**Guidance for Use of the Standardized Template**

**Cover Letter to be Attached to the PMDA Review Report When Utilizing the Reliance Review Pathway**

**Asia Committee, International Affairs, JPMA**

**Background for Template Development**

The Japan Pharmaceutical Manufacturers Association (JPMA) has, with the cooperation of the Pharmaceuticals and Medical Devices Agency (PMDA), actively engaged with regulatory authorities in various Asian markets to promote the formulation of a reliance review pathway utilizing PMDA’s review reports. As a result, Japan has been recognized as a reference country under the reliance review pathway by regulatory authorities in Taiwan, Thailand, Malaysia, Indonesia, the Philippines, and newly Vietnam (from July 2025 onward). Although there are increasing number of cases of approval in Asian markets by the reliance review pathway utilizing the PMDA review report, such case remains limited. Utilizing the review report issued by PMDA has an advantage in that regulatory authorities in each market can directly make inquiries to PMDA regarding any concerns or questions related to the review report.

The JPMA recommends that applicants submit a cover letter, indicating their desire to utilize the reliance review pathway, attached to the review report when submitting to the respective regulatory authorities. However, this cover letter is not a part of the required documentation for Asian regulatory authorities, nor it is used in reliance review pathways that leverages review reports from other authorities. As a result, the existence of this letter is not always communicated to the receiving regulatory authorities, nor to the local regulatory affairs personnel or application agents responsible for the actual submission process in each market.

By creating a common template and user’s guide for such a cover letter, we aim to promote its utilization, raise awareness of the benefits of employing PMDA’s review reports, and thereby encourage the use of the reliance review pathway based on PMDA’s review reports (the content of the letter has been agreed upon with PMDA). We hope that applicants will communicate with PMDA’s Office of Asia Training Center and International Cooperation (OAIC) when preparing this letter, share their intention of using reliance review pathway with PMDA, and obtain more detailed support from PMDA when submitting the application via reliance review pathway.

**User’s Guide for Template**

* The letter should be attached as a cover letter to the PMDA’s review report and included in the relevant session of the review report in Module 1 of the Common Technical Document (CTD) /ASEAN CTD.
* Use a consistent letter title in principle unless there is a special reason. Other sections may follow the company’s format as long as mandatory items are preserved. Sections highlighted in yellow should be modified according to the product, target market, and nature of submission, etc.
* Approximately one month prior to submission, applicants are highly encouraged to contact PMDA Office of Asia Training Center and International Cooperation (OAIC) (pmda-gd@pmda.go.jp) to check the contact details such as generic e-mail address, and the names and email addresses of the department in charge (division manager and person in charge in each market).
* The following items must be included:
* Name of product for registration
* Application route
(e.g., in Malaysia, applying via the Abbreviated Review under the Facilitated Registration Pathway referencing PMDA as a reference country, etc.)
* Marketing Authorization Holder in Japan and Applicant in target market
* How to prepare an English review report
(e.g., using the English review report issued by PMDA with masked sections translated by a third-party translation agency, or translating the original review report (in Japanese) issued by PMDA into English through a third-party translation agency).
* A statement that PMDA will respond directly to inquiries from the regulatory authorities regarding questions on the review content in PMDA’s review report
* Generic e-mail address of the PMDA's OAIC, and names and e-mail addresses of the division manager and person in charge in each market

If you have any questions about the template and user guide, please contact the secretariat of JPMA International affairs (Sato, Katsumata).

Secretariat of JPMA International Affairs (E-mail):
Keiko Sato: sato@jpma.or.jp, Yumi Katsumata: katsumata@jpma.or.jp

(Letter Template, Version 1.0 (2025/08/21))

Letter of Request for Drug Evaluation under Reliance Pathway

[Recipient Name]

[Name of Regulatory Authority]

[Authority Address]

Dear Sir/Madam or [Recipient Name],

We, [Company Name], are writing to formally inform you regarding our application for the approval of [Product Name]. [\*] [\*] This application intends to utilize the expedited review pathway as stipulated by pharmaceutical regulations in [Target market]. In Japan, [Product Name] was assessed by Pharmaceuticals and Medical Devices Agency (hereinafter referred to as PMDA) and approved by Ministry of Health, Labour and Welfare on [Date], under [Company Name] as the product owner. [\*]

For this application, we attach the PMDA’s Full Unredacted Assessment Report of [Product Name] (e.g., original in Japanese prepared by the PMDA, translated into English by third party translation company). [\*]

If there is any inquiry on the contents of the assessment report prepared by the PMDA, we recognize the PMDA will directly respond its inquiry. When contacting the PMDA, please include the PMDA officers below and the generic address (pmda-gd@pmda.go.jp) of Office of Asia Training Center and International Cooperation (OAIC), in order to ensure that your inquiry be surely conveyed. [\*]

PMDA Officers:

* Name, Title
(Email: ) [\*]

We agree to assist the [Regulatory Authority Name] with any request for information on the above therapeutic product.

We would highly appreciate it if you could kindly make a swift evaluation of [Product Name].

Sincerely,

[Your Name]

[Your Position]

[Your Company Name]

[Contact Phone Number]

[Email Address]