HEALTH SCIENCES AUTHORITY

Applied Sciences Group
Blood Services Group
Enforcement Group
Integrated Health Regulation Group

www.hsa.gov.sg

THERAPEUTIC PRODUCTS GUIDANCE

RETENTION OF THERAPEUTIC PRODUCT ON THE PRODUCT REGISTER

UPDATED APRIL 2022

HSA
Health Sciences Authority

Pursuant to Section 31 of the Health Products Act 2007, the registration of a therapeutic product under the Act shall **remain in force**, unless:

a) The registration is suspended or cancelled by HSA under Section 37(1), or

b) The registration is cancelled by HSA upon the application by the registrant, or

c) The registrant has failed to make a payment for an **annual** retention fee, thereafter referred to as "retention fee", within 60 calendar days after the retention fee due date.

Retention Fee Payment Due Date

The retention fee due date for each therapeutic product falls on every anniversary of the date of registration of the therapeutic product.

Note: The products' retention fee due date will reflect as the current retention due date until the payment collection is successfully completed. Please note that the GIRO collection process would usually be completed about **1 – 2 weeks after** the retention fee due date of the product registration.

Retention Fee Payment

If your company has a registered therapeutic product (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.

You are advised to update your particulars at amend@prism to ensure that retention notifications are received.

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 there are sufficient funds in your account for the required payment.

Companies with a GIRO account with HSA can also choose to log on to Renew@PRISM to initiate the retention process ("manual retention") 60 days **in advance** of the auto-retention process.

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).

Depending on whether you have a GIRO account with HSA, you will be notified of the retention fee payment due date according to the schedule outlined below:

	Companies with GIRO Account with HSA	**Companies without GIRO Account with HSA**
60 calendar days before the retention fee payment due date	• System-generated retention notice will be sent to product registrant. • Registrants to ensure sufficient funds for GIRO deduction.	• 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	• 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.	• 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 before the retention fee payment due date		

	Companies with GIRO Account with HSA	Companies without GIRO Account with HSA
1 calendar day **After** the retention fee payment due date	NA	• 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	• 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.	• 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	• A notice will be sent to the product registrant if the payment has not been made. • If the registrant intends to retain the product registration, the required payment must be made via electronic payment mode (e.g. credit card or eNETS) at Renew@PRISM, and accompanied by reasons for late payment. • This payment must be done before the specified date (i.e. 60 calendar days after payment is overdue).	
60 calendar days **After** the retention	• If payment is not made by the specified date (i.e. 60 calendar days after payment is overdue),	

	Companies with GIRO Account with HSA	Companies without GIRO Account with HSA
fee payment due date	registration will be **cancelled** the next day after the specified date.	

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.

Completion of Retention Process

After payment collection is successful an email will be sent to your company to inform of the completion of the retention procedure. Regardless of when the retention process is initiated and completed, the new retention fee due date will fall on the next anniversary of the date of registration.

The registration status of the product registrations can be verified online via the Register of Therapeutic Products (InfoSearch).

PZ4972 INFOSEARCH - THERAPEUTIC PRODUCTS

Product Details – Therapeutic Products	
Product Name:	
Registration No:	SIN P
Registrant:	
Approval Date:	'2014
Forensic Classification:	Prescription Only
ATC Code:	
Dosage Form:	TABLET
Route of Administration:	ORAL
Status:	ACTIVE

Canceling Registrations Which Company Does Not Wish to Retain

The option to "opt-out" of auto-renewal is not applicable to therapeutic products. 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.

Once a product registration is cancelled, a new application will have to be submitted if your company intends to register the product again. Submission will have to comply to current regulatory requirements and applicable screening and evaluation fees will be chargeable. HSA will not consider any requests for reinstatements of product registrations once the product registration has been cancelled 60 days after the payment due date.

For therapeutic products which have been cancelled, a supplier may continue to supply the therapeutic product, before its expiry date, by administration to a person or by **retail sale**[1].

[1] Reg 60 of the Health Products (Therapeutic Products) Regulations 2016, a supplier of a registered therapeutic product may continue to supply the therapeutic product, before its expiry date, by administration to a person or by retail sale, despite a cancellation of its registration and despite the prohibition in section 15(1) of the Act against the supply of a health product that is not registered, if —

(a) the cancellation of the registration is either made by the Authority under section 37(2) of the Act or upon the application of the registrant under section 37(3) of the Act;
(b) the supplier has taken possession of the therapeutic product before the cancellation of its registration; and
(c) the Authority does not direct a recall of the therapeutic product from the market.

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