Flowcharts for
EDA Chairman Decree 450 for the year 2023

Year 2025

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Table of Contents

Introduction:

This document presents the procedures for registering pharmaceutical products, covering both locally manufactured generic products and imported products. The process has been updated to align with the EDA Chairman's memorandum issued on August 13, 2025, and EDA Chairman Decree (450/2023) regulatory guide version 5, and follows the unified "One Submission" pathway for CTD dossiers. This harmonized approach aims to streamline registration activities and ensure consistent regulatory expectations for all applicants.

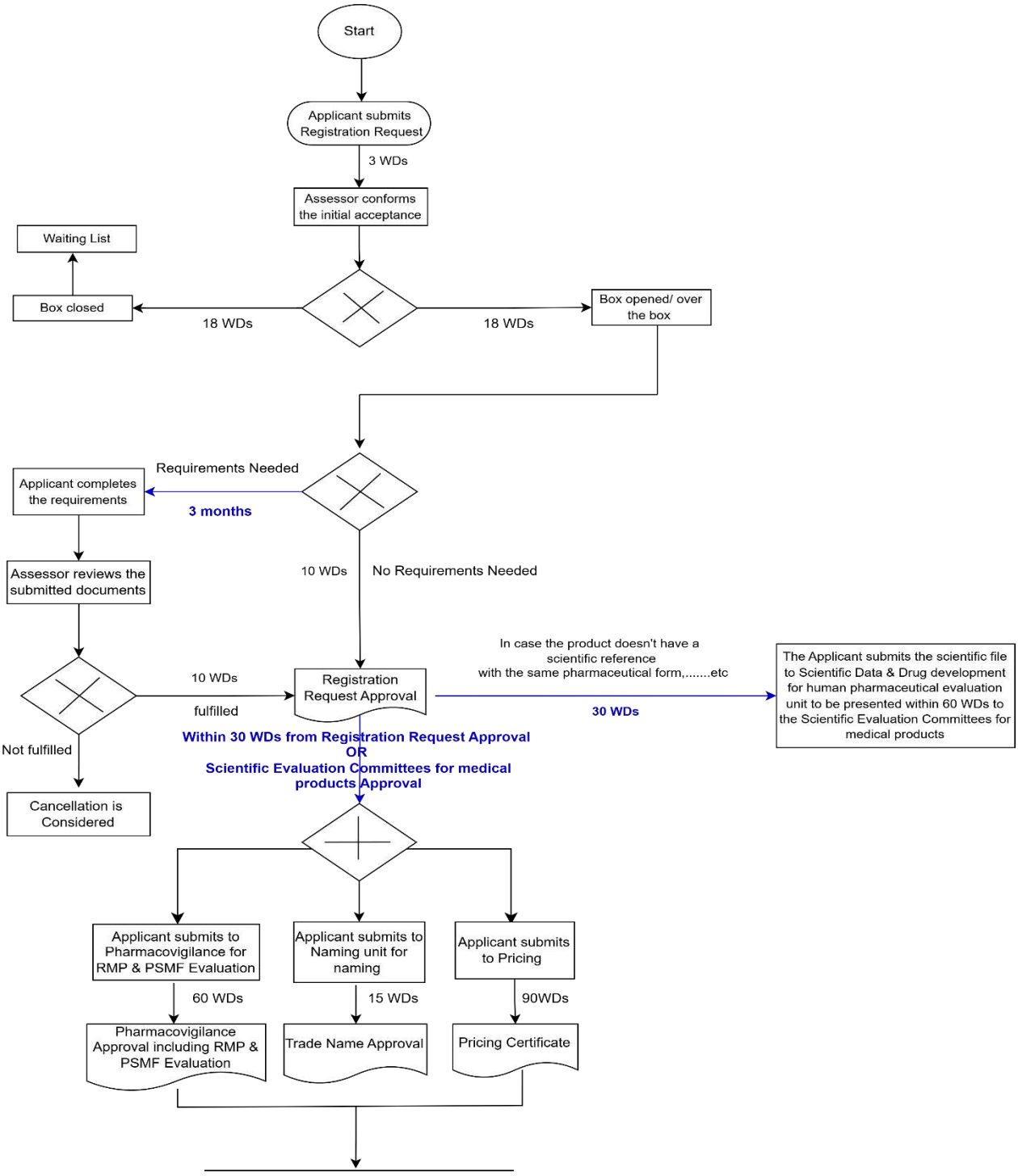
While the general workflow for submitting a registration dossier is consistent for all product types and all cases, the key distinction lies in the respective assessment timeframes. This document highlights those distinctions to help applicants prepare their submissions accurately and efficiently.

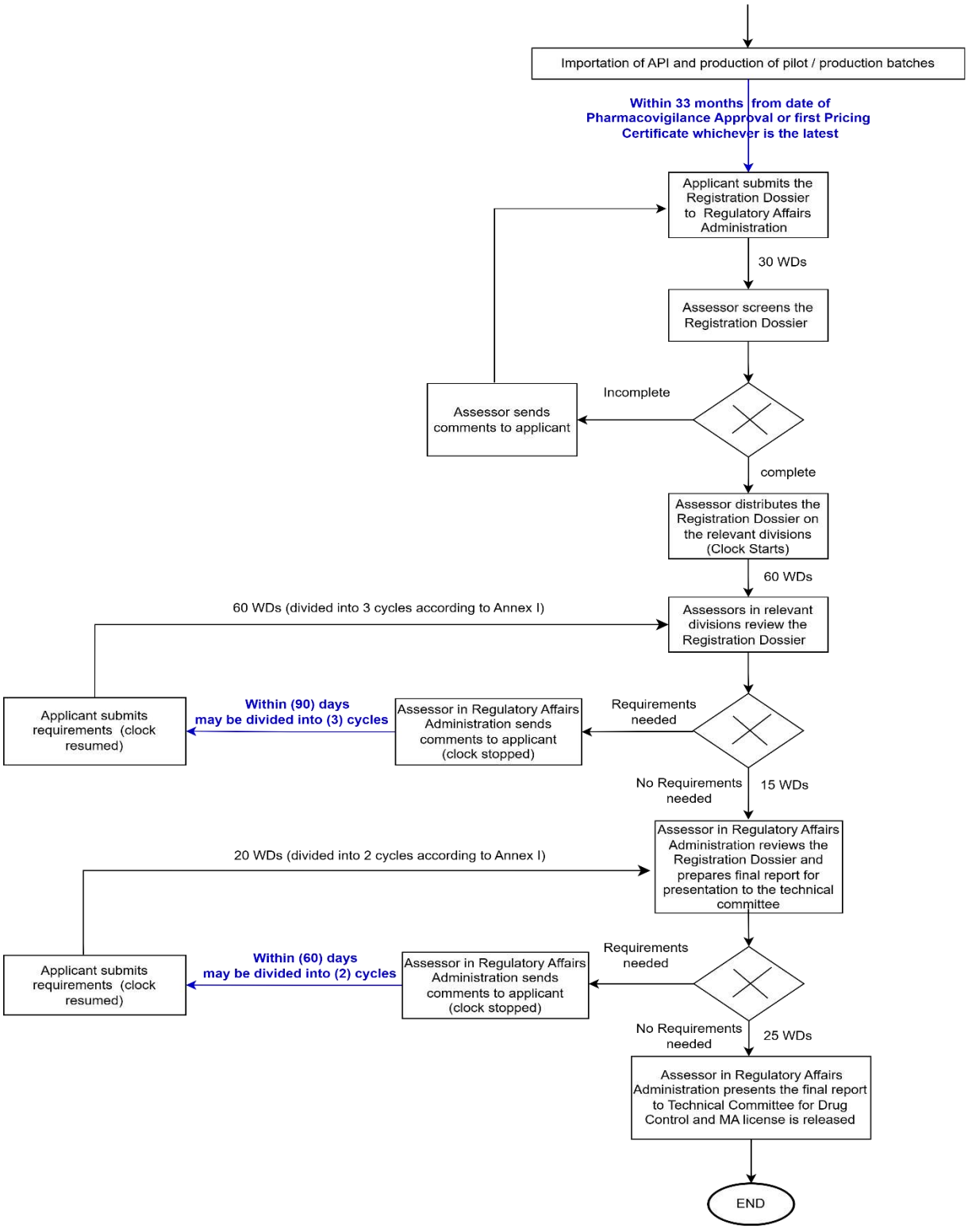
Presenting the process in a structured and accessible manner, facilitates smoother interactions with the regulatory authority, improves submission quality, and support timely evaluation of pharmaceutical products intended for the local market.

Key Section:

Text and lines highlighted in **blue** indicate actions or timelines that are the applicant's responsibility to complete. This visual distinction supports easier navigation of the process and helps applicants understand their required tasks at each stage of the workflow.

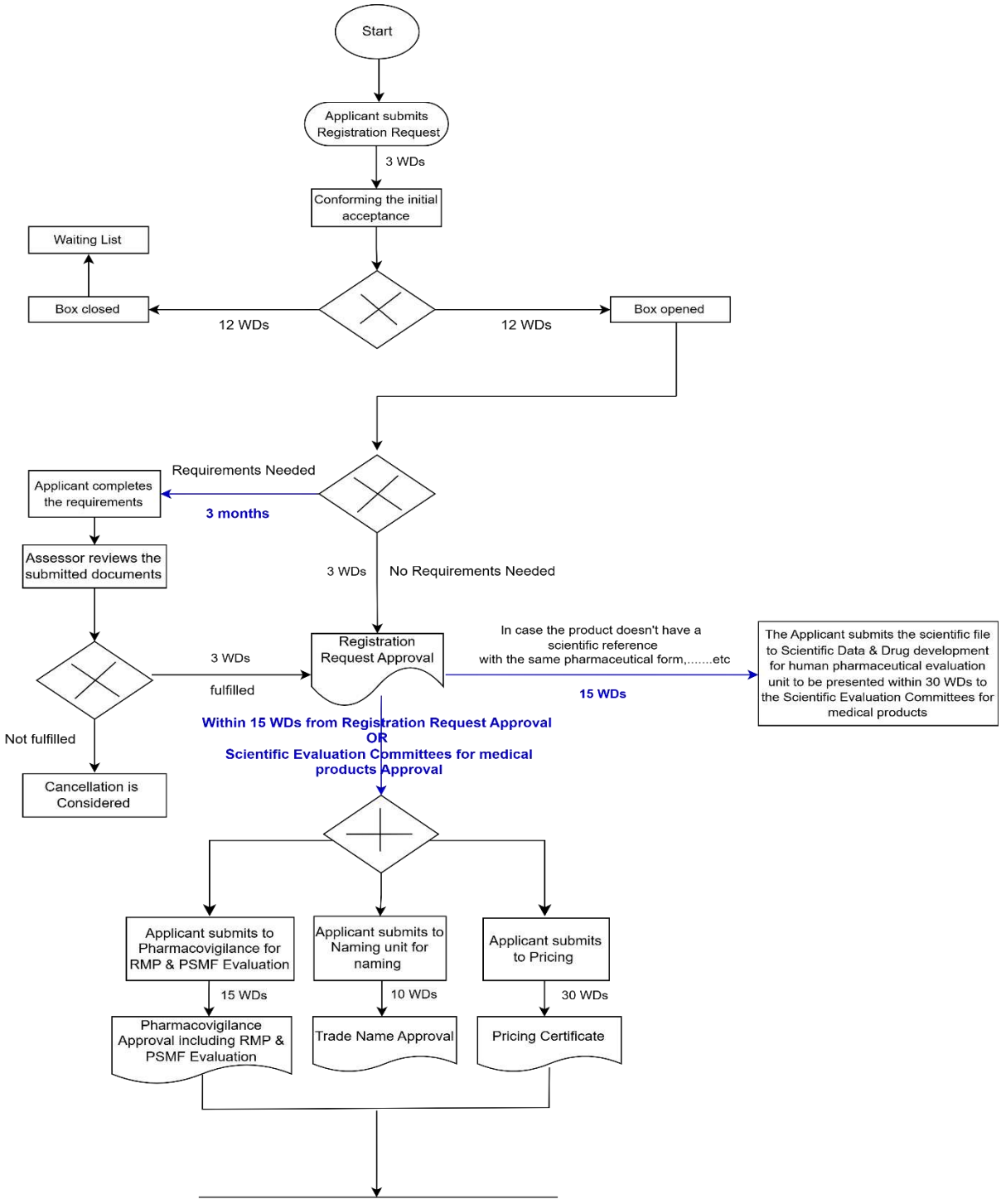
EDA Chairman Decree (450/2023) Flowchart for Locally Manufactured Generic Products with assessment timelines

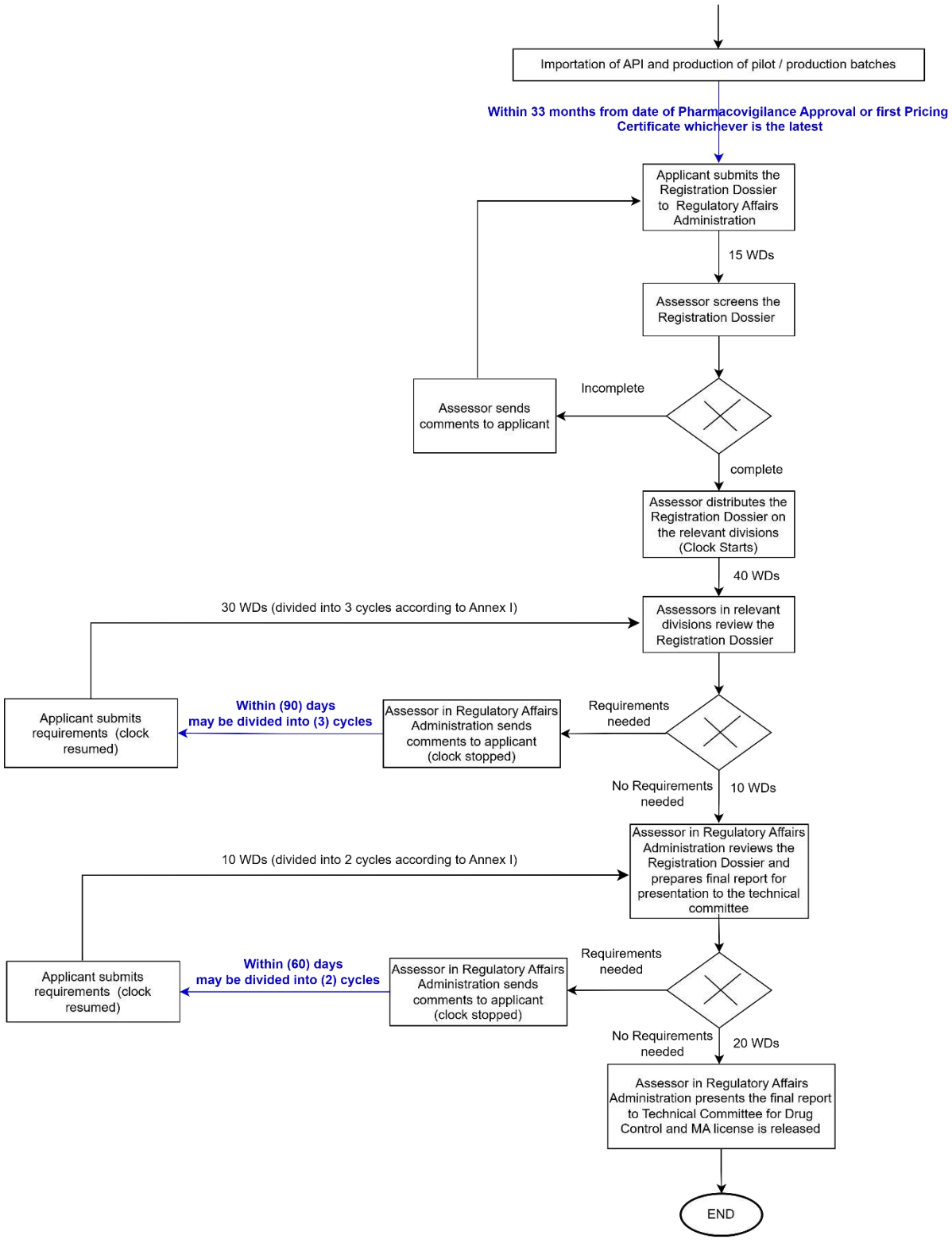



Importation of API and production of pilot / production batches
Within 33 months from date of Pharmacovigilance Approval or first Pricing Certificate whichever is the latest
Applicant submits the Registration Dossier to Regulatory Affairs Administration
30 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
60 WDs
60 WDs (divided into 3 cycles according to Annex I)
Assessors in relevant divisions review the Registration Dossier
Applicant submits requirements (clock resumed)
Within (90) days may be divided into (3) cycles
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Requirements needed
No Requirements needed
15 WDs
Assessor in Regulatory Affairs Administration reviews the Registration Dossier and prepares final report for presentation to the technical committee
20 WDs (divided into 2 cycles according to Annex I)
Applicant submits requirements (clock resumed)
Within (60) days may be divided into (2) cycles
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Requirements needed
No Requirements needed
25 WDs
Assessor in Regulatory Affairs Administration presents the final report to Technical Committee for Drug Control and MA license is released
END

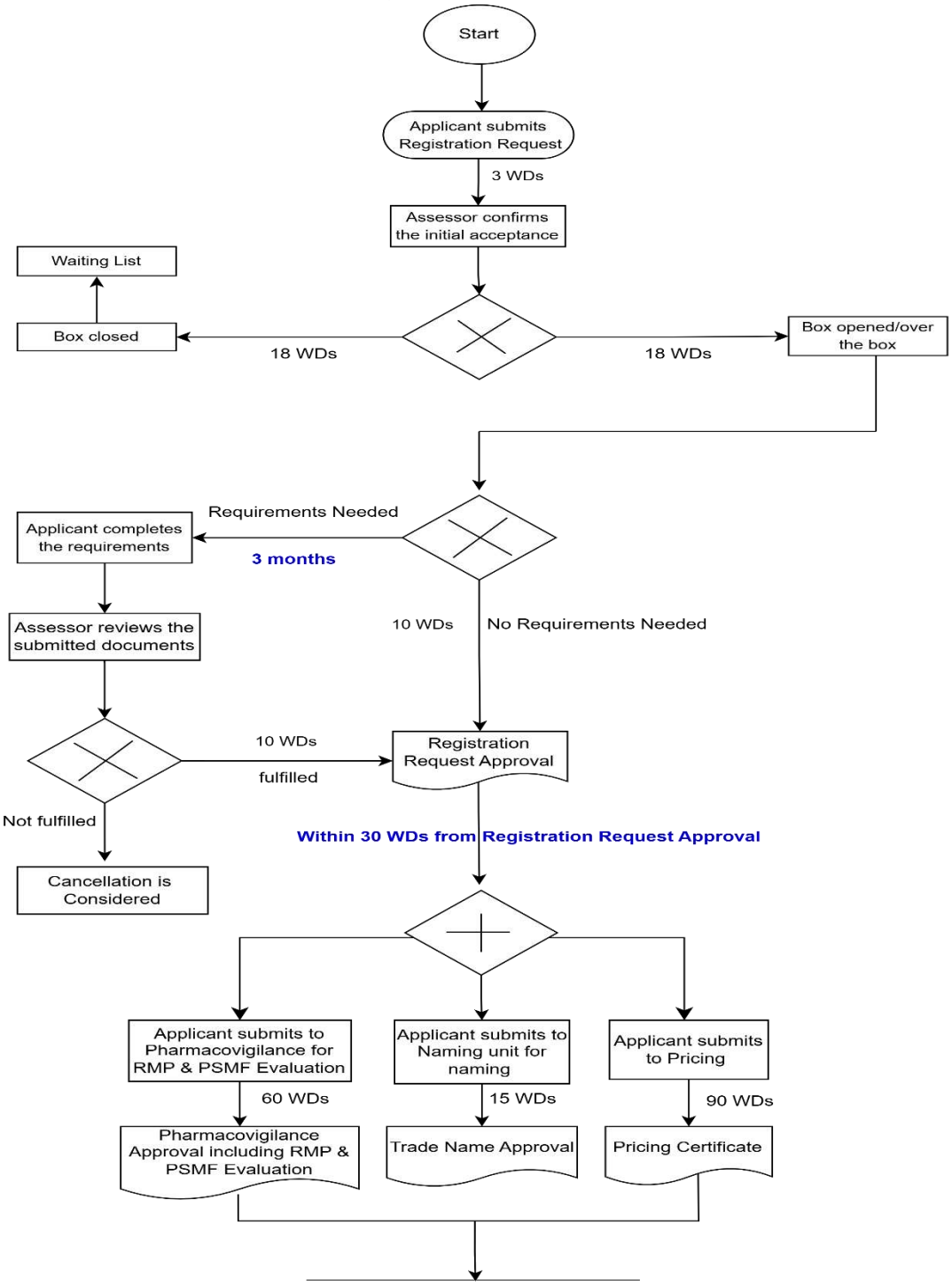
- **Note:**
  - In case the applicant wants to manufacture production batches instead of pilot batches, it is required to submit the first three production batches for analysis by the Central Administration for Drug Control before the issuance of the Marketing Authorization License.

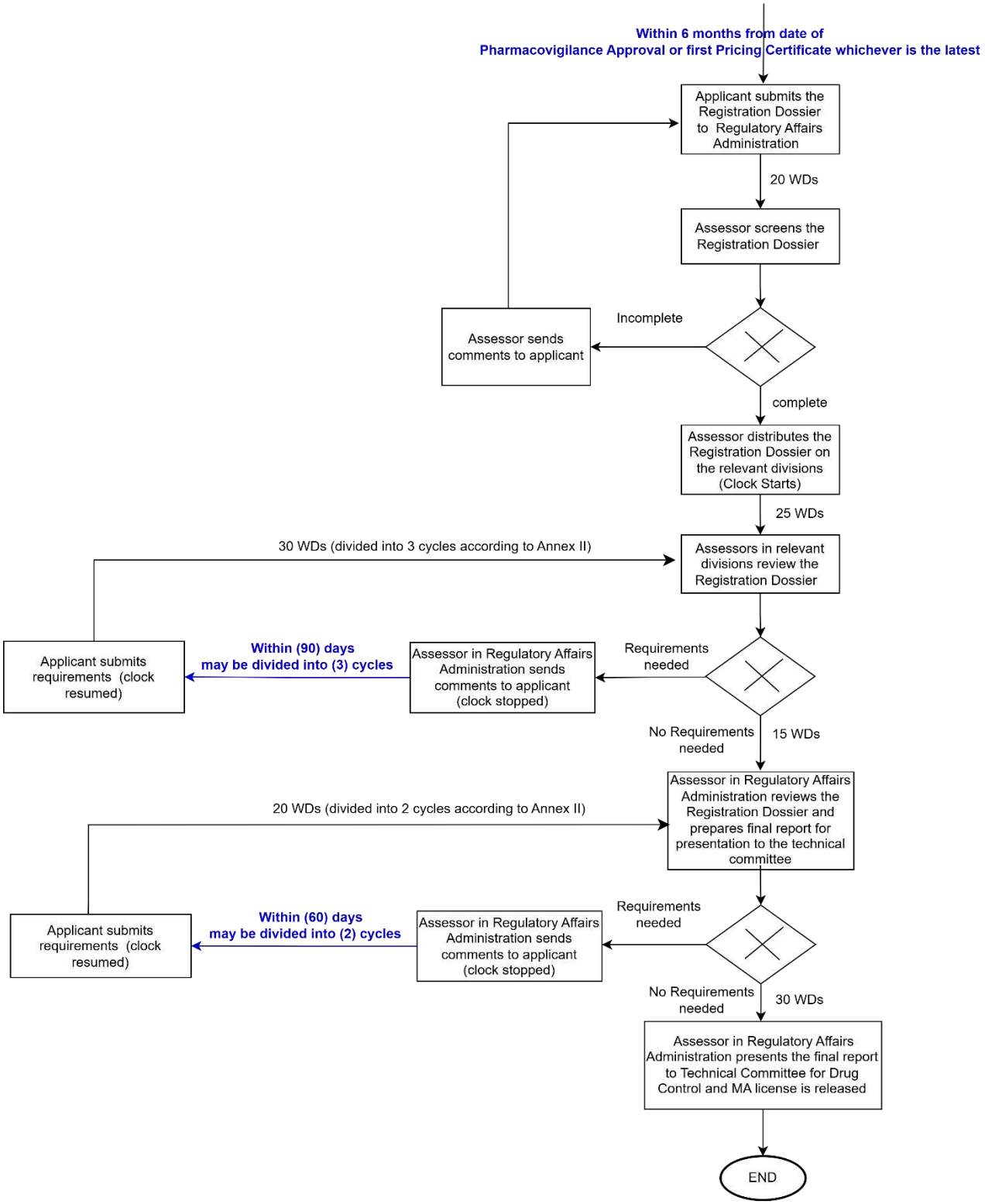
EDA Chairman Decree (450/2023) Flowchart for Locally Manufactured Generic Products with assessment timelines (Fast Track)



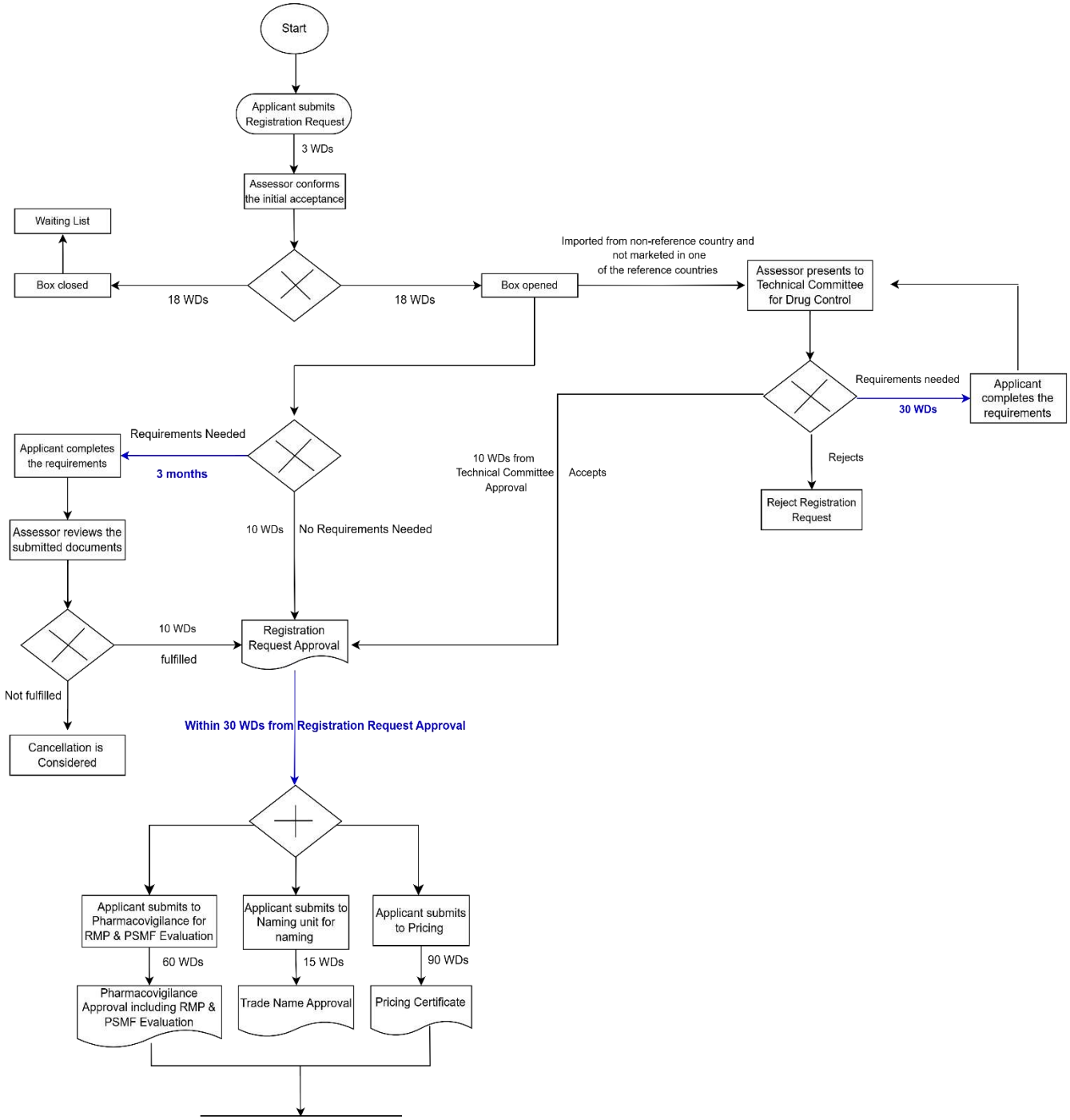

Importation of API and production of pilot / production batches
Within 33 months from date of Pharmacovigilance Approval or first Pricing Certificate whichever is the latest
Applicant submits the Registration Dossier to Regulatory Affairs Administration
15 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
40 WDs
30 WDs (divided into 3 cycles according to Annex I)
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (90) days may be divided into (3) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
10 WDs
Assessor in Regulatory Affairs Administration reviews the Registration Dossier and prepares final report for presentation to the technical committee
10 WDs (divided into 2 cycles according to Annex I)
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (60) days may be divided into (2) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
20 WDs
Assessor in Regulatory Affairs Administration presents the final report to Technical Committee for Drug Control and MA license is released
END

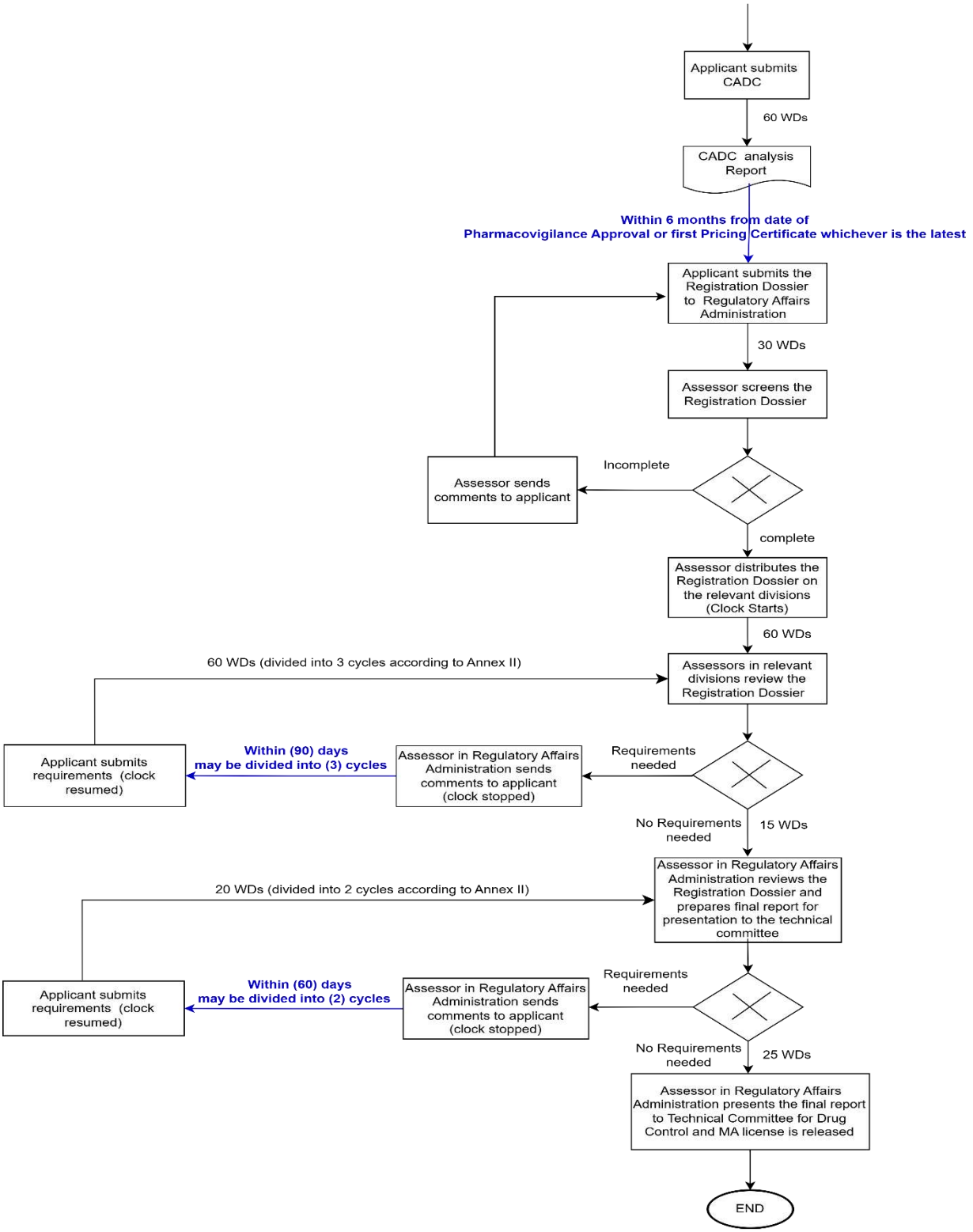
EDA Chairman Decree (450/2023) Flowchart for Imported Products marketed in one of SRAs or WHO-Prequalified with assessment timelines



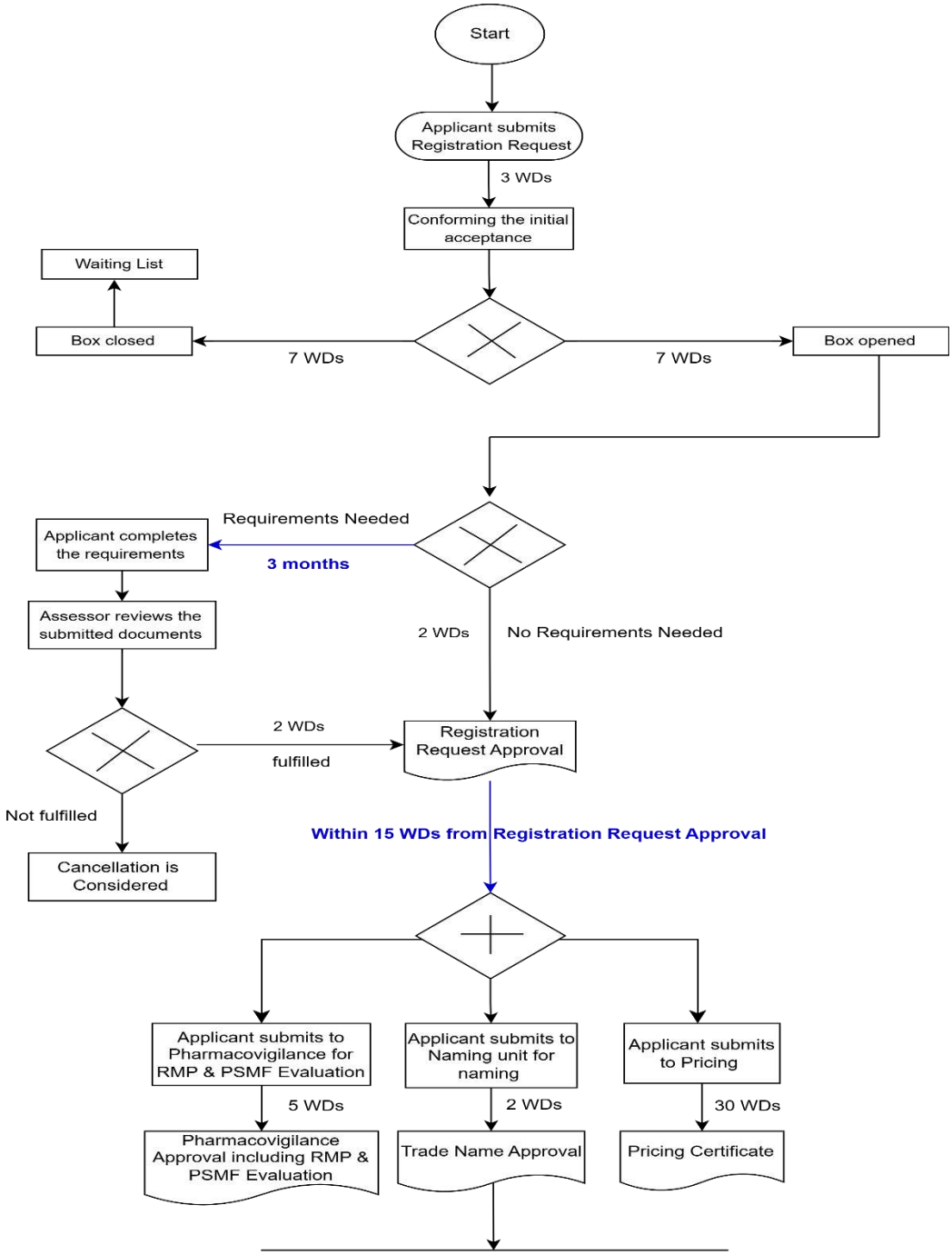

Within 6 months from date of
Pharmacovigilance Approval or first Pricing Certificate whichever is the latest
Applicant submits the Registration Dossier to Regulatory Affairs Administration
20 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
25 WDs
30 WDs (divided into 3 cycles according to Annex II)
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (90) days
may be divided into (3) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
15 WDs
20 WDs (divided into 2 cycles according to Annex II)
Assessor in Regulatory Affairs Administration reviews the Registration Dossier and prepares final report for presentation to the technical committee
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (60) days
may be divided into (2) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
30 WDs
Assessor in Regulatory Affairs Administration presents the final report to Technical Committee for Drug Control and MA license is released
END

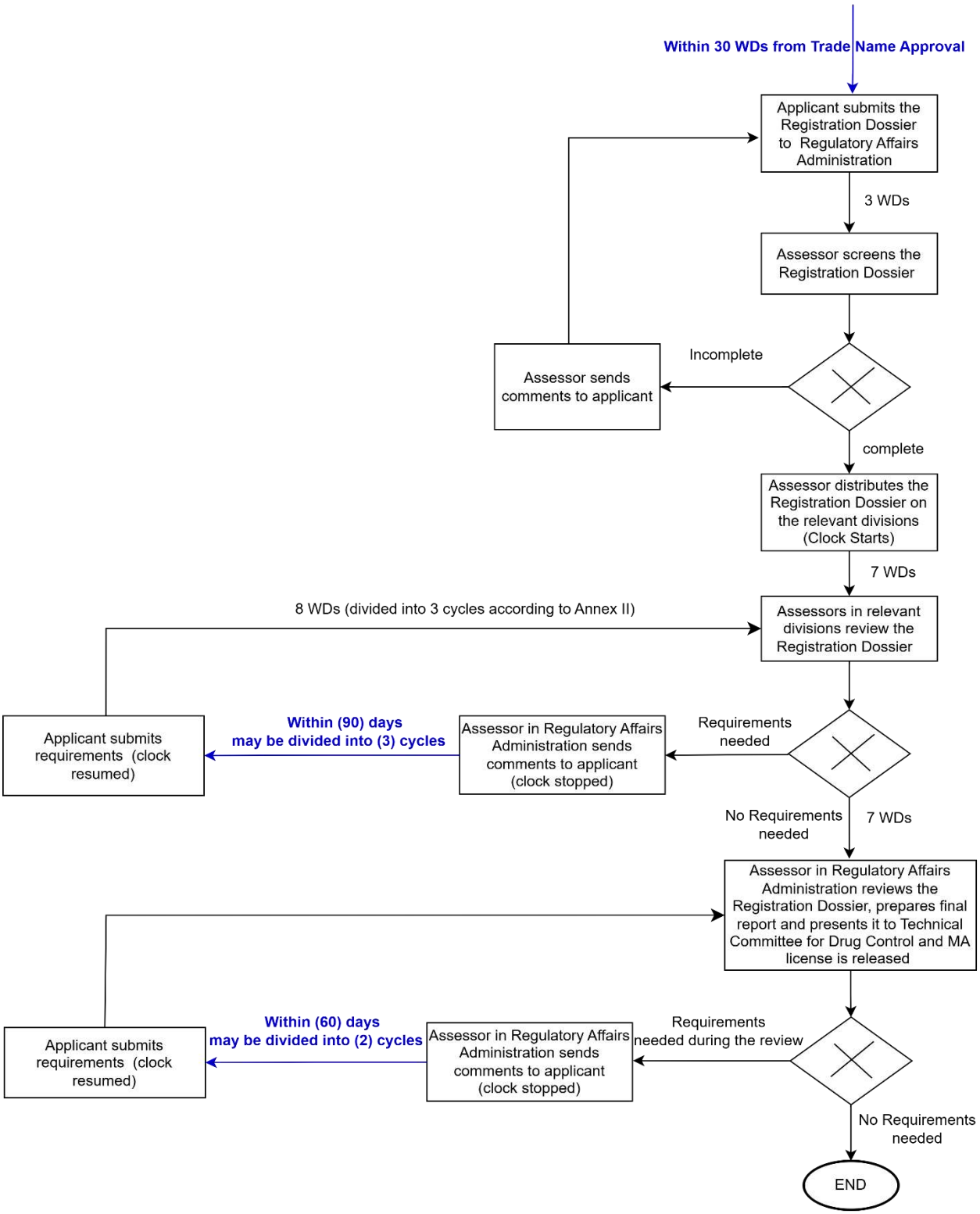
EDA Chairman Decree (450/2023) Flowchart for Imported Products from non-reference country and not marketed in one of reference countries with assessment timelines



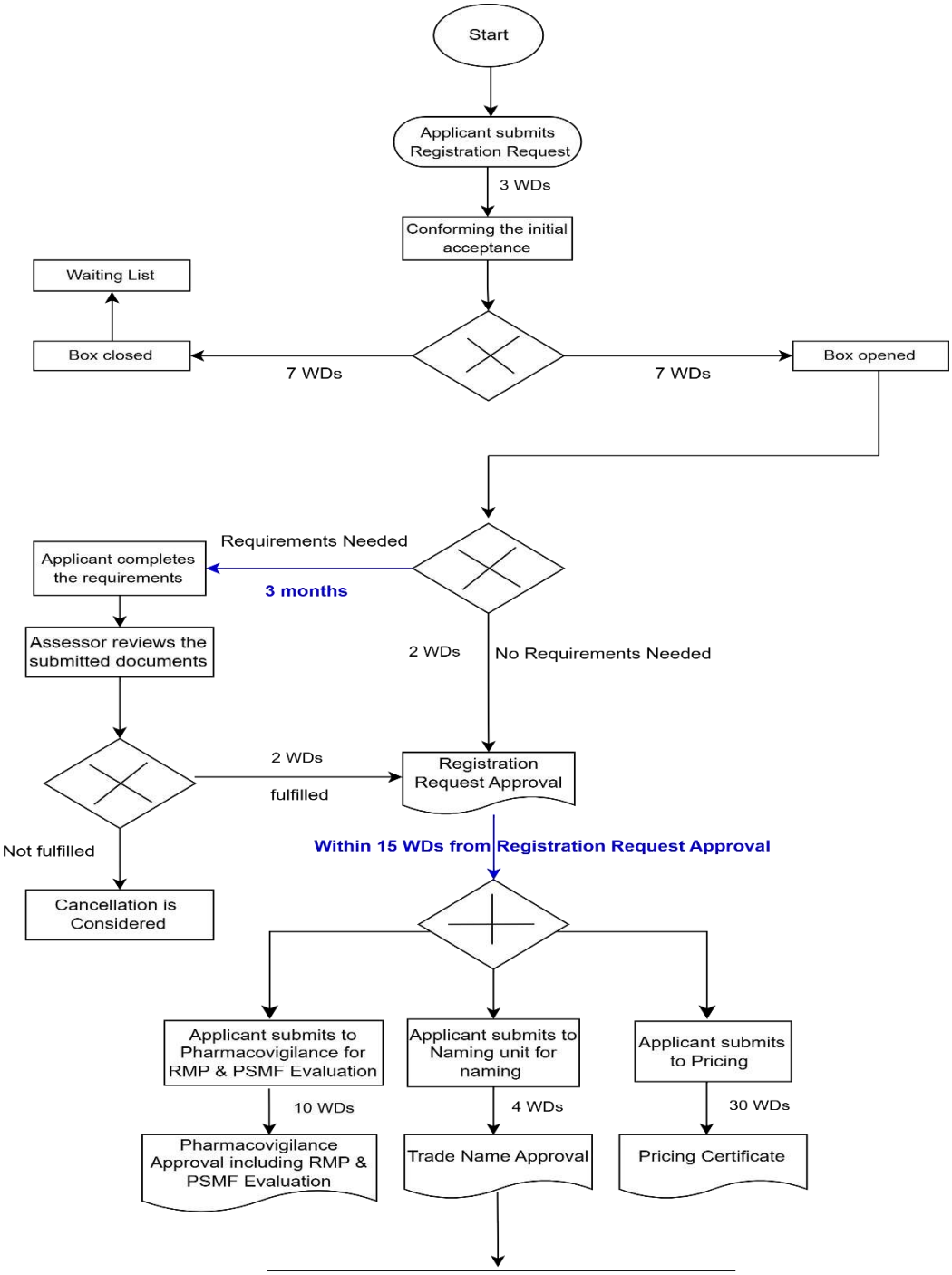

Applicant submits CADC
60 WDs
CADC analysis Report
Within 6 months from date of Pharmacovigilance Approval or first Pricing Certificate whichever is the latest
Applicant submits the Registration Dossier to Regulatory Affairs Administration
30 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
60 WDs
60 WDs (divided into 3 cycles according to Annex II)
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (90) days may be divided into (3) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
15 WDs
20 WDs (divided into 2 cycles according to Annex II)
Assessor in Regulatory Affairs Administration reviews the Registration Dossier and prepares final report for presentation to the technical committee
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (60) days may be divided into (2) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
25 WDs
Assessor in Regulatory Affairs Administration presents the final report to Technical Committee for Drug Control and MA license is released
END

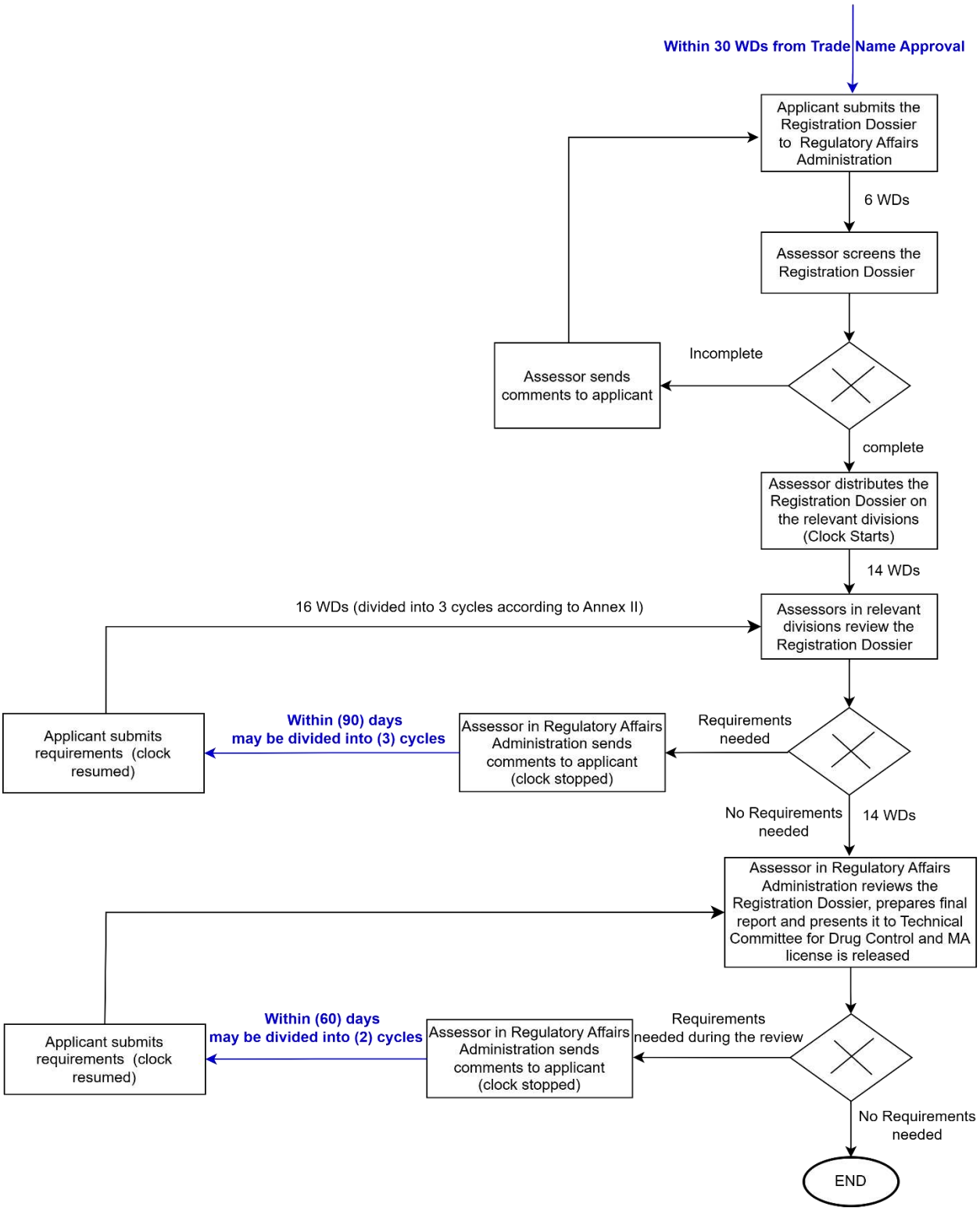
EDA Chairman Decree (450/2023) Flowchart of Imported products approved from FDA and EMA in addition to one of the SRAs or WHO prequalified with assessment timelines (Fast Track)



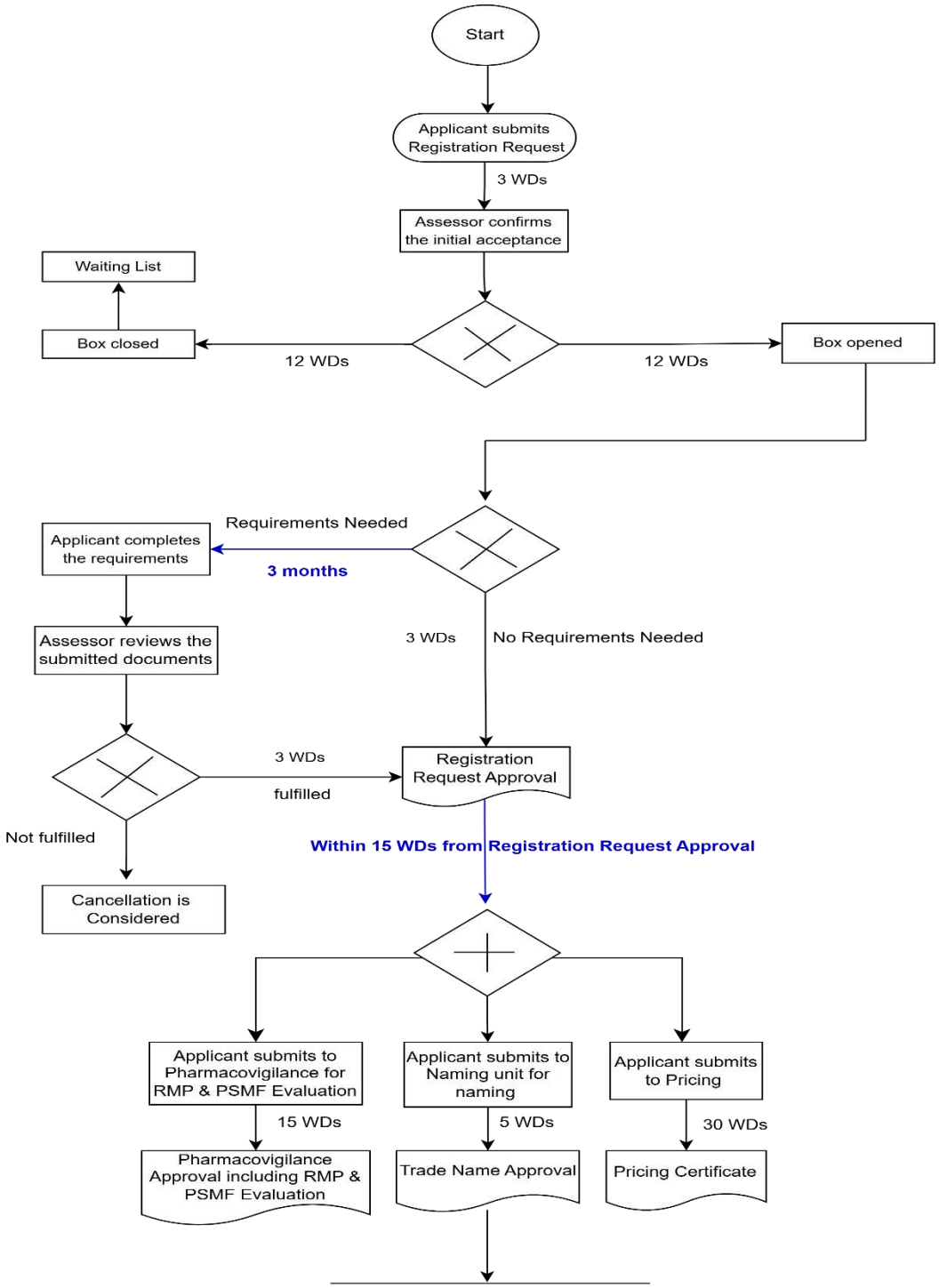

Within 30 WDs from Trade Name Approval
Applicant submits the Registration Dossier to Regulatory Affairs Administration
3 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
7 WDs
8 WDs (divided into 3 cycles according to Annex II)
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (90) days may be divided into (3) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
7 WDs
Assessor in Regulatory Affairs Administration reviews the Registration Dossier, prepares final report and presents it to Technical Committee for Drug Control and MA license is released
Requirements needed during the review
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (60) days may be divided into (2) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
END

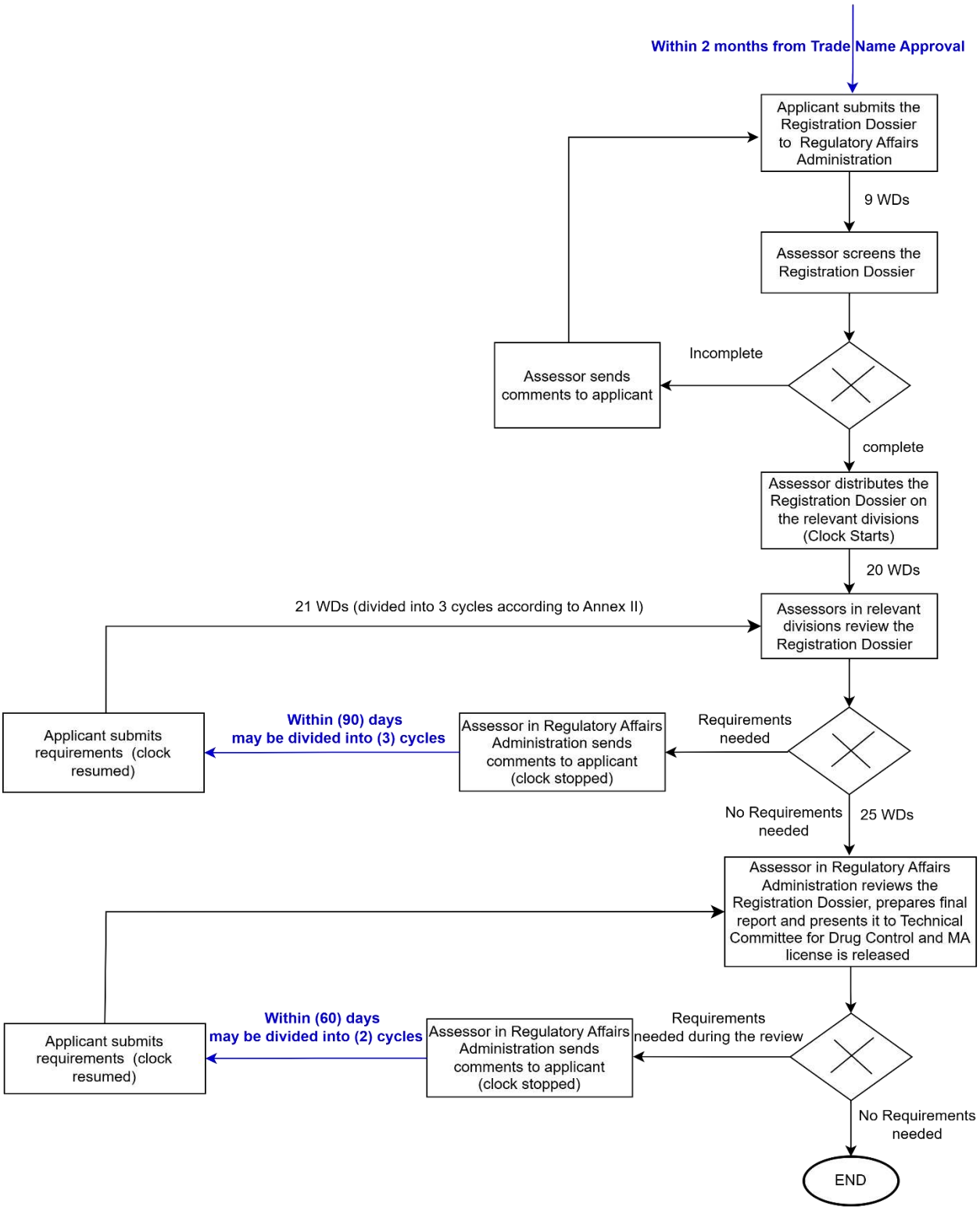
EDA Chairman Decree (450/2023) Flowchart of Imported products approved from FDA or EMA in addition to one of the SRAs or WHO prequalified with assessment timelines (Fast Track)



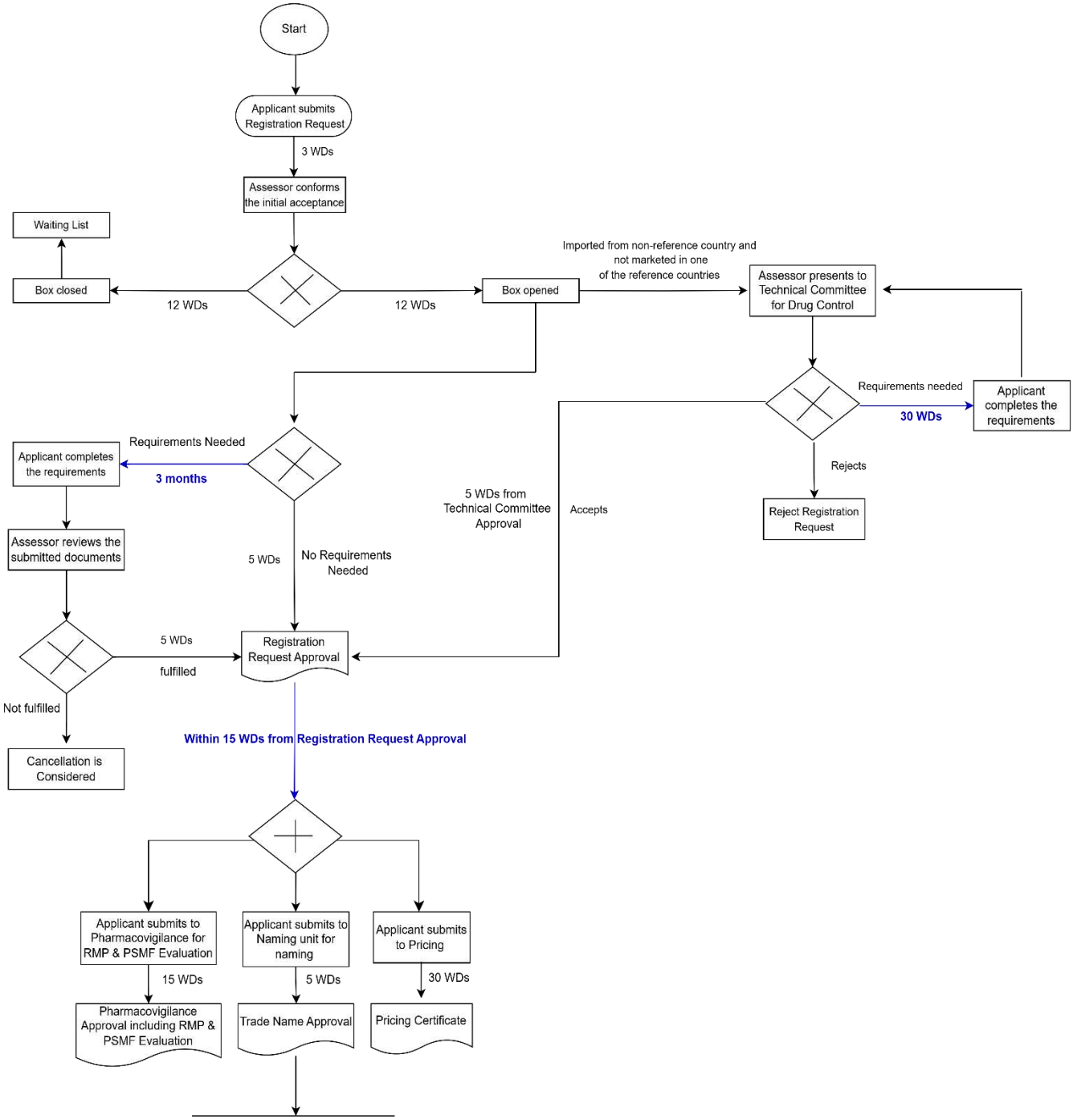

Within 30 WDs from Trade Name Approval
Applicant submits the Registration Dossier to Regulatory Affairs Administration
6 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
14 WDs
16 WDs (divided into 3 cycles according to Annex II)
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (90) days may be divided into (3) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
14 WDs
Assessor in Regulatory Affairs Administration reviews the Registration Dossier, prepares final report and presents it to Technical Committee for Drug Control and MA license is released
Requirements needed during the review
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (60) days may be divided into (2) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
END

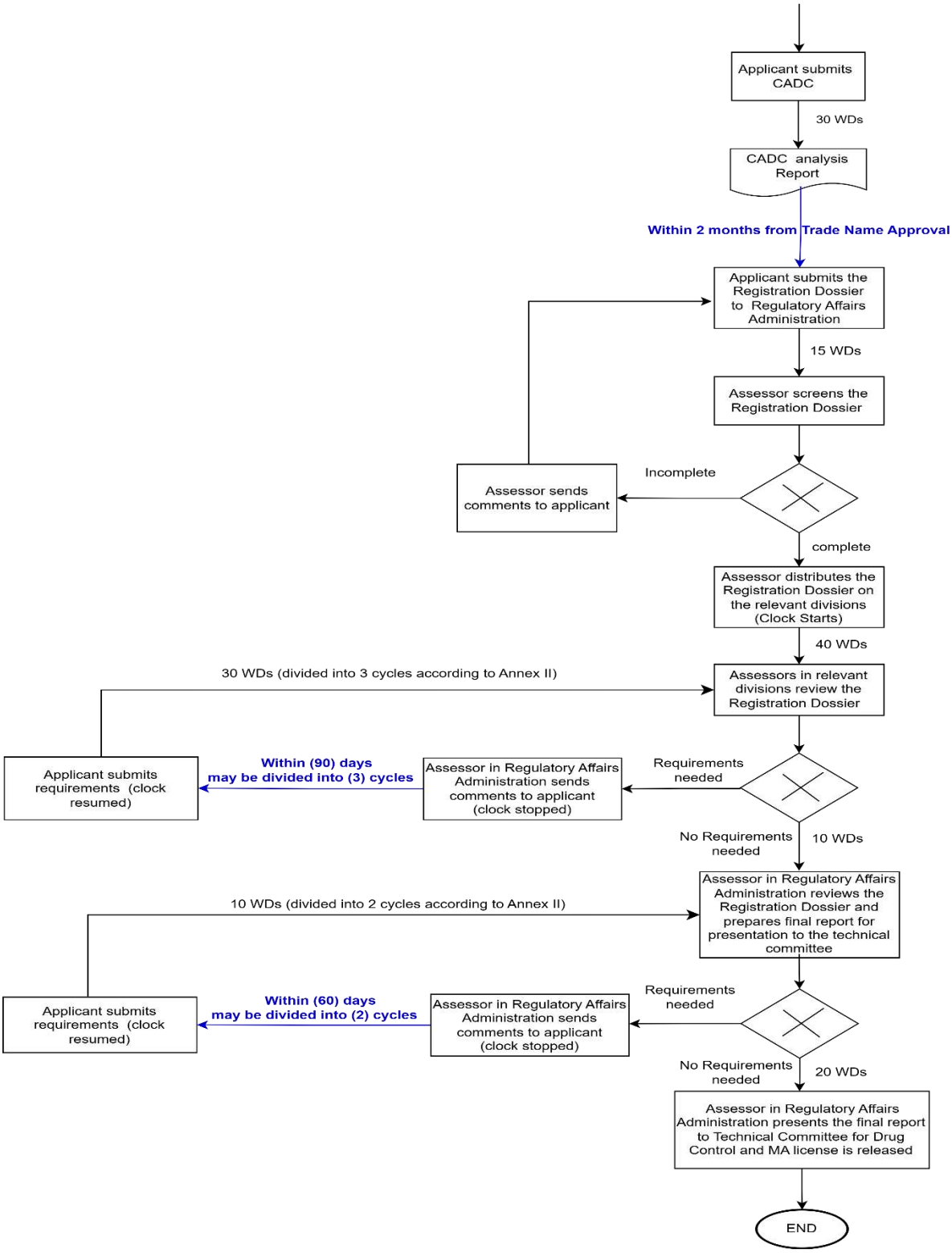
EDA Chairman Decree (450/2023) Flowchart for Imported Products marketed in one of SRAs or WHO-Prequalified with assessment timelines (Fast Track)



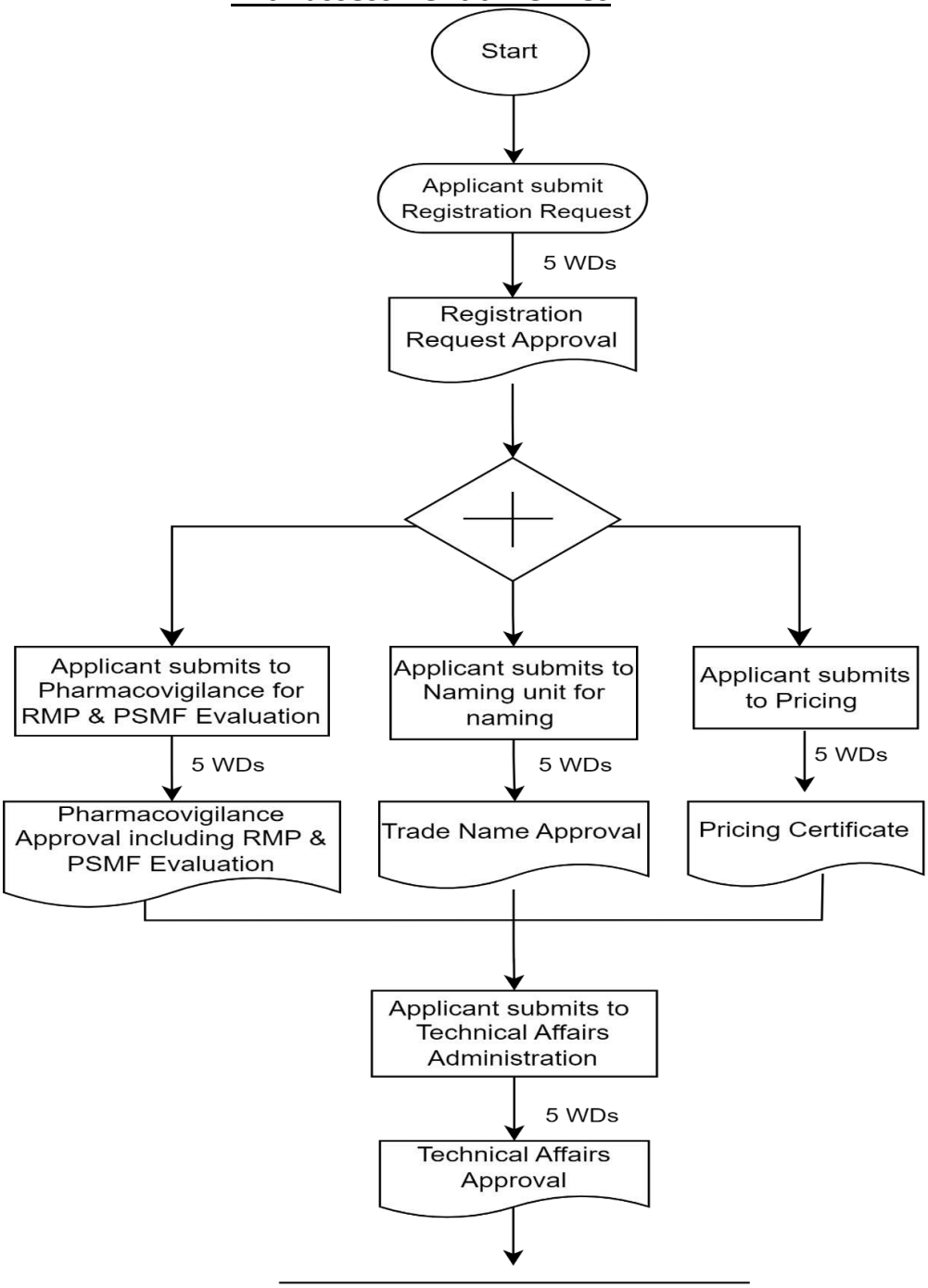

Within 2 months from Trade Name Approval
Applicant submits the Registration Dossier to Regulatory Affairs Administration
9 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
20 WDs
21 WDs (divided into 3 cycles according to Annex II)
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (90) days may be divided into (3) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
25 WDs
Assessor in Regulatory Affairs Administration reviews the Registration Dossier, prepares final report and presents it to Technical Committee for Drug Control and MA license is released
Requirements needed during the review
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (60) days may be divided into (2) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
END

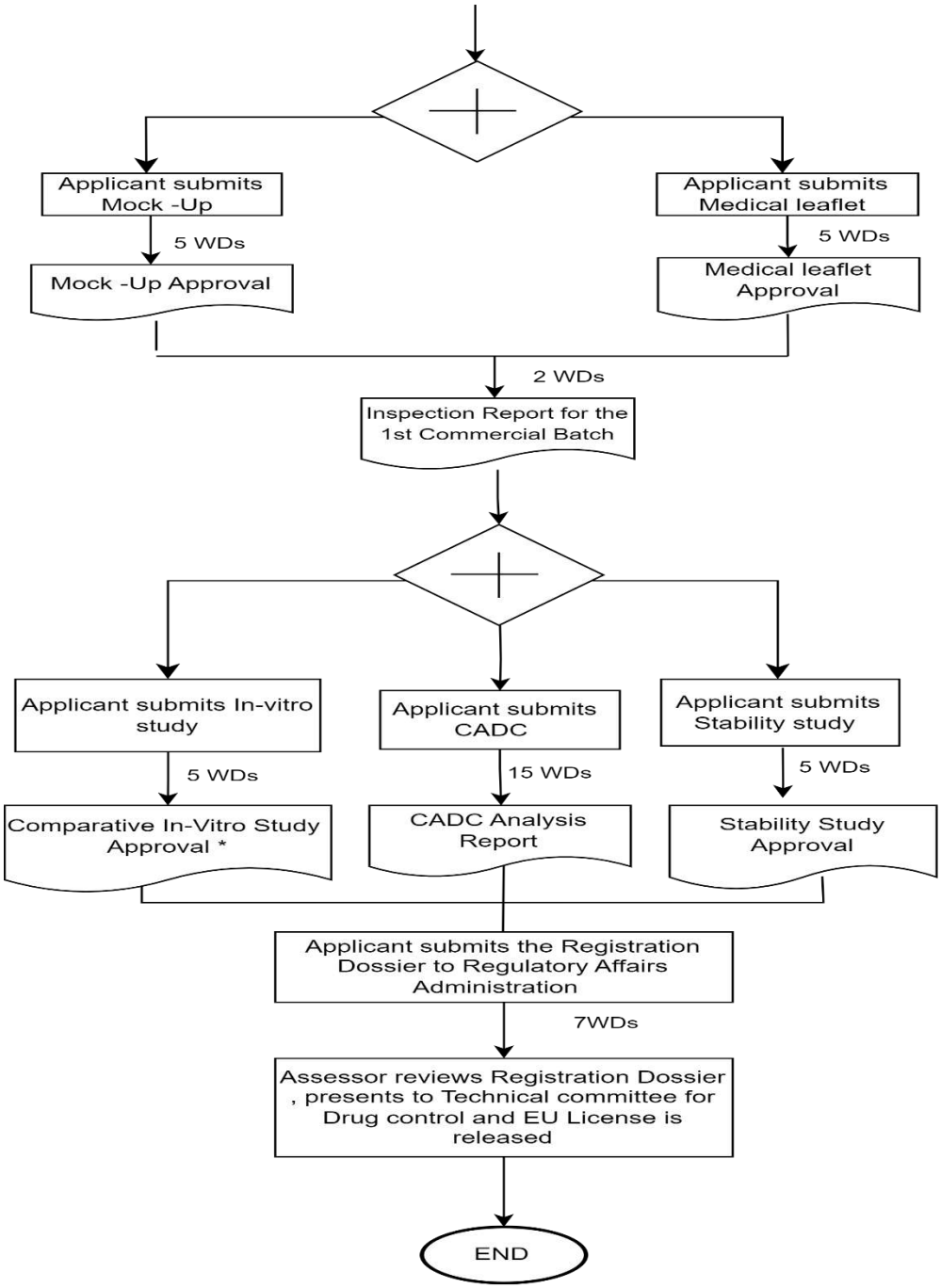
EDA Chairman Decree (450/2023) Flowchart for Imported Products from non-reference country and not marketed in one of reference countries with assessment timelines (Fast Track)




Applicant submits CADC
30 WDs
CADC analysis Report
Within 2 months from Trade Name Approval
Applicant submits the Registration Dossier to Regulatory Affairs Administration
15 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
40 WDs
30 WDs (divided into 3 cycles according to Annex II)
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (90) days may be divided into (3) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
10 WDs
10 WDs (divided into 2 cycles according to Annex II)
Assessor in Regulatory Affairs Administration reviews the Registration Dossier and prepares final report for presentation to the technical committee
Requirements needed
Assessor in Regulatory Affairs Administration sends comments to applicant (clock stopped)
Within (60) days may be divided into (2) cycles
Applicant submits requirements (clock resumed)
No Requirements needed
20 WDs
Assessor in Regulatory Affairs Administration presents the final report to Technical Committee for Drug Control and MA license is released
END

Emergency Use Approval of Locally Manufactured Generic Products Flowchart with assessment timelines

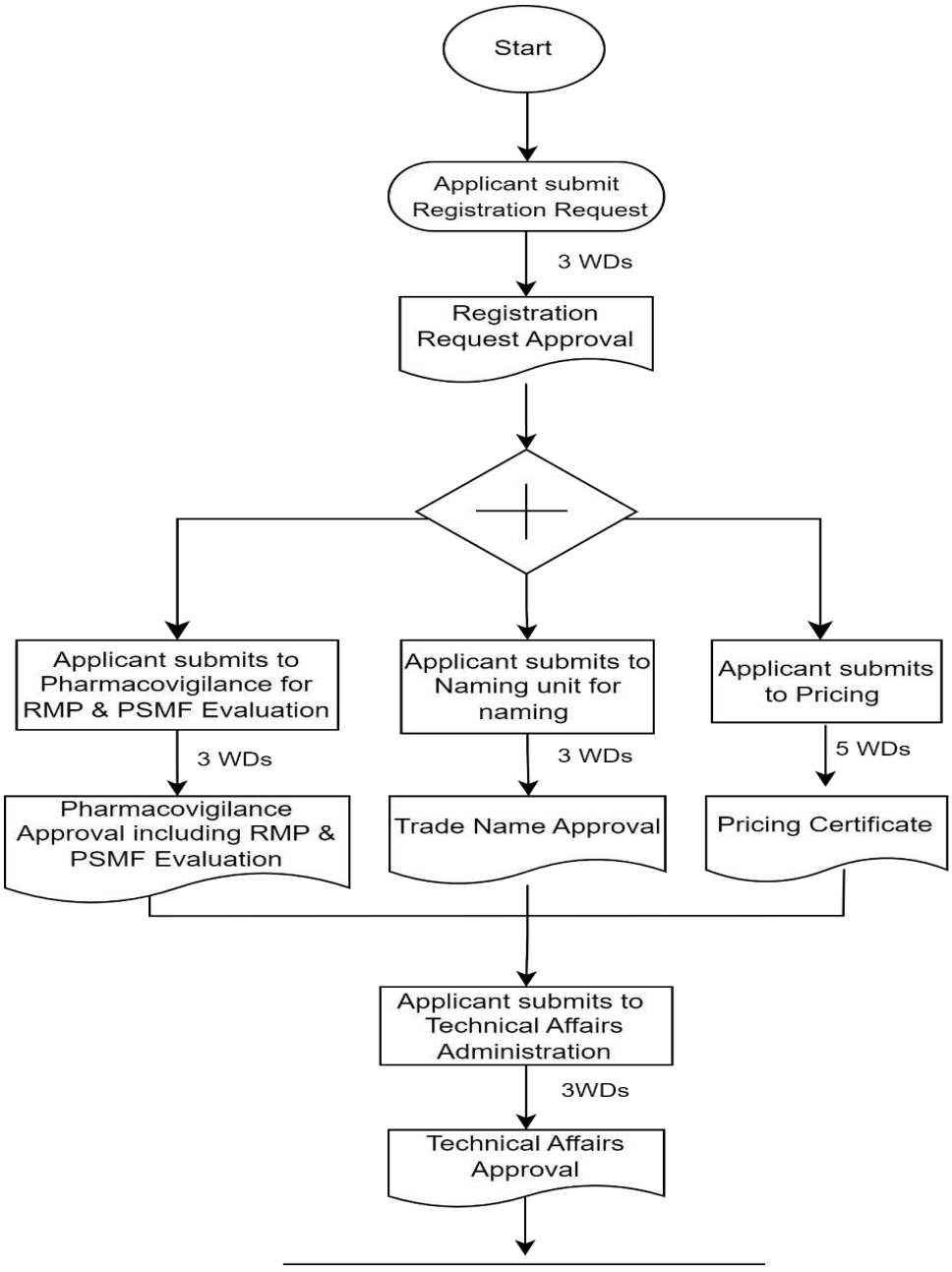


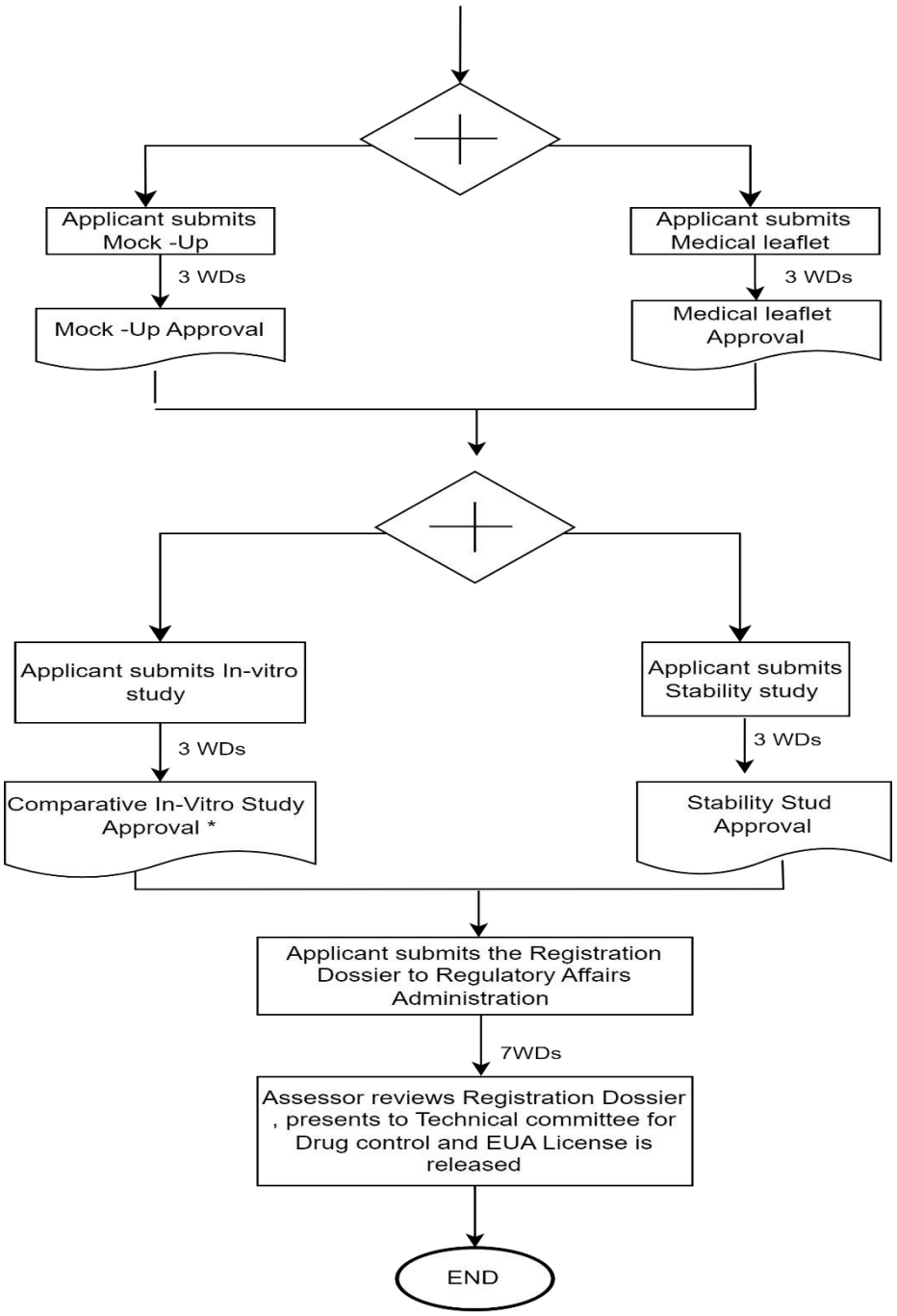


- Assessment timelines start from receiving complete files from applicants
- Total Assessment Timeline = maximum 44 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

*Bioequivalence study approval is a condition for the commercial batch release (if applicable)

Emergency Use Approval of Imported Products Flowchart with assessment timelines





- Assessment timelines start from receiving complete files from applicants
- Total Assessment Timeline = maximum 24 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

*Bioequivalence study approval is a condition for the commercial batch release (if applicable)

Annex I
Locally Manufactured Generic Products' Timeframes

EDA's Assessment Timeframe:

Application type	Application	Pricing +Naming+ PV	Screening &Evaluation
local Generic	31	90	210
local Generic (Fast Track)	18	30	125

* **The timeline mentioned above:**
  - **Includes all cycles required by the EDA to complete the evaluation and its supplementary.**
  - **Does not include the time needed for the applicant to fulfill the comments only EDA's assessment time.**

Registration Assessment Time Frames Breakdowns:

Serial	Screening steps of dossier	First & Third case (Normal track)	Second case (Fast Track)
1	**Screening** [1]	(30) working days	(15) working days
2	**Distribution and Technical Evaluation** [2]	Technical Evaluation and sending letter of comments = (60) working days Review of 1st Supplementary Documents = (20) working days Review of 2nd Supplementary Documents = (20) working days Review of 3rd Supplementary Documents = (20) working days	Technical Evaluation and sending letter of comments = (40) working days Review of 1st Supplementary Documents = (10) working days Review of 2nd Supplementary Documents = (10) working days Review of 3rd Supplementary Documents = (10) working days
3	**Review and Final report preparation for presentation to the Technical Committee**	Technical Evaluation and sending letter of comments = (15) working days Review of 1st Supplementary Documents = (10) working days Review of 2nd Supplementary Documents = (10) working days	Technical Evaluation and sending letter of comments = (10) working days Review of 1st Supplementary Documents = (5) working days Review of 2nd Supplementary Documents = (5) working days
4	**Presentation to Technical Committee and MA License release**	(25) working days	(20) working days

[1] **Screening:** An initial review of the registration dossier is conducted by Administration of Regulatory Affairs for Human Pharmaceuticals to ensure the presence of all required technical studies and approvals, ensuring completeness before proceeding with the technical evaluation.

[2] **Technical Evaluation:** A detailed technical review is being conducted by the relevant administrations and units.

Annex II
Imported Products' Timeframes

EDA's Assessment Timeframe:

Application type	Application	Pricing +Naming+ PV	Screening &Evaluation
Imported Products marketed in one of SRAs or WHO-Prequalified	31	90	140
Imported from non-reference country and not marketed in one of the reference countries	31 (After reviewing site master file and module 3 and inspection on the factory overseas)	90	210
Imported products approved from FDA & EMA in addition to one of the SRAs or WHO prequalified (Fast track)	12	30	25
Imported products approved from FDA or EMA in addition to one of the SRAs or WHO prequalified (Fast track)	12	30	50
Imported Products marketed in one of SRAs or WHO-Prequalified with assessment timelines (Fast Track)	18	30	75
Imported from non-reference country and not marketed in one of the reference countries (Fast Track)	20 (After reviewing site master file and Module 3 and inspection on the factory overseas)	30	125

* **The timeline mentioned above:**
  - **Includes all cycles required by the EDA to complete the evaluation and its supplementary.**
  - **Does not include the time needed for the applicant to fulfill the comments only EDA's assessment time.**

Registration Assessment Time Frames Breakdowns:

Serial	Procedure/Time Frame for Files submitted according to	First & Third case (Normal Track)		Second case (Fast Track)			
		Imported Products marketed in one of SRAs or WHO-Prequalified	Imported from non-reference country and not marketed in one of reference countries	Track A Imported products approved from FDA & EMA in addition to one of the SRAs or WHO prequalified	Track B Imported products approved from FDA or EMA in addition to one of the SRAs or WHO prequalified	Track C Imported Products marketed in one of SRAs or WHO-Prequalified	Track C Imported from non-reference country and not marketed in one of reference countries
1	Screening (1)	(20) WDs	(30) WDs	(3) WDs	(6) WDs	(9) WDs	(15) WDs
2	Distribution and Technical Evaluation (2)	1st Evaluation and sending letter of comments. = (25) WDs Review of 1st Suppl. Doc. = (10) WDs Review of 2nd Suppl. Doc. = (10) WDs Review of 3rd Suppl. Doc. = (10) WDs	1st Evaluation and sending letter of comments. = (60) WDs Review of 1st Suppl. Doc. = (20) WDs Review of 2nd Suppl. Doc. = (20) WDs Review of 3rd Suppl. Doc. = (20) WDs	1st Evaluation and sending letter of comments. = (7) WDs Review of 1st Suppl. Doc. = (3) WDs Review of 2nd Suppl. Doc. = (3) WDs Review of 3rd Suppl. Doc. = (2) WDs	1st Evaluation and sending letter of comments. = (14) WDs Review of 1st Suppl. Doc. = (6) WDs Review of 2nd Suppl. Doc. = (6) WDs Review of 3rd Suppl. Doc. = (4) WDs	1st Evaluation and sending letter of comments. = (20) WDs Review of 1st Suppl. Doc. = (8) WDs Review of 2nd Suppl. Doc. = (8) WDs Review of 3rd Suppl. Doc. = (5) WDs	1st Evaluation and sending letter of comments. = (40) WDs Review of 1st Suppl. Doc. = (10) WDs Review of 2nd Suppl. Doc. = (10) WDs Review of 3rd Suppl. Doc. = (10) WDs
3	Review and Final report preparation for presentation to the Technical Committee	Technical Evaluation and sending letter of comments = (15) WDs Review of 1st Suppl. Doc = (10) WDs Review of 2nd Suppl. Doc = (10) WDs	Technical Evaluation and sending letter of comments = (15) WDs Review of 1st Suppl. Doc = (10) WDs Review of 2nd Suppl. Doc = (10) WDs	(7) WDs	(14) WDs	(25) WDs	1st Evaluation and sending letter of comments. = (10) WDs Review of 1st Suppl. Doc. = (5) WDs Review of 2nd Suppl. Doc. = (5) WDs
4	Presentation to Technical Committee and MA License release	(30) WDs	(25) WDs				(20) WDs

(1) **Screening:** An initial review of the registration dossier is conducted by Administration of Regulatory Affairs for Human Pharmaceuticals to ensure the presence of all required technical studies and approvals, ensuring completeness before proceeding with the technical evaluation.

(2) **Technical Evaluation:** A detailed technical review is being conducted by the relevant administrations and units.

Annex III
Applicant Completions Time Frames Breakdowns

	Administration	First & Third case (Normal Track)	Second case (Fast Track)
1	**All administrations and units concerned with the technical evaluation**	The applicant is committed to submitting the completions within **(90) days** from the date the supplementary is sent, which may be divided into **(3) cycles**	The applicant is committed to submitting the completions within **(90) days** from the date the supplementary is sent, which may be divided into **(3) cycles**
2	**Administration of Regulatory Affairs of Human Pharmaceuticals**	The applicant is committed to submitting the completions within **(60) days** from the date the supplementary is sent, which may be divided into **(2) cycles**	

***In the event that the total deadline for required completion is exceeded, the applicant is obliged to pay service consideration for extending the deadline for completing completions for the General Administration of Human Pharmaceuticals Registration.**

Abbreviations:

- RMP: Risk Management Plan
- PSMF: Pharmacovigilance System Master File
- WD: Working Days
- SRA: Stringent regulatory authority
- Suppl.: Supplementary
- Doc.: Documents

Document History:

Version Number	Issue Date	Summary of Change
1	13/8/2023	New Issue
2	18/12/2023	Updating the receiving steps of registration dossier and timelines according to version 2 of EDA Chairman Decree 450/2023 regulatory guide
3	15/4/2024	Addition of Rolling and One Submission General flowcharts
4	4/8/2024	• Clarification in rolling submission "The applicant submits Module 1 to Regulatory Affairs administration" • Clarification of EDA's Assessment Timeframes
5	9/1/2025	• Update the registration process for locally manufactured products by stipulating that product analysis occurs subsequent to the issuance of the MA license and is a mandatory requirement for the release of the product in the market (page 3-4) • Removal of General Flowcharts • Addition of Locally manufactured products timeframe (Page 31-33) • Addition of Imported products timeframe (Page 34-36)
6	1/11/2025	Update of the registration procedures for locally manufactured human pharmaceutical products as per the EDA Chairman's memorandum dated August 13, 2025, to harmonize local and imported product registration under "One Submission" pathway.