Provisional Translation (as of September 2024)*

Administrative Notice September 6, 2024

To: Prefectural Health Department (Bureau)

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

Submitting documents to be attached in the application for approval of new ethical drugs

We have previously notified the requirement for documents to be attached in the application for approval in the “Guidelines for preparing documents to be attached to applications for approval of the manufacture or import of new drugs” (PSB/ED Notification No. 899 dated June 21, 2001 by the Director of PSB/ED, MHLW. Hereinafter, referred to as “the Director’s Notification”). Although we had previously allowed CTD Parts 3, 4, and 5 listed in Section 3 of the Director’s Notification to be submitted in English, in order to eliminate drug-lag/drug-loss and to make it easier for foreign companies to apply for marketing approval in Japan, we have temporarily decided, as a trial measure, to permit the submission of the entire application document in English as shown below. We ask you to cooperate in informing related parties under your administration of this matter.

Note

1. Submission of application documents for marketing approval in English

(1) It is acceptable to submit the entire document, including the written application for approval and the draft package insert, in English at the time of submission of the application.

(2) For the time being, this administrative notice allows foreign companies without a Japanese corporation or office in Japan to submit documents in English, when applying for approval of new ethical drugs (limited to drugs listed in (1) to (3) of Appendix 2-(1) of the "Drug Approval Applications" (PFSB Notification No. 1121-2 dated November 21, 2014 by the Director-General of the PFSB, MHLW) in Japan. The scope of the companies will be discussed to be expanded in the future, considering the results of this trial in terms of needs, costs, and other factors.

* This English version of the Japanese Administrative Notice is provided for reference purposes only. In the event of any inconsistency between the Japanese original and the English translation, the former shall prevail.

(3) When an applicant plans to submit the documents in English based on this administrative notice, they must consult with the Office of Review Management, Pharmaceuticals and Medical Devices Agency, in advance of the submission.