



## **NEW SELF-GUIDED ALGORITHM AND REVISED MIV ENQUIRY FORM**

**Dear Industry Stakeholders,**

We are pleased to introduce a self-guided algorithm for post-approval variation applications (MIV) aimed to enable applicants to determine the application type, variation category and the documentary requirements for such variations. This is part of HSA's ongoing efforts to enhance clarity and transparency in our regulatory process and requirements, thereby encouraging good quality submission and minimising applicants' need to make such enquiries.

With this, the MIV Filing and Submission Enquiry Form is revised and supplemented with the self-guided algorithm. There are no technical changes made to the application types, variation categories or documentary requirements. Accordingly, Appendix 12, Guidance on Therapeutic Product Registration in Singapore is updated and will take effect from 1 July 2018.

To facilitate a smooth transition for industry to adopt the new Enquiry Form, applicants may continue to use the old version until 31 August 2018.

From 1 September 2018 onwards, we will accept only enquiries that are accompanied by the new Enquiry Form.

A copy of the revised MIV enquiry form and the self-guided algorithm is available [here](#)

Thank you.

For enquiries, please [click here](#)

Thank you.

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

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