Position Paper
on New Drug Review Cooperation
between Japan and Taiwan

2 October 2019

Under the Arrangement between the Interchange Associations and the Association of East Asian Regulations for the Establishment of the Framework of the Cooperation on the Medical Product Regulation (hereinafter, "Framework") signed 5 November, 2013, the Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) and the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare / Center for Drug Evaluation (CDE) confirmed mutual positon regarding new drug review cooperation on 2 October, 2019, as follows:

1. PMDA and TFDA/CDE will exchange information regarding the review and registration of New Drug Application (NDA).
2. The exchange of information will be conducted subject to the prior consent of the company that have intention to apply NDA.
3. Confidential and non-public information may be exchanged under "Cooperation on New Drug Review" described in the Attachment. By virtue of this paper, the cooperation will be stipulated, specifying which kinds of information and on what basis PMDA and TFDA/CDE may exchange.
4. Further collaboration on this issue may be discussed under the Framework.
5. This paper is not intended to create any legally binding obligations.
6. Any differences arising from the interpretation or implementation of this position paper will be resolved through the consultations under the Framework.
7. This position paper may be amended in the future, when it would be confirmed jointly.

This position paper was jointly prepared by
MHLW/PMDA and TFDA/CDE,
and will be opened to stakeholders in Japan and Taiwan.

Attachment

Cooperation on New Drug Review between Japan and Taiwan
-The New Drug Review Scheme-

The Ministry of Health, Labour and Welfare (MHLW) / Pharmaceuticals and Medical Devices Agency (PMDA) and the Taiwan Food and Drug Administration (TFDA) of the Ministry of Health and Welfare / Center for Drug Evaluation (CDE) have been promoting collaboration on Medicinal product regulations and information sharing under the Arrangement between the Interchange Associations and the Association of East Asian Regulations for the Establishment of the Framework of the Cooperation on the Medical Product Regulation (hereinafter, "Framework") signed 5 November, 2013.

In terms of (1) developing reliance, (2) addressing unmet medical needs, and (3) achieving early access to medical products, "The New Drug Review Scheme" is established as a review platform under the Framework to exchange information and deepen understanding on new drug review issues. It is recognize there exists clear benefit that the final decision-making for marketing approval relies on the other side's approval result, based on the submission dossiers and local regulations.

To facilitate the review cooperation on NDA between PMDA and TFDA/CDE, Japanese or Taiwanese pharmaceutical industries (hereinafter, "Companies") are encouraged to apply NDA under this Scheme. Companies, which fulfill the criteria of eligibility (described in following section), could state the interest of participation in an appropriate manner[1] before submission. The application on this scheme from the Company needs to be adopted by PMDA and TFDA/CDE before starting collaborative activity in this scheme.

The Company can decide types of information to be exchanged, but for the purpose of this Scheme, at least the full review report written in English made by approved side should be included. Users of the information and control of confidential information need to be clarified in a signed the Consent Document by the Company and PMDA and TFDA/CDE preferably before the beginning of NDA review process. The Form of Consent Document is as reference.

---

[1] In Taiwan: describe on the cover letter of NDA submission package or inform with regulator
In Japan: inform with regulator

Criteria of eligibility for the Scheme

This Scheme aims on NDA from Companies that intend to obtain marketing approval of the drug product in Taiwan/Japan. Eligibility of this scheme is the products of NDA that is already approved by either one and is planned to be applied to the other voluntarily; however, the time gap between one approval date and the other NDA submission date is strongly recommended to be less than one year.

Activities of the NDA review cooperation

1. NDA from the Company will be reviewed through this review processes following regulations in Taiwan/Japan, respectively.
2. Under this Scheme, the English-version review report (unmasked) made by one side which had already approved will be submitted by the Company and the other side uses it for NDA review.
3. During the NDA review, PMDA and TFDA/CDE can exchange information and may have meetings to deepen understanding on review issues based on the documents and information relating to NDA will be shared during the process of the review, if needed.
4. Start from the time when the review report was received from the applicant, the review side will inform the expected review progress of the product possibly every two months to the other in order to facilitate smooth communication described in the above. The review progress could be informed through email, if necessary, through teleconference.
5. The performance and activities under this Scheme will be assessed under the Framework and they may be presented at the Taiwan-Japan Joint Conference on Medical Products.
6. A review side needs to consider efficient utilization of obtained information from the other side.

Reference

Consent for Use of NDA Related Documents and Information under the New Drug Review Scheme between MHLW/PMDA and TFDA/CDE

Dear Managers of the Pharmaceutical and Medical Devices Agency (PMDA),
the Taiwan Food and Drug Agency (TFDA) and the Center for Drug Evaluation(CDE) :

We, [Name of the Company], hereby permit that PMDA and TFDA/CDE use/share documents for our New Drug Application (NDA) with the information contained therein and/or related thereto, including but not limited to, the information derived from or supplementary to the review report (hereinafter "Information") under the purpose of the review cooperation as New Drug Review Scheme under the Arrangement between the Interchange Associations and the Association of East Asian Regulations for the Establishment of the Framework of the Cooperation on the Medical Product Regulation (hereinafter, "Framework") signed 5 November, 2013, subject to the following conditions;

1. Product
   Japan: [Drug name, dosage form and strengths]; NDA Submission date : [Date-Month-Year]
   Taiwan: [Drug name, dosage form and strengths]; NDA Submission date : [Date-Month-Year]

2. Subject documents (hereinafter "Documents")
   Review report
3. Purposes and conditions
   1) Purposes
      Documents will only be used for NDA review to cooperate and exchange views for the product review under the New Drug Review Scheme under the Framework.
   2) Term
      Documents may be used during the term ending on the completion of the new drug review under the Framework. This term may be extended with the prior written consent of [Name of the Company].
   3) User
      Only the employees of PMDA and TFDA who are involved in the New Drug Review Scheme described above, may have access to the Documents. In addition, the employees of The Center for Drug Evaluation (CDE) Review Team for this product may also have access to the

Documents.

4) Control of publication and confidential information

Information which is not in public domain (including without limitation, review report) shall not be disclosed to other third parties except for the above mentioned "3) User" and shall be held and kept confidential, using at least the same degree of care toward it as used towards PMDA/TFDA's own confidential information, but no less than a reasonable degree of care. Any information included in the "2. Subject documents" above as well as any information created based thereon or derived therefrom may not be disclosed at the presentations, press releases or otherwise, without [Name of the Company]'s prior written confirmation.

CONFIRMED

For PMDA

In charge By : _____(Signature)_____ Date:

Name:

Title:

e-mail :

TEL:

For TFDA

In charge By : _____(Signature)_____ Date:

Name:

Title:

e-mail :

TEL: , FAX:

For CDE Review Team for this product

In charge By : _____(Signature)_____ Date:

Name:

Title:

e-mail :

TEL: , FAX:

AGREED AND ACCEPTED

For [Name of the Company]

By :_____(Signature)_____ Date:

Name:

Title:

e-mail :

TEL: , FAX: