



NEW INITIATIVES FOR REGISTRATION OF THERAPEUTIC PRODUCTS

Dear Industry Stakeholders,

The Therapeutic Products Branch (TPB), Health Products Regulation Group is pleased to share the following new initiative.

Online MIV Enquiry Form

HSA is introducing a new online form (click [here](#)) to enable electronic submission of enquiries related to post-approval variation applications (MIV). The online enquiry form will replace the existing Word document form which is currently submitted via email. This is part of HSA's drive to digitalise business processes and enhance efficiency.

Registrants are strongly encouraged, before submitting an enquiry to HSA, to use the [self-guided tool](#) and refer to Appendix 13 and 14 of the [Guidance on Therapeutic Product Registration](#) to determine the category and type of MIV. The enquiry mode should be reserved for situations where the registrant lacks the ability to make the necessary assessment for MIV submission and require specific advice from HSA.

The online form is available from 1 May 2019 for a trial run of 3-month period until 1 August 2019. For registrants who require specific advice on MIV submission, we invite you to use the online form in lieu of the Word document form (Appendix 12) and we would be happy to receive any feedback that would help us further improve the users' experience.

Q: Can I still use the current version of the MIV enquiry form?

A: While we highly encourage registrants to use the online form, you may still use the current Word document form during the trial period. However, if the trial is successful after 3 months, the current form will be replaced by the online form.

Q: Would I be able to receive a copy of the form for my reference?

A: Yes, a pdf copy of the online form which you have filled up and submitted will be sent to your email address. The email subject will include a unique reference number for your reference. The officer-in-charge will get back to you through the email address which you have specified in the form. Hence, it is important to ensure that a valid email address is provided.

Q: Can I include attachments?

A: Yes, you may attach files up to a total size of 7MB per enquiry form. If you wish to submit multiple files, it is recommended to compress them in a zip folder (max size 7MB) prior to uploading.

Q: How do I follow up with TPB if I do not receive any response?

A: Please allow us at least 5 working days to get back to you on your enquiry. If you do not hear from us after 5 working days, you may contact us via our [online web feedback](#), citing the form reference number and the date of submission of the form so that we can further assist you.

For enquiries, please [click here](#)
Therapeutic Products Branch
Medicinal Products Pre-Market Cluster
Health Products Regulation Group
Health Sciences Authority