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Translation of Council of Ministers' Resolution No. (377) dated 04/07/1442 AH

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After reviewing the decision received from the Royal Court No. 30388 dated 03/06/1442 AH including the telegram of His Excellency/ Chairman of the Board of Directors of the General Authority for Food and Drug No. 1439-1685230 dated 13/10/1439 AH concerning the medical devices and supplies system project.

After reviewing the aforementioned draft system.

After reviewing the minute No. (637) dated 10/5/1441 AH, memos No. (848) dated 22/10/1441 AH, No. (1088) dated 29/11/1441 AH, No. (548) dated 04/04/1442 AH prepared in the Council of Experts in the Council of Ministers.

After reviewing the recommendation prepared by the Council of Economic and Development Affairs No. (D/42/16-16) dated 18/04/1442 AH.

After reviewing the decisions of Shura Council No (57/330) dated 11/02/1442 AH, No. 14/69) dated 28/05/1442 AH.

After reviewing the recommendation of the General Committee of the Council of Ministers No. 4240 dated 26/06/1442 AH, the following decisions were issued:

First: approval of the Medical Devices and Supplies Regulation, as attached and the draft royal decree has been prepared for this, the wording of which is attached to this.

Second: The Saudi Food and Drug Authority monitors the commitment of the health care provider to implement technical and clinical standards for radioactive medical materials within health care facilities and, refers any violations that appear to the Nuclear and Radiation Control Authority by virtue of its jurisdiction.

Prime Minister

Medical Devices and Supplies Regulation

Article 1:

The following words and definitions, whenever stated, have the meaning indicated before each of them, unless the context requires otherwise.

Regulation: Medical Devices and Supplies Regulation.

Authority: The Saudi Food and Drug Authority.

Council: Board of Directors.

Chairman: The Chief Executive Officer of the Authority.

Rule: The executive rule of the Regulation.

Medical Device: any instrument, apparatus, implement, machine, appliance, implan in vitro reagent or calibrator, software, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human being for diagnosis, prevention, monitoring, treatment or alleviation of disease, alleviatio of or compensation for an injury or handicap, investigation, replacemen modification, or support of the anatomy or of a physiological process, supporting o sustaining life (vital functions of a human being), control of conception, disinfectio of medical devices, providing information for medical or diagnostic purposes b means of in vitro examination of specimens derived from the human body; and whic does not achieve its primary intended action in or on the human body b pharmacological, immunological or metabolic means, but which may be assisted i its intended function by such means.

Medical Supply: medical materials and products, used in diagnosis, treatmen replacement, orthodontics, disabilities, or other medical uses for human being including medicinal gases.

Medical Device Accessory: a product or material intended specifically by its manufacturer to be used together with a medical device to enable that medical device to achieve its intended purpose.

Innovative medical device/supply: Medical devices and supplies with an innovative idea in technology, use or performance and has not previously been placed in the market, locally and overseas.

Assembled medical devices and supplies: what is assembled in one kit to meet the user requirements. Also, it may contain non-medical devices and supplies.

Single-use medical device and supply: what is made to be used during medical procedures on a single patient and then disposed of.

Radioactive medical materials: a substance from which ionizing radiation is released, either alone or within other medical devices and supplies, which is used for diagnosis and treatment.

Fraudulent medical devices and supplies: it refers to devices or supplies that its identity or its source is deliberately changed for the purpose of fraud. The device and the medical supply are considered fraudulent if its content changes in a way that adversely affects its safety or if it is packed in counterfeit packages.

Reprocessing: procedures performed on a previously used medical device for safe re-use, including: cleaning, disinfection, sterilization, testing and restoring its technical and safety functions.

User: who uses the medical device and supplies, whether a professional, layperson or a patient.

Establishment: a statutory entity engaged in an activity related to medical devices and supplies.

Manufacturer: Any national or foreign establishment that one of its purposes is to design and manufacture medical devices and supplies to be released for use under its name, whether inside or outside the Kingdom. The manufacturing process includes refurbishing, assembling, packaging, and labelling.

Health care provider: Any governmental or private establishment that provides health care services.

Authorized representative: means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer inside the kingdom. Trading of medical devices and supplies: It is provided free of charge or for a cost, whether for distribution or use.

License: A document issued by the Authority to carry out any of the activities subject to the Regulation.

National Registry: The National Registry of Medical Facilities and Medical devices and supplies with the Authority.

Registration: a procedure for recording medical devices, supplies and establishments that practice any of the activities subject to the Regulation in the National Registry.

Marketing Authorization: A document issued by the Authority for any medical device or supply to be allowed for trading in the market.

Free Sales Certificate: A document issued by the Authority stating that the manufacturer is registered in the Kingdom and that the medical devices and supplies to be exported have marketing authorization.

Verification of clinical studies: an applied research in which a medical device or supply is used on human being or more to evaluate its safety and adequacy when in use.

Classification system: a system adopted by the Authority that evaluates the level of risk associated with a medical device or supply, and evaluates its safety.

Quality Management System: a system adopted by the Authority to verify the quality, effectiveness and safety of the medical device in accordance with latest version of the technical standard (ISO 13485) or equivalent, according to what is indicated by the rules.

Quality Assurance: a group of tests, measurements and technical calibrations adopted by the Authority, to verify the safety, accuracy and quality of medical imaging devices, to ensure the effectiveness and adequacy of diagnosis and treatment.

Technical Regulations: mandatory documents issued by the Authority related to medical devices and supplies that specify safety, performance and manufacturing principles and instructions regulating this, including: terminology, symbols, packaging, and identification information requirements.

Standard: Non-mandatory documents adopted by the Authority containing rules, guidelines, characteristics of medical devices and supplies or associated production processes and methods, including: Terminology, symbols, packaging, and identifying information requirements.

Identification information: Any statement or information drawn or illustrated in written or printed on the medical device and supply, including information on its definition, technical description, how to use, storage and transport methods.

Technical and clinical standards: A set of standards that determine the quality, effectiveness and safety of using radioactive material in medical applications.

Field Safety Notice: A notice issued by the NCMDR explaining the risk associated with a medical device or supply and the corrective actions required to avoid the associated danger.

Field Safety Corrective Action: an action taken by the manufacturer to reduce the risks that affect the safety of the medical devices and supplies.

Adverse Event of Medical Devices and Supplies: Any deficiency or change in the characteristics or performance of the medical device and supply that may cause or contribute directly or indirectly to the death or serious injury of the user.

NCMDR: National Center for Medical Devices Reporting

Article 2:

The following activities shall be subject to the provisions of the Regulations:

1. Design and manufacture of medical devices and supplies.
2. Importing, marketing, distributing and storing medical devices and supplies.
3. Provide conformity assessment services for medical devices and supplies compliance to the technical regulations, quality management system, and verification of quality assurance.

4. Verification of clinical studies.
5. Provide technical consultation services in the field of medical devices and supplies.
6. Provide medical devices and supplies inspection services to ensure their compliance with technical regulations and standards.
7. Provide maintenance services for medical devices and supplies.
8. Represent overseas manufacturer.

Article 3:

They are considered as medical devices and supplies subject to the provisions of the law: their accessories, and assembled medical devices and supplies.

Article 4:

Considering terms of reference of the Nuclear and Radiological Regulatory Commission to issue the necessary licenses to practice the activities related to the use of radioactive medical materials. The approval of the Authority is required for the technical and clinical standards of these materials before they are licensed by the Nuclear and Radiological Regulatory Commission.

Article 5:

Application of the Regulation's provisions shall not prejudice the authority of Nuclear and Radiological Regulatory Commission to issue the license for protecting against ionizing radiation omitted from medical devices.

Article 6:

With regard to the provisions of Article 4, no establishment is allowed to carry out any of the activities subject to the Regulation, before registering and obtaining the license, in addition to obtaining the industrial license from the competent authority with regard to the manufacturers.

Article 7:

The licensee to carry out the verification of clinical studies must obtain the Authority approval before starting any verification processes, as specified by the rule.

Article 8:

No medical device or supplies is allowed to for trading before registration, and obtaining marketing authorization. The Authority may exempt some medical devices and supplies from the requirement to obtain marketing authorization, after ensuring their safety and not using them for commercial purposes in accordance with the rules approved by the Council.

Article 9:

The authority may exclude the innovative medical device or supply from some of the conditions and procedures required to obtain marketing authorization in a manner that does not affect its safety when it used, in accordance with the rules.

Article 10:

The rules specify the necessary conditions and procedures for the registration process, issuing marketing authorization, obtaining, renewing, updating, transferring, and terminating the license.

Article 11:

Clearance of imported medical devices and supplies is not allowed before obtaining the Authority approval.

Article 12:

The rule specifies the necessary requirements for issuing a Free Sales Certificate.

Article 13:

The Authority may allow the entry of medical devices and supplies for personal use according to a medical report and in limited quantities, noting that it shall not be used for any commercial purpose.

Article 14:

Anyone who prescribed or sold a defrauded, unregistered or non-authorized medical device shall report to the Authority as soon as he becomes aware of the information related to what was prescribed or sold and its quantity, name and address of the party to whom the medical devices and supplies was sold or prescribed, and the purchasing price to be refunded to the buyer.

Article 15:

With regard to provisions stated in the Law of Commercial Agencies; overseas manufacturer, upon desire to trade its products in the Kingdom, appoints an authorized representative for it. The rule shall specify the conditions to be met by the authorized representative, as well as the obligations and responsibilities of the two parties.

Article 16:

The manufacturer shall provide after-sales services for its medical devices and supplies, applying the provisions stipulated in the Regulation and the rule.

Article 17:

All establishments shall adhere to the identification information to be available on the medical devices and supplies, and the rule specifying this information.

Article 18:

The health care provider shall not deal with any establishment engaged in any of the activities subject to the Regulation unless it is registered and licensed by the Authority in the same field of activity.

Article 19:

Single-use medical devices and supplies may not be reprocessed.

Article 20:

Used medical devices and supplies may not be destroyed, reprocessed, refurbished, resold, loaned, or donated; unless as per the conditions specified by the rule.

Article 21:

The manufacturer shall classify medical devices and supplies according to the classification system.

Article 22:

Establishments wishing to trade in medical devices and supplies in the Kingdom must adhere to implementing the quality management system.

Article 23:

In accordance with the classification system, high-risk medical devices and supplies may not be used outside the health-care provider's facility without prescription. The Authority issues a list of such devices and medical supplies.

Article 24:

It is not allowed to advertisement or promote medical devices and supplies without the approval of the Authority and in accordance with the conditions specified by the rule.

Article 25:

It is not allowed to conduct awareness campaigns or charitable campaigns, related to medical devices and supplies, unless after obtaining approval from the Authority and in accordance with the conditions specified by the rule.

Article 26:

The Authority monitors the commitment of health care providers in implementing the technical regulations within health care facilities, so as to ensure the safety, adequacy of medical devices and supplies in diagnosis and treatment.

Article 27:

The establishment and the authorized representative shall provide to the Authority with every document or information that it requires to carry out its functions stipulated in the Regulation and the rule.

Article 28:

The manufacturer, authorized representative, and the healthcare provider are obligated to report adverse events related to their medical devices and supplies to the NCMDR.

Article 29:

The NCMDR issues a Field Safety Notice to alert the user and the health-care provider of the risks arising from the use of medical devices and supplies.

Article 30:

The manufacturer and the authorized representative are obligated to inform the NCMDR in relating to their medical devices and supplies of the following:

1. Field Safety Notice issued by similar regulatory authorities outside the Kingdom.
2. Risks affecting the safety of the medical devices and supplies.
3. Completion of the corrective action for the field safety notice alert.

Article 31:

In the event of a field safety notice, the establishment and the health-care provider must suspend the trading of medical devices and supplies, until a notification from the NCMDR is issued for completing the corrective action plan of the field safety notice.

Article 32:

The establishment and the authorized representative shall respond to the Authority's request for tracing the medical devices and supplies, the rule determines the procedures related to this.

Article 33:

The Authority inspects the establishments, medical devices and supplies so as to ensure the implementation of provisions of the law, rules and technical regulations, through inspectors, who are considered criminal investigation officers assigned by a decision of the President of the Council, and

they shall have the following:

1. Collecting medical devices and supplies that violate the provisions of the Regulations.
2. Handling violating collections as following:
   a) Reserving it and related documents, when required.
   b) Collect samples for analysis
   c) Recommendation to destroy fraud devices or what causing harm. The destruction shall take place after a decision is issued by the Authority, in accordance with the generally accepted technical assets. A committee or more formed for this purpose by a decision of the council chairman shall execute the destruction process and the violator shall bear the destruction costs

Article 34:

Anyone, who is subject to the provisions of the Regulations, shall keep the confidentiality of information which may be obtained by virtue of his or her mission.

Article 35:

The inspector shall provide his job ID card when performing inspection and seizure duties. The establishment shall enable him to perform his work, and not hinder him from performing it.

Article 36:

According to president decision, the Authority inspectors may be granted financial rewards for performed work.

Article 37:

According to president decision, an incentive bonus not exceeding (25%) of the amount of the due fine may be granted to assistants other than Authority's inspectors in detecting a violation of the provisions of the Regulations and rule.

Article 38:

The Authority shall, in agreement with the Ministry of Finance, set the regulations governing the awarding of the bonuses referred to in Articles 36 and 37 of the Regulation.

Article 39:

The Authority may take the necessary precautionary measures in the events that it believes there is a damage, misleading claim, or an impact on the safety, and adequacy of medical devices and supplies, as specified by the rule.

Article 40:

Medical devices and supplies may not be traded if the Authority decides to withdraw them from the market or prohibit their trading.

Article 41:

The following shall be considered a violation:

1. Participated in or attempted to fraud any medical devices or supplies.
2. Sold, prescribed, or possessed for the purpose of trading fraudulent medical devices and supplies, with the knowledge of this.
3. Enter into the Kingdom an unregistered, defrauded or non-authorized medical device or supply, or attempt to enter any of this.
4. Manufacture a medical device or supplies in violation of any of the provisions of the Regulations, rule and technical regulations.
5. Use false information to promote medical devices, either attached to the device or to advertise for it.
6. Transfer or store a medical device or supply in violation of the conditions of transportation and storage specified by the Authority.

7. Enter or try to enter packages or covers of a medical device or supply with the intent of fraud.
8. Manufacture, print, possess, sold, or displayed packages or covers of a medical device or supply with the intention of fraud.
9. Commits any other violation of the provisions of the Regulation.

Article 42:

1. Whoever commits any violation of the provisions of the Law or the Regulations shall be punished by one or more of the following penalties, without prejudice to any more severe penalty stipulated in any other law:
   a. A fine not exceeding (five million riyals).
   b. Temporarily close the establishment for a period not exceeding (one hundred and eighty days).
   c. Suspending the Marketing Authorization of the medical devices and supplies subject of the violation, for a period not exceeding one year.
   d. Terminate Marketing Authorization of the medical devices and supplies, subject of the violation.
   e. Suspend violator from practicing any activity related to medical devices and supplies, for a period not exceeding (one hundred and eighty days).
   f. Terminate the license.

In case of repeating violation, the imposed penalty may be doubled in accordance with sub-paragraphs (a), (b), (c) and (e), and the violation shall be considered repeated if it is committed within a year from the date of the first violation.

2. If the violation represented in committing any of the acts stipulated in paragraphs (1), (2), (3), (7), and (8) of Article 41, then the penalty shall be imprisonment for a period not exceeding (ten years) or a fine not exceeding (ten million riyals), or both penalties. In addition, any of the penalties stipulated in subparagraphs (b), (c), (d), (e) and (f) of paragraph (1) of this article may be applied, and the penalty will be doubled in the event of recurrence.

Article 43:

The Authority is entitled to impose the penalties stipulated in Paragraph (1) of Article 42, according to a schedule issued by the Board which include a classification of the violations and the specific penalties considering the activity nature and the violation committed, and its prominence in each case separately, as well as the aggravating and mitigating conditions.

Such penalties shall be approved by a decision of the President or whoever he delegates. In all cases, the Authority may, when necessary, take such precautionary measures as it deems necessary.

Article 44:

1. A committee (or more) shall be formed by a decision of the Board, provided that the number of its members is not less than (three), one of whom is at least a regulatory consultant, so as to consider the grievances submitted to the Authority against the sanctions decisions issued in accordance with Paragraph (1) of Article 42.
2. The rules and procedures for the work of the committee and the remuneration of its members shall be determined by a decision of the Board.
3. The committee's decisions may be objected before the administrative court.

Article 45:

If the violation included in paragraph (2) of Article 42, it shall refer to the Public Prosecution Office for investigation, and for referral to the competent court for statutory procedures.

Article 46:

The sentence may be included, as the case may be, upon stipulating the publication of his statement at the expense of the violator in a local newspaper published in his residency. In case of absence of local newspaper in his residency, it shall be published using any other appropriate means, according to the type of violation committed, its severity and its impact, provided that the publication is performed after the judgment has acquired the final status, or the decision missed the deadline for grievance, or a final judgment was issued rejecting the grievance.

Article 47:

Any person affected by any violation of the Regulation has the right to claim compensation before the competent court for damages caused by that violation.

Article 48:

The council shall issue the rule within (one hundred and eighty days) from the date of publication of the Regulation in the official gazette, and it shall be in application from the date of its entry into force.

Article 49:

The Regulation shall be enforceable one hundred and eighty days after the date of its publication in the official gazette.