Article Content

Title： Enforcement Rules of Medical Devices Act CH

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Category： Ministry of Health and Welfare（衛生福利部）

Article 1 The Enforcement Rules are stipulated in accordance with Article 84 of Medical Devices Act (hereinafter referred to as the Act).

Article 2 Under any of the following circumstances, the material is not considered to be medical device advertisements governed by Article 6 of the Act.
1. The material only lists the product name, price, discount, specifications, material, image of the appearance of the product, and the name and address or telephone of the firms, and does not publicize the therapeutic effect of a product.
2. The material is used to make announcement for a special incident and does not publicize the therapeutic effect of a product.
3. The material is used to differentiate an authentic and a fake medical device and does not publicize the therapeutic effect of a product.
4. The material provides complete information of labels and instructions approved in accordance with the Act and does not contain any content mentioned in the preceding three Subparagraphs or any content that aims to solicit sale.
5. Health education material.

Article 3 The so-called health education material referred to in Subparagraph 5 of the preceding Article shall meet one of the following conditions:
1. The material is used to promote health or prevent illness and does not promote a specific medical device.
2. The material is provided to medical professionals for health education of patients or specific target audience and the content only describes the disease, perioperative care, a specific medical device, information about follow-up appointment or attentions and it does not contain any contact information of any medical device firm.

Article 4 Under any of the following circumstances, health education materials referred to in Subparagraph 5 of Article 2 will be considered as medical device advertisements:
1. The material is printed on the same page or a continuous layout of a print advertisement of medical device(s).
2. The material is broadcasted with a dynamic medical device advertisement.
3. The performers or endorsers of the health education material are the same persons in a medical device advertisement and

consumers may be misled to believe that the health education material is an advertisement.

Article 5 The so-called “foreign objects that affect product quality are mixed or packed" with medical devices referred to in Subparagraph 6 of Article 8 of the Act refers to substance that may affect the quality is mixed or packed with medical devices in the complete packaging of the product.

Article 6 Terms used in Subparagraph 1 of Article 10 of the Act shall have the following meanings:
1. Manufacturing: refers to the physical or chemical process(es) through which materials, substances or components are transformed into medical devices. Completion of packaging, labeling or sterilization are not considered necessary steps of manufacturing.
2. Packaging: refers to the operation added onto the main unit of the medical device to maintain the value and status of a medical device. Subpackaging is included in the operation.
3. Labeling: refers to the operation of adding the label(s) of a medical device onto the smallest packaging unit for sale of the medical device or the main unit of the medical device.
4. Final inspection and release: refers to the operation to verify that the final medical device product matches the originally designed safety, therapeutic effect and quality and so the medical device can be released.

Article 7 The so-called “repair” referred to in Article 11 of the Act refers to the operation of removing malfunctioning, damaged or defective parts from the medical device and restoring the medical device to good condition or restore the function, or dissembling a medical device for inspection. But the following situations are excluded:
1. Cleaning of a dirty product.
2. Conducting function test of a product, checking related components, replacing consumables according to the instruction manual or conducting other autonomous maintenance work.
3. Replacing defective medical device.
4. Calibration of a product.

Article 8 Items required for approval and registration of a medical device firm referred to in Paragraph 2 of Article 13 of the Act are as follows:
1. Type of medical device firm.
2. Name of the medical device firm.
3. Business address of the medical device firm and the warehouse address of the medical device dealer.
4. Name and national identification card number or number of the identification document of the responsible person.
5. Business items.
6. For manufacturer or dealer engaging in the import or repair of medical device, as defined in Article 15 of the Act, name and national identification card number or number of the identification document of the medical device technician.

7. Operating status.
8. For specific medical devices included in the categories and items with restriction on their sale or supply type announced by the central competent authority in accordance with the provisions of Article 18 of the Act, the announcement will stipulate particulars required for registration.
9. Other particulars that shall be indicated, as announced by the central competent authority.

Article 9

According to the provisions of Paragraph 2 of Article 13 of the Act, any business with the intent to become a medical device firm shall file an application with the municipal or county/city competent authority for approval and registration and shall submit the following documents and information, and pay the license fees:
1. For firms that shall employ qualified technicians, documents proving the employment relationship between the firm and the employee as well as certificate(s) of the employee shall be submitted.
2. For a medical device firm organized as a company, photocopies of the company registration and articles of incorporation shall be submitted; for a medical device firm organized as business, photocopies of the business registration shall be submitted.
3. For institutions, schools, legal entities or organizations that are not companies or business, the consent letter of the competent authority in charge of the target business shall be submitted.
4. For medical device dealers, the firm’s business address, and a basic floor plan showing the premises and warehouse storing medical devices and principal equipment shall be submitted.
5. For medical device manufacturers that manufacture medical devices in accordance with the provisions of Subparagraph 1 of Article 10 of the Act, photocopies of the factory registration documents shall be submitted. However, firms that are exempt from factory registration under the Factory Management Act do not need to submit such documents.
6. Other documents and information designated by the municipal or city/county competent authority.
For a newly established firm organized as a company or a business, as referred to in Subparagraph 2 of the preceding Paragraph, the municipal or city/county competent authority shall first issue establishment permit documents to the firm, so the firm can complete the procedures to obtain its corporate registration, business registration or factory registration with the establishment permit documents. After the firm has obtained proof documents, the competent authority can then issue a medical device business permit to the firm.

Article 10

When the municipal or city/county competent authority issue a medical device business permit to a firm, the provisions of Articles 9 through 11 of the Act shall be followed with respect to which type of medical device firm and business items to be stated in the business permit.

Article 11 A medical device business permit shall be hung at a conspicuous location at its place of business.

Article 12 Medical device firms who have applied for registration and obtained pharmaceutical firm's licenses in accordance with the provisions of Paragraph 1 of Article 27 of the Pharmaceutical Affairs Act before enforcement of the Act do not need to reapply for medical device business permit after the enforcement of the Act. In case that there are any change made in the particulars registered, the firm shall apply for change of registration in accordance with the provisions of Paragraph 2 of Article 13 of the Act for re-issuance of medical device business permit.

Article 13 For changes related to “items required for approval and registration” referred to in Article 8, medical device firms shall apply for such changes within 30 days from the date of occurrence of a change in accordance with Paragraph 2 of Article 13 of the Act.

Article 14 To carry out changes related to “items required for approval and registration” referred to in the preceding Article, the firm shall submit the application for change with the competent authority that originally approved its registration.
However, if the aforementioned change is not for change of business address, but pertaining to change of company organization or business registration, the firm shall first apply for change of registration with the relevant competent authority for commercial matters.

Article 15 Medical device dealers engaging in import that need to employ qualified technicians in accordance with the provisions of Paragraph 1 of Article 15 of the Act shall include the medical device the license holders, those who have completed the listing, and their authorized persons.

Article 16 Medical device firms that transfer from the original place to another municipal city, or county/city shall apply for dissolution; however, the firm does not need to hand in its medical device license for cancellation.

Article 17 The so-called data referred to in Article 31 of the Act refers to documents and information that medical device firms need to submit to complete registration and market approval or listing in accordance with the provisions of regulations governing issuance of medical device license, listing and annual declaration.
The methods to make the aforementioned data available to the public are as follows:
1. Publish the information in the Government Gazette or other government publications.
2. Publish the information through government telecommunications network or on government websites.
3. Other methods that allow the information to be made available to the public.

Article 18 The so-called "smallest packaging unit for sale" referred to in Article 32 of the Act refers to the packaging sold directly to consumers or medical institutions.

Article 19 In accordance with Article 33 of the Act, the content and publishing methods of labels, instructions, or packaging of medical devices shall meet the following rules:
1. For domestically manufactured medical devices, the labels shall be primarily in traditional Chinese and any appended text in a foreign language shall be smaller than the Chinese. However, this does not apply to medical devices that are approved to be manufactured for export only.
2. On the smallest packaging unit for sale, the name of the product, license number or listing number, name and address of the license holder or the person who completed the listing shall be in traditional Chinese. Manufacturing date, period of validity or expiration date shall be stated in an identifiable way.

Article 20 For medical device firms that need to report in accordance with the provisions of Paragraph 4 of Article 34 of the Act, the content of the report shall include:
1. Name of the medical device firm.
2. Contact person for the report.
3. Name of the medical device.
4. License number or listing number.
5. Model number of the product.
6. Date when the firm is aware that it is incapable to continue with the manufacture, import, or sufficiently supply the medical device.
7. Reasons for the shortage in supply.
8. Inventory quantity.
9. Estimated time of available supply.
10. Other information designated by the central competent authority.

Article 21 Medical device license holder or the person who completed the listing shall submit the following document and information when they apply to publish or broadcast a medical device advertisement in accordance with the provisions of Paragraph 1 of Article 41 of the Act:
1. The application form for approval of medical device advertisements.
2. Photocopies of instructions and labels for approval: For Class 1 medical devices, photocopies of instructions, labels or packaging for the product can be used with an affidavit stating the authenticity of the content.
3. For advertisement that promotes product features that are not related to therapeutic effect, the documentary proof.
4. Other documents and information designated by the central competent authority.

Article 22 The content of medical device advertisement approved to be broadcasted or published in accordance with Article 41 of the

Act shall include the following items:
1. Product name on the license or listing.
2. Name of the license holder or the person who completed the listing.
3. Medical device license or listing number.
4. Number of the medical device advertisement approval document.
When the content of a medical device advertisement involves therapeutic effect, instructions, precautions, labels, package inserts, packaging or address of the firm, such content shall be limited to approved content on the registration and market approval or listing.

Article 23 If any of the following situations applies to the content of a medical device advertisement applying to broadcast or publish in accordance with Article 41 of the Act, the application shall be disapproved:
1. The content is identified as false, exaggerated, or misleading.
2. The content fails to use fair, objective and appropriate basis for comparison to compare its effectiveness or therapeutic effect with other products.
3. The content violates other laws and regulations.

Article 24 In accordance with the provisions of Article 43 of the Act, those who wish to apply to extend the validity period for their medical device advertisement approval documents shall file an application for extension and a checklist with the original approving authority.

Article 25 In the event that a medical device may cause harm to the health of human body, the medical device license holders or those who completed the listing, according to the provisions of Paragraph 1 of Article 49 of the Act, shall use the electronic system designated by the central competent authority to report within 7 days after the day of discovery; when necessary, such report can be done in writing, through e-mail, facsimile or telephone.
The aforementioned report shall include:
1. Name and contact information of the medical device license holder or the person who completed the listing.
2. Medical device license number or listing number; model number, batch or serial number, total quantity sold domestically and inventory.
3. Claims and reasons that the medical device has caused or may cause harm to the health of human body.
4. The content of corrective and preventive measures and the dates to undertake and complete the measures.
5. Other information designated by the central competent authority.
If the firm has not yet taken any corrective and preventive measures at the time of reporting in according to the preceding two Subparagraphs, the firm shall undertake corrective and preventive measures within a reasonable period or within a given time period designated by the competent authority.
Upon undertaking the corrective and preventive measures, the

medical device license holder or the person who completed the listing shall prepare a report on the result of corrective and preventive measures and such report shall be kept on file for future reference. The report shall include the following items:
1. Confirmation of whether or not the harm or potential harm exists; if the harm or potential does exist, the reasons for the harm.
2. Corrective and preventive measure undertaken, the implementation period and the outcomes.
3. The date and method to publish advisory contents and target audience of advisory contents.

Article 26 An informant may report violations to the competent authority by means of written communications, oral communications, emails or other methods. The report shall include the following information:
1. The informant’s name, national identification number or number of the identification document, contact information and address.
2. The violator’s name and address, or in case of a business, the name and address of the company or business as well as the representative’s name.
3. The specifics of the violation, including the acts of violation, location, relevant information or any leads that may help the investigation.
If the informant is not able to verify the information specified in Subparagraphs 2 and 3, the informant may leave it out of the report.
The government agency that receives a violation report through oral communication shall produce a written record and confirm the specifics of the report with the informant.
If the agency that receives the report does not have jurisdiction over the matters of violation, the agency shall identify the appropriate jurisdictional authority, forward the report within seven days of the identification and notify the informant of the case transfer.

Article 27 The competent authority shall respond to the violation report as described in the preceding Article with thoroughness and timeliness, and notify the informant of the progress of the response within thirty days beginning from the day of receiving the report.

Article 28 When a violation report helps the government discover defective medical devices, or firms manufacturing or importing medical devices without license or listing, as stipulated in Article 59 of the Act, a reward may be issued by the municipal or county/city competent authority according to the violation based on the point system below:
1. Reports of the manufacture or import of medical devices without license or listing: 4 points to 10 points.
2. Reports of the wholesale resale or transfer of medical devices manufactured or imported without license or listing: 2 to 5 points.

3. Reports of anyone sells, supplies, transports, stores, engaging in brokerage of, or display with intent to sell medical devices manufactured or imported without license or listing: 2 to 3 points.
4. Reports of the manufacture, import or sale of defective medical devices: 2 to 3 points.
The monetary amount correlated with each point will be determined by the municipal or county/city competent authority as it deems appropriate under the circumstances, and it shall also make budgetary allocations for that purpose.

Article 29 In the event that the case of reported acts of violation receives a verdict of not guilty, or the administrative sanction order is nullified or revoked for reasons not related to the validity of the report, the competent authority may not ask to recover the monetary reward already paid to the informant according to the preceding Article.

Article 30 Reports of following circumstance are not granted with reward:
1. Anonymous information.
2. The report is made with a forged name or identification or the report is false.
3. No factual statement.
4. The competent authority or other government agencies are already aware of the violation before receiving the report.

Article 31 When a violation report referred to in Article 28 is jointly made with two or more people, all informants receive the reward. If two or more persons separately report a case and the particulars of the case are the same, the reward shall be issued to the first person to make the report; if the order of reporting cannot be determined, the reward shall be divided equally among the persons who made reports.

Article 32 The competent authority shall keep the information regarding an informant’s name, age, address, written communications, drawings, information, appearance, identification and any other identifiable characteristics confidential. People who engage in acts of disclosing such information are subject to punishment or disciplinary actions under the Personal Data Protection Act, the Criminal Code or other applicable laws and regulations.
The violation reports, written records and other information provided by an informant shall be stored as classified documents. Third parties are prohibited from access or copy of the record.

Article 33 The competent authorities that accept violation reports may request the help of the local police to ensure the personal safety of an informant when necessary.
When an informant is exposed to threats, intimidation and other dangers due to making the violation report, the competent authorities shall request the aid of the police to resolve the situation according to the laws.

Article 34 The present Enforcement Rules shall be implemented on May 1st, 2021.