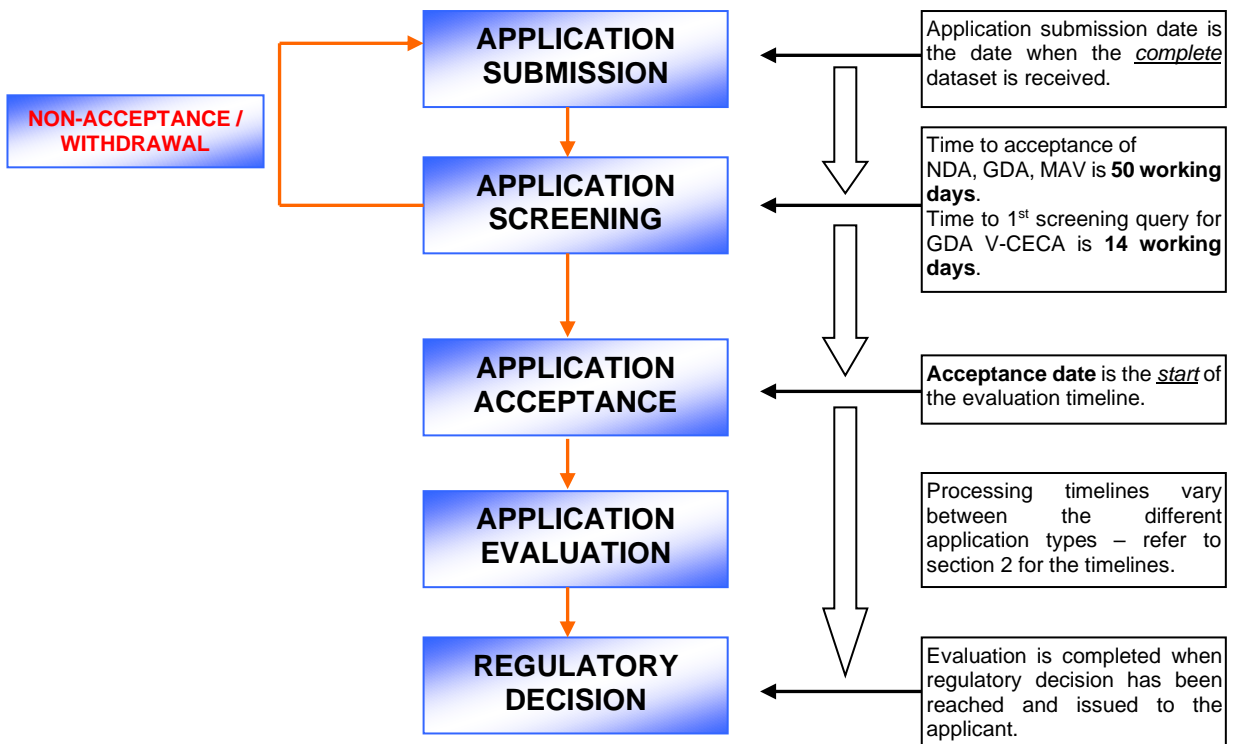


APPENDIX 5 TARGET PROCESSING TIMELINES

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.

Recalling Figure 1 in Chapter B of this guidance, a flowchart of the registration process and processing timelines can be seen below:



1 SCREENING TIMELINE FOR NDA, GDA AND MAV APPLICATIONS

The target processing timeline for the screening of the dossiers (NDA, GDA, MAV-1, MAV-2) 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.

In addition, for applications submitted under the CECA scheme, the target processing time to the first communication (Input Request or acceptance/non-acceptance notification) is **14 working days** from the date of receipt of the application dossier.

The screening timeline begins from the date of the dossier submission, which should be within 2 working days after PRISM 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, GDA, AND MAV 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	GDA	MAV-1	MAV-2
Full	270		270	
Abridged	180	240	180	180
Verification	60	120	60	
Verification – CECA		90		

After the application is accepted for evaluation, applicants can expect to receive the first evaluation Input Request by:

Type of Applications	Evaluation Route	No. of working days
NDA/ MAV-1	Full	160
NDA/ MAV-1	Abridged	120
GDA	Abridged	150

Note: excluding any stop-clock time between acceptance and issuance of first evaluation Input Request.

3 PROCESSING TIMELINE FOR MIV-1 APPLICATIONS

For MIV-1 applications, applicants will receive an “Acceptance” notification sent within 3 working days after submission of an MIV-1 application via PRISM.

The target processing timeline for a MIV-1 application is **120 working days** for applications submitted via the Abridged route, and **90 working days** for applications submitted via the Verification route. The target processing timeline starts from the date of receipt of the MIV-1 application in PRISM to the date of regulatory decision or withdrawal date, excluding stop-clock time.

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

4 NOTIFICATION TIMELINE FOR MIV-2 APPLICATIONS

For MIV-2 applications, the applicant can implement the proposed change(s) if HSA does not raise any objection within **40 working days** from the date of submission of the complete dataset for the application. The complete dataset includes the PRISM application submission, and the supporting documents required for the proposed changes.

If queries are raised on the completeness of the dataset, stop-clock time will apply. This stop-clock time is to be excluded from the 40 working days timeline.

5 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 with regard to 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. Applicants should refer to Track@PRISM for updates on the application status and processing time.

REVISION HISTORY

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