**Resolution of the Cabinet of Ministers of the Republic of Azerbaijan**

**No 460**

**Baku city, November 27, 2019**

**on the approval of**

**"Regulation for the recall of medicinal products"**

In order to ensure the implementation of the subparagraph 1.1.4. Decree No. 157 of June 27, 2018 of 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 “Amending the Law of the Republic of Azerbaijan “On Medicinal products”, the Cabinet of Ministers of the Republic of Azerbaijan **resolves**:

1. To approve the "Regulation for the recall of medicinal products " (attached).

2. Amendments to this resolution may be agreed with the paragraph 2.6-1 of the “Regulations on the preparation and adoption of regulatory legal acts of executive authorities”, approved by Decree No. 772 of August 24, 2002 of the President of the Republic of Azerbaijan.

**Prime Minister**
**of the Republic of Azerbaijan** **Ali Asadov**

**Approved** by Resolution № 460 of November 27, 2019 of the Cabinet of Ministers of the Republic of Azerbaijan

# Regulation for the recall of medicinal products

## 1. General provisions

1.1. This Regulation has been developed in accordance with the paragraph 12.3 of the Law of the Republic of Azerbaijan “On Medicinal products” and regulates the rule of removing unusable medicinal products from circulation in order to ensure the health and safety of the population.

1.2. This Regulation covers all stages (production of medicinal products, storage, transportation, sale, use and application) of the circulation of medicinal products.

1.3. Medicinal products belonging to the high-risk group (invasive medicinal products and medical gases) are equated with medicinal products for the purposes of this Regulation.

## 2.Basic concepts

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

2.1.1. Unusable medicinal product - a medicinal product that is dangerous to human health and is of poor quality;

2.1.2. Good Manufacturing Practice - being the main component of the quality guarantee, the system guarantees the compliance of the results of clinical trials of a medicinal product with state registration documents, prescription, verification, and constant compliance of the production of medicinal products with quality standards;

2.1.3. Good Distribution Practice – is a system that guarantees the compliance of purchase, storage and sale of medicinal products by wholesalers with state standards, the rules of sanitation, veterinary, fire safety rules, labor protection and safety rules.

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. Providing of information

3.1. Information on unusable medicinal products is directly provided by the following entities to "Analytical Expertise Center" LLC of the Ministry of Health of the Azerbaijan Republic (hereinafter referred to as the "Authority") or the marketing authorization holder of medicinal products, the manufacturer of medicinal products and medical products, legal entities engaged in the wholesale of medicinal products, legal entities and individuals engaged in the wholesale of medical devices (hereinafter - referred to as responsible person):

3.1.1. persons responsible for pharmacovigilance of medical institutions;

3.1.2. excluding the responsible persons provided in the paragraph 3.1 of this Regulation, other organizations involved in the circulation of medicinal products (hereinafter - referred to as organizations);

3.1.3 health care professionals and pharmacists;

3.1.4. consumers

3.2. The Authority and the responsible person must notify each other within 5 (five) business days after receiving information about the unusable medicinal product.

3.3. In the event that the responsible person voluntarily decides to recall after receiving information about the unusable medicinal product, he must prepare the notification form specified in the annex of this Regulation and immediately send it to the Authority.

## 4. Assessment of the provided information

4.1. In connection with the medicinal product, the Authority immediately analyzes the information sent accordingly to the 3rd part of this Regulation and decides on the implementation of the following measures, depending on the results of the review:

4.1.1. extension of medicinal product review and risk assessment by the responsible person;

4.1.2. suspension of the turnover of the relevant or all batches (series) of the medicinal product until adoption of the final decision for recall of the medicinal product.

4.1.3. if a decision is made to withdraw as a result of the review, the responsible person filling out the notification form specified in the annex of this Regulation.

4.1.4. conducting appropriate measures to prevent the recurrence of a defect in accordance with Good Manufacturing Practice.

4.1.5. in the case of non-compliance with a Good Manufacturing Practice, this non-compliance will affect other medicinal products produced in the manufacturing enterprise, the suspension of production and (or) import, export, sale and use of the medicinal product.

4.2. If a decision is made to recall a medicinal product as a result of a risk assessment, by determining the class and level of recall, the implementation of measures provided by this Regulation begins.

## 5. Recall class and level of medicinal product

5.1. The recall class and level of medicinal product is determined on the basis of an assessment of the nature of the defect and the risk of damage to the health of the consumer.

5.2. The following medicinal product recall classes are determined:

5.2.1. class I - cases when the medicinal product cause or could cause a life- and health-threatening for person;

5.2.2. class II - cases when the medicinal product cause or could cause temporary and treatable life- and health-threatening for person;

5.2.3. class III - cases when the medicinal product does not cause a direct life- and health-threatening for person; (defects in the primary or secondary packaging of the medicinal product, technical errors in the package insert, etc.).

5.3. The following medicinal product recall levels are determined:

5.3.1. level A - to the last consumer;

5.3.2. level B - to enterprises providing the last consumer with a medicinal product (retail enterprise, medical institution);

5.3.3. level C - to the wholesale enterprise.

## 6. Initiation of recall of medicinal product

6.1. The following cases result in recall of medicinal product:

Problems with quality, effectiveness and safety, results outside the specification, packaging defects, inconsistency of the license and permit issued for the manufacture, sale and import of the medicinal product in accordance with the Law of the Republic of Azerbaijan “On Licenses and Permits”, with registration documents and information of the

medicinal product, non-compliance of location manufacturing site with the requirements of Good Manufacturing Practice.

6.2. The Authority makes a decision on stopping or not stopping the sale and use of the other batches (series) sold and distributed, producing, importing and exporting medicinal products in order to protect public health after considering information and documents sent by the responsible person.

6.3. In the case when the Authority finds circumstances (excluding circumstances that make it necessary to recall the class I) leading to the recall of the medicinal product, for the first time in the last 5 (five) years, deciding on the temporary suspension of production, import, sale and distribution of the relevant series and (or) parties, has the right to require a written explanation from the responsible person.

6.4. The responsible person shall provide the explanation provided in the paragraph 6.3 of this Regulation to the Authority within 5 (five) business days.

6.5. Evaluating the clarification of the responsible person, the Authority complies with the requirements of the paragraph 9.1 of this Regulation on the adoption of the final decision on the medicinal product.

6.6. The Authority begins to implement measures in connection with the recall of the medicinal product in the case of the discovery of circumstances that form the primary recall of the medicinal product that arose for the first time in the last 5 (five) years, without requiring written explanation from the responsible person.

## 7. Announcement of recall

7.1. In the case when the Authority decides to recall the medicinal product, the responsible person immediately sends a written notice including the following information to the organizations according to the class and level of recall of the medicinal product:

7.1.1 title of the medicinal product;

7.1.2. form and dose of the medicinal product;

7.1.3. batches (series), the expire date of the medicinal product;

7.1.4. reason for recall of the medicinal product;

7.1.5. the class and level of recall of the medicinal product;

7.1.6. method of recall of the medicinal product;

7.1.7. form of compensation payment in connection with the recall of the medicinal product.

7.2. It is not allowed to place information of an advertising nature in the information of recall of the medicinal product sent by the responsible person.

7.3. In connection with the recall of the medicinal product, the Authority informs the public about the unusable medicinal product by using media and its own official website.

7.4. In connection with the recall of the medicinal product, the responsible person sends a written notice to the organizations that have unusable medicinal products and to individuals who have medical devices that provided in the paragraph 1.3 of this Regulation.

7.5. Taking into account the class of recall of the medicinal product, the responsible person controls the medicinal product within the following periods in order to recall the unusable medicinal product from circulation after sending the notice provided in the paragraph 7.1 of this Regulation and takes the measures specified in the Good Distribution Practice:

7.5.1. during the class I recall - within 24 hours;

7.5.2. during the class II recall - within 48 hours;

7.5.3. during the class III recall - within 72 hours.

7.6. The responsible person submits a weekly report on the measures taken in connection with the recall of the medicinal products to the Authority.

7.7. All information about the recall of medicinal product is posted on the official website of the Authority, which ensures their regular updating.

## 8. Suspension of the distribution and sale of recalled medicinal product

8.1. All enterprises with unusable medicinal products must suspend the distribution and sale of the medicinal product after the recall announcement.

## 9. Suspension and renewal of production, import or export of recalled medicinal product

9.1. Within 2 (two) business days after the recall decision of the medicinal product the Authority initiate a petition to the Ministry of Health of the Azerbaijan Republic (hereinafter-referred to as the Ministry) in order to decide whether to suspend or not to suspend the production, import or export of the recalled medicinal product. Within 3 (three) business days the Ministry makes a decision to suspend or not to suspend the production, import or export of recalled medicinal product.

9.2. The responsible person suspends the production, import or export of a medicinal product after receiving notification from the Authority about the decision of the Ministry to suspend the production, import or export of the recalled medicinal product.

9.3. After the responsible person provides information to the Authority about the measures taken in order not to repeat the circumstances leading to the recall of the medicinal product, which the Authority immediately assess and within 2 (two) business days initiate a petition to the Ministry to make a decision in connection with the continuation or non-continuation of the production, import or export of the recalled medicinal product. Within 3 (three) business days the Ministry decides whether to continue or not to continue the production, import or export of the recalled medicinal product.

## 10. Initial report

10.1. The responsible person within the periods specified in this Regulation depending on the class and level of recall takes measures for unusable medicinal products and within 10 (ten) business days after notifying of the decision about recall, prepares and sends the initial report to the Authority.

10.2. The following information should be indicated in the text of the initial report:

10.2.1 the quantity of the batch (series) produced, imported or exported and the first dates of marketing of unusable medicinal product;

10.2.2. the copy of information letters which sent to the location or the possible location of the medicinal product, respectively the class and level of recall;

10.2.3. report of the initial review and assessment on the cause of the defect;

10.2.4. information on the result of the assessment of complaints on similar defects.

## 11. Payment of compensation for a recalled medicinal product

11.1. The responsible person must fully pay the damage caused to individuals and legal entities in connection with the recall of the medicinal product.

## 12. Final report and completion of recall

12.1. The responsible person according to the level of recall prepares and provides the final report to the Authority no later than 12 (twelve) weeks after ensuring the recall of all unusable medicinal products in circulation.

12.2. The following information should be indicated in the final report of the responsible person:

12.2.1. the place where the information about the recall was sent, the date and form of report;

12.2.2. the acts showing the number of recalled medicinal products and organizations that comply with the recall announcement;

12.2.3. the name and number of organizations that have neglected the notice of recall of the medicinal product;

12.2.4 the main cause of the defect, information and documents on measures taken to prevent and eliminate it;

12.2.5. the total quantity of recalled medicinal products;

12.2.6. the measures taken in accordance with the 13th part of this Regulation on the recalled medicinal product.

12.3. The total quantity of the recalled medicinal product is determined by the Authority on the basis of the act in accordance with subparagraph 12.2.5 of this Regulation.

12.4. The Authority makes a decision on the completion of the recall according to the results of the assessment of information provided by the responsible person.

12.5. In case of unsatisfactory result of the recall, the Authority requires the responsible person to continue the measures taken in accordance with the 13th part of this Regulation.

## 13. Disposal or rectification of recalled medicinal product defects

13.1. If it is impossible to eliminate the defect found of the recalled medicinal product, the unusable medicinal product shall be returned or disposed of by the responsible person.

13.2. The Authority determines the elimination of an existing defect found in the recalled medicinal product by conducting an appropriate expertise procedure.

## 14. Completion of the recall procedure

14.1. After disposal, returning to the manufacturer or elimination of an existing defect of the medicinal product, the responsible person provides to the Authority for the evaluation the following information:

14.1.1. the implementation of measures aimed for elimination defects that entailed the recall of the medicinal product;

14.1.2. disposal, returning to the manufacturer or seller of the recalled medicinal product;

14.1.3. taking appropriate measures to prevent the recurrence of defects in the medicinal product.

14.2. If the Authority determines the implementation of the measures provided in subparagraphs 14.1.1-14.1.3 of this Regulation, it makes a decision on the completion of the recall and (or) initiates a petition to the Ministry within 5 (five) business days in order to re-release the medicine into circulation.

## 15. Responsibilities of the Authority on the recall of the medicinal products

15.1. The Authority takes the following measures on the recall of a medicinal product:

15.1.1. takes an appropriate decision within 5 (five) business days on the basis of information provided by the responsible person in accordance with the requirements of this Regulation;

15.1.2. controls for timely implementation of the recall;

15.1.3. takes measures to suspend the production, import or export of unusable medicinal product;

15.1.4. transmits electronic information to the Customs authority, in the case of decision is made to resume import or export or to suspend import or export by the Ministry.

## 16. Responsibilities of the responsible person on the recall of the medicine

16.1. The main responsibilities of the responsible person on the recall of unusable medicinal products are as follows:

16.1.1. immediately and effectively provides recall;

16.1.2. immediately informs the Authority about unusable medicinal products;

16.1.3. keeps all documents (certificates) associated with the recall at least 5 (five) years after the expiration date of the medicinal product;

16.1.4. owns a recall plan for timely and complete execution of the recall;

16.1.5. creates an operational communication system with organizations to which the medicinal products were distributed.

## 17. Responsibilities of other organizations on the recall of medicinal products, which is involved in the circulation of medicinal products

17.1. Excluding the responsible person, the responsibilities of other organizations involved in the circulation of medicinal products are as follows:

17.1.1. to prevent the use of the medicinal product after the notice of recall of the medicinal product and to take the measures provided by the responsible person;

17.1.2. to draw up an act on the quantity of recalled medicinal product in accordance with the level and the class of recall and provide this act to the responsible person;

17.1.3. to provide the information and documents requested by the Authority to ensure that the Authority conducts inspections in accordance with the Law of the Republic of Azerbaijan "On Regulation of inspections in the field of entrepreneurship and protection of the interests of entrepreneurs"

17.1.4. to own a recall plan for timely and complete execution of the recall;

17.1.5. to create an operational communication system with organizations where medicinal products were distributed.

**Annex** to "Regulation for the recall of medicinal products"

**Medicinal product recall**
**NOTIFICATION FORM**

**Medicinal product recall notification form № ____**

1. The following information is shown in the recall notification form of an unusable medicinal product:
1.1. name, form and dose of the medicinal product;
1.2. serial number (batch), expiration date and production date of the recalled medicinal product;
1.3. reason, date, detected defects specified in the decision of recall of the medicinal product;
1.4. prediction of risk for the unusable medicinal products;
1.5. consumer group under the risk;
1.6. total quantity of batches (series) of unusable medicinal products;
1.7. whether other batches (series) of medicinal products admitted into circulation fall under the influence of the defect;
1.8. whether batches (series) of unusable medicinal products were exported;
1.9. total quantity of distributed unusable medicinal products;
1.10. names of organizations (wholesaler, medical institution, as well as other organizations) to which batch (series) of unusable medicinal products were distributed and distributed quantity of medicinal products;
1.11. recall class and level;
1.12. contact information of the persons responsible for the recall;
1.13. post, last name, first name, father name and signature of the authorized person providing the notification.

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