Q&A for the New Drug Review Scheme
(Revised)

20 Nov 2023

PART 1: General

Questions	Answers
1. What is the main purpose for the New Drug Review Scheme?	(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. (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.
2. What are the benefits for industries joining the Scheme?	(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. (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. (3) Therefore, both TFDA/CDE and MHLW/PMDA encourage industries to participate in the Scheme to facilitate the review cooperation progress.
3. What are the criteria for joining the Scheme?	(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.

	*Including branch companies or contracted local distributors of global companies. (2) For the drug product: • It should be classified as "New Drug" according to local regulation. • It is recommended that the date of submission to one side is within one year from the date of approval in another.
4. If the drug product was designated as orphan drugs, will it be applicable for the Scheme?	As long as the drug product is classified as "New Drug" in the side that it is submitted, it is applicable for the Scheme.
5. In the New Drug Review Scheme, it is generally recommended that an application be filed within one year of approval by one country. What are the cases where application is accepted beyond one year after approval of its drug products by one country?	In the New Drug Review Scheme, for better utilizing the review report from the approval side, it is recommended that the submission of New Drug Application of the same product to the other side be made within one year after the approval, because information after the approval such as post-approval changes and unpredicted safety issues identified in clinical practice would not be presented in the original review report. However, to facilitate the review cooperation, applications filed beyond one year after approval could still be accepted. In such cases, post-approval information including additional clinical data, safety issues and post-approval changes would be taken into consideration. Applicants are encouraged to provide summaries of such post-approval information while expressing interest to join the Scheme, especially when the submission time gap was over one year.

PART 2: Application

Questions	**Answers**
1. How to join the Scheme?	(1) Application in Taiwan:

	• 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. • Step 2: If the new drug application fulfills the requirements of the Scheme, TFDA/ CDE will contact MHLW/PMDA for opinion. • 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. • 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. (2) Application in Japan: Ref: Revert TFDA/CDE to MHLW/PMDA, and Taiwan to Japan
2. Are there any additional requirement when submit for new drug registration under the Scheme?	(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. (2) For other submission dossiers, such as CTD documents or administrative documents requirements, there is no difference to regular practice following local regulations. (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.
3. How to request for the full unmasked review	(1) If the new drug was approved by TFDA/CDE: • An official letter is needed by the applicant.

report?	The applicant has to provide signed consent form to confirm the case is formally included under the Scheme. • TFDA/CDE will provide the unmasked full review report in English to the applicant. • The applicant must be the license holder. (2) If the new drug was approved by MHLW/PMDA: • The applicant needs to communicate with MHLW/PMDA.
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?	It would be acceptable as long as the company correctly translates the original language.
5. For applications utilizing the New Drug Review Scheme, is it necessary to submit safety information after marketing approval by the referred regulatory authority?	The post-approval safety information would be useful for the reviewing authority. The reviewing authority would coordinate for it with the applicant on an individual basis.

PART 3: Workflow

Questions	**Answers**
1. Will there be special review timeline for the applications utilizing the Scheme?	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.
2. How does the reviewers between both sides communicate?	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.
3. If the inquiries have been responded by the applicant to the Approval side, will the Reviewing side raise the same inquiries again?	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.
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?	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.
5. Which points should applicants take into consideration when the applicant submits a response to an inquiry from the regulatory authority?	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.

PART 4: Others

Questions	**Answers**
1. What points should be considered for the review to be finished within the standard review time?	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.