UPDATE ON GUIDANCE ON MEDICINAL PRODUCT REGISTRATION IN SINGAPORE

Dear Industry Stakeholders

From the Health Products Regulatory Conference (HPRC) on 9 September 2013, proposals to revise the stability data requirements and implement the ASEAN Variation Guideline (AVG) were announced.

The Therapeutic Products Branch (TPB) appreciates the time and effort spent on reviewing the announced proposals and would like to thank you for your comments and feedback during the consultation period.

We have reviewed the feedback and are pleased to announce updates to the Guidance on Medicinal Product Registration in Singapore (April 2011), as summarised below. Full details on the updates can be found on the HSA website.

1. Briefing sessions

Briefing sessions on updates to the *Guidance on Medicinal Product Registration in Singapore* will be held to further your understanding of the amended requirements. Each session will be a maximum of 2 hours in duration.

Venue: The Auditorium, Health Sciences Authority Building opposite Outram MRT station, 11 Outram Road, Singapore 169078.

You will only need to attend any one session on the following dates and times – **these sessions will be free of charge**:

3 March 2014 (Mon)	7 March 2014 (Fri)
10-12pm	10-12pm
3-5pm	3-5pm

Please register your attendance by providing the following information through email to david_woo@hsa.gov.sg and katherine_lim@hsa.gov.sg with the email subject heading "*Briefing Session on Updates to Registration Requirements*":

- Your name, company and contact details (*note*: you may register multiple attendees from the same company in one email).
- Date and time of the session of your 1st and 2nd choice.

There is a limited capacity for each session and registration will be on a first-come, first-serve basis. **Registration will close on 21 February 2014.** We highly recommend that you attend a session.

2. Drug Product Stability Data Requirements

a) The site specific drug product stability data requirements *at the time of submission* of a new product application have been revised, as announced at the HPRC.

   The changes made to the stability data requirements at the time of submission do not apply to biologic medicinal products. A case-by-case approach will be taken for the site-specific stability data requirement for biological products; inquiries can be submitted to HSA_MedProd_Registration@hsa.gov.sg.

   These changes are effective **from 1 January 2014**.

b) Version 6.0 of the *ASEAN Guideline on Drug Product Stability Study* will be implemented on **1 April 2014**. However, there will be an additional 6-month grace period for applications that still cannot meet the requirements set out in version 6.0 of the *ASEAN Guideline on Drug Product Stability Study*. **Full implementation** of version 6.0 of the *ASEAN Guideline on Drug Product Stability Study* **will commence on 1 October 2014**.

Affected sections to the *Guidance on Medicinal Product Registration in Singapore* have been revised (annotated and clean copies) to reflect these changes to the requirements:
Chapter C, section 14.3.2, subsection *Drug Product Stability Data*, p. 40-41
Chapter D, section 17.3.2, subsection *Drug Product Stability Data*, p. 57-58

3. Drug Master File procedures

As work-sharing on generic drug registration with other regulatory agencies continues to progress, a new DMF Submission Form will be introduced to facilitate identification of submitted dossiers that are common to these agencies.

This form will apply to submission of new Drug Master Files (DMFs) in support of all product applications (i.e. NDAs, GDAs, MIVs) *and* to submission of DMF updates. The form can be submitted in hard copy or soft copy but it must be included when the DMF is submitted to HSA. Please communicate this requirement to the DMF Holder when the DMF is required to support your product application.

This form will be implemented on **1 April 2014**. However, as the form is now available, it is *highly recommended* that the form be included with the DMFs when the DMF holder submits the DMF in support of your product application.

Affected sections to the *Guidance on Medicinal Product Registration in Singapore* have also been revised (annotated and clean copies) to reflect these changes to the requirements:
Chapter C, section 14.3.2, subsection *Drug Product Stability Data*, p. 36-37
Chapter D, section 17.3.2, subsection *Drug Product Stability Data*, p. 54-55

4. ASEAN Variation Guideline

Implementation of the ASEAN Variation Guideline (AVG) will be implemented in two phases:

- **Phase 1 will be implemented on 1 April 2014.** There will be 6-month grace period but **full implementation** will be on **1 October 2014**.
- Phase 2 will be implemented in 2015.

Affected sections to the *Guidance on Medicinal Product Registration in Singapore* have been revised to reflect these changes to the requirements:
Appendix 15 – Guideline on Minor Variation Applications for Chemical Drugs
Appendix 16 – Guideline on Minor Variation Applications for Biologics

We will continue to engage you and look forward to working closely with you on future improvement initiatives.

For enquiries, please contact:

HSA MedProd Registration
Email: HSA_MedProd_Registration@hsa.gov.sg
Therapeutic Products Branch, Pre-Marketing
Health Products Regulation Group

www.hsa.gov.sg