Recalling and Withdrawal of Pharmaceutical and Medicinal Preparations, Matters, Materials, Combinations and Herbal Preparations

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Objective

Article 1- The objective of this regulation is to specify the rules, authorities and liabilities, along with the control principles to be followed when recalling and withdrawing pharmaceutical and medicinal preparations, matters, materials, combinations and herbal preparations, which are deemed to be defective and faulty for the health and safety of the consumer or to be inconvenient for use, from the market in a short time and effectively.

Scope

Article 2- This regulation applies to all factories, laboratories, businesses, warehouses and pharmacies which import, export, distribute and sell pharmaceutical and medicinal preparations, matters, materials, combinations and herbal preparations.

Definitions

Article 3- The terms used in this regulation refer to as follows;

a) Ministry: The Ministry of Health and Social Services,

b) Act: The Pharmaceutical and Medicinal Preparations Act with the number 1262 amended by the acts numbered 6243 and 4348,

c) Product: All pharmaceutical and medicinal preparations, matters, materials and combinations of chemical, herbal and biological origin used directly and indirectly to protect the health and for treatment,

d) Defective Product: The product which poses a threat for the health and security of the consumer, or which was detected to have quality defects,

e) Recall: The withdrawal of the defective product from certain distribution chains by the producer or the importing company,

f) Responsible Company: The company which performs the manufacturing, contract manufacturing, marketing or importing of the defective product and which is in charge of the recalling process,

g) Classification of Recalling: The degree of recalling to be applied according to defective quality of the product or the feature of the product to harm the health,

i) Contamination: Matters of mechanic, chemical and microbiologic origin, which are not present within the natural structures of the materials included in the combination of the product and not desired to penetrate into the drug (impurity and degradation products are excluded from the scope of this definition),

i) Cross Contamination: The situation where a pharmaceutical preparation is mixed with or contaminated to another pharmaceutical preparation or its components due to a mistake or some other reasons,

j) Foreign Matter: Abnormalities indicating coloration, flavor, lubricity and other means of degradation, along with all kinds of organic and inorganic matters except for those the definition and limits of which are specified with the monograph,
k) Undecided Substances: Pending, undissolved particles and fibers, except for air bubbles, which are not desired to be present within parenteral solutions,

1) Withdrawing: Recalling performed by the Ministry.

**The Objective of Recall and Withdrawal**

**Article 4**- Recalling and withdrawing are applied with a view to secure the presence of nondefective and qualified product in the market and to prevent use and/or distribution of the defective product within the shortest time and effectively in order to be able to protect the health and security of the consumer.

Recalling and withdrawing are commenced either with the demand of the ministry or upon the manufacturer’s consideration as necessary. Recalling process is fulfilled by the responsible company under the care of the Ministry. The responsible company is liable to take all the measures prescribed by the Ministry and to act responsibly and bonafide.

**Liability**

**Article 5**- Each manufacturing and importing company is liable to accomplish the following provisions in respect of the recalling process.

a- Distributional records should be arranged in such a manner to allow the recognition of each batch and client and recalling of the product within the shortest time when deemed necessary. Such records are kept for one more year as of the expiry date of the product.

b- A withdrawal plan which shall enable to be put into force immediately at any time and ensure withdrawal effectively within the shortest period of time is schemed. This plan specifies the responsibilities, the course to be followed, the places to be announced and informed, the way of the announcement, and the recording and keeping processes concerning the recalled drug for each withdrawal.

c- A system which shall make it possible to forward the required information and directives to the degrees the withdrawal shall catch within the shortest time is established.

d- The responsible company immediately informs the Ministry regardless of working days and hours on life-critical occasions.

e- The ministry is also informed about the amendments and annexations applied to the recalling plan.

**Classification of Recalling**

**Article 6**- The grade of the recalling is determined considering the danger or defect posed by the product.

FIRST GRADE RECALLING: The occasions when serious and life-sustaining health problems arise or there are acceptable reasons as to the possibility that such problems may arise,

SECOND GRADE RECALLING: The occasions when temporary, treatable health problems occur or might occur.

THIRD GRADE RECALLING: The occasions when the use of the product poses no threat to the health.

**Limits of Recalling**
**Article 7**- The degree until what level of the distributional chain the recalling shall catch is determined as follows.

LEVEL A: It catches until consumer level, and the first grade recalling is performed at this level.

LEVEL B: It catches until retailer level (pharmacy, hospital pharmacies, institutions etc.). Second grade recalling is performed at this level.

LEVEL C: Until warehouse level. Third grade recalling is performed at this level.

**Reasons for Recalling**

**Article 8**- Main reasons for recalling are the quality of the product, good manufacturing practices inadequacies and defects pertaining to labeling.

The occasions that require recalling are as follows:

I) **PACKAGING DEFECTS:**
- Leakage
- Destruction
- Material Defect
- Manufacturing Fault
- Inconvenient Package

II- **LABELING AND PRINTING DEFECTS:**
- Label confusion
- Label falls
- Mislabeled
- Inadequate labeling
- Insufficient information
- Misprinting
- Printing Error

III- **CONTENT DEFECTS:**
- Unit weight deviations
- Deviation in the amount of drug substance
- Wrong substance
- The activity’s being below and above the predetermined limits

(Subpotency- Superpotency)
- Foreign Matter
- Contamination
- Cross contamination
- Non-sterilization of those which are to be sterile
- Pyrogenic agent presence
- Chemical decomposition
- Defects with appearance, shape, odour and taste
- Sedimentation, blurriness
- Defective distribution time
- Undecided matters (fiber, particle)
- Deviations from the predetermined standards

DEFECTS ASSOCIATED WITH THE AFFECT:

- Inefficiency
- Serious perverse (Adverse) effects
- Toxicity

V-OTHERS :

- Unauthorized Manufacturing
- Unauthorized amendments with the formula, package, prospectus, and manufacturing site
- Those whose expiry dates were amended or terminated
- Failure of the manufacturing site conditions to comply with good manufacturing practices provisions

Recall Commenced by the Ministry

Article 9- In the case that an occasion that requires recalling is detected by the Ministry, the Ministry informs the responsible company about the situation and demands the company to start recalling process. In the recalling process started by the Ministry, the Ministry determines the grade and the level of the recalling. The company that starts recalling process informs the Ministry about the details specified in the Article 10 concerning the recalled product. The responsible company is also liable to provide additional information the Ministry deems necessary.

Recall Commenced by the Company

Article 10- In the case that a company decides to recall a product, it starts the recalling process immediately and notifies the Ministry about that decision together with the information below.

- The name of the product, the pharmaceutical form and dose,
-The number and production date of the batch to be recalled,

-The reason and date of the recalling decision, and the cases where the defect or the probable defect is detected

-The prediction of the risk concerning the defect, and the consumer group under risk,

-Total number of defective batch(es),

-The amount of the product to have been distributed,

-The names of the places to which the distribution has been performed (warehouses, hospitals, pharmacies and other institutions) and the amount of the product to have been distributed,

-The grade and limit of the recalling,

-The communication means to be used while recalling (letter, etc.) a copy of it if available, and if not, how the communication shall be practiced,

-The names, office and home phone numbers of the people responsible for the recalling process.

The ministry analyzes the information provided by the responsible company and makes amendments on the grade and limit of the recalling process when deemed necessary.

Announcement

Article 11- In the first grade recalling cases, the Ministry warns the public via all kind of mess media and requests that the defective products not be used. Necessary measures are taken in order to get the defective product in the market under control within 24 hours after the announcement is published.

Announcement of the Recall

Article 12- When a recalling decision is taken, the responsible company notifies the establishments and persons that might have the product according to the level the recalling catches via proper means of communication (letter, telephone, telex, etc.) within the shortest time. No matter what means of notification is chosen, a written announcement should certainly be employed. Upon the performance of the announcement, the control is established over the defective batch within 3 days for the second grade recalls and 6 days for the third grade recalls.

The Scope of the Announcement

Article 13- There mustn’t be any advertisement element in the recalling announcement made by the responsible company; the announcement should be made only for the purpose of informing. Such announcement should contain the following information about the product at least.

-The name of the product,

-Pharmaceutical form and dose,

-Batch number and manufacturing date,

-The reason of recalling,

-The means of recalling,

-The way the recalled product shall be indemnified,
Suspension of the Sale and Distribution-Measure

**Article 14**- Upon the recalling announcement, those who have the defective product stop the distribution and/or sale of the product. Such persons are liable to take all the necessary measures until the recalling process is completed.

Stopping the Production

**Article 15**- Once a recalling decision has been made, the responsible company stops the manufacturing of that product. After the information about the measures taken to prevent the repetition of the defect, the Ministry notifies its decision to the company on whether the manufacturing of the product shall be unblocked or not.

Paying Back

**Article 16**- The responsible company is liable to compensate for the recalled product until the level the recalling process catches. The way to be followed for that process is determined by the company and specified in the announcement. The responsible company is liable to perform this process in such a period of time that will not put the persons and establishments to whom the recalling process has been applied to in a tight position. Such period of time may not exceed 2 months.

Recall

**Article 17**- Having ensured that all defective products present in the market has been recalled until the level the recalling process catches, the responsible company composes a report including the following details and submits to the Ministry.

- Distributional records of the defective batch(es) of the product (the name and the amount),
- The places notified about the recall; the date and the way of the notification,
- The number of the clients acting according to the recalling announcement and the amount they have,
- The clients not complying with the notification,
- Total amount of the recalled product (this amount is detected by the regional health authority with a report.),
- The process to be applied to concerning the product recalled,

The information about the first grade recalls is notified to the Ministry on daily basis.

Ending the Recall

**Article 18**- The decision to end up the recalling process is taken by the Ministry. Having evaluated the information provided by the responsible company, the results of the inspection performed in the Ministry and the information gathered from other sources, the Ministry decides on the completion of the recalling process. In the cases that recalling process is considered inadequate, the Ministry demands the responsible company to go on.

Tasks to Be Performed

**Article 19**- The procedure suggested by the responsible company concerning the recalled product is submitted to the approval of the Ministry. On the occasion that the suggestion is approved by the Ministry, the required process is performed. The responsible company is liable to provide detailed information to the Ministry concerning the procedure applied.
Disposal

Article 20- In the cases that adjustment is theoretically not possible, the defective product is disposed of. The disposal procedure is performed by the responsible company before the team organized by the Ministry. The samples taken from the product to be disposed of prior to the disposal procedure by the Ministry officers are sent to the Ministry for identification. In the case that the defective product is decided to be adjusted, the adjustment process and the adjusted samples are examined by the Ministry after the adjustment procedure is completed.

Closing Down the Recall

Article 21- The information provided by the responsible company is evaluated by the Ministry after the decision to end up the recall is taken by the Ministry. The Ministry closes down the recalling file after having ensured that;

- The recalling process has been performed properly,
- The disposal and adjustment of the recalled product are completed,
- And the measures have been taken to prevent the repetition of the same defect.

Conservation of the Information

Article 22- All the information concerning the recalling process is kept by the responsible company.

Contacting

Article 23- Warehouses and other establishments performing bulk distribution are liable to establish a system that ensures communication with the places they provide the product to within the shortest time.

Inspection

Article 24- The Ministry inspects the performance of the recalling at all stages.

Inadequacy in Recall

Article 25- In the cases that the responsible company is inadequate in performing the recalling procedure and that may pose health problems, the Ministry takes the necessary measures.

Penalty

Article 26- The provisions of the related Act and Turkish Penalty Code are applied for the responsible company according to the defective quality of the recalled or withdrawn defective product or the degree to which it is harmful to the health.

Ignoring the Announcement

Article 27- The criminal provisions of the related Act and Turkish Penalty Code are applied for those who continue selling the defective product after the recalling announcement made by the responsible company.

Judgment of Court and Disposal

Article 28- In the case that any recalled batch(es) of the defective product in the market after the completion of the recalling process, such products are sealed and disposed by court decision.
Provisional Article- All the importing and manufacturing companies, warehouses and other establishments performing bulk distribution are liable to submit a withdrawal plan they arrange to the Ministry within 2 months as of the publication date of this regulation.

Validity

Article 29- This Regulation enters into force on the publication date.

Enforcement

Article 30- The clauses of this Regulation are enforced by the Ministry of Health and Social Services.