

Notice to Applicants

Request for Expressions of Interest (EOI) to Participate in the HSA-NPRA Generic Medicines Work Sharing Initiative

Dear Generic Medicines Applicants,

As part of our efforts to further strengthen the bilateral cooperation between the Health Sciences Authority (HSA) of Singapore and the National Pharmaceutical Regulatory Agency (NPRA) of Malaysia in the area of pharmaceutical regulation, we are pleased to announce the launch of the ***HSA-NPRA Generic Medicines Work Sharing Initiative*** for generic medicines registration applications filed with both the HSA and NPRA. This initiative entails a joint collaborative assessment of the application with the intent to benefit the industry in terms of reduction in regulatory burden with the filing of common dossiers to both Agencies. It is also anticipated that the initiative would facilitate simultaneous market entries of generic medicines in both countries.

As a pilot, we are targeting a potential candidate of an immediate release oral solid dosage form supported by bioequivalence data. Initial expressions of interest to participate in this pilot should be submitted to both Agencies. It is encouraged that Part II of the ACTD (or Modules 2 and 3 of the ICH CTD) of the application submitted to both Agencies contain common information i.e. same technical dossier. Any differences in the dossier must be clearly identified and summarized by the applicant using the template provided within the Expression of Interest form. Country-specific administrative documents (i.e. Part I for ACTD or Module 1 for ICH CTD) remain as per the requirements of the respective Agencies.

The application should be submitted to both Agencies simultaneously on the same day. Once the application is accepted for evaluation by both Agencies, the review will take place simultaneously. It can be expected that any queries related to the technical dossier will be similar or the same. This means that the applicant will most likely not be required to address two separate sets of queries. While it is anticipated that the work sharing review will arrive at the same assessment, the individual Agency will make its own independent decision. The processing time of the application will not be any worse-off than the standard timelines of the respective Agencies. Additional information on the work sharing procedure and various milestones of the process are described in the document *Operational Procedures*. Please take note that the applications received will not be eligible for priority review.

Applicants who are interested in participating in the pilot should submit their completed *Expression of Interest (EOI) form* to the Director of NPRA (Malaysia) and HSA_TP_Enquiry@hsa.gov.sg (Singapore).

For further information, please contact us as follows with the email subject "HSA-NPRA Generic Medicine Work Sharing Initiative":

- HSA (Singapore): HSA_TP_Enquiry@hsa.gov.sg
- NPRA (Malaysia): npra@npra.gov.my