Resolution of the Cabinet of Ministers of the Republic of Azerbaijan

№ 503

Baku city, December 25, 2019

on the approval of

“Regulations of the pharmacovigilance of medicinal products”

In order to ensure the implementation of subparagraph 1.1.3 of the Decree No. 157 of June 27, 2018, the President of the Republic of Azerbaijan on “Application of the Law No. 1150-VQD of May 18, 2018 of the Republic of Azerbaijan on “Amendment of the Act of the Republic of Azerbaijan “On Medicinal products”, the Cabinet of Ministers of the Republic of Azerbaijan **resolves**:

1. To approve the "Regulations of the pharmacovigilance of medicinal products" (attached).
2. Amendments to this Resolution may be consistent with paragraph 2.6-1 of the “Regulation on the preparation and adoption of regulatory legal acts of executive authorities”, approved by Decree No. 772 dated August 24, 2002 of the President of the Republic of Azerbaijan.
3. This Resolution becomes effective on July 1, 2020.

Prime Minister

of the Republic of Azerbaijan **Ali Asadov**

Approved by Resolution № 503 of December 25, 2019 of the Cabinet of Ministers of the Republic of Azerbaijan

Regulations of the pharmacovigilance of medicinal products

1. General provisions

1.1. This Regulation has been developed in accordance with paragraph 8.6 of the Law of the Republic of Azerbaijan “On Medicinal products” in order to implement state control on the effectiveness and safety of medicinal products and it defines a set of measures to detect, evaluate and prevent adverse reactions that occur when using medicinal products and others undesirable consequences.

1.2. This Regulation applies to all medical institutions regardless of ownership and legal organizational form, the marketing authorization holder of medicinal product and their authorized responsible persons.

2. Basic concepts

2.1. The basic concepts used in this Regulation express the following meanings:

2.1.1. **unexpected adverse reaction** - adverse reaction not corresponding to the specified information in the instructions for use of the medicinal product;

2.1.2. **individual case safety report** (ICSR) - notification of an adverse reaction;

2.1.3. **serious adverse reaction** - any negative reaction leading to cause of death, life-threatening, hospitalization or prolongation of stay in a medical institution, temporary disability or disability (limitation of health), or congenital anomaly or developmental defect when using medicinal product;

2.1.4. **pharmacovigilance** - the activity carried out in the direction of detection, evaluation and prevention of adverse reactions and other undesirable consequences when using medicinal products;

2.1.5. **person responsible for pharmacovigilance** - in connection with implementation of pharmacovigilance activities provided by this Regulation, persons with a medical education or a specialty of a pharmacist, who are hired in accordance with the Labor Code of the Republic of Azerbaijan by medical institution, by marketing authorization

holder of state registration of the medicinal product (hereinafter referred to as the marketing authorization holder) and by organization conducting measures for pharmacovigilance;

2.1.6. **pharmacovigilance system** - the system established by the marketing authorization holder and the Analytical Expertise Center LLC of the Ministry of Health of the Republic of Azerbaijan (hereinafter referred to as the - “Authority”) to carry out the activities provided in this Regulation and designed for monitoring the safety of the medicinal products and identifying all changes that can be in the benefit-risk balance;

2.1.7. **pharmacovigilance system master file** (PSMF) - the collection of documents that completely describe the pharmacovigilance system used in connection with the safety of one or more medicinal products used by the marketing authorization holder;

2.1.8. **biotechnological (high technological) medicinal products** - medicinal products` active substance, which obtained through biotechnological methods such as immunological engineering, enzyme engineering, hybrid, cell engineering and genetic engineering technology;

2.1.9. **biological medicinal products** - medicinal products` active substance, which obtained from biological sources (microorganisms, plants, animal or human) and biological origin;

2.1.10. **biosimilar medicinal product (biosimilar)** - biological medicinal product (similarity confirmed with reference biological medicinal product by comparative quality, in preclinical or clinical trials) which has shown similarity in terms of quality, efficacy, safety and immunogenicity to the reference product with state registration, the exclusive patent right of which has expired on original medicinal products;

2.1.11. **periodic safety update report** (PSUR) – an evaluation report of the benefit-risk balance of a medicinal product prepared by the marketing authorization holder at defined time points and form after state registration phase of the medicinal product;

2.1.12. **risk** - all types of risks associated with the quality, safety or effectiveness of the medicinal product in relation to the health of patients or the public or leading to undesirable effects on the environment;

2.1.13. **risk management system** - measures designed to identify, prevent or minimize risks associated with a medicinal product in the framework of pharmacovigilance and a system established to evaluate the effectiveness of these measures;

2.1.14. **risk management plan** (RMP) - a detailed description of the risk management system;

2.1.15. **post-authorization safety study** - research conducted to assess the effectiveness of risk management measures or confirm the risk profile of a medicinal product, determining the possibility of these risks and risks that may affect the safety of a registered medicinal product;

2.1.16. **signal** - information forming new assumptions received about existing causal relationship or presence of a new causal relationship between use of the medicinal product and the adverse reaction;

2.1.17. **organization conducting measures for pharmacovigilance** (hereinafter referred to as the - Organization) - a legal entity that is fully or partially providing the duties of the marketing authorization holder for pharmacovigilance on contractual basis;

2.1.18. **spontaneous report** - notification of adverse reaction, voluntarily sent to the Authority or the marketing authorization holder by the consumer, medical or pharmaceutical staff;

2.1.19. **reporting form** - a form used to notify one or more adverse reactions that have occurred in a patient against a specific medicinal product at a specific time;

2.1.20. **consumer** - a person using a medicinal product for personal use, who is purchasing or ordering a medicinal product;

2.1.21. **benefit-risk balance** - assessment of the positive therapeutic results of the medicinal product in relation to its risks associated with its use;

2.1.22. **summary of product characteristics** (SmPC) - a document confirmed by the marketing authorization holder, covering information on the use of the medicinal product;

2.1.23. **Good Pharmacovigilance Practice** - is the guidance of the Ministry of Health of the Republic of Azerbaijan (hereinafter referred to as the - Ministry) on the implementation of pharmacovigilance activities.

2.2. Other concepts used in this Regulation have the meanings defined by the Law of the Azerbaijan Republic " On Medicinal products " and other regulatory legal acts of the Azerbaijan Republic in this area.

3. General requirements for pharmacovigilance

3.1. Pharmacovigilance covers determination of adverse reactions and other undesirable consequences when using a medicinal product, medication errors in case of improper use of medicinal product, counterfeit and medicinal products which effectiveness, quality and safety cannot be determined (substandard), effectiveness of medicinal product, cases of medicinal product abuse and interactions of medicinal products.

3.2 Pharmacovigilance is applied to medicinal products that have been registered or applied for state registration, medicinal products that are recommended by the World Health Organization on the basis of relevant approving documents, medicinal products intended for the treatment of diseases requiring specific treatment or rare diseases, also herbal medicinal products, traditional medicinal products, biological medicinal products, vaccines,

blood derived medicinal products and high risk group medical devices (invasive medical devices).

3.3. Pharmacovigilance is carried out in accordance with the requirements of Good Pharmacovigilance Practice.

3.4. The Authority develops a list of medicinal products under additional monitoring and submits it to the Ministry for approval. The Authority monitors the safety of medicinal products included in the approved list of medicinal products under additional monitoring.

3.5. The Authority by using the mass media, provides information for the public about medicinal products that health-threatening for human, publishes information on the safety of medicinal products and dear healthcare professional letters on its website.

3.6. Regardless of ownership and legal organizational form, all medical institutions, the marketing authorization holder or its authorized person, carry out pharmacovigilance measures in accordance with the requirements of Good Pharmacovigilance Practice and this Regulation in order to ensure the safe use of the medicinal product, including appointment of person responsible for pharmacovigilance.

3.7. Person responsible for pharmacovigilance of medical institutions, the marketing authorization holder or its authorized person provide information on adverse reactions of medicinal products and other undesirable consequences, including pharmacovigilance information and reporting documents to the Authority.

3.8. Information and reports on pharmacovigilance (RMP, PSUR, PSMF) are provided in paper or electronic form in accordance with the Law of the Republic of Azerbaijan "On Electronic Signature and Electronic Document" in one of the languages: Azerbaijani, Russian or English.

4. Responsibilities of the Marketing Authorization Holder in field of Pharmacovigilance

4.1. The marketing authorization holder carries out the following measures in connection with the implementation of pharmacovigilance:

4.1.1. conducts constant monitoring of the safety of medicinal products, informs the Authority of all types of changes that may affect the assessment of the benefit-risk balance, including prohibitions and restrictions applied by authorized bodies of other countries where the medicinal product is registered and ensures updating of information on medicinal products based on scientific data;

4.1.2. establishes a pharmacovigilance system and by evaluating the information obtained through this system takes measures to minimize or prevent risk.

4.1.3. uses the terminology MedDRA (medical vocabulary for regulation, developed by the International Conference for Harmonization (ICH)) in classification of adverse reactions of a medicinal product;

4.1.4. conducts a systematically audit in the pharmacovigilance system, adds its results to the pharmacovigilance system master file as a note and ensures the development and implementation of an action plan aimed for elimination existing problems, based on the same results;

4.1.5. appoints the person responsible for pharmacovigilance and his deputy. Provides information (name, surname, patronymic, education and curriculum vitae) about the person responsible for pharmacovigilance and his deputy, including contact information (address, phone number, fax, email address) to the Authority within 7 (seven) business days after appointment date to position;

4.1.6. in case of replacement of the person responsible for pharmacovigilance and his deputy, appoints new employees in their position no later than 3 (three) months and inform the Authority in accordance with subparagraph 4.1.5 of this Regulation;

4.1.7. ensure the participation of person responsible for pharmacovigilance and his deputy in the main training program on pharmacovigilance organized by the Authority and support the participation of these persons in other pharmacovigilance training programs;

4.1.8. develops the pharmacovigilance system master file and provides it to the Authority;

4.1.9. develops and updates the risk management system in accordance with identified or potential risks in connection with a medicinal product, as well as post registration safety information, monitors pharmacovigilance information to determine the presence or absence of new risks, changes in risks or any changes in the benefit-risk balance of a medicinal product and informs the Authority in case of a change;

4.1.10. controls the results of the measures taken in accordance with the risk management plan;

4.1.11. ensures the participation of person responsible for pharmacovigilance in the trainings and conducts registration of trainings;

4.1.12. adds the standard text specified in Good Pharmacovigilance Practice to the instructions for the medicinal product for providing information about adverse reactions to the Authority by medical and pharmaceutical staff, including consumers;

4.1.13. carry out the measures provided in the Good Pharmacovigilance Practice on medicinal products under additional monitoring;

4.1.14. in the case of problems with the safety of the medicinal product are founded, it immediately informs the Authority of plans to suspend the sale or to refuse registration of medicinal product or other measures provided by this Regulation;

4.1.15. timely and fully comply with the requirements of the Authority provided in this Regulation.

4.2. In case of the pharmacovigilance system established together with several marketing authorization holder, they have the right to appoint a unified person responsible for pharmacovigilance.

4.3. The marketing authorization holder is responsible for the correctness and periodic updating of information and documents that provided directly or through another organization to the Authority.

4.4. The marketing authorization holder has the right to carry out pharmacovigilance measures by organisation without appointing person responsible for pharmacovigilance, excluding the provisions of paragraph 4.5 of this Regulation.

4.5. In cases where pharmacovigilance activities partially is conducted by the organization, the marketing authorization holder appoints a person responsible for pharmacovigilance.

4.6. The person responsible for pharmacovigilance and his deputy cannot hold a position in the sales and marketing departments when performing their duties.

5. Responsibilities of medical and pharmaceutical staff in the field of pharmacovigilance

5.1. Spontaneous notification to the Authority about adverse reactions and other undesirable consequences when using medicinal products by patients is carried out by medical and pharmaceutical staff, who are observing these cases, in accordance with paragraph 16.1 of this Regulation.

6. Responsibilities of medical institutions in the field of pharmacovigilance

6.1. Responsibilities of medical institutions in connection with the implementation of pharmacovigilance:

6.1.1. establish a pharmacovigilance system within the institution and conduct activities in accordance with this Regulation;

6.1.2. appoint the person responsible for pharmacovigilance of the medical institution and to provide information to the Authority about him/her as provided in subparagraph 4.1.5 of this Regulation;

6.1.3. ensure the participation of the person responsible for pharmacovigilance of the medical institution in the main training program on pharmacovigilance organized by the

Authority and support the participation of this person in other pharmacovigilance training programs;

6.1.4. timely and fully comply with the requirements of the Authority provided in this Regulation in connection with conducting pharmacovigilance.

7. Responsibilities of the Authority in the field of pharmacovigilance

7.1. The Authority carries out the following activities in connection with the implementation of pharmacovigilance:

7.1.1. establishes a unified pharmacovigilance system and improves according to modern scientific and technological progress, including the use of this system to collect information on the risks of medicinal products;

7.1.2. conducts expertise procedure of pharmacovigilance documents (RMP, PSUR, PSMF);

7.1.3. educates medical and pharmaceutical staff, including consumers, on the need to inform the Authority about the adverse reactions of medicinal products;

7.1.4. in order to ensure the safe use of medicinal products it systematically monitors, registers, evaluates, archives the results of adverse reactions and other undesirable consequences, that occure when using medicinal products and the benefit-risk balance, as well as sends this information to the Drug Monitoring Center of the World Health Organization.;

7.1.5. sends to the marketing authorization holder a notification about serious adverse reactions of the medicinal product, within 15 (fifteen) days after receiving it;

7.1.6. requires the perform of the duties provided in this Regulation by medical and pharmaceutical staff in order safe use the medicinal product;

7.1.7. notifies the marketing authorization holder on taken decisions and inform the international organization about the taken measures specified in subparagraph 7.1.4 of this Regulation;

7.1.8. organizes the main training programs on pharmacovigilance;

7.1.9. develops a list of medicinal products under additional monitoring and submit it to the Ministry for approval;

7.1.10. in the occurence problem affecting the benefit-risk balance of a medicinal product that registered or has subbmited for state registration, it requires the marketing authorization holder to provide a risk management plan;

7.1.11. evaluates changes in the risk management plan, monitors the results of risk minimization activities;

7.1.12. requires from the marketing authorization holder information confirming the maintenance of the effectiveness of the benefit-risk balance;

7.1.13. requires from the marketing authorization holder to provide the pharmacovigilance system master file and other pharmacovigilance documents in connection with the safety assessment of the medicinal product within 7 (seven) business days to the Authority;

7.1.14. requires from the marketing authorization holder to provide the logbook in case of finding incompatibility in the information of the pharmacovigilance system master file by the Authority;

7.1.15. by using the mass media, provides information for the public about medicinal products that health-threatening for human, publishes information on the safety of medicinal products and dear healthcare professional letters on its website.

7.2. If expertise procedure is carried out in connection with the pharmacovigilance documents after the registration of the medicinal product provided in subparagraph 7.1.2 of this Regulation , relations between the parties, including the scope, duration, cost of the service, are regulated on the basis of a contract concluded between the Authority and the marketing authorization holder or organization.

7.3. In the case when the main training programs for employees of private medical institutions, the marketing authorization holder and organizations provided in subparagraph 7.1.8 of this Regulation relations between the parties, including the scope of training, duration, cost of the service, are regulated on the basis of a contract concluded between the Authority and these entities.

8. Structure of the pharmacovigilance system master file

8.1. The following information is included in the pharmacovigilance system master file by the marketing authorization holder in accordance with the pharmacovigilance system:

8.1.1 the following information about the person responsible for pharmacovigilance, in case of his/her absence, about the person performing his/her duties:

8.1.1.1. a description of responsibilities of the person responsible for pharmacovigilance;

8.1.1.2. name, last name, patronymic, curriculum vitae of the person responsible for pharmacovigilance;

8.1.1.3. contact information (address, phone, fax and email) of the person responsible for pharmacovigilance;

8.1.2. in the case of absence of the person responsible for pharmacovigilance, information on the delegation of his/her responsibilities;

8.1.3. a description of the organizational structure of the marketing authorization holder and a list of addresses where pharmacovigilance is carried out;

8.1.4. information on resources (electronic information systems and electronic databases) used for receiving , collecting, registering and sending the safety information of the medicinal product to destination;

8.1.5. information on the processing and registration of data;

8.1.6. decision-making procedure for taking appropriate measures based on the results of continuous monitoring of the benefit-risk balance of medicinal product;

8.1.7. information in connection with the control of the results of risk minimization activities and the risk management systems;

8.1.8. the rule for the collection, assessment and notification of individual case safety reports;

8.1.9. the rule for the preparation and submission of a periodic safety update report;

8.1.10. in case of changes in the instructions for the safety of the medicinal product, including SmPC information, the rules for educating medical and pharmaceutical staff and the public about these changes and problems in connection with the safety of the medicinal product;

8.1.11. a description of the quality system used in pharmacovigilance, including the following:

8.1.11.1. a description of the structure based on the implementation of pharmacovigilance;

8.1.11.2. a description of the registration management system specified in the 17th part of this Regulation, including the place of storage of documents used in the implementation of pharmacovigilance;

8.1.12. in the case when pharmacovigilance is carried out by the organization, a description of pharmacovigilance activities carried out by the organization.

9. The structure of the annex of the Pharmacovigilance System Master File

9.1. The following are included in the annex of the pharmacovigilance system master file:

9.1.1. a list covering the name, active substance or international nonproprietary name (INN) of the substances and the names of the countries in which the medicinal products are currently registered, which are included in the pharmacovigilance system master file;

9.1.2. a list covering the contracts concluded between the marketing authorization holder and the organization, medicinal products prescribed in the contract and their documents;

9.1.3. a list of planned and conducted audits;

9.1.4. a list of the pharmacovigilance system master file related to the same marketing authorization holder;

9.1.5. the logbook of the main pharmacovigilance system master file.

10. Updating the pharmacovigilance system master file

10.1. Updating the pharmacovigilance system master file is provided by the marketing authorization holder, taking into account the experience gained, technical and scientific updates and changes in Good Pharmacovigilance Practice.

10.2. The marketing authorization holder is assigned a number for each update of the pharmacovigilance system master file and its annex by indicating the date of the last update.

10.3. Along with those specified in the 8th part of these Regulation, the pharmacovigilance systemmaster file should be reflect deviations on measures related to pharmacovigilance (deadline for the implementation of measures and provision of information, etc.), their impact, management and resolvement.

11. The form of the documents in the pharmacovigilance system master file

11.1. Documents in the pharmacovigilance system master file are given in the form of graphs or diagrams and must be readable and accurate;

11.2. In order to ensure the accuracy and availability in a short time of documents of the pharmacovigilance system master file, all documents are collected and archived in chronological order.

11.3. It is allowed to provide documents of the pharmacovigilance system master file by sections in accordance with Good Pharmacovigilance Practice.

11.4. It is allowed to save documents of the pharmacovigilance system master file in electronic form with printing possibility of copy of documents and the availability of an electronic database during the audit and determine the compliance of the pharmacovigilance system with Good Pharmacovigilance Practice.

11.5. Excluding the information specified in the subparagraph 8.1.1 and in the 9th part of this Regulation, registration of changes (their date, reason and indicating the person responsible for making these changes) in the pharmacovigilance system master file in the last 5 (five) years is carried out by the marketing authorization holder in the logbook.

12. Place of storage and availability of the pharmacovigilance system master file

12.1. The pharmacovigilance system master file is stored at the address where the pharmacovigilance is carried out.

12.2. The marketing authorization holder ensures the availability of the pharmacovigilance system master file for the person responsible for pharmacovigilance at any time.

12.3. The pharmacovigilance system master file should be available for audit at the storage address.

13. The content of the reports of adverse reactions of the medicinal products

13.1. Adverse reaction reports of medicinal products shall be sent by the marketing authorization holder to the Authority by using reporting form.

13.2. The marketing authorization holder is responsible for the accuracy of the information on the adverse reactions reports of medicinal products.

13.3 The reports referred to paragraph 13.2 of this Regulation covers information on suspected medicinal product, adverse reaction, reporter and patient, including other information provided in Good Pharmacovigilance Practice.

13.4. The marketing authorization holder registers the information specified in paragraph 13.3 of this Regulation in order to monitor reports of adverse reactions and documents the results of monitoring in accordance with Good Pharmacovigilance Practice.

13.5. Along with the information specified in paragraph 13.3 of this Regulation, the marketing authorization holder in connection with each case should add the following information to the adverse reactions reports of the medicinal products:

13.5.1. type, date and number of report, initial report date, date of last information and other additional documents in connection with the case;

13.5.2. surname, name, patronymic, address and specialty of the reporter;

13.5.3. initials of the patient, age when an adverse reaction occurs, weight, height, gender, if an adverse reaction occurs a fetus, last menstruation date and (or) the pregnancy period;

13.5.4. information about patient`s health condition;

13.5.5. name of the medicinal product (s) suspected of causing adverse reaction, medicinal products interactions, or the name of the active substance of the medicinal product which name is unknown, other characteristics that may be useful for determining

the medicinal product, name of the marketing authorization holder, form of medicinal product and method of use, indications, dosage, date of start and end of use, measures taken after the occurrence of arverse reactions, the effect to the patient after the suspension and reuse of the medicinal product;

13.5.6. if there is a suspicion of a defect affecting the quality of the medicinal product used, the nature of the defect, the serial number of the drug and their expiration dates, also including the serial numbers in relation of biological products obtained from plasma and vaccines;

13.5.7. medicinal products not directly affecting to the occurrence of adverse reactions, but used concomitantly with the suspected medicinal product and medical treatment previously applied to the patient or to his parent;

13.5.8. the start and end date of suspected adverse reactions or the duration, the severity, the result at the time of the last observation, the period between the use of a suspected medicinal product and the occurrence of an adverse reaction and an explanation of the first reporter of adverse reaction (reactions);

13.5.9. the results of analysis in connection with adverse reactions and measures taken;

13.5.10. in case of patient’s death, date of death and results of autopsy if performed;

13.5.11 an explanation of treatment measures indicating the clinical condition of the patient for serious adverse reactions, the results of these measures and recieved monitoring information in chronological order;

13.5.12. reason for cancellation of the report of adverse reaction or making changes to it;

13.5.13. other information received about the adverse reaction.

14. Structure of the periodic safety update report

14.1. A periodic safety update report is based on new information received in the period after the last report and all information on the risks and benefits of the medicinal product and consists of a scientific assessment of the benefit-risk balance of the medicinal product.

14.2. Including all information obtained in connection with the sales volume and the amount of the prescription, information on the group of the population where the use of the medicinal product is expected, the results of a qualitative and quantitative analysis of the actual use of the medicinal product, including the results found during medicinal product use research and observational studies are provided in the periodic safety update report.

14.3. A periodic safety update report also covers the results of evaluating the effectiveness of risk minimization measures in connection with the assessment of the benefit-risk balance.

14.4. In the risk assessment section of a periodic safety update report a detailed explanation of the case is given, which is important for scientific analysis of the received signal or safety concern associated with medicinal product.

14.5. Based on the assessment of the collected safety data and the analysis of the benefit-risk balance, the marketing authorization holder notes the results whether there is a need for any measures and (or) changes in the SmPC information, instructions for the use of medicinal product which is included in the periodic safety update report.

14.6. Except for the cases provided in paragraph 14.7 of this Regulation, for medicinal products containing the same active substances and registered under the same marketing authorization holder (regardless of the date of registration and registration under a different name of the medicinal product), a unified periodic safety update report is developed with indicating method of use, doses (dosage regimens) of the medicinal product.

14.7. The Authority has the right to request a separate submission of a periodic updated safety report for each pharmaceutical form.

14.8. In the case when the active substance is registered as part of a fixed compound (combination), periodic safety update reports for each active substance or information on the compound (combination) are provided in one of the periodic safety update reports for one active substance and in a periodic update report on safety cross-references to other active substances in the compound (combination) are included.

15. Structure of the risk management plan

15.1. The following are included in the structure of the risk management plan drawn up by the marketing authorization holder:

15.1.1. a description of the safety profile of the medicinal product, as well as information in connection with the determination of indicators for a detailed description of the safety profile;

15.1.2. documentation of the evaluation results of the effectiveness of measures and other measures aimed at minimizing or preventing the risks associated with the medicinal product;

15.1.3. in case of reference to the post-authorization study in risk management plan of the medicinal product should include, information about the reason for conducting the research (voluntarily or at the request of the regulatory authorities of the countries where the medicinal product is registered), management and financing.

15.2. All requirements provided by the regulatory authorities of the countries in which the medicinal product is registered after state registration are indicated in the form of a list together with a schedule for the fulfillment of these requirements in the summary of the risk management plan.

15.3. For medicinal products with the same active substance in the composition and the same marketing authorization holder a unified risk management plan is drawn up.

15.4. When the marketing authorization holder updates the risk management plan, provides an updated version of the risk management plan to the Authority with a new number and date.

16. Information, notifications and reports provided to the Authority and their assessment

16.1. Healthcare professionals and pharmacists send reports about adverse reactions that occurred when using medicinal products and may be associated with the use of the medicinal product, directly or through the person responsible for pharmacovigilance of the medical institution to the Authority within 15 (fifteen) calendar days. Serious adverse reactions that occur when using medicinal products are sent to the Authority within 48 (forty-eight) hours.

16.2. The marketing authorization holder carries out the following about information, notification and reports:

16.2.1. carries out the registration and archiving of all adverse reactions detected during the post-authorization safety study or spontaneously notified by patients or healthcare professionals and pharmacists in the Republic of Azerbaijan or in other countries where the medicinal product is marketed;

16.2.2. sends information about all adverse reactions that have occurred in connection with the use of the medicinal product in the Azerbaijan Republic, including sends control information in connection with the initial notification to the Authority within 15 (fifteen) calendar days.

16.2.3. if adverse reaction reports of medicinal product marketed in other countries change the benefit-risk balance, immediately sends this information to the Authority after receiving it.

16.2.4. informs the Authority about the detected resources of all adverse reactions that occurred when using the medicinal product in the Republic of Azerbaijan, including the scientific and medical literature for 15 (fifteen) calendar days;

16.2.5. improves the methods for acquiring information about the scientific evaluation of adverse reactions reports;

16.2.6. in case of suspicion of the patient to get infected with a particular disease as a result of the use of a medicinal product, immediately sends the received information to the Authority;

16.2.7. provide a risk management plan in the following cases:

1. in case of applying for registration of medicinal product not previously registered in the Republic of Azerbaijan with new active substance, new composition (combination) of active substances, biotechnological, biosimilar medicinal products and generic medicinal products, if necessary, take additional risk minimization activities for the original;
2. when new methods of use and pediatric indications are added to the registration documents on the state registration of a medicinal product, significant changes in the indications for use, also the use of a new manufacturing process for biotechnological or biosimilar medicinal product;
3. upon request by the Authority before or after state registration;
4. when identified problems related to safety in any phase of the life cycle of medicinal product or by the initiative of the marketing authorization holder;

16.2.8. develops and submits to the Authority a periodic safety update reports every six months within 2 (two) years after the state registration of a medicinal product in the Azerbaijan Republic, once a year for the next 2 (two) years, also once every three years after state re-registration of medicinal product;

16.2.9. submits to the Authority a periodic safety update report after 18 (eighteen) months after the medicinal product is marketed, also if the number of patients taking the medicinal product reaches up to ten thousand or state re-registration of medicinal product;

16.2.10. when the marketing authorization holder is changed, the periods for the submission of pharmacovigilance information continues regarding the initial date of registration;

16.2.11. continues to systematically assess of the safety of the medicinal products by developing a periodic safety update report and submits to the Authority for change in connection with acquisition of new safety information affecting on benefit-risk balance or on change in the instructions for use of the medicinal product;

16.2.12. notify the Authority before or at the time of informing the public about safety concerns related to the use of medicinal products;

16.3. The Authority requires according to the “Regulation for Conducting Scientific, Preclinical and Clinical Studies of Medicinal products” approved by the Resolution of the Cabinet of Ministers of the Republic of Azerbaijan No. 83 dated April 30, 2010 or internationally recognized regulation for conducting preclinical and clinical studies from the authorization holder to perform the following:

16.3.1. to conduct post-authorization safety studies in connection with the risks of a state registered medicinal product;

16.3.2. to conduct post-authorization efficacy studies to prove the effectiveness of the medicinal products.

16.4. The Authority scientifically evaluates all information through the pharmacovigilance system by taking into account the following:

16.4.1. the results of activities aimed at minimizing the risk within the risk management plan;

16.4.2. updates in the risk management system;

16.4.3. conducting assessments, including a periodic safety update report, by determining the possibility of new risks or the likelihood of change of these risks or their impact on the benefit-risk balance.

16.5. The Authority and the marketing authorization holder should inform each other when new risks arise or changes occur in the benefit-risk balance.

16.6. After the evaluation, the Authority should decide on the following measures by informing the marketing authorization holder:

16.6.1. to conduct post-authorization safety studies by the marketing authorization holder;

16.6.2. to take measures to minimize risk by the marketing authorization holder;

16.6.3. apply to the Ministry to ensure the implementation of paragraph 4.3-1 of the Law of the Republic of Azerbaijan “On Medicinal products” and/or paragraphs 13.1 and/or 8.1 of the “Regulations of state registration and register compilation of medicinal products” approved by Resolution of the Cabinet of Ministers of the Republic of Azerbaijan No. 108 dated July 13, 2007;

16.6.4. to conduct such changes as limitations of indications for use, reduction of the recommended dose, addition of new contraindications to the information of medicinal product by the marketing authorization holder;

16.6.5. development by the marketing authorization holder or the Authority of a dear health professional letter and presentation to the healthcare professionals and pharmacists;

16.6.6. the recall of the medicinal product.

17. Registration and storage of information

17.1. The marketing authorization holder register documents in connection with pharmacovigilance activities by complying with the following requirements:

17.1.1. provision for the possibility of re-acquisition of documents;

17.1.2. the use of methods of re-monitoring and controlling of adverse reaction reports;

17.2. The marketing authorization holder ensures the storage of information on pharmacovigilance activities in accordance with Good Pharmacovigilance Practice.

17.3. The marketing authorization holder takes appropriate measures to store the documents and information provided in the 9th part of this Regulation for at least 5 (five) years after the official termination of the system, which is described in the pharmacovigilance system master file.

17.4. Documents and data on pharmacovigilance of medicinal products are stored during the registration period of the medicinal product and at least 10 (ten) years after the expiration of the registration period.

18. Conducting of audit

18.1. Conducting periodic risk-based audits in order to determine the effectiveness and compliance of the quality system with the requirements of Good Pharmacovigilance Practice and the 17th part of this Regulation. The participation of the person responsible for pharmacovigilance and his/her deputy in the audit is not allowed.

18.2. After taking measures to eliminate the deficiencies discovered during the audit, a re-audit is carried out and information about it, including data on their results, is added to the pharmacovigilance system master file.

19. Final provisions

19.1. Adverse reaction reports associated with the off-label use or abuse of a medicinal product, related to the occupational exposure of the medicinal product, as well as with the ineffectiveness and poor quality of the medicinal product should sent to the Authority in accordance with these Regulation.

19.2. The Authority takes measures to protect the confidentiality of information about the patient or healthcare professional and pharmacists specified in the reports sent to the Authority, and the disclosure of these data is not allowed without the permission of these persons except the cases provided for by law.

19.3. The provisions of paragraph 19.2 of this Regulation apply to marketing authorization holder, medical institutions and organizations.

19.4. The Authority determines the conformity of the activities of marketing authorization holder, medical institutions and organizations in the field of pharmacovigilance with Good Pharmacovigilance Practice in accordance with this Regulation.

19.5. Before the state registration of a medicinal product the Authority has the right to determine the conformity of this system in accordance with the Good Pharmacovigilance

Practice in order to establish the correct and effective application of the pharmacovigilance system of the marketing authorization holder.

19.6. In case of the assessment of the compliance of the pharmacovigilance system of the marketing authorization holder with the Good Pharmacovigilance Practice a contradiction to the requirements of these Regulation is revealed, the Authority immediately inform the Ministry of such contradictions.

19.7. In order to eliminate the contradictions specified in paragraph 19.6 of this Regulation, the Ministry appoints to the marketing authorization holder a period for its elimination not less than 15 (fifteen) days, not more than 3 (three) months, depending on the nature of the contradiction and if the contradiction is not resolved within the prescribed period and the required documents are not provided, the state registration of the medicinal product is going to be canceled.

19.8. Deficiencies identified in connection with the organization of pharmacovigilance of medical institutions, marketing authorization holders and organizations should be addressed in accordance with Good Pharmacovigilance Practice.