UPDATE ON HPRG'S INITIATIVES
PILOT PROJECT ON SCREENING TURNAROUND TIME AND UPDATES ON MIV

Dear Industry Stakeholders

The Therapeutic Products Branch (TPB) is conducting a pilot project with the aim to establish a target turnaround time (TAT) for screening of NDA, GDA, MAV and MIV-1 applications. With an established TAT for the screening of product applications, there is greater predictability of overall processing timelines and thus, facilitate the planning for product launches into the market.

TPB is also proposing several initiatives to the MIV application process to ultimately facilitate more timely processing of MIV applications.

PILOT PROJECT ON SCREENING TURNAROUND TIME

Current Screening Timelines

Currently, timelines for review of responses after the first and subsequent rounds of queries during screening for an application are not committed, and there is no cap on the number of rounds of screening queries. Therefore, the overall screening timeline for each application is unpredictable. So, the screening TAT pilot project was developed with the goal to establish a screening TAT to give greater predictability. Details of the project are as follows:

Screening TAT Pilot Project

Objectives
Based on actual NDA, GDA, MAV and MIV-1 applications screened during the course of the pilot project, the data obtained will be used to:

- formulate the overall screening TAT from the point of receipt of application to acceptance/non-acceptance; and
- derive a potential cap on the number of rounds of screening queries.

Applications Involved
All NDA, GDA, MAV and MIV-1 applications, regardless of the evaluation route (full, abridged, verification, or verification CECA), will be included in the pilot project.

Duration of the Pilot Project
For NDA, GDA and MAV – one year, from 1 October 2014 to 30 September 2015
For MIV-1 – 6 months, from 1 November 2014 to 30 April 2015

Impact to Industry
The focus of the project is data collection. The screening process will proceed as usual, and there will be no cap on the number of rounds of screening queries imposed during the pilot project. However in future, there may be a maximum number of rounds of screening queries imposed (e.g. 3 rounds), and applicants may be asked to withdraw the application if the dossier is still deficient after the stipulated number of rounds has been exceeded.

Applicants are strongly encouraged to submit complete dossiers and to provide complete responses to queries in a timely manner so as to generate representative screening data that will accurately and fairly reflect the time required for screening of all applications.

Completion of Pilot Project
Following the completion of the pilot project, the overall screening TAT and cap on the number of rounds of screening queries will be announced to the industry.

Four initiatives are being implemented to the MIV-1 application process to improve on the processing times.

Initiatives to MIV-1 Application Process

1. PRISM application form 0.4 Amendments Details

   Applicants are to indicate the applicable MIV Checklist Title in Appendices 15 and 16 (Guidance on Medicinal Product Registration in Singapore 2011) in PRISM via a drop-down list, instead of the current free-text format, in Section "0.4 Amendments Details". This is to better categorise MIV applications and facilitate the tracking of non-consequential changes.

   There should be only one MIV-1 Checklist Title per application. In situations when an application contains consequential changes, the main change is to be reflected as the primary change in "0.4 Amendments Details (Primary Change)" and each consequential change should be entered in "0.5 Amendments Details (Secondary Change)" (new feature to be built into PRISM) in the PRISM application form.

   For variation changes not covered under Appendices 15 and 16, e.g., those provided as a result of MIV Inquiries, please select "Others" from the drop-down list and indicate the relevant details in the text box provided.

   Non-consequential MIV-1 changes are strictly not allowed. For instance, for a CMC MIV-1 application, MIV-1 updates to the product labelling unrelated to CMC changes will not be accepted. However, MIV-2 changes are still allowed to ride on an MIV-1 application as per status quo.

   Actual PRISM screenshots will be shared with the industry before the implementation date for reference.

2. Increase in number of MIV1 applications from 3 to 5

   The number of MIV1 applications that can be submitted in PRISM at any one time will be raised from the current 3 to 5. This initiative will allow the submission of non-consequential changes as separate MIV-1 applications. There is no change to the number of MIV-2 submission.

3. No additional changes allowed after acceptance of applications

   For timely processing of MIV-1 applications, requests to replace proposed labelling materials (e.g. package insert, outer carton, inner label) with a newer version after acceptance will no longer be allowed, unless such changes are HSA-initiated changes related to safety or/and efficacy concerns. In addition, requests for additional changes to ride on existing MIV-1 applications post-acceptance will not be allowed.

   These changes have been carefully considered due to (i) an increasing number of requests to replace the original proposed labelling materials with newer versions at various time points during the review process, (ii) ad-hoc requests to add new MIV-1 changes, and (iii) undeclared discrepancies between the updated labelling materials (submitted midway through evaluation) versus that initially submitted, hence posing significant challenges in the timely processing of MIV-1 applications.

4. Proper annotations for labelling materials

   Applicants are reminded that annotations should be made based on the actual text to be added and on the currently-approved labelling materials. Currently-approved text proposed for deletion should be struck through, whereas addition of new proposed text should be underlined or highlighted. Currently-approved text that is not intended to be deleted should not be annotated. However, translocation of currently-approved text from one section to another can be allowed in its entirety. Both the annotated and clean copy of the labelling materials should be submitted. An Input Request will be sent to the applicant for a proper set of annotated labelling materials before the screening/evaluation would be resumed.

Implementation

Target date for implementation for all initiatives: 1 November 2014

Impact to Industry

The requirement for non-consequential MIV-1 changes to be split into separate applications is not new. The initiative to increase the number of MIV-1 application from 3 to 5 is aimed to facilitate the timely submission of MIV updates.

Applicants are strongly encouraged to indicate in the PRISM application form and introductory letter: (i) If the proposed change(s) affects multiple products; and (ii) If there are pending (MAV/MIV) applications for the same product. Applicants are also encouraged to submit applications for multiple strengths of the same product at the same time.

Please refer to the slide deck as attached for more details and illustrations.

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