***Expression of Interest (EOI) Form to Participate in the HSA-NPRA Generic Medicines Work Sharing Initiative***

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| --- | --- | --- | --- |
| **Product Information** | | | |
| **Product Name (should be same as on product label):**  **Pharmaceutical (dosage) Form:** | | | |
| Pharmaceutical Form | Route | | Strength(s) |
|  |  | |  |
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|  |  | |  |
| **Active Pharmaceutical Ingredient**  Name (including salt and solvated form, if applicable):  How many Active Substance Master File (ASMF)/Drug Master File (DMF) will be submitted?  How many Certificates of Suitability (CEP) will be submitted? | | | |
| **Applicant Information** | | | |
| Name | | | |
| Address: | | | |
| Tel: | | Email: | |
| **Application/submission filing information** | | | |
| Proposed filing date to HSA:  Proposed filing date to NPRA:  Please note that applications should be submitted to HSA and NPRA simultaneously or as agreed with the respective agencies. | | | |
| **Consent to share regulatory information (to be signed by the applicant)** | | | | |
| The undersigned hereby acknowledges and gives consent to the sharing of assessment reports between HSA and NPRA.  Name of Authorised Signing Official:  Title, Company:  Signature\*:  Date:  \*Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted. | | | | |
| **Consent to share regulatory information on the Restricted Part of the DMF (to be signed by the DMF holder)** | | | |
| The undersigned hereby acknowledges and gives consent to the sharing of assessment reports on the restricted part of the DMF between HSA and NPRA.  Name of Authorised Signing Official:  Title, Company:  Signature\*:  Date:  \*Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted. | | | |

**Summary of Differences -** Modules and numbering reflect the ICH Common Technical Document. The technical dossiers submitted to both drug regulatory agencies should be the same. Where differences exist, please specify the differences and provide the rationale for the differences in the table below. If the section of the dossier concerned is not pre-specified in table below, please provide the relevant details under ‘Other sections’.

| **Differences in Quality Dossier** | | | | |
| --- | --- | --- | --- | --- |
|  | **Application to be filed with HSA** | **Application to be filed with NPRA** | | **Rationale for differences** |
| ***3.2.S Drug Substance*** | | | | |
| 3.2.S.2.1 Manufacturer |  |  | |  |
| 3.2.S.4.1 Specification |  |  | |  |
| ***3.2.P Drug Product*** | | | | |
| 3.2.P.3.1 Manufacturer |  |  | |  |
| 3.2.P.5.1 Specification |  |  | |  |
| ***Other sections – please specify*** | | | | |
|  |  |  | |  |
|  |  |  | |  |
| **Differences in Clinical Dossier (Bioequivalence Data)** | | | | |
| Reference Product used in BE study  E.g. Product name, drug product manufacturer |  | |  |  |
| Test Product used in BE study  E.g. Product name, drug substance and drug product manufacturer |  | |  |  |
| Approved strengths of Singapore/Malaysian reference product |  | |  |  |