and results of clinical-pharmatotoxicological trials

5.3 Specialized expertise is to be conducted within 180 calendar days from the date the applicant makes payment for the expertise

5.4 In the case provided for in the section 1.4.4 of the present Regulations the specialized expertise of the documents of medicinal products presented for re- registration and information changes made to the documents of state registration is to be conducted within 90 calendar days

5.5 If needed the Ministry of Health can demand the applicant to submit additional information and reagents

5.6 Time the applicant spends on submitting additional information and reagents is not included in the time of specialized expertise indicated in the sections 5.3 and 5.4 of the present Regulations. If the additional information is not presented within 90 calendar days the conduction of the specialized expertise is to be suspended.

When the specialized expertise is suspended the documents and samples the applicant presented along with the payment made for the specialized expertise are not to be returned

5.7 Medicinal product with the suspended specialized expertise can be repeatedly submitted for the state registration

5.8 Report on the results of the specialized expertise is to be presented to the Ministry of Health from the side of specialized expertise agency of the Ministry of Health

6. Additional specialized expertise of the documents presented for the state registration.

6.1 In case the documents presented for the specialized expertise for the state registration of medicinal product are not sufficient for the medicinal products manufacturing, import to the Azerbaijan Republic and use in the medical practice, and in case when quality, safety and efficacy of the medicinal product are not proved, the Ministry of Health takes the decision to send the results of the expertise within 10 calendar days from the date of report for the additional specialized expertise from the side of Expert Council on Pharmacology and Pharmacopeia. One copy of this decision is to be presented to the applicant

6.2 Additional specialized expertise consists of the expertise of documents presented by the applicant, the expertise of report indices made by the specialized expertise and/or laboratory analysis of medicinal products

6.3 Additional expertise is to be conducted within 30 calendar days

6.4 If needed the Expert Council on Pharmacology and Pharmacopeia of the Ministry of Health can demand the applicant to submit additional information concerning the expertise

6.5 Time the applicant spends on submitting additional information and reagents is not included in the time of specialized expertise indicated in the section 6.3 of the present Regulations. If the additional information is not presented within 90 calendar days the specialized expertise is to be suspended

6.6 When the specialized expertise is suspended the documents and samples are not to be returned to the applicant

6.7 Medicinal product with the suspended additional specialized expertise can be submitted repeatedly for the state registration

6.8 Report on results of additional specialized expertise is to be presented to the Ministry of Health from the side of specialized expertise agency of the Ministry of Health

7. Taking decision on the results of the additional specialized expertise:

7.1 Basing on the results of specialized expertise and in the cases provided for by section 6 of the present Regulations basing on the report made by the Expert Council on Pharmacology and Pharmacopeia of the Ministry of Health of the Azerbaijan Republic, the Ministry of Health takes one of the following decisions:

7.1.1 to state register medicinal product

7.1.2 to refuse from the state registration of medicinal product

8. Grounds for refusal in medicinal product state registration:

8.1 Ministry of Health refuses from state registration of the medicinal product in the following cases:

8.1 in case of discrepancy between information and documents presented

8.1.2 if the composition of the medicinal product contains the substance forbidden for use in the Azerbaijan Republic

8.1.3 in case of discrepancy between quantity and quality indices to those presented in the documents

8.1.4 when therapeutic efficacy is not proved

8.1.5 in case of the negative result of clinical tests and other trials conducted to evaluate safety, efficacy and quality of medicinal product

8.1.6 in case of serious side effects of medicinal product during registration process

8.1.7 in case of the negative conclusion on the results of the expertise of the manufactory

8.1.8 in case of the negative conclusion on the results of the specialized expertise and/or additional specialized expertise of the Expert Council on Pharmacology and Pharmacopeia

8.2 While taking the decision to refuse from the state registration of the medicinal product the applicant is to be provided with the sound answer in the written form

9. Issuing certificate about state registration:

9.1 In case the decision to state register the medicinal product is taken within 15 calendar days the registration certificate is to be issued to the applicant in the form indicated in Enclosure 11 of the present Regulations

9.2 At the simultaneous state registration of several pharmaceutical forms of the same medicinal product individual registration certificate is to be presented to each pharmaceutical form

9.3 At the state registration of medicinal product manufactured at several manufactures situated in various countries individual certificate is to be issued for each medicinal product manufactured by each manufacturer

9.4 In case the dosage of early registered medicinal product is changed or at the registration of each next dosage, in case the package is changed (dosage quantity per pack) and at the registration of each regular package, in case the name of the medicinal product and/or manufacturer are changed (in case the name and address of manufacturer are changed) and at the registration of each next manufacturing branch, in case the preliminary package is changed and at the state registration of amendments to the coloring and stabilizing substances included into the medicinal product, aromatizers, capsules and tablets covering, at state registration of change of additional substances in medicinal product a new registration certificate form is to be drawn up. The new form is to contain the information about previous registration number and date of

state registration of the change. In such cases period of validity of the registration certificate is determined by the previous registration date.

While making other changes to the registration documents, state registration is conducted without drawing up a new registration certificate.

10. Period of the state registration validity.

Medicinal product state registration is valid within 5 (five) years. After this term is expired medicinal products are to undergo the procedure of the state registration repeatedly

11. Approval of indication for use of the medicinal product and the medicinal product referring to the “List of OTC medicinal products”:

11.1 Indication for use of the medicinal product is to be approved by the Expert Council on Pharmacology and Pharmacopeia of the Ministry of Health of the Azerbaijan Republic after the specialized expertise is conducted

11.2 Medicinal product referring to the “List of OTC medicinal products” is to be determined by the Expert Council on Pharmacology and Pharmacopeia of the Ministry of Health of the Azerbaijan Republic

12. Register compilation of medicinal products:

12.1 Medicinal products undergone the state registration in the Azerbaijan Republic are to be included into the “Register of medicinal products of the Azerbaijan Republic”

12.2 Following indices concerning medicinal product are to be included into the register:

12.2.1 Trade name

12.2.2 International nonproprietary name

12.2.3 Pharmaceutical form

12.2.4 Manufacturer

12.2.5 Date, number and term of state registration validity

12.3 In case the state registration of the medicinal product is cancelled this product is to be excluded from the register

12.4 Registration information (register) is to be recorded in the medicinal products register. Register book of medicinal products is compiled both in paper and electronic versions

12.5 Paper register book is to be in hard-cover, tied and sealed. Each register book is made up at the beginning of the year and next year it is changed for the new one

12.6 Electronic version of medicinal products register book is to differ from paper version neither by the form nor by the content

12.7 Any person can get acquainted with register information concerning him/her or of any interest for him/her

13. Grounds for state registration cancellation:

13.1 Ministry of Health cancels medicinal product state registration in the following cases:

13.1.1 If the application for registration of information changes made to the registration documents is not submitted

13.1.2 In case of the discrepancy between the documents presented for the state registration

13.1.3 In case the information in the documents for the state registration does not represent the facts

13.1.4 If there is a decision of competent organs that the registered medicinal product presents threat for human life and health

13.1.5 In case 3 series of registered medicinal product imported to the country and manufactured within the country do not meet quality requirements

13.1.6 In case serious side effects are revealed after the state registration

13.2 In case state registration is cancelled and medicinal product is excluded from the "List of medicinal products of the Azerbaijan Republic" within 5 working days after the Ministry of Health takes the correspondent decision a written notification is presented to the applicant.



Section 5 – Medicines Regulation

This section details the pharmaceutical regulatory framework, resources, governing institutions and practices in Azerbaijan.

5.1 Regulatory Framework

In Azerbaijan, there are legal provisions establishing the powers and responsibilities of the Medicines Regulatory Authority (MRA).

The MRA is a semi-autonomous agency with a number of functions outlined in Table 5. The MRA operates as an Analytical Expertise Centre of Medicine under MoH. The MRA has its own website, for which the URL address is <http://www.pharma.az/>.

Table 5: Functions of the national MRA²³

Function	
Marketing authorisation / registration	Yes
Inspection	Yes
Import control	Yes
Licensing	Yes
Market control	Yes
Quality control	Yes
Medicines advertising and promotion	No
Clinical trials control	Yes
Pharmacovigilance	Yes

As of 30/03/2011, there were 137 permanent staff working for the MRA¹¹. The MRA receives external technical assistance from WHO and MRAs of other countries to strengthen the capacity of experts to conduct specialized examinations¹¹. The MRA is involved in harmonization/collaboration initiatives such as DRUGNET WHO/EURO and CIS council. An assessment of the medicines regulatory system has been conducted in the last five year²⁴. Funding



for the MRA is not provided through the regular government budget. The MRA is funded from fees for services provided¹⁹. The Regulatory Authority retains revenues derived from regulatory activities. This body utilizes a computerized information management system to store and retrieve information on processes that include registrations, inspection etc¹¹.

5.2 Marketing Authorization (Registration)

In Azerbaijan, legal provisions require marketing authorization (registration) for all pharmaceutical products on the market, however exceptions/waivers for registration do exist^{25,26}. Medicines for humanitarian purposes, rare medicines, medicines used to cure diseases that require specific treatment and WHO pre-qualification medicines without public registration in Azerbaijan may be imported only for non-commercial use. Mutual recognitions mechanisms are not in place⁹. Explicit and publicly available criteria exist for assessing applications for marketing authorization of pharmaceutical products²⁷.

In 2011, there were 3,703 pharmaceutical products registered in Azerbaijan. There are legal provisions requiring the MRA to make the list of registered pharmaceutical products publicly available and update it regularly. This register is updated every year. The updated list can be accessed through <http://www.pharma.az>.

Medicines are always registered by their INN (International Non-proprietary Names) or Brand name + INN. Legal provisions require a fee to be paid for Medicines Market Authorization (registration) based on applications¹¹. The registration fee for both applications, new chemical entity (NCE) and generic pharmaceutical product, is 126 US\$¹¹. The expertise fee for a NCE is 1,386 US\$ and for a generic the fee is 1,059 US\$¹¹.

5.3 Regulatory Inspection

In Azerbaijan, legal provisions exist allowing for appointment of government pharmaceutical inspectors²⁸. Legal provisions exist permitting inspectors to inspect premises where pharmaceutical activities are performed; such



inspections are required by law and are a pre-requisite for the licensing of public and private facilities²⁹. Where inspections are legal requirements, these are the same for public and private facilities¹¹. Inspections are carried out on a number of entities, outlined in Table 6.

Table 6: Local entities inspected for GMP compliance¹⁹

Entity	Inspection	Frequency
Local manufacturers	Yes	No certain frequency assigned
Private wholesalers	Yes	No certain frequency assigned r
Retail distributors	Yes	No certain frequency assigned
Public pharmacies and stores	Yes	No certain frequency assigned
Pharmacies and dispensing points if health facilities	Yes	No certain frequency assigned

5.4 Import Control

Legal provisions exist requiring authorization to import medicines³⁰. Laws exist that allow the sampling of imported products for testing.

Legal provisions exist requiring importation of medicines through authorized ports of entry. Regulations or laws exist to allow for inspection of imported pharmaceutical products at authorized ports of entry, one sample from each imported batch is inspected³¹.



5.5 Licensing

In Azerbaijan, legal provisions exist requiring manufacturers to be licensed¹⁹.

Legal provisions exist requiring manufacturers (both domestic and international) to comply with Good Manufacturing Practices (GMP). As explained in section 4.2 domestic manufacturers should present their manufacturing license when GMP is lacking. Good Manufacturing Practices are not published by the government⁹.

Legal provisions exist requiring importers/wholesalers/distributors to be licensed (see table 7)¹⁹ and to comply with Good Distributing Practices³².

Table 7: Legal provisions pertaining to licensing

Entity requiring licensing	
Importers	Yes
Wholesalers	Yes
Distributors	Yes

Good Distribution Practices are published by the government³².

Legal provisions exist requiring pharmacists to be registered and requiring private pharmacies to be licensed³³. National Good Pharmacy Practice Guidelines are published by the government³². A list of all licensed pharmaceutical facilities is not required to be published.

5.6 Market Control and Quality Control

In Azerbaijan legal provisions exist for controlling the pharmaceutical market³⁴. A laboratory exists in Azerbaijan for Quality Control testing¹¹. The laboratory is a functional part of the MRA¹¹.

Existing national laboratory facilities have not been accepted for collaboration with the WHO pre-qualification Programme¹¹. Medicines are tested for a number of reasons, summarised in Table 8.



Table 8: Reason for medicines testing¹¹

Medicines tested:	
For quality monitoring in the public sector ⁱⁱⁱ	Yes
For quality monitoring in the private sector ^{iv}	Yes
When there are complaints or problem reports	Yes
For product registration	Yes
For public procurement prequalification	Yes
For public program products prior to acceptance and/or distribution	Yes

Samples are collected by government inspectors for undertaking post-marketing surveillance testing¹⁹.

In the past 2 years, 58,929 samples were taken for quality control testing. Of the samples tested, 39 (or 0.066%) failed to meet the quality standards. The results are not publicly available; they are only presented to corresponding bodies¹¹.

5.7 Medicines Advertising and Promotion

In Azerbaijan, legal provisions exist to control the promotion and/or advertising of prescription medicines. Ministry of Health is responsible for regulating promotion and advertising of medicines¹⁹.

Legal provisions prohibit direct advertising of prescription medicines to the public under any circumstances and pre-approval for medicines advertisements and promotional materials is required for non-prescription medicines. Guidelines and Regulations exist for advertising and promotion of non-prescription medicines. There is a national code of conduct concerning advertising and promotion of medicines by marketing authorization holders.

The code of conduct applies to domestic manufacturers and multinational manufacturers. The code contains a formal process for complaints and sanctions. It is not clear whether there is a publicly available list of the complaints and sanctions for the last two years³⁵.

ⁱⁱⁱ Routine sampling in pharmacy stores and health facilities

^{iv} Routine sampling in retail outlets



5.8 Clinical Trials

In Azerbaijan, legal provisions exist requiring authorization for conducting Clinical Trials by the MRA. There are additional laws requiring the agreement by an ethics committee or institutional review board of the Clinical Trials to be performed. Clinical trials are required to be entered into a national registry, by law³⁶. Legal provisions exist for national GMP compliance of investigational products and require the sponsor, investigator to comply with good clinical practices (GCP)³⁶.

5.9 Controlled Medicines

Azerbaijan is a signatory to a number of international conventions, detailed in Table 9.

Table 9: International Conventions to which Azerbaijan is a signatory³⁷

Convention	Signatory
Single Convention on Narcotic Drugs, 1961	Yes
1972 Protocol amending the Single Convention on Narcotic Drugs, 1961	Yes
Convention on Psychotropic Substances 1971	Yes
United Nations Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988	Yes

Laws exist for the control of narcotic and psychotropic substances, and precursors [Law of AR on "Narcotic drugs, psychotropic agents and their pre-requisites" is available at <http://health.gov.az/article.php?qanun18>, 2005]. The annual consumption of Morphine is 0.06379 mg/capita³⁸. In 2010 the International Narcotics Control Board reviewed the legal provisions and regulations for the control of narcotic and psychotropic substances to assess the balance between the prevention of abuse and access for medical need³⁹.



5.10 Pharmacovigilance

In Azerbaijan, there are legal provisions in the Medicines Act that provide for pharmacovigilance activities as part of the MRA mandate. Legal provisions also exist requiring the Marketing Authorization holder to continuously monitor the safety of their products and report to the MRA. Laws regarding the monitoring of Adverse Drug Reactions (ADR) exist in Azerbaijan. A national pharmacovigilance centre linked to the MRA exists⁴¹.

The pharmacovigilance centre has 4 full-time staff members. The centre has not published an analysis report in the previous two years and it does not publish an ADR bulletin. An official standardized form for reporting ADRs is used in Azerbaijan. Information pertaining to ADRs is stored in a national ADR database. The ADR database currently comprises 62 ADR reports, of which 62 have been submitted in the past 2 years, the database is not computerized. The reports are not sent to the WHO collaborating centre in Uppsala. Feedback is provided to reporters. There are no medication errors reported¹¹.

There is no national ADR or pharmacovigilance advisory committee able to provide technical assistance or causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication in Azerbaijan. A clear communication strategy for routine communication and crises communication does not exist¹¹.

A number of steps are being considered in order to enhance the pharmacovigilance system. These include: the attraction of a large number of physicians, the establishment of an e-database for a faster response and a better connection with the regions¹¹.