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NOTIFICATION

From the Ministry of Health:

NOTIFICATION ON THE PRINCIPLES AND PROCEDURES RELATED TO THE WARNING SYSTEM OF MEDICAL DEVICES

SECTION ONE

Objective, Scope, Legal Basis and Definitions

Objective

ARTICLE 1 – (1) The objective of this notification is to lay down the principles and procedures of the warning systems for the medical devices including the active implantable medical devices and in vitro medical diagnosis devices used directly or indirectly for the human health.

Scope

ARTICLE 2 – (1) This notification shall comprise the operations and procedures to be implemented by the manufacturer, authorized representative, importer, real or legal person responsible for the launch of the device in the market, applier / operator, user or the Ministry related to the principles and procedures related to the warning systems to be implemented on the adverse incidents occuring after the launch of the medical devices within the scope of the Regulation on Medical Devices, Active Implantable Medical Devices and In Vitro Medical Diagnosis Devices.

Legal Basis

ARTICLE 3 – (1) This notification has been prepared basing on the Law no. 4703, dated 29/6/2001, The Preparation and Implementation of Technical Legislation on the Products, article 17 of the Regulation on Medical Devices published in the Official Journal dated 9/1/2007 and with no 26398, article 15 of the Regulation on Active Implantable Medical Devices published in the official journal dated 9/1/2007 and with no 26398 and article 14 of the Regulation on In Vitro Medical Diagnosis Devices published in the official journal dated 9/1/2007 and with no 26398.

Definitions

ARTICLE 4 – (1) In addition to the definitions mentioned in the legislation stated in the article 3 of this notification,:

a) Ministry : the Ministry of Health,

b) Initial / Follow-up / Final report: The document whose format is present at the website of the Ministry and submitted to the Ministry about the corrective actions ensuring the safety of a device including the risk assessment reports and examination results carried out by the manufacturer, authorized representative, importer, real or legal person responsible for the launch of the device after an adverse incidents caused by the use of a device occurs,

c) Information letter: Information letter submitted to the users who are the parties of the adverse incident and the Ministry which includes the contact details of the related firm and prepared about the precautions to be taken against adverse incidents caused by the device or the users by the manufacturer, authorized representative, importer, real or legal person responsible for the launch of the device,

ç) Serious public health threat: Any condition resulting in death risk, serious deterioration in health or serious disease requiring urgent corrective actions,

d) Corrective action: All the actions and operations ensuring the prevention of undesired situations by the manufacturer, authorized representative, importer, real or legal person responsible for the launch of the device or the Ministry by halting the launch of the device to the market, withdrawing from the market, disposal, returning to the originated place not to use, making amendments in the design and / or production process and / or content of the product and / or label and users manual, changing the device causing the adverse incident with another device, preparing information letters about the usage of the device for the users, making additional changes on the device,

e) Law: The Law no 4703 on The Preparation and Implementation of the Technical Legislation related to the Products,

f) User: health institution, health personnel, nurse or patient using or maintaining the medical devices,

g) Adverse incident:

1) Any error or failure in the features and / or performance of the device,

2) Any situation that may cause the death or causing or may cause any serious deterioration in the health state of the patient, user or other people directly or indirectly due to any deficiency in the labelling or user guide,

ğ) any serious deterioration in the health state:

1) Any life- threatening illness

2) A persistent failure in the body functions or permanent damage in the body,

3) Observation of any situation that may require medical or operative interference to prevent the situation stated in sub-paragraphs (1) and (2),

4) Occurrence of a fatal distress syndrome, fatal death and / or congenital or birth defect,

h) Medical device (device): Device definitions included in the article 4 titled as "Definitions" of the Regulation on Medical Devices,

ı) Applier / Operator: Any person using the equipment,

i) Regulations: Regulation on the Medical Devices, Regulation on the Active Implantable Medical Devices and In Vitro Medical Diagnosis Devices to which the devices are subject depending on their spesifications,

j) Damage: Situations which have caused or may cause any deterioration in the health state, any physical injury or damage in the environment and external atmosphere that have not been foreseen previously.

SECTION TWO

Basic Principles, Responsibilities, Notification of the Adverse Incidents

Basic Principles

ARTICLE 5 – (1)The manufacturer establishes a system for the aim of reviewing the data obtained during the after manufacturing process and implementing the needed corrective actions by considering the usage of the device manufactured in accordance with the regulations, performance obtained from usage, undesired situations occuring during usage, side effects and risks and keeps this system up to date.

(2) When any data about any adverse incident related to the device is obtained, the situation is notified to the Ministry by the manufacturer, authorized representative, importer or the real or legal persons responsible for the launch of the device in the market and an investigation about the reason and termination of the incident is carried out. In the direction of the risk assessment to be performed, corrective actions for the usage of the product in a safe way are fulfilled. In the fulfilling of the corrective actions, there is a joint responsibility beginning from the manufacturer.

(3) The manufacturer keeps all the documents confidential in the content of the warning system to be submitted to the Ministry. The manufacturer, at the same time, informs the Approved Authority about the issues occured during the after production process and affecting the certification including the warning system.

(4) The manufacturer, authorized representative, importer, real or legal person responsible for the launch of the product in the market, health agency and institutions and the users inform the Ministry about;

a) any failure or defect about the features and / or performance of the device,

b) any situations causing or may cause any serious deterioration in the health state or may cause death of the patient, user or other people due to any deficiency in the labelling or user guide,

c) Decisions on withdrawing from the market or retrieving the devices due to technmical and medical terms depending on its specifications and performance by the manufacturer voluntarily.

Responsibilities of the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the device in the market

ARTICLE 6 – (1) The manufacturer, authorized representative, importer, real or legal people responsible for the launch of the product in the market are responsible jointly for,

a) Informing the Ministry about the adverse incidents having occurred in our country within the period stated in this notification,

b) Performing the needed investigation including the risk assessment in the direction of TS EN ISO 14971 Implementation of Risk Assessment Standard on Medical Devices related to the adverse incident, determining the main reason for the negative incident, submitting the justified risk assessment report, initial report, final report and follow-up report if required by the Ministry,

c) Determining the corrective actions to ensure the safety of the device and implementing them,

ç) Sending the information letter to the users and the Ministry,

d) Preparing separate initial report, final report and follow up report if demanded by the Ministry for each manufacturer in case of adverse incidents occuring as a result of usage of two or more devices or accesories manufactured by different manufacturers and submitting them to the Ministry,

e) Informing the Ministry immediately when any of this responsibilities under this notification is not obeyed,

f) Informing the Ministry about the reporting all damages directly or indirectly caused by the use of devices included in the content of the Regulation on In Vıtro Medical Diagnosis Devices.

(2) In case a model of the device is ceased or interrupted for launching in the market, all the rights of the manufacturer related to the warning system are reserved.

(3) In case there is a change in the commercial responsibilities or agreements of a manufacturer, all the responsibilities related to the warning system belonging to the previous legal person pass to the new legal person.

(4) The device having caused or may cause any adverse incident is sent to the manufacturer informing the Ministry without affecting the judicial investigation and questioning after the current situation is fixed with records. Changes on the device by the manufacturer and / or interferences affecting the performance are notified to the Ministry and the issues affecting the certification are notified to the Approved Agency.

Authority and Responsibilities of the Ministry

ARTICLE 7 – (1) The responsibilities and authorities of the Ministry are as follows:

a) Follows and assesses the reports belonging to the investigations realized by the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market about the adverse incident related to the device in question.

b) Monitors the actions of the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market in the content of the medical device warning system, may interfere in the investigation or can start an independent investigation and takes the needed precautions in this direction.

c) Reserving the sanctions stated in the Article 13 in the cases stated in the (e) paragraph of the first part of the Article 6, the Ministry ex officio determined the corrective actions to be implemented. The mentioned corrective action is implemented by the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market.

ç) The Ministry ensures the fulfilling of all the actions needed for the safe usage of the device in accordance with the Article 11 of the Law.

Responsibilities of the appliers / operators and users

ARTICLE 8 – (1) Responsibilities of the appliers / operators and users are as follows:

a) The appliers / operators and users are responsible for informing the ministry about the adverse incidents in the content of the warning system of the devices.

b) The health institution managers, health personnel, people responsible for the maintenance, repair and calibration of the device and other related personnel, the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market are responsible for cooperating with the Ministry.

c) The personnel of the health agency and institutions inform the personnel in their structures about the adverse incident and take the necessary precautions to fulfill their responsibilities under this notification.

ç) The health agency and institutions determines the personnel for tracking the operations related to the adverse incident and send the contact information to the Ministry in the electronic platform. Changes in the mentioned information are immediately notified to the Ministry.

d) In the content of the medical device warning system, when there is any adverse incident, the appliers / operators and users having witnessed the incident notifies the Ministry with a record. The model, brand, manufacturer and / or importer, serial / lot number of the device are sent.

e) The appliers / operators and users keep the devices causing or possible to cause any incident together or with the warehouse stocks. Without affecting the judicial

investigation and questionings, when required by the Ministry or by informing the Ministry, they are sent to the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market.

Principles related to the notification of the adverse incidents

ARTICLE 9 – (1) Issues to be notified to the Ministry includes the responsibilities related to the launch of the safe products stated in the law and the following issues.

a) Any defect, failure or unexpected affect and / or interaction in the performance and / or features of the device when used as stated in the user guide,

b) Obtaining false positive or false negative test result from the device,

c) Occurrence of an unexpected, unpredicted and / or adverse reaction or state not written on the label or user guide,

ç) Insufficient information on the label and / or user guide causing wrong or inappropriate usage by the users,

d) Error or failure of the device despite appropriately using resulting in public health threat, causing a serious deterioration in the health state of a patient or causing death of the patient or the user,

e) Features or reasons related to the performance causing the manufacturer collect the products in the market back,

f) When the current adverse incident causes the death of the patient, user or others or possible to cause death of them if re-occurred,

g) When the adverse incident occurs for the first time or re-occurs, causing serious deterioration in the state of the user or others,

ğ) Any damage caused by the false diagnosis or in vitro test result despite being used appropriately by the user.

(2) During the periods determined by the Ministry, the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market prepares the needed forms at the website of the Ministry and submits them to the Ministry.

(3) For the operations and procedures related to the warning system, the medical device electronic record notification system in the structure of the Ministry is taken as the basis. In case there is a change in the contact information of the firm int he electronic records, the needed updates are done by the firm within twenty days after the change. If the changes belonging to the branches and exporters and importers are not updated within the stated periods, the notifications to the addresses already recorded will be considered to have received by the related firm and related legal actions are implemented.

Issues not to be notified as negative incident

ARTICLE 10 – (1) The below stated reporting and notifications cannot be done in the content of the medical device warning systems:

a) When it is detected by the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market that the situation of the patient is caused by the previous actions and this is justified by an expert doctor,

b) When the shelf life or expiry date stated by the manufacturer in the guide is over,

c) When the device is used appropriately as stated in the guide and according to the stated aims, the adverse effects that are already stated in the guide or label of the device, well known, predictable clinically, and acceptable when the benefit of the patient is thought,

ç) Reserving the rights related to the inappropriate products are thought, insufficient features of the device detected by the user before usage.

Notification, reporting, risk analysis and corrective actions

ARTICLE 11 – (1) Reserving the terms in the regulation, the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market decides about the adverse incident after assessing the incident for the first time in the content of the criteria stated in the Article 9 and informs the Ministry. When the adverse incident is needed to be notified, the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market prepare the initial report and submit it to the Ministry not exceeding the below stated periods:

a) In case of a serious public threat, within two days immediately after the manufacturer is notified about the situation if there is a force majeure,

b) Immediately after the manufacturer is notified about the situation and detects the relation between the device and the incident,

c) Expecting the cases stated in (a) and (b) paragraphs;

1) within ten days in case of death or serious deterioration in the health state,

2) within thirty days in other cases,

(2) Following the presentation of an initial report by the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market in the report format and investigation schedule an investigation to determine the reason of the adverse incident is started and risk assessment is performed.

(3) In the process of risk assessment related to the adverse incident and deciding about the corrective action, the below conditions are taken into consideration:

a) Main requirements included in the regulation,

b) Requirements of TS EN ISO 14971 Standard on Risk Management Implementation on Medical Devices.

(4) The manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market submits a follow up report if required by the Ministry. In this report, the phase of the investigation report, need for additional time or not and other issues required are stated with reasons.

(5) The manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market determines the corrective actions basing on the TS EN ISO 14971 Standard on Risk Management Implementation on Medical Devices and the results of the investigations. In the final report, there shall be;

a) Insufficiency or defect of the device,

b) Function failures,

c) In case the device causing the adverse incident is continued to be used, the details about its possible harms to the patients, users and other people,

ç) Risk assessment and investigation results including the potential risks for the patients of the device causing the adverse effect in question,

d) Reasons for the devices not affected with other serial / lot / party numbers,

e) Corrective actions to be applied to the devices in the affected serial / lot / party number, submitted to the Ministry.

(6) The manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market notifies the users and the Ministry about the corrective actions and recommendations.

Protection of the information and documents

ARTICLE 12 – (1) Related to the situations stated in the Article 9 and 11, the manufacturer, authorized representative, importer or real or legal people responsible for the launch of the product in the market shall keep the preventive and corrective actions for the safe operation of the device in terms of risk management, design correction to be submitted to the approved agency and / or to the Ministry.

Administrative Sanctions

ARTICLE 13 – (1) For the ones not obeying the terms of this notification, the sanctions stated in the Law and regulations and the terms of other regulations will be applied.

SECTION THREE

Last Terms

Enforcement

ARTICLE 14 – (1) This notification enforce by the date of its publication.

Execution

ARTICLE 15 – (1) The provisions of this Notification shall be executed by the Ministry of Health.