



SEEKING INDUSTRY FEEDBACK ON DRAFT REVISED GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION (UPDATED 2016)

Dear Industry Stakeholders,

The Therapeutic Products Branch (TPB) invites industry stakeholders to give feedback on the proposed revision to the Guidance on Therapeutic Product Registration in Singapore. Industry stakeholders are welcome to provide feedback from **1 August 2016 to 31 August 2016**.

This is part of HSA's ongoing initiative to enhance clarity of the submission requirements for therapeutic product registration, as well as to ensure that the technical requirements are updated and stay relevant with the rapid developments of the pharmaceutical industry. Concurrently, the Guidance document is also revised to reflect the changes in process and terminology consequential to the transfer of controls of pharmaceutical products from the Medicines Act (Cap. 176) and Poisons Act (Cap 234.) to the Health Products Act (Cap. 122D).

The revised Guidance will take effect from 1 November 2016. There will be a phase-in period for 6 months, from 1 November 2016 to 30 April 2017, to enable the industry to make the necessary adjustment prior to full implementation.

We are happy to share with you some of the key changes to the Guidance document.

Highlights of Key Changes to the Draft Guidance

1. Change in Terminology Consequential to Portover of Controls of Pharmaceutical Products to the Health Products Act

With the implementation of the Health Products (Therapeutic Products) Regulation 2016 on 1 November 2016, pharmaceutical products, commonly known as chemical or biologic drugs, will be called “therapeutic products”.

The terminology changes are summarised below:

Medicines Act	Health Products Act
Medicinal product	Therapeutic product
Product Licence	Product Registration
Licence number	Registration number
Applicant	Applicant
Product Licence holder	Product registrant
Licence conditions	Registration conditions
Licence renewal	Registration retention
Revoke (revocation) licence	Cancel (cancellation) registration
Cancel licence	Cancel registration
Suspend licence	Suspend registration

2. 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 draft checklist is currently in PDF format, which will be available in editable format when the final document is implemented.

3. Simplification of Requirements for Translation of Non-English Documents

The requirements for translation is simplified to allow for the submission of a verified translation. A sample verification document for translator is provided in the new Appendix 4 for reference.

4. Removal of Requirement of Submission of the Singapore Quality Overall Summary (SQOS)

The submission of the Singapore Quality Overall Summary (SQOS) is no longer required. The current documentation submission requirements, including the submission of ICH CTD / ASEAN CTD Quality Overall Summary, will remain.

5. Quality Requirements for Certification of Suitability (CEP), Parametric Release, Batch Analyses and Stability

Section 15.3.1 and Section 18.3.1 of the main guidance are revised to:

- a) Remove the requirements for submitting CTD S1 and to provide greater clarity on other CTD requirements for applications with CEP.
- b) Provide more clarity on the drug substance batch analyses requirements.

Section 15.3.2 and Section 18.3.2 of the main guidance are revised to provide more clarity on the drug product stability requirements.

Section 15.1, Section 15.3.2, Section 18.1 and Section 18.3.2 of the main guidance are revised to provide more information on GMP and documentary requirements for applications with parametric release.

6. Product Interchangeability

Chapter D (Generic Drug Application Submission) and appendix on Product Interchangeability and Biowaiver Request for Chemical Generic Drug Applications (Appendix 12 in current version) are revised to provide greater clarity on current submission requirements (e.g. bioequivalence study, comparative dissolution profile testing, biowaiver criteria) for generic drug applications.

7. Pharmacovigilance Requirements for NDA and Biosimilar Applications

Appendix 15 (Guidance on Registration of Biosimilar Products) is updated with new pharmacovigilance requirements for biosimilar products.

A new appendix, Appendix 16 (Guideline on Submission Requirements for Risk Management Plan Documents), is introduced to provide guidance on the submission of risk management plan (RMP) documents.

8. Variation Applications

The number of MIV-1 applications that can be submitted in PRISM at any one time is increased from 3 to 5.

The submission of the Declaration of Product Registrant for MIV-1 and MIV-2 is also no longer required.

9. Guidelines on PRISM Submission

The Guidelines on PRISM Submission is shifted from the main Guidance document to a new Appendix 17, and includes changes related to the TP Portover. The appendix also outlines the submission process for variation applications and provides guidance on responding to Input Request.

10. Change in Contact Email Address

The email contact of the Therapeutic Products Branch will be 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.

Details of the proposed changes and feedback form are available on the [HSA website](#).

Please send us your feedback in the following format as per the Excel template provided:

- i. Company name
- ii. Chapter or Appendix in the Guidance where you would like to make a comment
- iii. Specific Section/Line in Guidance where you would like to make a comment
- iv. Your comment/feedback
- v. Suggestions or Proposals from Industry Perspective

Please provide your feedback to HSA_MedProd_Registration@hsa.gov.sg by 31 August 2016.

Your input is highly valued and we thank you for your time and constructive feedback.

Thank you.

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

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