NEW INITIATIVES FOR REGISTRATION OF THERAPEUTIC PRODUCTS

Dear Industry Stakeholders,

As part of HSA's ongoing initiative to streamline the regulatory controls for health products and improve predictability and transparency of timelines, the Therapeutic Products Branch (TPB), Health Products Regulation Group (HPRG) would like to share with you the new initiatives that will be implemented in the upcoming 6 months, as below.

Highlights of New Initiatives

1. Implementation of MIV-1 Verification Route

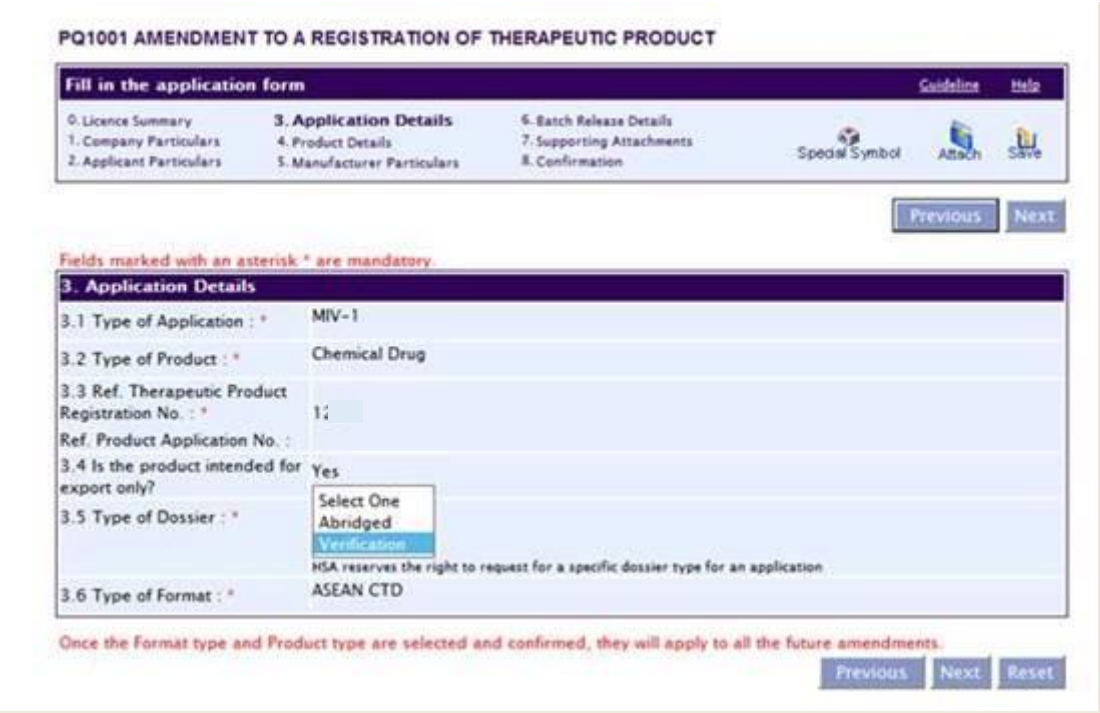
We are pleased to announce the full implementation of the Verification Route for MIV-1 application, following the successful completion of the pilot study. This new evaluation route will have a shorter processing timeline of 90 working days, compared to the Abridged Route. The official implementation will take effect from 01 December 2017.

This enhancement aimed to improve process efficiency through greater leveraging of the assessments done by HSA's reference agencies, thereby minimise duplication of efforts. The Verification Route also provides a new option for product registrants to submit MIV-1 applications, in addition to the Abridged Route. A product registrant can choose to file a MIV-1 application via the route that best suits its regulatory strategies for effective product life-cycle management.

To qualify for the Verification Route, the proposed variations must be identical to those approved by one of HSA's reference agencies, accompanied by the proof of approval of that reference agency. HSA's reference agencies include Australia TGA, Health Canada, EMA, UK MHRA and US FDA.

Quick points on submission of an application via the Verification Route:

- Please select "Verification" under Section 3.5 of the PRISM application form.



- ❖ In addition to the approval letter or approved product labels from a HSA reference agency, 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

2. Overall Screening Turn-Around Time (TAT)

To improve transparency and predictability of screening time for applications, we will be introducing a screening TAT of 50 working days for the following application types:

- New drug applications (NDA)
- Generic drug applications (GDA)
- Major variation applications (MAV)

This new TAT starts from the date of receipt of the application dossier and ends on the date of acceptance or non-acceptance/ withdrawal of the application, excluding stop-clock (i.e. time taken by applicants to respond to Input Request (IR) from HSA). Aggregated stop-clock time will also be published on a half-yearly basis. All data will be anonymised to ensure information on individual application is not disclosed.

The number of rounds of IR will be capped at 2. An applicant will be given 20 working days to respond to each round of IR. After 2 rounds of IR, if deficiencies remain inadequately addressed, the application must be withdrawn. Further details will be provided in the next revision of the Guidance on Therapeutic Product Registration in 2018.

The new screening TAT is targeted for implementation in April 2018.

For any enquiries related to these new initiatives, please click here to submit an enquiry.

Thank you.

Therapeutic Products Branch
Pre-Market Cluster
Health Products Regulation Group
Health Sciences Authority

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