UPDATE ON IMPLEMENTATION OF HEALTH PRODUCT (THERAPEUTIC PRODUCTS) REGULATIONS 2016

Dear Industry Stakeholders,

As part of HSA's ongoing initiative to update and streamline the regulatory controls for health products and bring them under a single legislation, the legislative control for pharmaceutical products (conventionally known as chemical and biologic drugs), has been transferred from the Medicines Act and Poisons Act to the Health Products (Therapeutic Products) Regulations 2016 under the Health Products Act (HPA). This group of products has been added to the First Schedule of the HPA as "therapeutic products" and the new regulations are effective 1 November 2016.

In conjunction with the legislative transfer, the Guidance on Therapeutic Product Registration has been revised as of 1 November 2016. There will be a phase-in period for 6 months for the implementation of the revised requirements, from 1 November 2016 to 30 April 2017, to enable the industry to make the necessary adjustment prior to full implementation.

Industry was consulted on the proposed revision in August 2016 and HSA had reviewed the feedback received and made refinement to the Guidance. We are happy to share with you the key changes, as below.

Highlights of Changes

1. **Changes Consequential to Portover of Controls of Pharmaceutical Products to the Health Products Act**

   Product licence conditions are transferred to Registration conditions. The conditions have been revised to align with the terminology changes under the new legislation, concurrently certain conditions are also updated to ensure their relevance. Product registrants may view their product registrations and the updated registration conditions at Enquire@PRISM on 1 November 2016.

   With the legislative change, each therapeutic product on the register has a retention fee due date. For products which have obtained a Product Licence under the Medicines Act, the retention fee due date corresponds to the date of expiry of the

Product Licence. For new Product Registrations, the retention fee due date will be on each anniversary of the date of registration of the therapeutic product.

All registered therapeutic products will remain on the Register, unless:

- The registration is suspended or cancelled by HSA, or
- The registration is cancelled by the registrant, or
- The registrant has failed to make a payment for an annual retention fee within 60 calendar days after the retention fee due date.

Please refer to the Guidance for Retention of Therapeutic Product on the Product Register for more information.

2. **Move Towards Digitization**

The administrative documents (Module 1 / Part I) should be submitted in electronic format. A colour scanned copy of the original documents should be attached **in PRISM**. The original hardcopies (including certificates and signed letters) are no longer required. However, HSA reserves the rights to request for the submission of the original or certified true copy of the submitted document if there is any doubt that the submitted scanned document is not an accurate reflection of the original document. Please refer to the revised Guidance on Therapeutic Product Registration for more information.

Please note that the applicant is responsible for submitting the application and all the accompanying supporting documents (including but not limited to the dossier, responses to HSA's queries and commitment letters) in PRISM.

3. **Mandatory Submission of Application Checklist**

The application checklists (Appendices 2A, 2B, 3A, 3B) are updated with pointers to provide additional guidance to applicants in preparing the application submissions.

The submission of the application checklist is **mandatory** for submission of NDA, GDA and MAV applications, which will enable HSA to counter-check the completeness of the dossier based on the same checklist as submitted by the applicant. This serves to enhance the transparency and efficiency of the screening process, such that submission deficiencies could be promptly identified and addressed by the applicant.

The editable Portable Document Format (e-PDF) of the application checklists can be downloaded from the website (click here).

4. **Simplification of Requirements for Translation of Non-English Documents**

The requirements for translation of documents that are not in English have been revised and stratified into certified translation or verified translation, depending on the type of document which is to be translated. Please refer to the revised Guidance on Therapeutic Product Registration for more information.

5. **Submission of Application via the Verification Route**

For submission of applications via the verification route, the complete unredacted assessment reports should be available at the point of making the application. Applications submitted to HSA without the complete unredacted reports from the primary reference agency will not qualify for the verification evaluation route. The applicant will be required to withdraw and resubmit the application via the abridged route if the applicant intends to pursue the application.

Companies who face difficulties in obtaining the unredacted reports (i.e. clinical, quality and/or DMF assessment reports) can write in via email (HSA_TP_Enquiry@hsa.gov.sg) prior to submission of the registration application, to request for assistance from HSA to retrieve the unredacted reports directly from the reference agencies involved (i.e. US FDA or EMA). The registration application should only be made **after** HSA receives the assessment reports from the reference agency.

6. **Submission of Product Label for Sample Packs**

The submission of product label for sample packs is no longer required, as long as the container closure system (CCS) and pack size of the sample pack is already registered with HSA.

As such, the submission of variation applications to include "sample pack" CCS or sample pack label will not be required.

7. **Changes to Product Registration PRISM Application Form**

Section 4.7 Packaging, Shelf Life & Storage Conditions of the form has been revised to include the field *4.7.1 Cold Chain*, which will enable the applicant to indicate whether the product requires cold chain management.

Section 8 Confirmation of the form has been revised to allow applicants to "opt-in" for auto-inclusion of the product registration to their Importer's Licence upon the approval of the product, as long as the Importer's Licence is valid and fulfils the required criteria at the point of product registration (i.e. product approval). This selection cannot be amended once the registration application is submitted.

Please refer to Appendix 17 Guideline on PRISM Submission of the revised Guidance on Therapeutic Product Registration for more information.

8. **Variation Applications**

The submission of the Declaration of Product Registrant for MIV-1 and MIV-2 is no longer required. Please refer to the revised Appendix 13 - Guidance on MIV Applications for Chemical Therapeutic Products and Appendix 14 - Guidance on MIV Applications for Biologic Therapeutic Products for more information.

9. **Change in Contact Email Address**

The email contact of the Therapeutic Products Branch is changed to HSA_TP_Enquiry@HSA.gov.sg with effect from **1 November 2016.**

The new email address will replace the 2 existing contact email addresses: HSA_Medprod_Enquiry@HSA.gov.sg and HSA_Medprod_Registration@HSA.gov.sg.

Thank you.

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

www.hsa.gov.sg