附件二

IGDRP
International Generic Drug Regulators Pilot

Expression of Interest (EOI) Request to Participate in the First Information Sharing Pilot for the *Evaluation of Generic Drug Applications involving the Decentralised Procedure of the European Union*

Product Information			
Product Name (should be same as on product label):			
Active Pharmaceutical Ingredient:			
Pharmaceutical Form	Route	Strength	Conditions of Use
Applicant Information			
Name (Full legal name):			
Address:			
Contact Person:			
Tel:	Fax:	Email:	
Application/submission filing information			
Intended filing date in EU Reference Member State:			
Reference Member State (RMS):			
DCP-Number (if already known):			
Concerned Member States (CMS):			
Non-EU agencies proposed for this pilot: ☐ Australia (Therapeutic Goods Administration (TGA)) ☐ Canada (Health Canada) ☐ Chinese Taipei (Taiwan Food and Drug Administration (TFDA)) ☐ Switzerland (Swissmedic, Swiss Agency for Therapeutic Products)			
Confirmation of Meeting Eligibility Criteria for Pilot			
This marketing application complies with all of the eligibility criteria listed in the Expression of Interest Notice including the following: Original generic drug application for the following pharmaceutical (dosage) forms: ☐ immediate-release, solid oral ☐ solutions (e.g., oral, injectable) ☐ When in-vitro or in-vivo comparative studies against a reference product are warranted, comparative			

studies comply with the requirements of the non-EU agencies proposed in this EOI request, as substantiated by evidence appended to the completed EOI Request.

☐ A completed Summary of Quality Differences form is included as part of this EOI Request.

Consent to share regulatory information

The undersigned hereby acknowledges and gives consent to the sharing of DCP assessment reports with the IGDRP agencies proposed in this EOI Request.

In addition, the undersigned hereby acknowledges and gives consent to the sharing of the same information :

☐ with all IGDRP agencies*, or
☐ with the following agencies:_____

Name of Authorized Signing Official: _____

Title, Company: _____

Signature**: _____

Date: _____

* Agencies from the following jurisdictions form part of IGDRP: Australia, Brazil, Canada, China, Chinese Taipei, the European Union, the Republic of Korea, Japan, Mexico, New Zealand, Russia, Singapore, South Africa, Switzerland and the United States as well as the World Health Organization.

**Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted.

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Summary of Quality Differences

This form must be completed and submitted to each Non-EU agency proposed in the EOI Request

Summary of Quality Differences

Modules and numbering reflect the ICH Common Technical Document.

Modules where there are no differences between the products filed with the EU DCP and the non-EU agency should be reported as "No differences". Where minor differences exist for a listed module, **a brief summary** of the details should be described.

Module	Information in application to be filed with the EU DCP	Information in application to be filed with the non-EU agency	Brief discussion of noted differences
3.2.S Drug Substance			
3.2.S.1 General Information			
3.2.S.2 Manufacture			
3.2.S.3 Characterisation			
3.2.S.4 Control of the Drug Substance			
3.2.S.5 Reference Standard or Materials			
3.2.S.6 Container Closure System			
3.2.S.7 Stability			
3.2.P Drug Product			
3.2.P.1 Description and Composition of the Drug Product			
3.2.P.2 Pharmaceutical Development			
3.2.P.3 Manufacture			
3.2.P.4 Control of Excipients			

Summary of Quality Differences

Modules and numbering reflect the ICH Common Technical Document.

Modules where there are no differences between the products filed with the EU DCP and the non-EU agency should be reported as "No differences". Where minor differences exist for a listed module, **a brief summary** of the details should be described.

Module	Information in application to be filed with the EU DCP	Information in application to be filed with the non-EU agency	Brief discussion of noted differences
3.2.P.5 Control of Drug Product			
3.2.P.6 Reference Standard or Materials			
3.2.P.7 Container Closure System			
3.2.P.8 Stability			