Q&A for the New Drug Review Scheme

新藥審查合作方案問答集

12 Oct 2022

PART 1: General

Questions	Answers
1. What is the main purpose for the New Drug Review Scheme? 新藥審查合作方案的目的是什麼？	(1) The main purpose for the New Drug Review Scheme is to develop mutual understanding and reliance between TFDA/CDE and MHLW/PMDA on the regulations and review consideration of the registration of pharmaceutical products to address unmet medical needs and achieve early access to medical products. 新藥審查合作方案的主要目的是要建立 TFDA/CDE 與 MHLW/PMDA 間對於新藥查驗登記法規與審查的了解與互信，以滿足醫療需求並達成增進藥品可近性的目標。 (2) Both TFDA/CDE and MHLW/PMDA confirmed that this cooperation could facilitate new drug approval by utilizing each other's review reports and information sharing. TFDA/CDE 及 MHLW/PMDA 雙方均認同這項合作可以透過應用彼此的審查報告及資訊交流，來加速新藥上市。
2. What are the benefits for industries joining the Scheme? 加入新藥審查合作方案對業者有什麼好處？	(1) The New Drug Application dossier and unmasked full review report submitted under the Scheme would help regulatory authorities of both sides to identify the difference on review considerations, and facilitate the review process through information sharing and mutual communication. 透過新藥審查合作方案下，業者所提交的新藥查驗登記申請文件以及無遮蔽的完整

	審查報告，可有助於雙方法規單位釐清審查考量的差異，並藉由資訊交流與溝通加速審查程序。 (2) From long-term aspect, with accumulated experience, mutual trust on new drug review could be built that review convergence and reliance could be achieved. 從長期的角度來看，隨著雙邊審查合作經驗累積，可以建立雙方對於新藥審查互信，進而達成法規一致性及互認的目標。 (3) Therefore, both TFDA/CDE and MHLW/PMDA encourage industries to participate in the Scheme to facilitate the review cooperation progress. 因此，TFDA/CDE 及 MHLW/PMDA 均鼓勵業者可參與臺日新藥審查合作方案，以促進雙邊審查合作進展。
3. What are the criteria for joining the Scheme? 參加新藥審查合作方案的條件是什麼？	(1) The applicants should be pharmaceutical companies that: • Are located in Taiwan or Japan, and • Intend to obtain marketing approval of the drug product in both Taiwan and Japan. 申請者必須為具備以下條件之製藥業者： • 為臺灣或日本當地製藥業者，且 • 規劃於臺灣及日本取得藥品上市許可。 (2) For the drug product, it should be: • Classified as “New Drug” according to local regulation, and • The date of submission to one side is within one year from the date of approval in another. 所申請的藥品，應具備以下條件： • 依據當地法規認定屬「新藥」的藥品，且 • 向一方提出送件申請的日期，與另一方的核准日期，間隔應小於一年。
4. If the drug product was designated as orphan	As long as the drug product is classified as “New Drug” in the side that it is submitted, it is

drugs, will it be applicable for the Scheme? 若所申請的藥品被認定為 orphan drug，是否適用新藥審查合作方案？	applicable for the Scheme. 只要所申請的藥品符合申請國當地法規所認定的「新藥」定義，即可適用新藥審查合作方案。

PART 2: Application

Questions	Answers
1. How to join the Scheme? 如何加入新藥審查合作方案？	(1) Application in Taiwan: 向臺灣方面提出申請的方式： • Step 1: An official letter describing the interest to join the Scheme, and brief summary for the drug product, including product name, proposed indications, route of administration and dosage, approval status, and submission plan should be provided to TFDA/CDE. 第一步：向 TFDA/CDE 提交正式公文，敘明參與新藥審查合作方案之意願，並對申請藥品做簡要背景說明，包含藥品名稱、擬申請之適應症、給藥途徑、劑量、核准狀態，以及提出新藥查驗登記之送件時程規劃。 • Step 2: If the new drug application fulfills the requirements of the Scheme, TFDA/CDE will contact MHLW/PMDA for opinion. 第二步：若所提出新藥查驗登記申請案符合新藥審查合作方案之要求，TFDA/CDE 會聯繫 MHLW/PMDA 並詢問其意見。 • Step 3: Once both sides decide to include the case, TFDA/CDE will ask the applicant to sign the consent form for TFDA/PMDA to exchange information of the product. 第三步：當雙邊都同意將該申請案納入新藥審查合作方案，此時 TFDA/CDE 會

	函復申請人並要求簽署三方同意書，以進行所申請藥品之資訊交流。 • Step 4: With the signed consent form, the case is formally included under the Scheme. Full review report from Japan side translated in English would be required when submitted for new drug registration in Taiwan. 第四步：完成三方同意書簽署之後，此申請案即正式納入新藥審查合作方案，當申請人正式檢送新藥查驗登記申請資料時，即須一併提供完整無遮蔽的日方審查報告(英譯版本)。 (2) Application in Japan: 向日本方面提出申請的方式： Ref: Revert TFDA/CDE to MHLW/PMDA, and Taiwan to Japan 請參考前述向臺灣方面申請的方式，並將「臺方」與「日方」、「TFDA/CDE」與「MHLW/PMDA」作互換。
2. Are there any additional requirement when submit for new drug registration under the Scheme? 新藥審查合作方案下，在檢送新藥查驗登記申請時，是否有額外的送件要求？	(1) A full unmasked review report from the Approved side is necessary. The review report should be translated in English if it was written in the original language. 必須要檢附由核准方提供的完整無遮蔽的審查報告。該審查報告若以當地語言撰寫，則須先翻譯成英文。 (2) For other submission dossiers, such as CTD documents or administrative documents requirements, there is no difference to regular practice following local regulations. 至於其他的送件資料，例如 CTD 文件或行政文件等的要求，與一般查驗登記送件要求並無不同。 (3) Due to the approval time gap, applicant would be encouraged to submit post-marketing surveillance/changes and clinical/safety updates to the Reviewing side.

	考量從一方核准到向另一方送件的時間差，鼓勵申請者可儘量向審查方提供上市後監控或變更資料，以及更新的臨床與安全性資訊。
3. How to request for the full unmasked review report? 如何取得完整無遮蔽的審查報告？	(1) If the new drug was approved by TFDA/CDE: 若申請之新藥已由 TFDA/CDE 核准： • An official letter is needed by the applicant. The applicant has to provide signed consent form to confirm the case is formally included under the Scheme. 申請者須提交正式公文，並檢附已完成三方簽署的同意書，以確認該申請案已納入新藥審查合作方案。 • TFDA/CDE will provide the unmasked full review report in English to the applicant. 經確認後，TFDA/CDE 會提供以英文撰寫且無遮蔽的完整審查報告給申請者。 • The applicant must be the license holder. 申請者必須為該藥品許可證持有者。 (2) If the new drug was approved by MHLW/PMDA： 若申請之新藥已由 MHLW/PMDA 核准： • The applicant needs to communicate with MHLW/PMDA. 申請者須向 MHLW/PMDA 洽詢。
4. As to unmasked review report which is necessary to be submitted under the New Drug Review Scheme, is it possible for applicant to submit company translation? 新藥審查合作方案下，查驗登記送件時須檢附的完整無遮蔽審查報告，可以由申請者自行翻譯嗎？	It would be acceptable as long as the company correctly translates the original language. 只要申請者可以正確翻譯語意及內容，即可接受。
5. For applications utilizing	The post-approval safety information would be

the New Drug Review Scheme, is it necessary to submit safety information after marketing approval by the referred regulatory authority? 對於納入新藥審查合作方案的申請案，一定要檢附在核准方上市後的安全性資料嗎？	useful for the reviewing authority. The reviewing authority would coordinate for it with the applicant on an individual basis. 上市後安全性資訊對於審查方是相當有幫助的。審查方是否會要求申請者檢送上市後安全性資料，可能須視個案而定。

PART 3: Workflow

Questions	Answers
1. Will there be special review timeline for the applications utilizing the Scheme? 納入新藥審查合作方案的申請案，會適用特別的審查時程嗎？	The review pathway and timeline remain the same as current practice following local regulations. However, there may be cases where answers to potential inquiries are confirmed in the submitted English review report, resulting in fewer numbers of inquiries compared to reviews that do not fall under the Scheme. 審查機制及時程仍然會依循當地既有的法規。然而，在一些案例中，若申請者提供的完整審查報告已經包含對申請者補件資料的審查結果時，審查方可能會相對減少需補件的議題。
2. How does the reviewers between both sides communicate? 台日雙方的審查人員如何進行溝通？	For the Reviewing side, the application dossiers will be reviewed based on local regulations and guidelines. The full review report from the Approved side will be utilized as review tools. If the reviewers have issues regarding the application dossiers or the review report, the issues will be sent to the Approved side through email. Teleconference might be held when further discussion is needed on an individual basis. 從審查方的角度，申請者送件資料會依據當地法規及指引進行審查。由核准方所提供的完整審查報告則是作為審查工具加以應用。若審查方對於送件資料或審查報告內容有疑問時，會以電郵方式向核准方詢問。若需要進一步的討

	論時，視個案會召開電話會議溝通。
3. If the inquiries have been responded by the applicant to the Approval side, will the Reviewing side raise the same inquiries again? 若補件議題已經向核准方回復過了，審查方還會再提出相同的補件議題嗎？	If applicants could provide response to inquiries from the Approved side, then the Reviewing side might not raise the same question to applicant again. However, it might be case-dependent if more information from the applicant is needed. 若申請者可檢附向核准方提交的補件議題回復資料，審查方可能就不會再提出相同的補件議題，但這仍需視個案而定。
4. There are differences in the definition of orphan drugs and requirements for clinical trials according to the country/region. Which points should applicants take into consideration? 對於 orphan drug 的認定條件以及臨床試驗的要求，會依據國家或地區而有所不同。申請者應該注意哪些事項？	Even though there are regulatory differences, the scientific approach is expected to be common. Therefore, it would be important for the applicant to respond based on a scientific perspective. 雖然有法規上的差異，但在審查時所依據的科學實證考量仍是一致的。所以，申請者應該採科學性的角度來說明及回復審查議題。
5. Which points should applicants take into consideration when the applicant submits a response to an inquiry from the regulatory authority? 當申請者向法規單位回復補件議題時，應該注意哪些事項？	Submitting accurate responses in batches after preparing the necessary information leads to efficient review. Applicants should avoid submitting responses intermittently or submitting incomplete responses that may lead to further inquiries. If an inquiry is expected to require time to respond, it is advised that the applicant consults it with the reviewing authority in advance. 檢送正確的、整理過的回復內容對於提升審查效率是有幫助的。申請者應避免斷斷續續的提交補充資料，或檢送不完整的補件回復內容，這樣可能導致有更多的補件議題衍生。若申請者認為需要更多時間來準備補件議題的回復資料，建議可事先向審查單位說明及諮詢。

PART 4: Others

Questions	Answers
1. What points should be considered for the review to be finished within the standard review time? 要讓審查可於標準審查時程內完成，需要注意哪些事項？	It is important that the translated English review report should be submitted at the same time of application for marketing approval. The applicant should ensure that there are no errors/failures in either the application dossier or additional documents submitted at least. 將完整未遮蔽的英文版審查報告，於新藥查驗登記送件時一併提供是很重要的。申請者至少應確保送件資料或附加補充資料沒有錯誤或缺失。