



CLARIFICATION ON RETENTION OF THERAPEUTIC PRODUCT REGISTRATION AND UPDATE TO GUIDANCE ON THERAPEUTIC PRODUCT REGISTRATION 2016

Dear Industry Stakeholders,

We would like to provide clarification on retention of therapeutic product registration and update to some appendices of the Guidance on Therapeutic Product Registration.

1. Retention of Therapeutic Product Registration

With the implementation of the Health Products (Therapeutic Products) Regulations 2016 effective from 1 November 2016, all registered therapeutic products are entered into the Register of Therapeutic Products. An annual fee is payable for retaining the therapeutic product on the register, thereafter referred to as retention fee. Each therapeutic product on the Register has a **retention fee due date** instead of an expiry date.

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. For new Product Registrations, the retention fee due date will be on each anniversary of the date of registration of the therapeutic product.

All registered therapeutic products will remain on the Register, unless:

- The registration is suspended or cancelled by HSA, or
- The registration is cancelled by the registrant, or
- The registrant has failed to make a payment for an annual retention fee within 60 calendar days after the retention fee due date.

In the previous licence renewal system, payment of fee for the renewal of Product Licence prior to its date of expiry is required. Under the Health Products Act, registered therapeutic products will remain on the Register if the retention fee is paid within 60 days after the retention fee due date. Product Registrants are not required to pay the retention fee prior to the retention fee payment due date. For companies with GIRO payment arrangements with HSA, the product's retention fee will be debited from their accounts upon the retention fee payment due date. Companies without any GIRO payment arrangements with HSA will be required to make manual payment in [PRISM](#). The product's retention fee due date will be revised (to the date one year later) upon payment of the retention fee.

The registration status of therapeutic products can be found online on the [Register of Therapeutic Products \(InfoSearch\)](#).

Please refer to the [Guidance for Retention of Therapeutic Product on the Product Register](#) for more information.

2. **Update to Guidance on Therapeutic Product Registration 2016**

- a) The Patent Declaration Forms (Appendix 1) of the Guidance have been revised.

Applicants are reminded to download and submit using the revised forms for all new product applications (NDA and GDA).

- b) The Application Checklist for NDA, GDA and MAV (Appendices 2A, 2B, 3A and 3B) have been revised.

New product applications and major variation applications should be submitted with the relevant Application Checklist. For ease of data entry, we have provided the checklists in Word format instead of PDF format.

Applicants should take note that the completed Application Checklist should be submitted in Word format to HSA (instead of PDF) as a supporting document under PRISM section 1.2.

Thank you.

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

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