HEALTH SCIENCES AUTHORITY

REGULATORY GUIDANCE

18 APRIL 2022

THERAPEUTIC PRODUCTS GUIDANCE

CHANGE OF REGISTRANT FOR REGISTERED THERAPEUTIC PRODUCT

TPB-GN-001-001

HSA
Health Sciences Authority

REVISION HISTORY

Guidance Version (Publish Date)

TPB-GN-001-001 (uploaded 18 Apr 2022)

The change of registrant (COR) for therapeutic products refer to the transfer of a therapeutic product registration from one local company (existing product registrant) to another local company (new product registrant).

There are two parts to a COR application:

A. The initiation of the transfer by the existing product registrant; and
B. The acceptance of the transfer by the new product registrant.

Conditions of the transfer:

- 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.
- There is no pending variation application for the therapeutic product for which the registration is to be transferred.
- There is no pending retention application for the therapeutic product for which the registration is to be transferred.
- If a product registration is due for retention during the process of the transfer (i.e. prior to approval of the COR application by HSA), the retention fee will be borne by the existing registrant.

Part (A) - The initiation of the transfer by the existing product registrant

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
(b) HSA Client code of the new registrant
(c) Email address of the authorised person acting on behalf of the new registrant; and
(d) Registration number and name of the therapeutic product(s) for which the registration will be transferred to the new registrant.

Upon successful submission of the COR application by the existing registrant, a **transaction number** will be generated by the system. An email notice will also be sent to the new registrant.

Note:

Each COR application allows the transfer of a maximum of 20 registered therapeutic products.

If there were mistakes made when entering the information of the new registrant (e.g. wrong UEN, client code, email address etc.), the new registrant will not be able to continue with Part B of the submission of the COR application. For such situations, please contact us at HSA_TP_Enquiry@hsa.gov.sg for assistance to withdraw Part A of the COR application.

Do note that we will require time to assist you on the request. Hence to avoid any delays, please ensure that the information entered in the application is accurate.

Part (B) - The acceptance of the transfer by the new product registrant

Upon receipt of the email notice, the new registrant is required to complete the COR application online via Transfer@PRISM within 30 calendar days.

To complete the COR application, the new registrant must submit the following supporting documents as attachments in the PRISM application form:

(a) Letter of Authorisation (LoA) from the product owner, which must:

i. Be a colour scanned copy of the original documents*

ii. 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;

iii. Include a statement authorising the new registrant to be the registrant of the product in Singapore;

iv. Include a statement to withdraw the authorisation granted previously to the existing registrant; and

v. Indicate the proposed effective date for the transfer.

(b) Written confirmation that arrangement has been made between the existing registrant and the new registrant for the hand-over of the relevant product registration files.

Note: If the proposed effective date is not clearly indicated in the authorisation letter, the COR application will be processed according to the current processing timeline.

* Original hardcopy of documents is not 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.

Upon successful submission of the COR application by the new registrant, an **application number** will be generated by the system.

The current processing timeline is 14 working days from the date of receipt of the complete submission of the COR application by the new registrant.

Both the existing registrant and new registrant will be notified via email on the outcome of the COR application.

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

If there are any changes to be made to the product labelling of the affected products after the completion of the COR application, the new registrant will have to submit minor variation applications for HSA's review before the import and supply of the products with the revised labelling.

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

Therapeutic Products Branch (TPB)
Medicinal Product Pre-Market Cluster
Health Products Regulation Group
Health Sciences Authority

HSA
Health Sciences Authority