



APPLICATION FOR CONSIGNMENT APPROVAL OF UNREGISTERED THERAPEUTIC PRODUCTS FOR PATIENTS' USE

Dear Stakeholders,

This is a reminder that the 5-months transition period for switching from fax to e-submission for application for consignment approval of unregistered therapeutic products for patients' use will end on **1 February 2020**. If you encounter issues with online submission, please let us know by emailing to us at HSA_TP_SAR@hsa.gov.sg.

Online Application Form for Consignment Approval of Unregistered Therapeutic Products for Patients' Use

TPB introduced an e-form on 2 September 2019 to enable online submission of applications for consignment approval of unregistered therapeutic products for patients' use. The e-form will replace the existing hardcopy application form currently submitted via fax. This is part of HSA's on-going drive to digitalise business processes and enhance efficiency.

Following the consultation with stakeholders on 25 October 2019, we have reviewed and incorporated your feedback in the e-form. The main changes are as follow:

- 1) **Streamlined the submission of the Signed Request form.** Signed Requests from the Requesters will only need to be attached as supporting document in the e-form.
- 2) **Increased the maximum file size allowable for each Signed Request form to 3MB and adjusted the number of requests per form to 2 Requesters.** This is to enable submission of attachments of larger file size and to simplify the e-form based on the average number of requests observed in each submitted application during the trial period.
- 3) **Added option for application outcome email to be sent concurrently to importer and the healthcare institution** to allow for timely communication.
- 4) **Removed the requirement for submission of the Enclosure for Methadone.** Applicants are no longer required to submit this form.

For greater clarity, we are introducing specific **Signed Request forms for Named-Patient Application** and **Buffer-Stock Application**. Applicants are advised to ensure that the correct form is completed by the Requester when making the application.

The enhanced e-form for online submission and new Signed Request forms is available on the [HSA website](#) since **2 January 2020**. Applicants are strongly encouraged to use the online submission while the fax submission will continue to be available till 31 January 2020. **The fax submission will be discontinued from 1 February 2020 onwards.**

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

www.hsa.gov.sg