UPDATE ON HPRG'S INITIATIVES
PILOT PROJECT ON MIV-1 VERIFICATION ROUTE

Dear Industry stakeholders

The Therapeutic Products Branch (TPB) is conducting a pilot project with the aim to study the feasibility of a new verification route for Minor Variation (MIV-1) applications.

PILOT PROJECT ON MIV-1 VERIFICATION ROUTE

Background

TPB is exploring the feasibility of introducing a verification route for MIV-1 applications, which aims to enable greater leveraging of reference agencies' assessments and minimises duplication of effort. This new initiative is part of our on-going effort to enhance process efficiency, in particular for effective life cycle management for registered medicinal products.

Following consultation and positive feedback from the industry on the proposal, we plan to roll out a 6-month pilot project which will run from 1 July to 31 December 2016, to assess the optimum turnaround time and any necessary fine-tuning of eligibility criteria and review approach.

Eligible Applications

MIV-1 applications submitted in PRISM from 1 July 2016 to 31 December 2016 that meet the following:

Qualifying criterion	• All of the proposed variations are the same as those approved by at least one reference agency
Documentary requirements	• **Quality/CMC variations:** Approval letter from reference agency specifying the variations concerned • **Clinical variations:** Approved product label from the reference agency. Additional supporting documents may be requested during evaluation.
Exclusions	• **Quality/CMC variations:** Change of shelf-life for products where ASEAN storage condition applies • **Clinical variations which require evaluation to assess local impact:** 1. Rewording of indication 2. Amendment of dosing regimen for special populations 3. Drug interactions information 4. Deletion of contraindication(s)

*HSA's reference agencies: Australia TGA, Health Canada, EMA, UK MHRA and US FDA.

Impact to Industry

- There will be no changes made to the MIV submission process in PRISM, except for the following:
  - Under PRISM form Section 0.7 "*Does this change affect other product licences (Y/N)*" - Select "***Yes***"

- Under Section 0.8 "*If yes, please provide relevant Licence No or Application No.*", type in ***"Pilot MIV verification route"***

❖ The documentary requirements specified in Appendix 15 and 16 of the Guidance on Medicinal Product Registration in Singapore 2011, remain applicable:

i) PRISM application form
ii) Table of contents
iii) Declaration of the product licence holder for MIV-1
iv) Checklist for MIV(s) and all required supporting documents stated within.
v) Table of Amendment Details
vi) Current and proposed product labels (annotated and pristine copies), where applicable

❖ Turnaround timeline: There is no change to the target processing timeline of 120 days during the pilot run.

Completion of Pilot Project

The pilot project is targeted for completion by 31 December 2016. The actual implementation of the new route will be predicated on the outcome of the pilot project.

For enquiries, please contact:
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For clinical variations - Ms Pe Shu Ai (PE_shu_ai@hsa.gov.sg) or Mr Mark Wong (Mark_Wong@hsa.gov.sg)