IYAKUKIHATSU 0130 1Go
January 202030 days

Directors of health departments (bureaus) of each prefecture

Director, MD Examination and Licensing Division,
Pharmaceutical and Medical Products Bureau, MHAW
(public mark Ministryomitted)

Complete revision of "Procedures for changing raw materials for medical devices"

For procedures when changing raw materials for medical devices, see "Changing Raw Materials for Medical Devices"The Act on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (Act No. 145 of 1960; hereinafter referred to as the "Act") has been revised as follows: (Notification No. 0329-7 of the Director of the Medical Devices Evaluation and Licensing Office, Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated March 29, 2013, regarding the change procedures)
The scope of minor change notifications pursuant to Article 23-2-5, Paragraphs 13 and 14 of the same Act is set out in Article 114-25 of the Enforcement Regulations of the Act on Ensuring Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, etc. (Ministry of Health and Welfare Ordinance No. 1 of 1961). However, regarding the procedures for changes to raw materials of medical devices within the scope of minor change notifications (the scope of minor change notifications) that are not considered to affect the quality, efficacy and safety of the product and do not require approval from the Minister of Health, Labour and Welfare under Article 23-2-5, Paragraph 13 of the Act, as set out in Article 114-25, Paragraph 1, Item 3 of the same Act,In order to clarify the contents of the previous raw material change notification, we have organized it as follows, so please inform the relevant organizations and businesses in your jurisdiction. In addition, with the issuance of this notification, the previous raw material change notification and the Q&A collection for the notification, "Q&A Collection Regarding Procedures for Changing Raw Materials for Medical Devices (Q&A)" (published by the Pharmaceutical and Food Safety Agency on May 29, 2013) have been published.
Notification No. 4 of 2005-29 from the Director of the Medical Device Review Office, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare) will be abolished.
In addition, copies of this notice will be submitted to the President of the Pharmaceuticals and Medical Devices Agency,We would like to inform you that the letter will be sent to the Chairman of the Japan Federation of Medical Devices Associations, the Chairman of the American Medical Device & IVD Manufacturers Association, the Chairman of the Medical Device & IVD Committee of the European Business Council, and the Representative Director of the Japan Association of Registered Certification Bodies under the Pharmaceutical and Medical Device Act.

Note

1. Raw materials covered by this notification

"Points to note when preparing an application for approval to manufacture and sell medical devices"(Notification No. 1120-1 of the Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated November 20, 2014) and "Medical Devices

"Points to note when preparing a manufacturing and sales certification application for(2014

Among the ingredients listed in "5. Ingredients" of Notification No. 1120-4 of the Pharmaceutical and Food Safety Agency dated November 20, 2019, this notification applies to ingredients that come into direct or indirect contact with living organisms.

However, the raw materials listed below should be handled with even greater care, and therefore this notification will be limited to cases where it is clear that the risk of changing the raw materials is low. For example, in accordance with "4. Considerations regarding previous examples of raw material use" below, if it can be confirmed that the risk of changing the raw materials is low even for those that fall under the following categories by utilizing previous approvals or certifications both domestically and internationally, or by utilizing sufficient clinical use records, then they may be subject to this notification.

This notice applies only to low-risk ingredients:

- Raw materials for the implantable parts of implantable medical devices
- Raw materials for components/parts whose duration of contact with the body is classified as "long-term contact"
- Biologically derived raw materials

  However, if the material is derived from humans or other living organisms, it is subject to the Standards for Biologically Derived Materials (2003)
  Ministry of Health, Labour and Welfare Notification No.210) does not apply (specifically, "biologically derived"
  Regarding the implementation of imported raw material standards(PFSB/ELD Notification dated October 2, 2014)
  (Items exempt from the application of the standards pursuant to Article 1002 No. 1, Article 1002 No. 5 of the Pharmaceutical and Food Safety Agency, etc.) 1(2), 4(1), 5(2), 6(3), 7(1), etc. In the following, "biologically derived raw materials" will also refer to raw materials of the same scope.
- biodegradable raw materials
- Functional coating materials (antithrombogenic coating, highly lubricating coating, etc.)

2. How to fill out the ingredients section of the application form

Of the raw materials subject to this notification shown in 1 (including raw materials limited to low-risk cases and low-risk), the following raw materials are deemed to have a sufficiently minor impact on the quality, efficacy, and safety of the product if changed, so it is acceptable to list only the generic name in the raw material column of the approval/certification application form. However, biological raw materials, biodegradable raw materials, and raw materials for implanted parts are excluded from this handling.

(1) Raw materials with extremely short contact times (equivalent to "Medical devices with brief tissue contact" in ISO 10993-1, "Biological evaluation of medical devices - Part 1" (hereinafter referred to as "ISO10993-1"))

(2) Raw materials used to fasten other parts or seal between parts, with a clearly small contact area with blood, body fluids, mucous membranes, etc. However, this does not apply when sealing parts that come into direct contact with circulating blood and when the continuous use of a single product is for a long period of time.
(3) Coloring materials applied only to the surface of medical devices that clearly have no effect on the strength of the product
(4) Raw materials for auxiliary and protective parts of mechanical mechanisms

If ingredients are listed by generic name only in accordance with this section, the reason for omitting ingredient specifications must be noted in the ingredients column.

3. Procedures for changing ingredients through minor change notification

Regarding raw materials subject to this notification as shown in 1, if the changes do not affect the essential quality, efficacy, and safety, it is possible to carry out the change procedure by filing a minor change notification.

The following are types of changes that affect essential quality, efficacy, and safety and do not fall under the change procedures based on minor change notification. Please note that when making any of these changes, at least partial change approval/certification application procedures are required, and depending on the content of the change, new approval/certification application procedures may be required.

(1) Material changes that increase existing risks or create new risks to the quality, efficacy or safety of the product
(2) The impact of the change in raw materials on the quality, efficacy and safety of the product cannot be fully estimated.
(3) The change clearly exceeds the scope of the product's intended use or the classification of insurance coverage.
(4) The effect of the change in raw materials on the treatment or diagnostic effect cannot be said to be minor.
(5) A change in raw materials to resolve a serious defect that occurred after the product was launched

When a manufacturer (or authorized manufacturer in the case of special foreign approval, etc., designated manufacturer; the same applies below) submits a minor change notification to change raw materials, the manufacturer must attach a self-declaration to the minor change notification stating that the impact on the quality, efficacy, and safety of the medical device in question has been confirmed, verified, or evaluated in advance. In this case, the manufacturer must write "As of January 2026" in the remarks column of the minor change notification.Notification No. 0130 of the Pharmaceuticals and Medical Devices Evaluation and Licensing Office dated the 30th
Please state "Change in ingredients based on Notification No. 1."

In addition, if verification tests and evaluations are conducted under self-guarantee in accordance with this notification, the manufacturers are responsible for properly storing the test results and other documents.

If it is determined during the review process that documents related to the change in raw materials are necessary, the applicant may be asked to submit the necessary documents.

4. How to think about precedents for using raw materials

As one of the considerations regarding the scope of this notification shown in 1, if the changed raw material meets all of the following conditions ① to ⑥ and is already used in a medical device that has been approved or certified domestically or overseas (a country that has a track record of regulatory harmonization with Japan and has an approval system that is recognized as being at a high level, or an equivalent system (e.g., the United States)), the raw material will be considered to have a precedent for use. Note that if a medical device approved or certified overseas is to be considered a precedent for use, it must have sufficient clinical use history.

① The changed raw materials are not biological raw materials.

② The change is not to the raw materials of the components/parts to be implanted in the implantable medical device, or, although the raw materials of the components/parts to be implanted are changed, there is no change in the generic name of the raw materials before and after the change.

③ The standards and specifications (physical properties, etc.) of the changed raw materials, the types and amounts of additive ingredients, etc. are the same as those of the raw materials whose usage history is being referred to.

④ Regarding the degree of physical contact,The medical device has a proven track record of use in a category based on contact points of the medical device in accordance with ISO 10993-1, either in an equivalent category or in a category with a higher risk.

⑤ Regarding the duration of contact with the body, the medical device must have a track record of use in a category based on the cumulative total contact time of the medical device (temporary contact, short- to medium-term contact, long-term contact) equivalent to or higher risk than the category specified in ISO10993-1.

⑥ It can be confirmed that no reports of recalls or serious adverse events caused by the raw materials have been submitted to the authorities for the medical device to be used as a precedent.

5. Things to keep in mind

Regarding the handling of individual raw materials under this notification, please consult with the Pharmaceuticals and Medical Devices Agency (PMDA) via simple consultation, or with a registered certification body via individual consultation, if necessary.