

A REGULATION

by Turkish Medicines and Medical Devices Agency:

RECALL REGULATION**CHAPTER ONE****Purpose, Scope, Basis and Definitions****Purpose**

ARTICLE 1 – (1) This Regulation sets forth the rules, authorizations and responsibilities, and principles of oversight for investigating products which are suspected or found to be defective, or considered unfit for use, and when necessary, for effecting voluntary or enforced recall of such products rapidly and in an effective manner to safeguard consumer health and safety.

Scope

ARTICLE 2 – (1) This Regulation applies to final consumers and all organizations who are engaged in the manufacture, importation, storage, distribution or sales of human medicinal products, medical gasses, traditional herbal medicinal products, foods for special dietary use, homeopathic products, advanced therapy products, human tissue-based and cellular products, and any raw materials used in their production, falling within the Agency's mandate.

Basis

ARTICLE 3 – (1) This Regulation is based on Law #1262 dated 14.05.1928 on Pharmaceutical and Medicinal Products and Articles 27 and 40 of Decree Law #663 dated 11.10.2011 on the Organization and Mandate of the Ministry of Health and Its Subordinate Agencies.

Definitions

ARTICLE 4 – (1) For the purposes of this Regulation:

- a) 'Recall' means the recovering of products known or suspected to be defective from the specified distribution channels by the responsible company;
- b) 'Recall classification' means the degree and level of recall to be implemented, based on the degree of product's harmfulness to health or the nature of the defect;
- c) 'Defective product' means a product which poses a threat to consumer health or safety, or in which quality defects have been detected;
- ç) 'Suspected defective product' means a product for which solid indications exist which suggest that the product may pose a potential risk to consumer health or safety, or contain quality defects;
- d) 'Agency' means Turkish Medicines and Medical Devices Agency;
- e) 'Responsible company' means the company manufacturing/having manufactured the product and/or placing it on the market;
- f) 'Enforced recall' means enforced recovery from the marketplace of products not holding an Agency-issued license or authorization certificate;
- g) 'Product' means any of human medicinal products, medical gasses, traditional herbal medicinal products, foods for special dietary use, homeopathic products, advanced therapy products, human tissue-based and cellular products, and any raw materials used in their production; and
- ğ) 'Good Manufacturing Practice' means a part of the quality assurance system which ensures consistent control and manufacture of products and active substances in line with their intended purpose of use and quality standards.

CHAPTER TWO**Duties and Responsibilities, Reporting and the Decision-Making Process****Actions by the Agency**

ARTICLE 5 – (1) In connection with the evaluation and, when appropriate, recall of products detected to be defective during market supervision and oversight by the Agency or upon the receiving of a report, the Agency will take the following actions:

- a) Require the responsible company to submit information or clarification at the earliest possibility, if necessary;
- b) Evaluate the responsible company's response and if necessary require additional information;
- c) Evaluate the clarifications and proposals submitted by the responsible company, and decide on the classification and level of recall;
- ç) Where applicable, complete the product-related processes on the Drug Tracking System or similar software applications, and notify the responsible company;
- d) Follow-up to ensure that recall procedures are executed on time and in line with the designated classification;
- e) Suspend the manufacture or importation of the defective products, as appropriate, when deemed necessary;

f) If manufacturing or importation operations have been suspended, permit resumption of manufacturing or importation operations, as appropriate, immediately after establishing that appropriate measures have been put in place to prevent the same error from repeating;

g) Finalize the recall process and close the file, monitoring the product by conducting market audits;

ğ) Audit the conduct of the recall at any stage, when deemed necessary;

h) Take appropriate action when the responsible company is incapable of effectively implementing the recall and when health problems may arise;

ı) If the defective product can be rehabilitated, take action to ensure that the product is placed back on the market only after all of the necessary analyses/controls have been completed and indicate that the product is acceptable; and

i) Enforce the recall of the product if necessary.

Responsibilities of the responsible company and other organizations

ARTICLE 6 – (1) The responsible company and other organizations have the following duties and responsibilities for evaluating and when necessary recalling defective products from the marketplace:

a) The responsibilities of the responsible company include the following:

1) Have in place a procedure, setting forth the responsibilities, the approaches to be followed, recipients of information and announcements, the method of announcements, and the processes for maintaining and retaining records of the recalled products, to ensure that a recall can be immediately implemented and completed in a effective manner within a short timeframe.

2) Urgently notify the Agency of any products found or suspected to be defective;

3) Ensure that the recall is conducted immediately and effectively across the entire distribution chain in line with the recall plan; send out communications to all distribution channels, down to the level required by the recall; collect feedback from recipients of communications, on whether they have the product in question in their stock, and forward this information to the Agency along with any other relevant information, without any omissions; and communicate any relevant changes or additional information;

4) If the Agency requires clarification, complete an investigation and inform the Agency of its conclusions at the earliest possibility, and make a proposal for classification and level of the recall;

5) Maintain distribution records in a manner to facilitate a recall, if necessary, as quickly as possible, retaining them and all the other information and documents relevant to the recall process for at least five years from the product's expiration date;

6) In life-threatening situations, immediately notify the Agency regardless of regular working days or hours;

7) Inform the Agency about any changes in the recall plan;

8) Take all the precautions prescribed by the Agency in connection with the recall; provide all additional information required by the Agency; and always act responsibly and in good faith;

9) If the products were exported, notify the distributor and the relevant national authority;

10) In the event of a recall abroad, inform the Agency of the nature and causes of the recall taking place abroad, also in connection with the batches of an imported product authorized in Turkey, which were not imported into Turkey.

b) The responsibilities of all organization(s) engaged in the storage, distribution or sales of a product falling within the scope of this Regulation, excluding the responsible company, include the following:

1) After receiving the recall announcement, prevent use by the relevant parties, and immediately initiate action as instructed by the responsible company;

2) Issue a feedback report in response to the responsible company's recall announcement, based on the level and classification of the recall, and if the products are in stock, initiate the return procedure;

3) Submit any information or documents requested by the Agency, and remain available for auditing by the Agency when necessary;

4) Have in place a recall plan to implement a recall in a timely manner and without any omissions, when necessary; and

5) Have in place a system to contact at the earliest possibility the recipients to whom the products were distributed.

Reporting process

ARTICLE 7 – (1) Reports related to products suspected or found to be defective may be submitted to the Agency, provincial health directorates or the responsible company by any individuals, organizations or agencies.

(2) The following process applies for reports:

a) Where the report is made to the responsible company, the responsible company initiates complaint assessment upon receiving defective or suspected defective product report. Any reports or complaints communicated to the responsible company will be assessed in detail and if, based on the results of these assessments, the report is considered off-scope for the Regulation / not requiring a recall, the responsible company keeps the report or the complaint in its records. If the complaint or report is considered in-scope for this Regulation, and company completes the form in Appendix 1 hereto and sends it to the Agency.

b) Where the report is made to the Agency or a provincial health directorate, if the product being the subject matter of a defective or suspected defective product report to the Agency or a provincial directorate is physically available, it will be delivered to the Agency for examination and assessment. Where necessary, the Agency will forward the report to the responsible company and requests information. Any suspected cases of product quality, personally detected by the responsible company, will be reported to the Agency on the form in Appendix 1 hereto.

Assessment of reports

ARTICLE 8 – (1) The market supervision and oversight by the Agency and any reports made to the Agency will be urgently given consideration. When necessary, the Agency will seek information from the responsible company. After evaluating all of the available information, the Agency may decide to initiate the following actions:

- a) Require the responsible company to broaden its investigation related to the product, and conduct a risk assessment;
- b) Suspend the distribution of specific or all batches of the product until a final decision can be made, without actually taking a decision for recall;
- c) Take a decision for recall, and require [the responsible company] to complete the form in Appendix 1 hereto;
- ç) Require the taking of necessary and appropriate actions according to Good Manufacturing Practice to prevent the same defect from reoccurring; or
- d) If issues related with Good Manufacturing Practice are detected where other products manufactured at the same manufacturing site are affected, suspend the manufacture and/or importation of such other products affected, along with the product recalled.

(2) If the assessment results in a decision for recalling the products, a class and level will be assigned and the recall procedure will be initiated.

CHAPTER THREE

Recall Classification, Causes and Procedure

Classification of recall

ARTICLE 9 – (1) The class of a recall will be determined based on an assessment of the nature of the defect, and the potential harm to consumers' health from using the product which is or is suspected to be defective.

(2) The recall classes are as follows:

- a) Class I: Situations where admissible causes suggest that serious or life-threatening issues have occurred or may occur;
- b) Class II: Situations where temporary or treatable health issues have occurred or are probable;
- c) Class III: Situations where using the product would not be harmful to health.

Scope of recall

ARTICLE 10 – (1) The extent of a recall through the various levels of the distribution chain is determined as follows:

- a) Level A: goes down to the final consumer level.
- b) Level B: goes down to all retailer level.
- c) Level C: goes down to the wholesalers' level, including pharmaceutical wholesalers.

Causes and initiation of recall

ARTICLE 11 – (1) Causes of recall include, without limitation, any quality defects, efficacy or safety issues, out-of-specification results, packaging errors, inconsistency with the marketing authorization/license, noncompliance with regulatory requirements, or noncompliance with the requirements of Good Manufacturing Practice.

(2) Where a recall decision is taken by the Agency, the Agency will notify the responsible company and require it to complete and turn in the form in Appendix 1 hereto within five working days. After reviewing the information and documents submitted by the responsible company, the Agency will take a decision on whether to suspend the product's importation/manufacture, or suspend the sale of other batches of the product currently in stock or on the market, taking account of the public health interests.

(3) If the responsible company detects a situation that may warrant a recall, it will immediately initiate the recall procedure, and complete the form in Appendix 1 hereto and send it to the Agency. The Agency may modify the proposed recall classification or level.

(4) Excluding situations warranting a class I recall, in isolated cases where a similar noncompliance was not detected over the past five years, the batch concerned may be blockaded on the Drug Tracking System, and the responsible company may be asked for an explanation. In those cases, the Agency will give consideration to the explanation submitted to it by the company within five working days and adopt a final decision.

Announcement of recall

ARTICLE 12 – (1) When a recall decision is taken, the responsible company will communicate it to all organization(s) and individuals who may have it in their possession, according to the level of recall, in accordance with the announcement text in Appendix 2. It is mandatory that the announcement is made in writing and a copy thereof submitted to the Agency. Other means of communication may be also used to supplement the written announcement.

(2) The recall announcement released by the responsible company may not include any promotional elements; the announcement will be solely intended to give information.

(3) The following steps are executed, depending on the class of recall:

a) For class I recalls:

1) the Agency informs the general public using any mass communication means;

2) the responsible company sends out a written communication to all organization(s) and individuals who may have the defective batch in their possession, depending on the level of recall;

3) after the announcement, the responsible company takes appropriate steps to gain control of the defective products circulating on the market within 24 hours; and

4) the responsible company reports to the Agency weekly on the steps taken.

b) For class II recalls, following the release of the announcement, the responsible company takes appropriate steps to gain control of the defective products within 48 hours.

c) For class III recalls, following the release of the announcement, the responsible company takes appropriate steps to gain control of the defective products within 72 hours.

ç) Announcements related to recalls may be posted on the Agency's official website.

Suspension of distribution and sales

ARTICLE 13 – (1) Following the recall announcement, anyone who has the defective products in their possession are obligated to suspend the distribution and sales of these products, and take the appropriate steps until the recall procedure is finalized.

Resumption of manufacturing or importation operations

ARTICLE 14 – (1) When the Agency takes a decision to suspend the manufacturing or importation operations of a recalled products, the responsible company will cease manufacturing or importing the products. After a report is submitted to the Agency on the root cause of the defect and the actions implemented to prevent it from reoccurring, the Agency will urgently give consideration of the report and decide whether or not permit the resumption of the manufacturing or importation operations.

Preliminary report

ARTICLE 15 – (1) Depending on the classification and level of recall, appropriate steps will be taken with regard to the defective product within the specified timeframes, and a preliminary report, covering the aspects described in Appendix 3, will be prepared and sent to the Agency within ten working days.

Indemnification for products

ARTICLE 16 – (1) The responsible company is obligated to indemnify the parties concerned for their trouble, resulting from the product recall.

Final report and finalization of the recall procedure

ARTICLE 17 – (1) The responsible company will, after making sure that all of the defective products on the market have been completely recovered down to the specified level of recall, prepare and submit to the Agency a final report, covering the information listed in Appendix 4 hereto, at the latest within twelve weeks, unless an extension has been granted by the Agency upon request.

(2) The decision to finalize the recall will be made by the Agency, based on an evaluation of the information submitted by the responsible company. In cases where the recall is considered inadequate, the Agency may require the company to continue with the procedure.

Destruction or rehabilitation

ARTICLE 18 – (1) In cases where rehabilitation is not contemplated, the responsible company will, after the Agency completes the determination of the defective products, return the products to their source or proceed with their destruction per regulatory requirements. If the defective products are to be rehabilitated, they may be placed back on the market upon a decision to that effect by the Agency, after all of the required controls or analyses have been performed.

Finalizing the recall procedure

ARTICLE 19 – (1) After the destruction or rehabilitation procedures have been completed, the Agency gives consideration to the information submitted by the responsible company. The Agency will formally finalize the recall procedure after ensuring that:

a) the recall has been completely executed;

b) the rehabilitation of the recalled products has been completed, if applicable;

c) the recalled products, if designated for destruction, are duly delivered to the relevant institution or duly destroyed or returned to their source, according to the regulatory requirements; and

ç) appropriate steps have been taken to prevent the same defect from reoccurring.

CHAPTER FOUR

Miscellaneous and Final Provisions

Penalties

ARTICLE 20 – (1) For the instances of noncompliance detected, including the isolated cases specified in the fourth paragraph of Article 9, the responsible company will be subjected to the applicable provisions of Law #1262 on Pharmaceutical and Medicinal Products, for each batch of the products. For class II and class II recalls, voluntarily initiated by the responsible company, the provisions will not be applied for each batch, if multiple batches are involved.

(2) Any business, including companies, wholesalers or pharmacies, who continue selling the defective batch after the recall announcement will be subjected to the applicable provisions of Law #1262 on Pharmaceutical and Medicinal Products, Turkish Penal Code #5237 dated 26.09.2004, or Law #5326 on Misdemeanors, depending on the nature of their actions. Also, the marketing authorization will be suspended for products which did not execute a recall decision or which failed to close the recall file within three years from the recall decision. The marketing authorization will be revoked, if the recall file is still not closed within one year from the suspension date.

Repealed regulation

ARTICLE 21 – (1) The Regulation on Voluntary and Enforced Recall of Pharmaceutical and Medicinal Preparations, Substances, Materials and Compositions and Herbal Preparations, published in Official Gazette #19196 dated 15.08.1986 is hereby repealed.

Effectiveness

ARTICLE 22 – (1) This Regulation will enter into force on the date it is published.

Enforcement

ARTICLE 23 – (1) This Regulation will be enforced by the President of Turkish Medicines and Medical Devices Agency.

Appendix-1 Reporting Form for Products Found or Suspected to Be Defective

1. Product name, pharmaceutical form and strength
2. Batch number, expiration date and manufacturing date of the batch to be recalled
3. Cause and date of the recall, and the circumstances of its detection
4. Risk estimate of the defect, and the consumer group at risk
5. Total number of the defective batches
6. Whether other batches and products placed on the market are also affected by the defect
7. Whether the defective batch(es) of the product were exported
8. Quantity of products distributed
9. Names of recipients on a batch basis (i.e. wholesalers, pharmacies, hospitals and other organization(s)), and the quantity of products supplied
10. Proposed classification and level of recall
11. Contact details of persons responsible for the recall procedure

Appendix-2 Announcement Text

1. Product name
2. Pharmaceutical form and strength
3. Batch number and expiration date
4. Cause of recall
5. Class and level of recall
6. How the products would be recalled
7. How the recalled products would be arranged

Appendix-3 Content of the Preliminary Report

1. Quantity of the defective products manufactured/imported and the initial market placement date on a batch basis
2. A copy of the announcement letter sent to places who have or may have the product in their possession, based on the class and level of recall
3. Preliminary investigation and assessment report on the cause of the defect
4. A report derived from a review of complaints related to similar defects

Appendix 4 – Content of the Final Report

1. The places to whom the recall was communicated, and the date and method of communication

2. Number of clients who complied with the recall announcement, and the feedback reports, showing the quantities in their possession
3. Clients who ignored the recall announcement
4. The root cause of the defect and information and documents related to the preventive and corrective actions
5. Total quantity of the recalled products (this quantity should be formally determined by the local health authority)
6. Procedure to be followed for the recalled products