

HEALTH
SCIENCES
AUTHORITY

REGULATORY GUIDANCE

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THERAPEUTIC PRODUCTS GUIDANCE

CHANGE OF REGISTRANT FOR REGISTERED
THERAPEUTIC PRODUCT

TPB-GN-001-000



REVISION HISTORY

Guidance Version (Publish Date)

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1. This guidance is intended to assist you in your application for a change of registrant for registered therapeutic products from one company (existing registrant) to another company (new registrant).
2. The new registrant must be a business entity currently registered in Singapore with the Accounting and Corporate Regulatory Authority (ACRA) and has an active CRIS account with HSA. You may click on CRIS@HSA for more information about Client Registration and Identification Service (CRIS).
3. The existing registrant has to initiate the transfer of the affected therapeutic product registration via Transfer@PRISM with the following information:
 - (a) UEN (Unique Entity Number) of the new registrant to which the product registration is to be transferred;
 - (b) Email address of the authorised person acting on behalf of the new registrant; and
 - (c) Registration number and name of the therapeutic product(s) for which the registration will be transferred to the new registrant.
4. The existing registrant should conclude the following prior to submission of the transfer application in order for the new registrant to submit the transfer application:
 - (a) any pending variation application for the therapeutic product to which the transfer relates;
 - (b) any pending payment of annual retention fee by the existing registrant; *and/or*
 - (c) any pending application to cancel the product registration to which the transfer relates.
5. Up to 20 registered therapeutic products may be included in a single transfer

application. A separate application is required if the number of registered therapeutic product exceeds 20.

6. Upon submission of the transfer application by the existing registrant, a transaction number will be generated by the system and an acknowledgement page can be printed for record. An email notice will be also sent to the new registrant.
7. Upon receipt of the email notice, the new registrant is required to submit a transfer application online via Transfer@PRISM within 30 calendar days.
8. For the submission of a transfer application, the new registrant is required to submit the following supporting documents as attachments in the PRISM application form:
 - (a) Letter of Authorisation (LoA) from the product owner, which must:
 - i. Bear the company letterhead of the product owner and includes the full name of the therapeutic product and its Singapore product registration number as well as the name and address of the new registrant;
 - ii. Include a statement authorising the new registrant;
 - iii. Include a statement to withdraw the authorisation granted previously to the existing registrant
 - iv. Indicate the proposed effective date for the transfer (if the proposed effective date is not clearly indicated in the authorisation letter, your transfer application will be processed according to the current processing timeline).
 - (b) Written confirmation that arrangement has been made with the existing registrant for the handing over of the relevant product registration files

9. The original hardcopy of the Letter of Authorisation (LoA) mentioned in point 7(a) is also required to be submitted to the Therapeutic Products Branch within 2 working days following the submission of the PRISM application.

10. Both existing registrant and new registrant will be notified via email on the outcome of the transfer application. The processing timeline is 14 working days upon complete submission of the application by the new registrant.

11. Upon successful transfer of the product registration, the new registrant will be able to view the latest product registration information via Enquire@PRISM.

12. For enquiry, please contact the Therapeutic Products Branch (TPB) at email: HSA_TP_Enquiry@hsa.gov.sg

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

CONTACT INFORMATION

Therapeutic Products Branch (TPB)

Pre-market Cluster

Health Products Regulation Group

Health Sciences Authority

11 Biopolis Way, #11-03, Helios

Singapore 138667

www.hsa.gov.sg

Email: HSA_TP_Enquiry@hsa.gov.sg

Fax: 6478 9032

Website: www.hsa.gov.sg

