

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

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| **Product Information** | | | | | |
| Product Name (should be same as on product label): | | | | | |
| Active Pharmaceutical Ingredient: | | | | | |
| Pharmaceutical Form | Route | | Strength | | Conditions of Use |
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| **Applicant Information** | | | | | |
| Name (Full legal name): | | | | | |
| Address: | | | | | |
| Contact Person: | | | | | |
| Tel: | | Fax: | | Email: | |
| **Application/submission filing information** | | | | | |
| Intended filing date at EMA: | | | | | |
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| CP-Number (if already known): | | | | | |
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| 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. | | | | | |
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| **Consent to share regulatory information** | | | | | |
| The undersigned hereby acknowledges and gives consent to the sharing of CP assessment reports with  the IGDRP agencies proposed in this EOI Request.  If an Active Substance Master File (ASMF) is used with the application, please add consent from the ASMF holder to share the assessment report on the restricted part of the ASMF with the IGDRP agencies proposed in this EOI request. In case the ASMF holder consent is not provided, the assessment report on the restricted part of the ASMF will not be shared.  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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| **Consent to share regulatory information on the restricted part of the ASMF** |
| The undersigned hereby acknowledges and gives consent to the sharing of CP assessment reports on the restricted part of the ASMF 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. |