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 (TPB), Health Products Regulation Group, is pleased to share the following new initiatives.

Highlights of New Initiatives

Revision of Guidance on Therapeutic Product Registration in Singapore and Related Appendices

The following sections have been updated and the changes will take effect for applications submitted from 31 Dec 2020. The revised guidance documents will be published on the HSA website by this date.

1. Streamlined stability data requirements (Chapters C and D)

TPB is introducing a streamlined approach for stability data requirements for registration and variation applications, which replaces the current requirement for site-specific data where multiple drug product (DP) and/ or drug substance (DS) manufacturing sites are sought in the application. The streamlined requirements take into consideration the technical extrapolation of stability study results from one manufacturing site to another where scientifically justified.

With this, site-specific data is no longer required if the technical criteria specified in the revised guidance document are met, subject to compliance with ICH Q1A(R2) or ASEAN Stability Guidelines. The main changes are:

- For applications where multiple DP manufacturers are proposed, stability data from each site is not required if the formulation, manufacturing process, specifications and container closure system of the DP from all manufacturing sites are the same. The release results of the DP from each site must demonstrate comparability to the batches used in the stability studies.

- For applications where multiple DS manufacturers are proposed, stability data from each site is not required if the synthetic route, manufacturing process, specifications and container closure system of the DS from all manufacturing sites are the same. The release results of the DS from each site must demonstrate comparability to the batches used in the stability studies.

2. Other editorial/minor changes

- New Drug Application (NDA)/Major Variation Application (MAV-1) definitions and Good Manufacturing Practice (GMP) requirements (Chapters C and F)
- Screening checklists (Appendices 2A, 2B, 3A and 3B)
- Guidelines on PRISM submission (Appendix 17)

For enquiries, please click here

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