NEW POST APPROVAL INITIATIVES FOR THERAPEUTIC PRODUCTS

Dear Industry Stakeholders,

The Therapeutic Products Branch (TPB), Health Products Regulation Group, is pleased to share the following new post-approval initiatives.

Summary Report of Benefit-Risk Assessment & New Online Form for Registration Condition Fulfilment

1. Summary Report of Benefit-Risk Assessment

TPB is piloting a new initiative to prospectively publish Summary Reports of Benefit-Risk Assessments for approved new chemical and biologic entities.

In publishing the benefit-risk assessment which forms the basis of regulatory approvals, HSA aims to enhance regulatory transparency through open communication with stakeholders and public, in line with current international best practice among global regulatory agencies.

The report will contain a summary of the quality, efficacy and safety data contributing to the benefit-risk assessment, as well as HSA's conclusion on the benefit-risk balance of the approved indication. It will not include data that is confidential/proprietary information*. Product Registrants will receive a copy of the summary report for information before it is published on the HSA website.

TPB targets to initiate the pilot in June 2020. We will continue to review and fine-tune any necessary adjustments as we gather more experience following the initial implementation.

* Please refer to the definition of *confidential information*, as defined in regulation 26(2) of the *Health Products (Therapeutic Products) Regulations.*

2. New Online Form for Submission of Documents to Fulfil Registration Conditions

TPB has launched a new online form (click here) to facilitate the submission of post-approval data/documents to fulfil therapeutic products (TP) registration conditions.

The short form consists of 9 fields, and allows for multiple registrations under the same registrant to share one form, as long as the same documents apply to all product registrations that carry the same registration condition. i.e., each form can be used for submitting the same set of documents for fulfilling one registration condition for multiple products.

To ensure the confidentiality of the submitted documents, registrants are required to log in using CorpPass before accessing the form. This is similar to the use of CorpPass login when registrants log into PRISM to submit any TP related applications.

With effect from 1 May 2020, if you receive an email reminder on any outstanding registration condition, please submit your documents via the new e-form and do not reply to the email reminder.

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

www.hsa.gov.sg