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

Dear Industry stakeholders

Thank you for your support of the pilot project on MIV-1 Verification Route, which was rolled out on 01 July 2016. This initiative has been well received and we are pleased to extend the pilot project till 30 November 2017, followed by full implementation on 01 December 2017.

EXTENSION OF PILOT PROJECT ON MIV-1 VERIFICATION ROUTE

TPB introduced a pilot project on verification route for MIV-1 applications, which aims to enable greater leveraging of reference agencies' assessments and minimise duplication of effort. This initiative is part of our on-going effort to enhance process efficiency, in particular for effective life cycle management for registered therapeutic products.

Following the positive feedback from the industry, we will extend the pilot project to 30 November 2017. The extension will allow further data collection for determination of turnaround time for this new route.

Eligible Applications

MIV-1 applications that meet the following are eligible for submission via the verification:

Qualifying criterion	• All proposed variations are the same as those approved by at least one reference agency
Documentary requirements	• **Quality/CMC variations:** Approval letter from the 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 clinical impact in local context:** 1. Rewording of indication 2. Amendment of dosing regimen for special populations 3. 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 until 30 November 2017, 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 13 and 14 of the Guidance on Therapeutic Product Registration in Singapore Nov 2016, remain applicable:
  i) PRISM Application Form

ii) Table of Contents
iii) Cover Letter
iv) Checklist for MIV(s) and all required supporting documents stated within.
v) Table of Summary of Changes
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 phase.

Completion of pilot project and full implementation

The pilot project is targeted for completion by 30 November 2017, followed by plans for full implementation in December 2017.

For enquiries, please contact:
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