Ministry of Health, Labour and Welfare

Safety Division, Pharmaceutical Safety and Environmental Health Bureau

Translated by **Pharmaceuticals and Medical Devices Agency**

Office of Safety I

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Notification

PSEHB/ELD/OMDE Notification No. 1227-1
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To: Commissioner of Prefectural Health Department (Bureau)

Director of Office of Medical Device Evaluation, Evaluation and Licensing Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Director of Safety Division, Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare

Handling of Powdered Medical Gloves

The US Food and Drug Administration (FDA) recently announced its decision to ban the distribution of powdered medical gloves as the powder (cornstarch, etc.) used on medical gloves may pose safety risks.

Japan has also promoted switching to medical gloves without powder (hereinafter referred to as “powder-free gloves”) in related industries from before, and the percentage of powder-free gloves among the distributed medical gloves has steadily increased over the years. However, given the recent FDA announcement, Japan Glove Manufacturers Association has reported to the Ministry of Health, Labour and Welfare (MHLW) that they will further enforce switching to powder-free gloves by the industry.

In order to further ensure safety in our country, the following measures will be adopted to promote switching to powder-free gloves in the market. This notification requests your cooperation to circulate information to marketing authorization holders (MAHs) of medical devices, etc. under your supervision.

1. Scope of Notification

Medical gloves with the following generic names (including ones in set products, etc.).

- Natural rubber surgical gloves
- Natural rubber test/examination gloves
- Non-natural rubber surgical gloves
- Non-natural rubber test/examination gloves
- Dental gloves

2. Handling of powdered medical gloves

Switching to powder-free gloves (*) by the industry must be completed by the end of 2018. Therefore, after the effective date of this notification, applications for marketing certification or marketing notifications for powered products should be refrained from. For powdered products that have already been certified or notified for marketing, applicable procedures should be adopted (application for partial changes to certification, notification for changes to marketing notification, etc.) or such marketing certifications and marketing notifications should be withdrawn when necessary as quickly as possible.

* In the US, 2mg/glove or less is accepted as the maximum limit of residual powder. ASTM D6124 should be referred to in the meantime as the standard available to define the confirmation methods, etc. for the value.

3. Implementing provision of information, etc.

Until switching to powder-free gloves by the industry is completed, information to the following effect should be provided promptly to medical institutions, etc. In addition, the Precautions section of the package inserts should be reviewed to make sure a statement to the same effect is included and such statement should be added if it is not.

In addition, MAHs are requested to report the status of information provision as well as status of reviewing and revising the package insert, etc. to Pharmaceuticals and Medical Devices Agency (Office of Safety I, Medical Device Safety Division) by the end of March 2017.

(Natural rubber gloves)

Powder on gloves could be a carrier of natural rubber protein allergens and, in rare cases, the potential for inducing allergies or increasing the risk of granulomas and postoperative adhesions has been reported in association with it. Therefore, such risks should be considered before using natural rubber gloves.

(Non-natural rubber gloves)

Powder on gloves has been reported to increase the risk of granulomas and postoperative adhesions. Therefore, such risks should be considered before using non-natural rubber gloves.

4. Other

Revisions to the certification criteria related to the products in scope (JIS T9107, etc.) will be considered. An official notification of the results is intended within FY2017.