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, the Therapeutic Products Branch, Health Products Regulation Group is pleased to share the following new initiatives.

Highlights of New Initiatives

1. Removal of screening process for MIV-1 applications

With the introduction of the self-help tool on post-approval variation applications (MIV) and guided by the application checklists, applicants are now generally familiar with the regulatory requirements and are able to select the appropriate MIV application type. The improvement in submission quality by companies has enabled HSA to further streamline the process and remove the screening step for MIV-1 applications. This initiative will improve the predictability of the overall processing timelines and translate into an overall time savings for applicants by at least 25 working days, as the applications will proceed to the evaluation stage after submission.

The new process will take effect from 17 September 2018. There is no change to the application submission process in PRISM. Applicants will continue to receive a "Acceptance" notification, which will be sent within 3 working days after submission of an MIV-1 application via PRISM. Applicants are reminded to ensure the submission of complete dossiers by referring to the relevant MIV checklists and self-help tool on post approval variations to avoid a delay in the processing of the application.

The target Turn-Around Time (TAT)* for processing a MIV-1 application is 120 working days (abridged route) and 90 working days (verification route).

**TAT starts from the submission date of the MIV-1 application in PRISM, and ends on the date of regulatory decision or withdrawal date, excluding stop-clock (i.e. time taken by applicants to respond to Input Request (IR) from HSA).*

2. Going paperless

i. Currently, the official regulatory decision for therapeutic product applications (NDA, GDA, MAV, MIV-1) is issued electronically via PRISM, and concurrently in a separate hardcopy letter via postal service or as a scanned copy of the letter via email. As government services go digital, HSA will no longer issue regulatory decision in hardcopy letter from 17 September 2018. The official notice will continue to be issued electronically via PRISM as per current.

ii. In line with the whole-of-government move to streamline regulatory requirements, the requirement for company stamp on the patent declaration form has been removed. The patent declaration form and relevant sections* of the Guidance for Therapeutic Product Registration have been updated to reflect this change. Applicants are strongly encouraged to use the updated version when making an application.

**See section 3, 15.1, and 18.1 of the Guidance document*

3. **Seeking applicants' consent for disclosure of information within the Australia-Canada-Singapore-Switzerland (ACSS) Consortium**

A new section seeking applicants' consent for disclosure of information within ACSS has been added to the Application Checklists (Appendix 2A, 2B, 3A and 3B). This is to facilitate the exchange of information between HSA and partner regulatory authorities and to enable work-sharing. In addition to the upfront consent sought, HSA will notify the applicant in writing if such disclosure of information is eventually made. For applications submitted from 17 September 2018, applicants should use the updated version of the Application Checklist.

For enquiries, please click here

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www.hsa.gov.sg