檔　　號:
保存年限:

衛生福利部食品藥物管理署 函

地址：11561 臺北市南港區昆陽街161-2號
聯絡人：洪文怡
聯絡電話：02-27877423
電子信箱：wyhung0206@fda.gov.tw

受文者：中華民國製藥發展協會

發文日期：中華民國108年11月13日
發文字號：FDA藥字第1081411367號
速別：普通件
密等及解密條件或保密期限：
附件：「臺日新藥審查合作立場書」中、英文版本各1份（A21020000I108141136701-1.pdf、A21020000I108141136701-2.pdf）

主旨：茲檢送「臺日新藥審查合作立場書」中英文版本各一份，詳如說明段，請查照並轉知會員。

說明：

一、為建立審查互信、滿足急迫醫療需求，並增進藥品可近性，本署及財團法人醫藥品查驗中心，與日本厚生勞働省(MHLW)及獨立行政法人醫藥品醫療機器總合機構(PMDA)，基於「台日醫藥品法規合作架構」，於106年起啟動「新藥審查合作試辦計畫」以加深對彼此新藥審查法規及考量之了解，並於108年10月2日「第七屆台日醫藥交流會議」完成「臺日新藥審查合作立場書」，做為台日雙方於新藥審查合作之共同聲明。

二、符合資格之業者得依本立場書及其附件「臺日新藥審查方案」，向本署提出申請。

三、參與本合作方案之業者，須提交審查資料交流同意書(詳附件之「參考資料」)並以英文版本簽署，以利台日雙邊交流，該同意書內容為參考範本，申請者可視其個案考量酌

修。

四、前述立場書及其附件另公開載於本署首頁(www.tfda.gov.tw)／業務專區／藥品／新藥專區／新藥相關公告，請轉知所屬會員前往網站下載參閱。

正本：中華民國西藥代理商業同業公會、台灣醫藥品法規學會、台灣製藥工業同業公會、中華民國製藥發展協會、中華民國學名藥協會、台北市西藥商業同業公會、台灣研發型生技新藥發展協會、台北市西藥代理商業同業公會、台灣藥品行銷暨管理協會、中華民國開發性製藥研究協會、中華民國西藥商業同業公會全國聯合會

副本：財團法人醫藥品查驗中心 電子公文交換章 2019/11/15 13:40:51

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 Relations 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-

2 October 2019

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:

臺日新藥審查合作立場書

2019 年 10 月 2 日

基於日本臺灣交流協會與臺灣日本關係協會於 2013 年 11 月 5 日簽署之臺日醫藥品法規合作架構（以下簡稱「架構」）下，日本厚生勞働省（Ministry of Health, Labour and Welfare, MHLW）／醫藥品醫療機器總和機構（Pharmaceuticals and Medical Devices Agency, PMDA）及臺灣食品藥物管理署（Taiwan Food and Drug Administration, TFDA）／醫藥品查驗中心（Center for Drug Evaluation, CDE）於 2019 年 10 月 2 日就新藥審查合作確認雙邊立場如下：

1. PMDA 及 TFDA/CDE 將就新藥查驗登記申請案（New Drug Application, NDA）之審查與註冊進行資訊之交流。
2. 上述資訊交流須經該申請新藥查驗登記之業者事前同意。
3. 機密及非公開資訊的交流可依據附件「臺日新藥審查合作方案」進行。憑藉本立場書，將明定此合作方案下 PMDA 及 TFDA/CDE 進行資訊交流的依據及資訊類型。
4. 基於前述架構下，此議題的進一步合作可再進行討論。
5. 本立場書無產生任何法律約束義務之目的。
6. 任何因本立場書內容解讀或施行產生之歧義，可基於前述架構進行溝通諮詢予以解決。
7. 本立場書未來可於雙方共同確認後予以修訂。

本立場書由

MHLW/PMDA 及 TFDA/CDE 共同擬定

並將向臺灣及日本之相關單位公布

附件

臺日新藥審查合作

-新藥審查方案-

2019 年 10 月 2 日

日本厚生勞働省（Ministry of Health, Labour and Welfare, MHLW）／醫藥品醫療機器總和機構（Pharmaceuticals and Medical Devices Agency, PMDA）及臺灣食品藥物管理署（Taiwan Food and Drug Administration, TFDA）／醫藥品查驗中心（Center for Drug Evaluation, CDE），基於日本臺灣交流協會與臺灣日本關係協會於 2013 年 11 月 5 日簽署之臺日醫藥品法規合作架構（以下簡稱「架構」），致力於促進雙邊醫藥品法規及資訊交流之合作。

為建立審查互信、滿足急迫醫療需求，並增進藥品可近性，在前述架構下建立「新藥審查方案」作為審查合作平臺，以交換資訊並加深對新藥審查議題之了解。參採已核准一方審查報告，並依據申請實際檢附資料與當地法規作成審查一方最終審查決議，屬有利之作法。

為促進 PMDA 及 TFDA/CDE 間的新藥審查合作，鼓勵日本及臺灣之製藥業者（以下簡稱「業者」）於此合作方案下申請新藥查驗登記（new drug application, NDA）。業者如符合資格（如下段所述），於提出新藥查驗登記申請前，可以適當方式[1]聲明其參與意願。依此方案進行新藥查驗登記審查程序，須待 PMDA 及 TFDA/CDE 共同確認。

業者可自行決定可交換的資訊類型，但為利本方案之進行，應至少包含由已核准一方所撰寫英文版完整審查報告為可交換資訊。有關所交換資訊之使用者與機敏資訊的管控，由業者、PMDA 及 TFDA/CDE 在進行本方案下新藥查驗登記審查流程之前，於共同簽署之同意書文件中載明。同意書格式詳如參考資料。

[1]於臺灣，須在新藥查驗登記送件資料封面載明或通知法規單位人員；於日本，須通知法規單位人員。

本方案之申請資格：

本方案適用將於臺灣及日本申請新藥查驗登記之申請案。適用本方案的新藥須為已於任一方核准上市，並欲向另一方申請新藥查驗登記者，惟強烈建議其於一方之核准時間至另一方提出新藥查驗登記申請之時間差應小於一年。

新藥審查合作事項：

1. 業者所提出新藥查驗登記申請案將依臺灣與日本各自法規進行審查作業。
2. 在此方案下，未經遮蔽的英文版完整審查報告將由已核准一方交予業者，由業者向另一方提交，以應用於新藥查驗登記之審查。
3. 在新藥查驗登記審查過程中，PMDA 及 TFDA/CDE 可交換新藥查驗登記申請案之審查資訊，必要時可透過會議來加強對審查議題的理解。
4. 自收到業者提交英文版完整審查報告起，進行審查中的一方每兩個月會向另一方通知審查進度，以有助於前述之審查交流。通知的形式以電郵方式進行，必要時得電話會議溝通。
5. 在此方案下的審查合作成果與活動，將會在臺日醫藥交流架構下進行評估，並得於臺日醫藥交流會議上報告。
6. 進行審查中的一方須思考有效應用另一方所提供的審查資訊。

参考資料

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: