UPDATE ON HPRG'S INITIATIVES
STREAMLINING OF MIV-1 SCREENING PROCESS

Dear Industry Stakeholders

The Therapeutic Products Branch (TPB) is streamlining the screening process of MIV-1 applications as a result of continuous process review and industry feedback.

This initiative aims to improve the turnaround time from submission to acceptance for MIV-1 applications. As such, the overall processing timeline from submission to regulatory decision may be reduced.

Applications Involved
All MIV-1 applications.

New Screening Process
At the screening phase, the main checks will be to ascertain that administrative documents (e.g. certificates/authorisation letters) and certain critical documents, such as GMP conformity assessment documents and Drug Master File, have been submitted. The completeness and adequacy of other supporting documents will be checked and assessed during the evaluation phase.

Impact to Industry
Applicants may expect to receive fewer queries during the screening stage, and input requests will be sent during the evaluation phase when the dossier is found to be deficient. As per current requirement, **applicants are expected to submit complete dossiers**, as specified in the Guidelines on Minor Variation Applications. For timely evaluation and to ensure equity to those applicants who have diligently submitted complete dossiers, HSA reserves the right to reject an application at screening or evaluation stage if the dossier is found to be incomplete.

Implementation
The streamlined screening process will be implemented for applications submitted in PRISM from **23 February 2015** onwards.

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