

HPB/DPMM Notification No.1008-1

PSB/PED Notification No.1008-5

October 8, 2025

To: Prefectural Health Department (Bureau)

From: Director, Policy Planning Division for
Pharmaceutical Industry Promotion and Medical
Information Management, Health Policy Bureau
Ministry of Health, Labour and Welfare

(Official seal omitted)

From: Director, Pharmaceutical Evaluation Division
Pharmaceutical Safety Bureau
Ministry of Health, Labour and Welfare

(Official seal omitted)

Handling of Pharmaceutical Patents in Approval Reviews under the PMD Act
and NHI Drug Price Listing for Generic Drugs and Biosimilars

The approval reviews of generic drugs under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Act No.145 of 1960; hereinafter referred to as the “PMD Act”) and the handling of pharmaceutical patents related to listing in the National Health Insurance (NHI) Drug Price Standard (hereinafter referred to as “NHI drug price listing”) for generic drugs are set out in the “Handling of Pharmaceutical Patents in Approval Review under the Pharmaceuticals and Medical Devices Act and Drug Price Listing for Generic Drugs” (Notification jointly issued by the Director of the Economic Affairs Division, Health Policy Bureau, and the Director of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, dated June 5, 2009; hereinafter referred to as the “Directors’ Joint Notification”). To ensure a stable supply of pharmaceuticals, confirmation of whether there is any patent infringement between the original drug and the generic drug is required in the approval review process as indicated in the Directors’ Joint Notification.

In addition, when seeking NHI drug price listing for generic drugs for which patent concerns exist, the parties concerned are required to adjust beforehand and apply for listing procedures only for drugs for which stable supply is possible.

On the other hand, the same practice as for generic drugs has been applied, in accordance with the above Directors’ Joint Notification, to the approval review under the PMD Act and the handling of

pharmaceutical patents relating to NHI drug price listing for biosimilars (defined as a pharmaceutical comparable to a biotechnology-derived product already approved in Japan, which is developed by a different marketing authorization holder; the approved product being hereinafter referred to as the “original biopharmaceutical”).

The handling of pharmaceutical patents for generic drugs and biosimilars (hereinafter collectively referred to as “generic drugs, etc.”) has now been clarified as follows. We would like to ask you to disseminate this document to the relevant business operators under your jurisdiction.

The following notification and the administrative communications are abolished as of the date of issuance of this notice.

- The Directors’ Joint Notification
- “Handling of Pharmaceutical Patents Information in Approval Review” (Notification No.762 issued by the Director of the Evaluation and Licensing Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated October 4, 1994)
- “Patent Information to be Attached to Applications for Manufacturing (Importation) Approval of Pharmaceuticals” (Administrative Communication issued by the Evaluation and Licensing Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated February 9, 1995)
- “Patent Terms and Timing of Applications for Generic Drugs” (Administrative Communication issued by the Evaluation and Licensing Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated June 28, 1995)

1. Handling of Pharmaceutical Patents in Approval Reviews

Approval reviews for generic drugs, etc. under the PMD Act should be handled as follows. The existence of the patents described below is determined as of the expected approval date for generic drugs, etc.. However, it is permissible to file an application for approval of generic drugs, etc. in anticipation of expiration of the patent term, considering the standard administrative processing time for approval review.

- (1). Generic drugs, etc. are not approved if they cannot be manufactured or marketed due to the existence of a patent (drug substance patent) for an active pharmaceutical ingredient of the original drug (including the original biopharmaceutical and excluding an *in vitro* diagnostic drug; the same applies hereinafter).
- (2). When patents (method-of-use patents) exist for some indications, dosage and administration (hereinafter referred to as "indications, etc.") of the original drug, but it is possible to manufacture or market drugs with other indications, etc., generic drugs, etc. may be approved. In such cases, approval is not granted for the indications, etc. for which patents exist.

2. Submission of Materials on the Status of Patents

- (1) Applicants applying for marketing approval for generic drugs, etc. should sufficiently confirm in advance the existence of drug substance patents and method-of-use patents for active pharmaceutical ingredients of the original drug and information on these patents, considering the handling of Section 1 above. In addition, materials demonstrating that the product can be marketed promptly after obtaining marketing approval should be submitted either as attachments to the marketing approval application (e.g., the attachment for CTD Module 1.4, “Patent Status”) or in response to the request from the Ministry of Health, Labour and Welfare (MHLW) or the Pharmaceuticals and Medical Devices Agency (PMDA).
- (2) For example, the following data are applicable to the “Materials demonstrating that the product can be marketed promptly after obtaining marketing approval” mentioned in Section 2(1).
 - (a). Materials indicating that the patent right is extinguished:

A certified copy of the closed patent register, details of the patent (patent number, name of the patentee, patent term, etc.), or other relevant materials
 - (b). Materials showing invalidity of the patent:

A trial decision invalidating the patent, a court judgment, or other relevant materials (*)
 - (c). Materials indicating that the patent right is not infringed:

A court judgment or other relevant materials (*)
 - (d). Materials indicating that the consent of the patentee or the exclusive licensee has been obtained:

A copy of an agreement, written consent, or other relevant materials (*)

* Details of the patent (patent number, name of the patentee, patent term, etc.) should be attached for reference.

It is also permissible to submit a document describing the applicant's opinion on the existence of any patent infringement between the generic drugs, etc. concerned and the corresponding original drug, together with the above material.

3. Handling of Pharmaceutical Patents Related to Drug Price Listing Procedures

When NHI drug price listing is sought for products that may give rise to a patent dispute, prior coordination should be undertaken with the marketing authorization holder of the original drug (hereinafter referred to as the “originator company”) that is the patentee or licensee. Only products for which a stable supply of pharmaceuticals can be ensured should proceed to NHI drug price listing procedures.

4. Collection of Pharmaceutical Patent Information

When a drug substance patent or a method-of-use patent for an active pharmaceutical ingredient of the original drug exists (including extended patents, hereinafter the same), and is considered relevant to the approval review of generic drugs, etc., the patentee or the originator company must complete the “Pharmaceutical Patent Information Report Form” on the attached sheet and submit it to the Pharmaceutical Evaluation Division, Pharmaceutical Safety Bureau (hereinafter referred to as “PSB/PED”), MHLW, before the end of the re-examination period for the original drug.

In addition, when a drug substance patent or a method-of-use patent is newly registered after expiration of the re-examination period of the original drug, the patentee or the originator company must complete the “Pharmaceutical Patent Information Report Form” set forth in the attachment and submit it to the PSB/PED, MHLW within 30 days from the date of publication of the patent gazette.

Drug substance patents or method-of-use patents for active pharmaceutical ingredients of the original drug that are not reported on the Pharmaceutical Patent Information Report Form are not considered in the approval review of generic drugs, etc., in principle. However, in accordance with the “Handling of Pharmaceutical Patent Information in Approval Reviews” (Notification No.762 issued by the Evaluation and Licensing Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare, dated October 4, 1994), “Pharmaceutical Patent Information Report Form” that has already been submitted to the PMDA does not need to be resubmitted to the MHLW. In addition, for original drugs whose re-examination period had already expired as of the date of issuance of this notification, if no “Pharmaceutical Patent Information Report Form” has been submitted and there is a patent considered relevant to the approval review of generic drugs, etc., the “Pharmaceutical Patent Information Report Form” is required to be submitted to the PSB/PED, MHLW, by November 8, 2025.

The “Pharmaceutical Patent Information Report Form” will not be disclosed to the public.