

# Policy on the Handling of Pharmaceutical Patents in Relation to the Approval Review under the Pharmaceuticals and Medical Devices Act and the National Health Insurance Price Listing of Medical-use Generic Drugs and Biosimilars<sup>1</sup>

**Authorities: Director, Office of Pharmaceutical Industry Development and Medical Information Planning, Pharmaceutical and Medical Device Regulatory Affairs Bureau, Ministry of Health, Labour and Welfare - Director, Pharmaceutical Evaluation Division, Pharmaceuticals and Medical Devices Agency Bureau, Ministry of Health, Labour and Welfare**

Promulgation date: October 8, 2025.

With regard to the handling of pharmaceutical patents in connection with the review and approval process 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 listing for National Health Insurance reimbursement of medical-use generic drugs, the “Handling of Pharmaceutical Patents in Connection with the Review and Approval under the Pharmaceutical Affairs Act and the Listing for National Health Insurance Reimbursement of Medical-use Generic Drugs” (Joint Notification No. 0605001 of June 5, 2009, issued by the Director of the Economic Affairs Division, Pharmaceutical and Food Safety Bureau, and the Director of the Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau; hereinafter referred to as the “Joint Directors’ Notification”) provides that, from the perspective of ensuring a stable supply of pharmaceuticals, confirmation shall be made during the approval review process regarding whether any patent infringement exists between originator drugs and medical-use generic drugs.

In addition, with respect to the listing for National Health Insurance reimbursement of medical-use generic drugs for which patent-related concerns exist, it is required that prior coordination be conducted between the relevant parties, and that listing procedures be undertaken only for products deemed capable of stable supply.

On the other hand, with regard to biosimilars (meaning medicinal products developed by different marketing authorization holders as equivalent/similar products to already approved biotechnology-derived originator products in Japan; the same applies hereinafter), the handling of pharmaceutical patents in connection with the approval review under the PMD Act and listing for National Health Insurance reimbursement has, to date, been operated in accordance with the Joint Directors’ Notification, in the same manner as for medical-use generic drugs.

Accordingly, it has been decided to clarify the handling of pharmaceutical patents relating to medical-use generic drugs and biosimilars (hereinafter collectively referred to as “generic drugs,

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<sup>1</sup> Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law



etc.”) as set forth below. You are therefore requested to ensure that the relevant business operators within your jurisdiction are duly informed of this matter.

For the avoidance of doubt, the “Joint Directors’ Notification,” the “Handling of Pharmaceutical Patent Information in Relation to Approval Review” (Notification No. 762 of October 4, 1994, issued by the Director of the Evaluation Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare), the “Patent Information to be Attached at the Time of Application for Manufacturing (Import) Approval of Pharmaceuticals” (Administrative Communication dated February 9, 1995, issued by the Evaluation Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare), and the “Patent Term and Timing of Applications for Generic Products” (Administrative Communication dated June 28, 1995, issued by the Evaluation Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare) shall be abolished as of the date of issuance of this Notice.

## 1. Handling of Pharmaceutical Patents in the Approval Review Process

In the review and approval of marketing authorizations for generic drugs, etc. under the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (hereinafter the “PMD Act”), the following principles shall apply.

For the purposes of the provisions set forth below, the existence of a patent shall be determined as of the expected date of approval. However, it shall not preclude an applicant from submitting an application for a generic drug, etc. in anticipation of patent expiry, taking into account the standard administrative processing period for approval review.

(1) Where a patent covering the active pharmaceutical ingredient of an originator drug (including a prior-approved biosimilar equivalent and excluding in vitro diagnostic medicinal products; the same applies hereinafter) exists as a substance patent, and such patent prevents the manufacture or marketing of a medicinal product containing that active ingredient, no approval shall be granted for the relevant generic drug, etc.

(2) Where a patent exists for a part of the indications, dosage forms, dosage regimens, or other conditions of use (hereinafter collectively referred to as “indications, etc.”) of an originator drug (i.e., a use patent), approval may nonetheless be granted for a medicinal product claiming other indications, etc. that are not subject to such patent. In such cases, approval shall not be granted for the patented indications, etc.

## 2. Submission of Documentation Relating to Patent Status

(1) Applicants for marketing authorization of generic drugs, etc. shall, in consideration of the handling set forth in Section 1 above, conduct a thorough prior investigation of the existence and scope of substance patents and use patents relating to the active ingredients of originator drugs, as well as related patent information.



In addition, applicants shall submit documents demonstrating that the product can be marketed promptly following the grant of marketing authorization, either as part of the attached documents to the marketing authorization application, or upon request by the Ministry of Health, Labour and Welfare or the Pharmaceuticals and Medical Devices Agency (PMDA).

(2) The “documents demonstrating that the product can be marketed promptly following the grant of marketing authorization” referred to in Section 2(1) include, but are not limited to, the following:

(a) Where it is shown that the patent right has expired:

Certificate or extract from the closed patent register

Patent-related particulars (e.g., patent number, patentee name, term of patent, etc.)

(b) Where it is shown that the patent is invalid:

Final invalidation trial decision

Court judgment (etc.) (\*)

(c) Where it is shown that the patent is not infringed:

Court judgment (etc.) (\*)

(d) Where consent has been obtained from the patentee or exclusive licensee

A copy of the relevant contract, written consent, or other equivalent documentation. (\*)

(\*Note: Supporting reference materials concerning the patent (including patent number, patentee name, term of patent, etc.) shall be attached as reference information.)

In addition, it shall not preclude the submission, together with the above materials, of documents stating the applicant’s view regarding whether there is or is not patent infringement between the generic drug, etc. and the originator drug concerned.


### 3. Handling of Pharmaceutical Patents in Relation to the NHI Drug Price Listing Procedure

Where an applicant seeks listing for National Health Insurance reimbursement of a product that is considered to carry a risk of patent disputes, prior coordination shall be conducted with the patentee or the marketing authorization holder of the originator drug (hereinafter referred to as the “originator company”), which is the patentee or exclusive licensee.

Only products that are considered capable of ensuring stable supply, including in the future, shall proceed to the listing procedure.

### 4. Collection of Pharmaceutical Patent Information





Where a patentee or originator company considers that there exists a substance patent or use patent (including any patent term extension; the same applies hereinafter) relating to the active ingredient of an originator drug that should be taken into account in the approval review of generic drugs, etc., such entity shall, prior to the end of the re-examination surveillance period of the originator drug, complete the prescribed Pharmaceutical Patent Information Report Form (attached separately) and submit it to the Office of Pharmaceutical Evaluation and Licensing, Pharmaceutical Safety and Environmental Health Bureau, Ministry of Health, Labour and Welfare.

Furthermore, where a new substance patent or use patent is registered after the end of the said surveillance period, the prescribed report form shall be submitted within 30 days from the date of publication of the patent gazette.

As a general rule, substance patents or use patents relating to the active ingredients of originator drugs that are not reported through the Pharmaceutical Patent Information Report Form shall not be taken into account in the approval review of generic drugs, etc.

However, in accordance with the “Handling of Pharmaceutical Patent Information in Relation to Approval Review” (Notification No. 762 of October 4, 1994, issued by the Director of the Evaluation Division, Pharmaceutical Affairs Bureau, Ministry of Health and Welfare), patents that have already been submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) shall not be required to be resubmitted to the Ministry of Health, Labour and Welfare.

In addition, for originator drugs for which the re-examination surveillance period has already expired as of the date of issuance of this Notice, if there exist relevant patents that have not yet been reported through the Pharmaceutical Patent Information Report Form but that should be taken into account in the approval review of generic drugs, etc., such form shall be submitted no later than November 8, 2025, to the Office of Pharmaceutical Evaluation and Licensing, Pharmaceutical and Medical Devices Agency Bureau, Ministry of Health, Labour and Welfare.

The Pharmaceutical Patent Information Report Form shall not be made publicly available.

