

HEALTH
SCIENCES
AUTHORITY

REGULATORY GUIDANCE

01 NOVEMBER 2016

THERAPEUTIC PRODUCTS GUIDANCE

RETENTION OF THERAPEUTIC PRODUCT ON THE
PRODUCT REGISTER

TPB-GN-002-001



REVISION HISTORY

Guidance Version (Publish Date)

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1. With the transfer of the legislative controls for pharmaceutical products from the Medicines Act (Cap. 176) to therapeutic products under the Health Products Act (Cap. 122D) in November 2016, the requirement for a Product Licence under Section 5(1) of the Medicines Act is replaced by product registration under Section 15(1) of the Health Products Act.
2. All registered therapeutic products are entered into the Register of Therapeutic Products. The Register is a searchable database published on HSA website (i.e. [HSA InfoSearch](#)). An annual fee is payable for retaining the therapeutic product on the register, thereafter referred to as retention fee.
3. Under section 31 of the Health Products Act, all registered therapeutic products will remain on the Register, unless:
 - a) The registration is suspended or cancelled by HSA, or
 - b) The registration is cancelled by the registrant, or
 - c) The registrant has failed to make a payment for an **annual** retention fee within 60 calendar days after the retention fee due date.
4. Each therapeutic product on the register has a retention fee due date. The due date is defined as such:
 - a) 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.
 - b) For therapeutic products that are registered on or after the date of transfer of the legislative control to HPA, the retention fee due date will be on each anniversary of the date of registration of the therapeutic product
5. If your company has a therapeutic product on the register (i.e. you are the registrant), you will receive a payment notice via the preferred mode of contact selected in the product registration. However, you will not receive a

payment notice if you have submitted an application to cancel the registration.

6. If your company has a GIRO account with HSA, the retention fee will be debited from your account upon the retention fee due date. You should ensure that the funds in your account is sufficient for the required payment.
7. If your company does not have a GIRO account with HSA, you are strongly encouraged to apply for one ([click to download the application form](#)). Registrants without a GIRO account is required to log on to [Renew@PRISM](#) to make the necessary payment for the retention fee via electronic payment modes (e.g. eNETS, credit card payment).
8. You will be notified of the retention fee payment due date according to the schedule outlined below:

	Companies with GIRO Account with HSA¹	Companies without GIRO Account with HSA
60 calendar days before the retention fee payment due date	<ul style="list-style-type: none"> • System-generated retention notice will be sent to product registrant. • Registrants to ensure sufficient funds for GIRO deduction. 	<ul style="list-style-type: none"> • System-generated retention notice will be sent to product registrant. • Registrant to make payment online at Renew@PRISM.
30 calendar days before the retention fee payment due date	<ul style="list-style-type: none"> • A reminder notice will be sent to the product 	<ul style="list-style-type: none"> • A reminder notice will be sent to the product registrant if the

¹ Companies who had opted out of auto-renewal scheme would be considered a company without any GIRO account with HSA.

	Companies with GIRO Account with HSA¹	Companies without GIRO Account with HSA
15 calendar days before the retention fee payment due date	<p>registrant if the payment has not been made.</p> <ul style="list-style-type: none"> • Registrant to ensure sufficient funds for GIRO deduction. 	<p>payment has not been made.</p> <ul style="list-style-type: none"> • Registrant to make payment online at Renew@PRISM.
1 calendar day After the retention fee payment due date	NA	<ul style="list-style-type: none"> • A reminder notice will be sent to the product registrant if the payment has not been made. • Registrant to make payment online at Renew@PRISM.
15 calendar days After the retention fee payment due date	<ul style="list-style-type: none"> • A reminder notice will be sent to the product registrant if the payment has not been made. • Registrant to ensure sufficient funds for GIRO deduction. 	<ul style="list-style-type: none"> • A reminder notice will be sent to the product registrant if the payment has not been made. • Registrant to make payment online at Renew@PRISM.
30 calendar days After the retention fee payment due date	<ul style="list-style-type: none"> • A notice will be sent to the product registrant if the payment has not been made. • If the registrant intends to retain the product on the register, the required payment must be made via <u>electronic payment mode (e.g. credit card or eNETS)</u> at Renew@PRISM, and accompanied by reasons for late payment. 	

	Companies with GIRO Account with HSA¹	Companies without GIRO Account with HSA
	<ul style="list-style-type: none"> This payment must be done before the specified date (i.e. 60 calendar days after payment is overdue). 	
60 calendar days After the retention fee payment due date	<ul style="list-style-type: none"> If payment is not made by the specified date (i.e. 60 calendar days after payment is overdue), registration will be <u>cancelled the next day after the specified date.</u> 	

9. If you do not intend to retain your product on the register, you should cancel the registration via Cancel@PRISM prior to the product registration's retention fee due date. Any payment that had been collected will not be refunded in the event of any subsequent cancellation.

10. Once a product registration is cancelled, a new application (with applicable fees chargeable) will have to be submitted if your company intends to register the product again. HSA will not entertain any requests for reinstatements of product registrations once the product registration has been cancelled 60 days after the payment due date.

11. Notification for retention fee payment will not be sent for any therapeutic products which are suspended by HSA. Payment of retention fee will resume only after registration is reinstated.

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

HEALTH SCIENCES AUTHORITY

Health Products Regulation Group
Blood Services Group
Applied Sciences Group

www.hsa.gov.sg

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