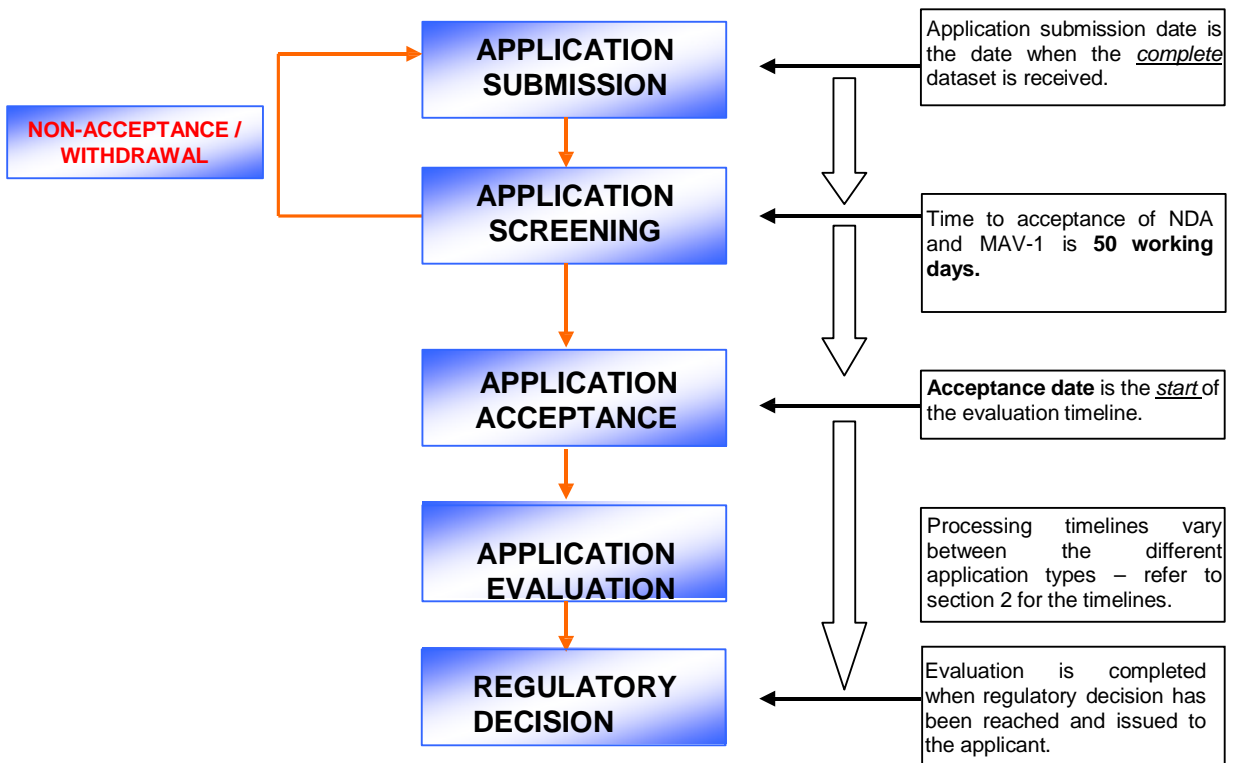


APPENDIX 6 Target Processing Timelines for Class 2 CTGTP Applications

HSA shall endeavour to meet the target processing timelines for all submitted applications. Applicants should ensure that the dossiers are complete before submission. Incomplete dossiers and untimely responses to queries will cause unnecessary delays to the registration process and thus, will have a negative impact on the target processing timelines.

A flowchart of the registration process and processing timelines can be seen below:



1 SCREENING TIMELINE FOR NDA AND MAV-1 APPLICATIONS

The target processing timeline for the screening of the dossiers (NDA and MAV-1) is **50 working days**, from the date of receipt of the application dossier to the date of acceptance or non-acceptance/withdrawal of the application, excluding stop-clock time.

The screening timeline begins from the date of the dossier submission, which should be within 2 working days after FORMSG submission to prevent delays in the processing of the application. The date of the dossier submission will be defined as the date when HSA receives the complete dataset for the application (e.g. the CD/DVDs and application checklist).

2 EVALUATION TIMELINE FOR NDA AND MAV-1 APPLICATIONS

The target processing timeline for the evaluation of an application is the period from the date of acceptance to the issuance of a regulatory decision, excluding stop-clock time. The target timelines for the various evaluation routes are as follows:

The timelines stated (in working days) are subject to change.

Evaluation Route	NDA	MAV-1
Full	270	270
Abridged	180	180

3 PROCESSING TIMELINE FOR OTHER VARIATIONS APPLICATIONS

For other variation applications, applicants will receive an “Acceptance” notification sent within 3 working days after submission of other variation application via FORMSG.

The target processing timeline for the MIV-1 application is **120 working days**. The target processing timeline starts from the date of receipt of the MIV-1 application in FORMSG to the date of regulatory decision or withdrawal date, excluding stop-clock time.

The MIV-2 application may be implemented within 40 days upon application submission if there are no objections raised by HSA.

Applicants are reminded to ensure the submission of complete dossiers by referring to the relevant other variations checklists to avoid a delay in the processing of the application.

4 STOP-CLOCK TIME

Stop-clocks can occur during the screening and evaluation stages of the application. All target timelines mentioned in this document refers to the time taken by HSA, excluding all stop-clock time.

Stop-clock time refers to the time taken by applicants to respond to any Input Request from HSA. The stop-clock starts when HSA requests for clarification or additional information regarding a product application. The stop-clock period ends when HSA receives a complete and satisfactory response to the query.

NOTE: the stated processing timelines are intended for reference only and do not necessarily represent the actual processing timelines for the applications.

REVISION HISTORY

Guidance Version (Publish Date)

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