

Flowcharts for EDA Chairman Decree 450 for the year 2023 Year 2024

Code: EDREX:NP.CAPP.064

Version No: 4

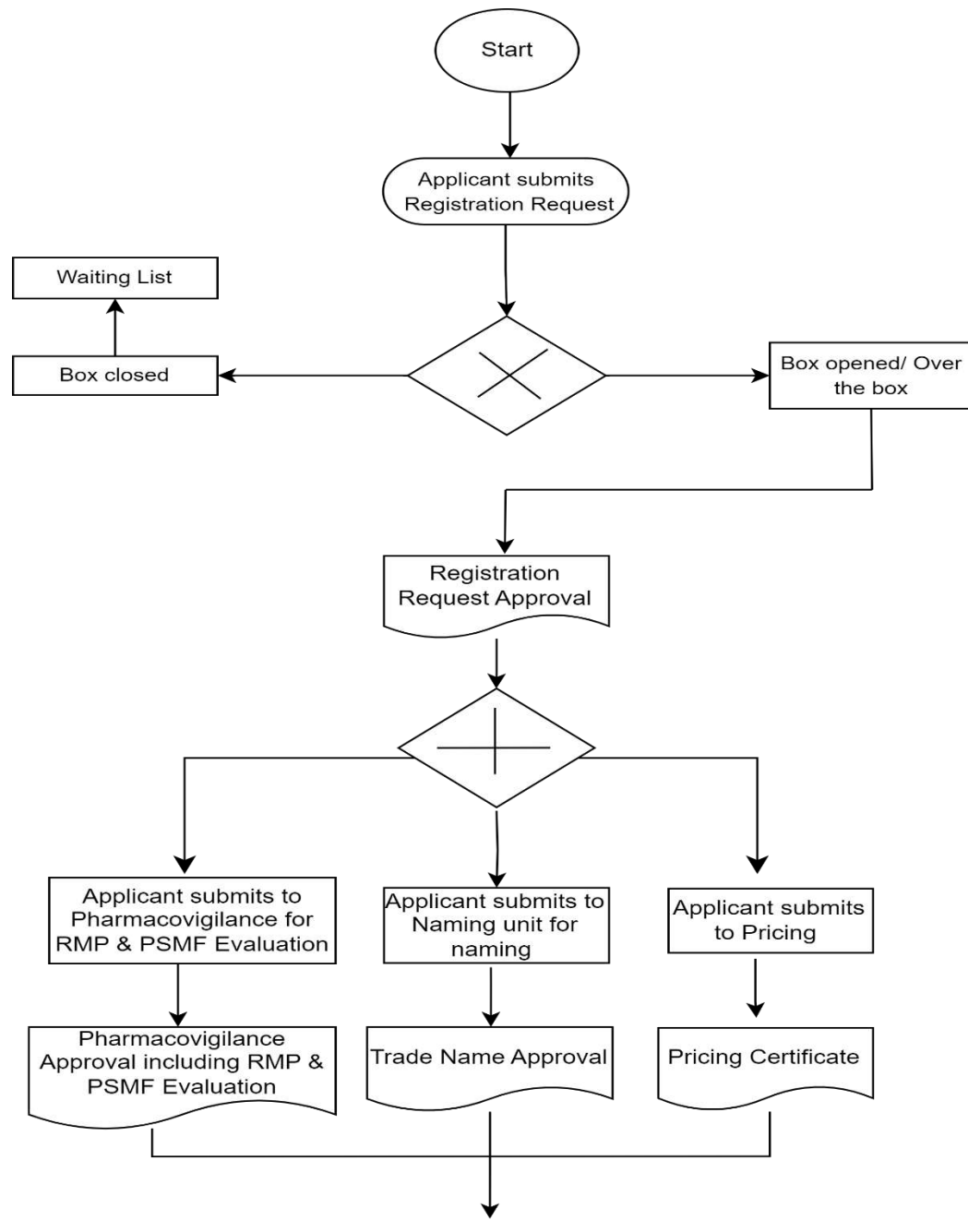
Issue Date: 4/8/2024

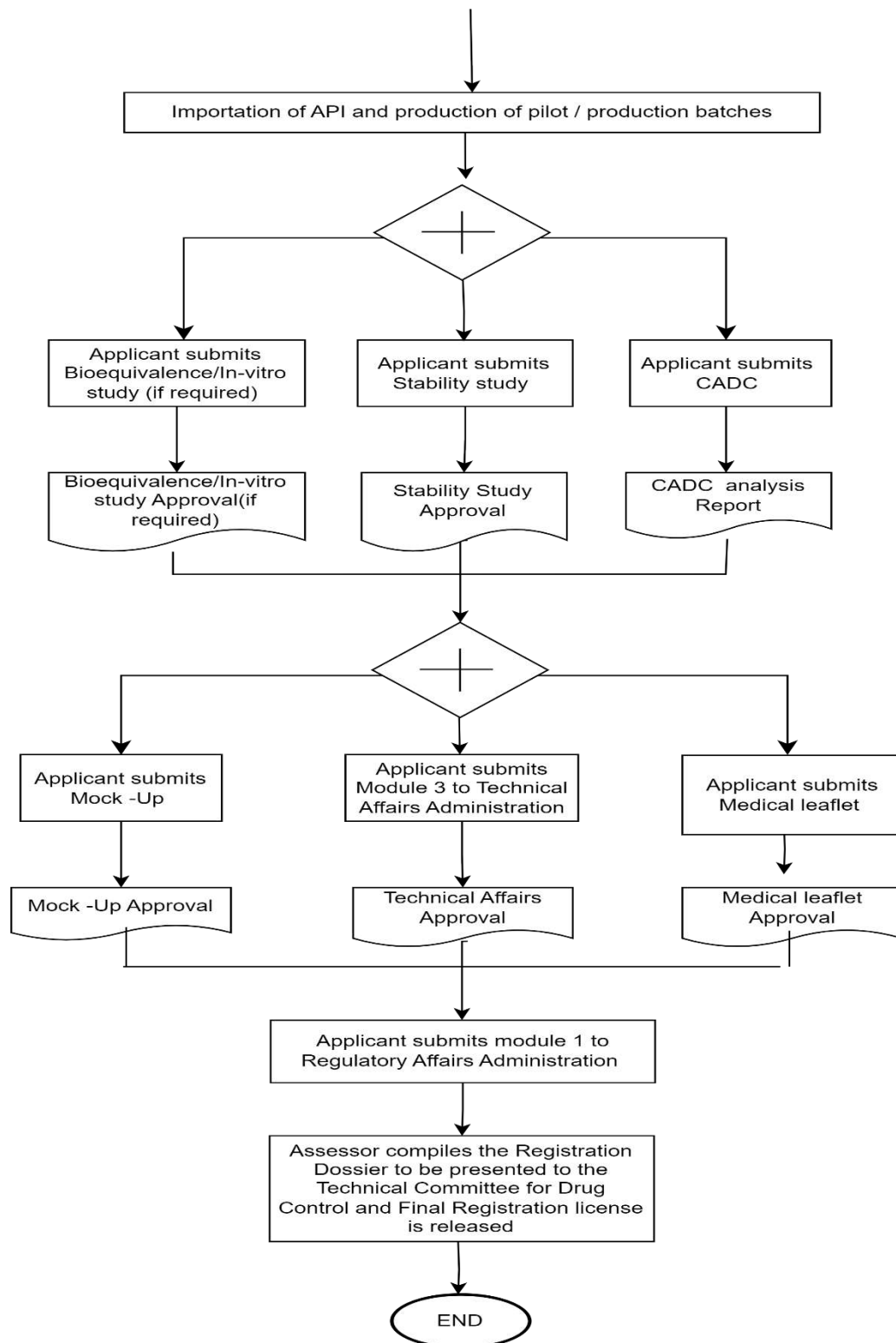
Effective date: 4/8/2024

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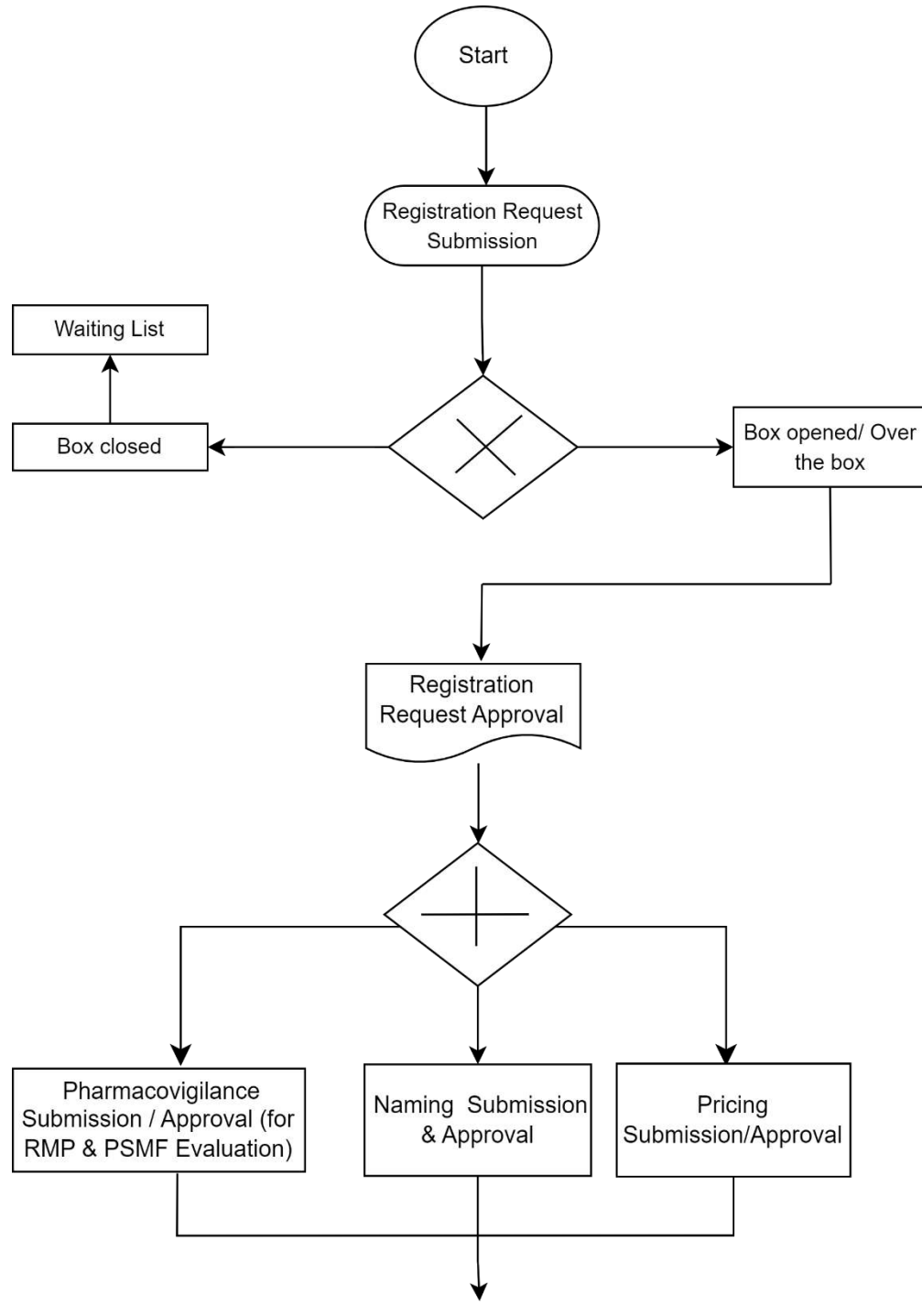
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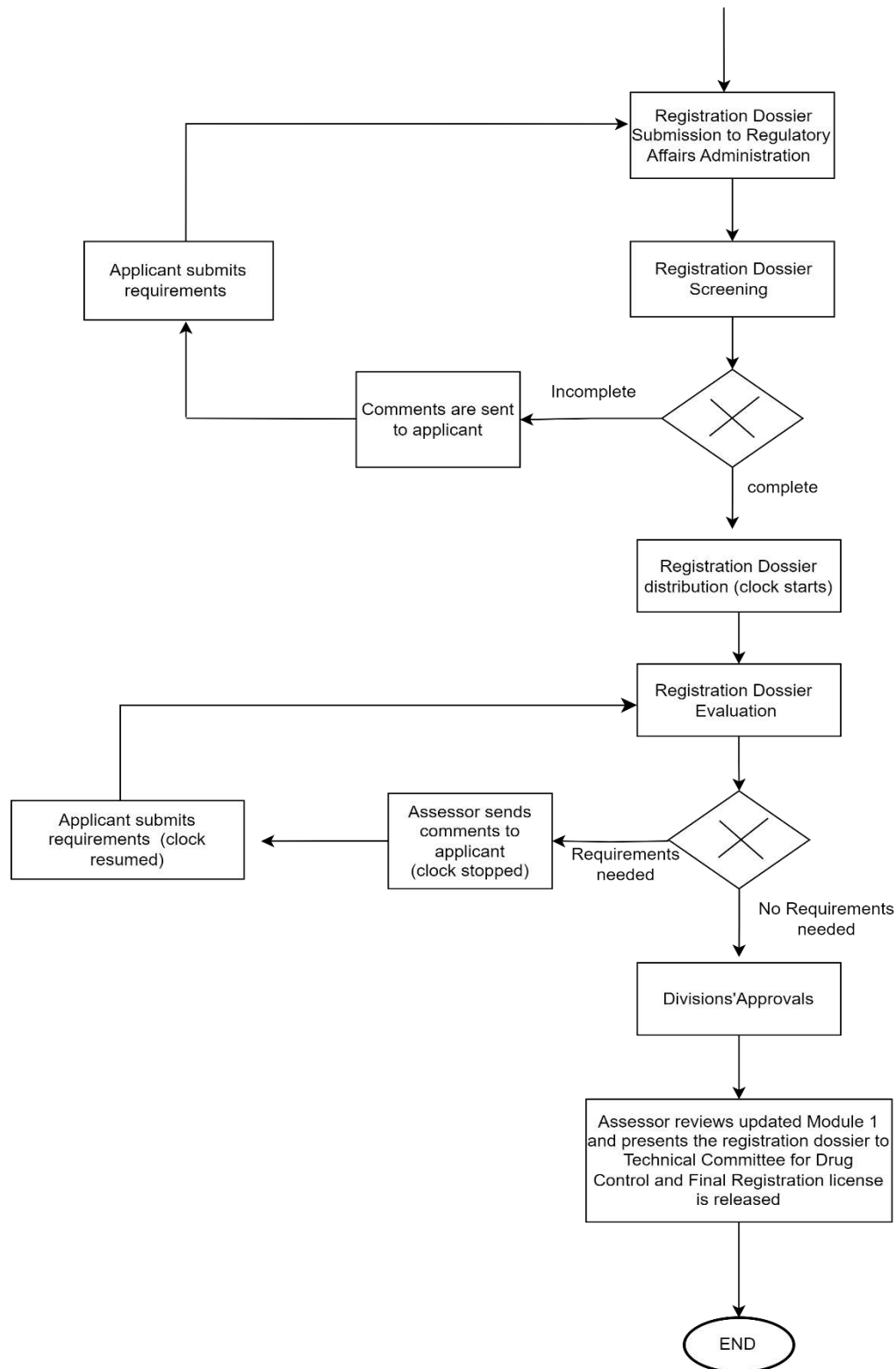
EDA Chairman Decree (450/2023) Rolling Submission General Flowchart



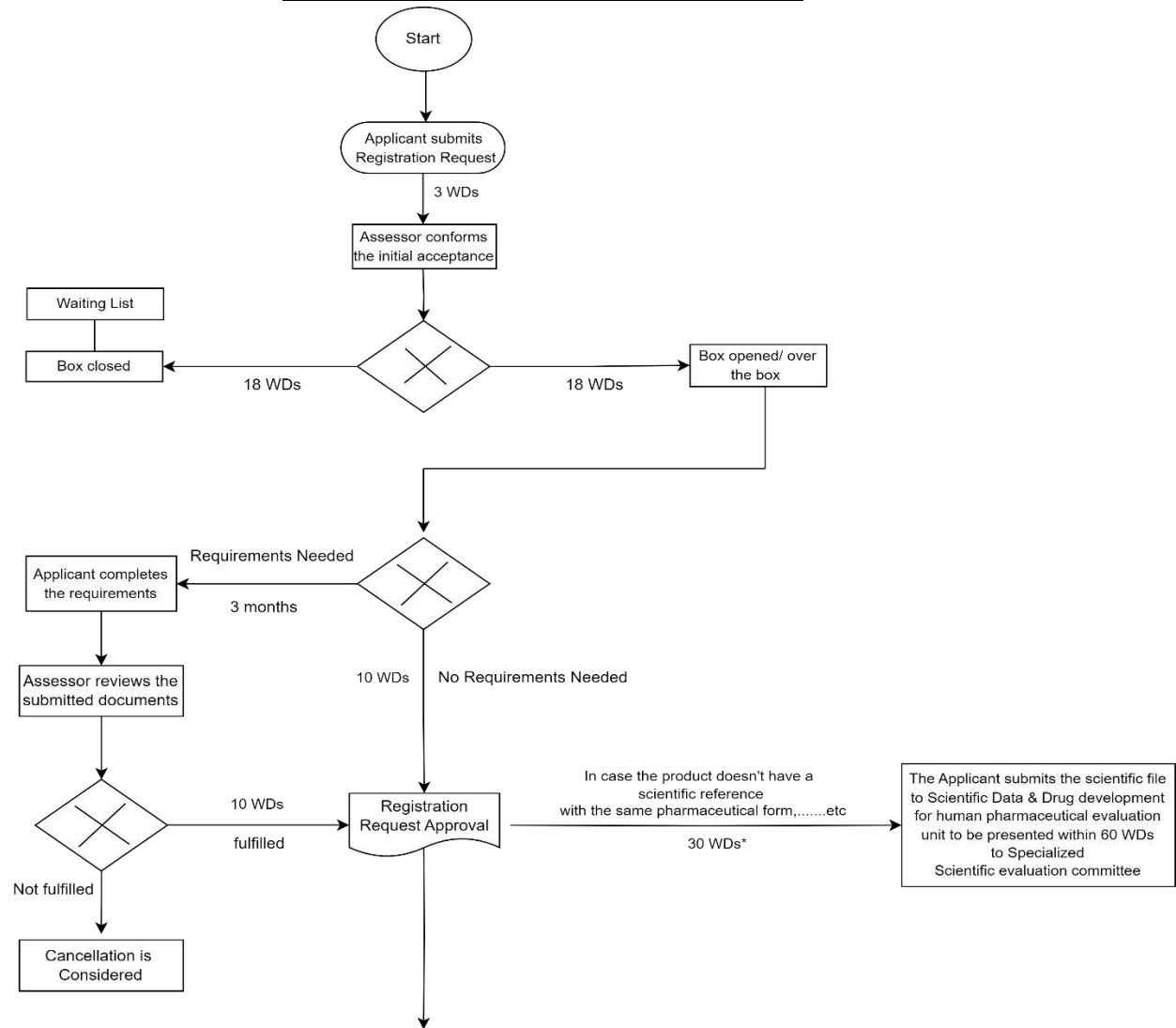


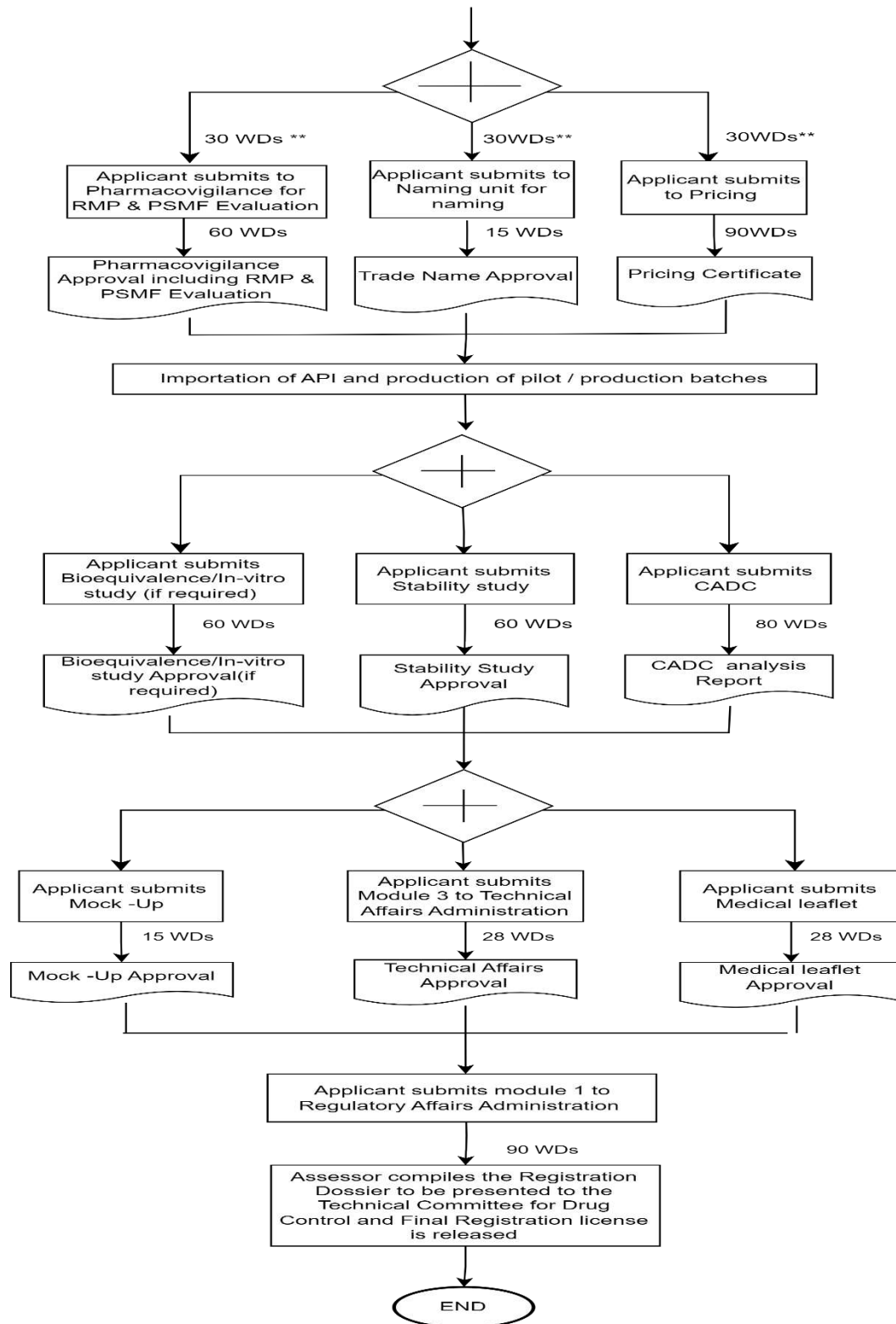
EDA Chairman Decree (450/2023) One Submission General Flowchart





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

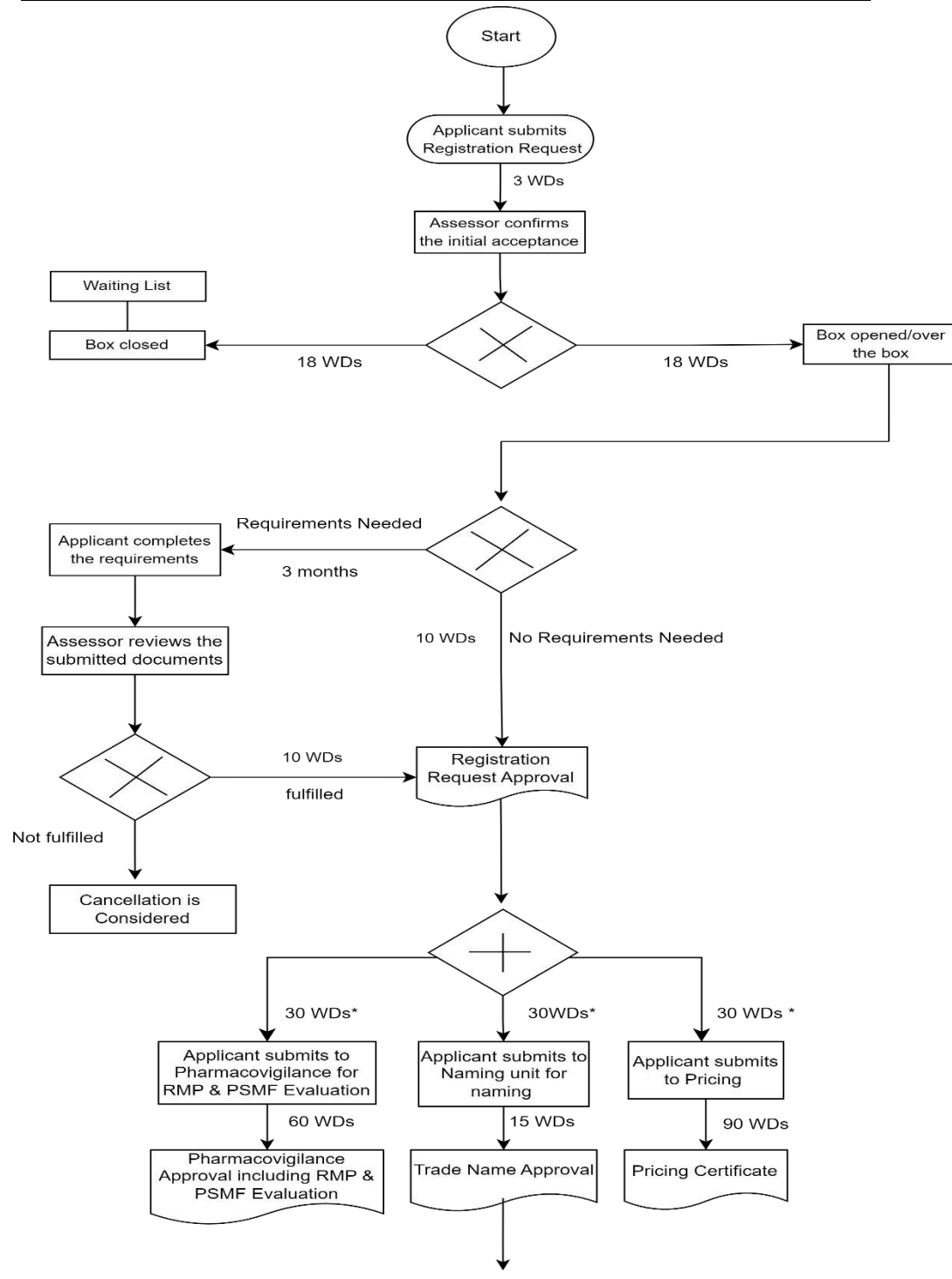


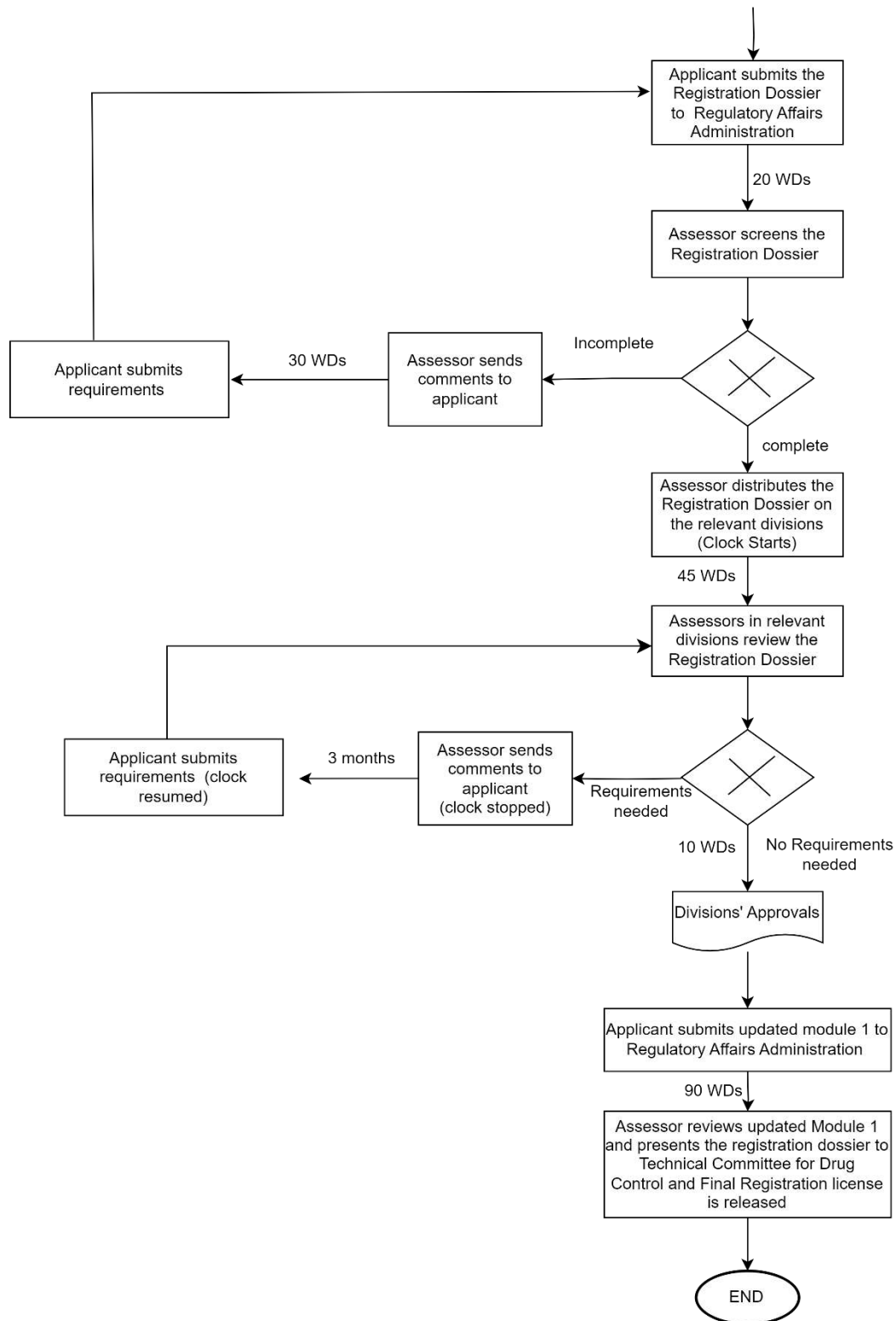


- Applicant Time:

- *The Applicant submits the scientific file to Scientific Data & Drug development for human pharmaceutical evaluation unit within 30 WDs from registration request approval (Incase the product does not have a scientific reference with the same pharmaceutical form, concentration or method of administration).
- ** Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from registration request approval (or from Specialized Scientific evaluation committee approval).
- Applicant has to submit Module 1 within 33 months (except in case III Track A: 21 months) from date of pharmacovigilance approval or first pricing certificate whichever is the latest.
- Assessment timelines in each relevant division starts from receiving complete file from the applicants.
- The declared working days are the maximum time needed for the process to be completed.

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

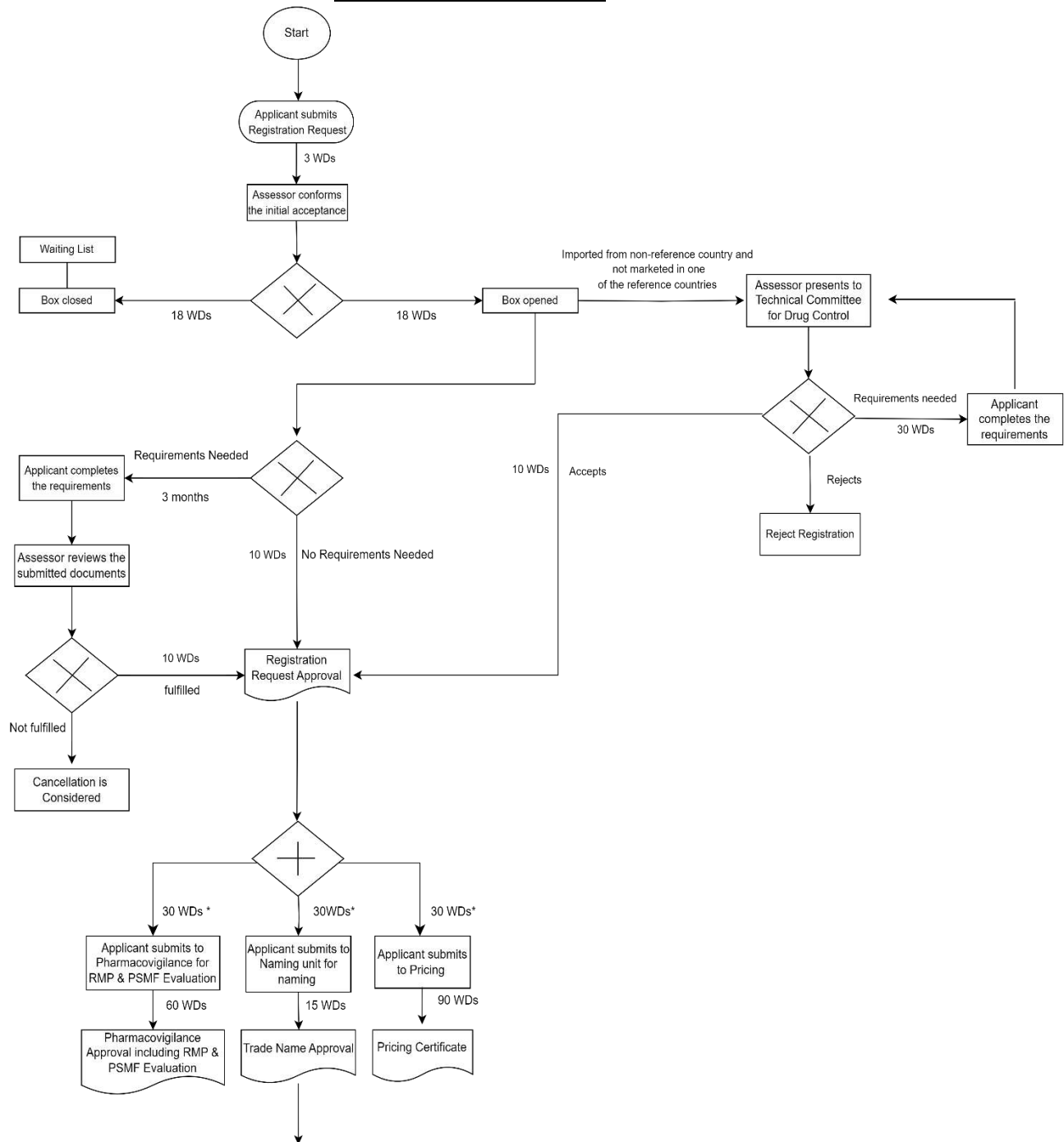


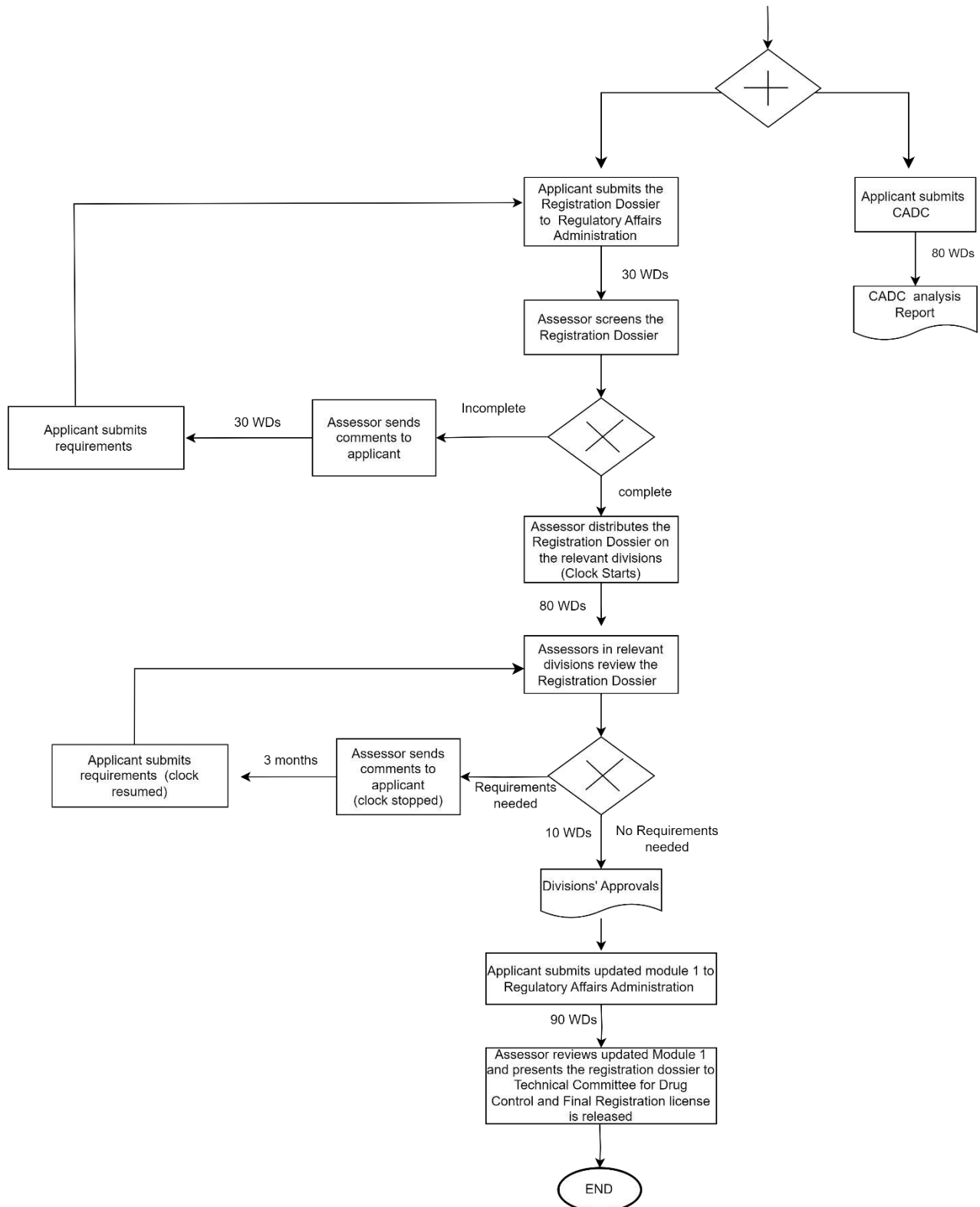




- Applicant Time:
 - * Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from registration request approval
 - Applicant has to submit the updated Module 1 within 6 months from date of pharmacovigilance approval or first pricing certificate whichever is the latest.
- The declared working days are the maximum time needed for the process to be completed.

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

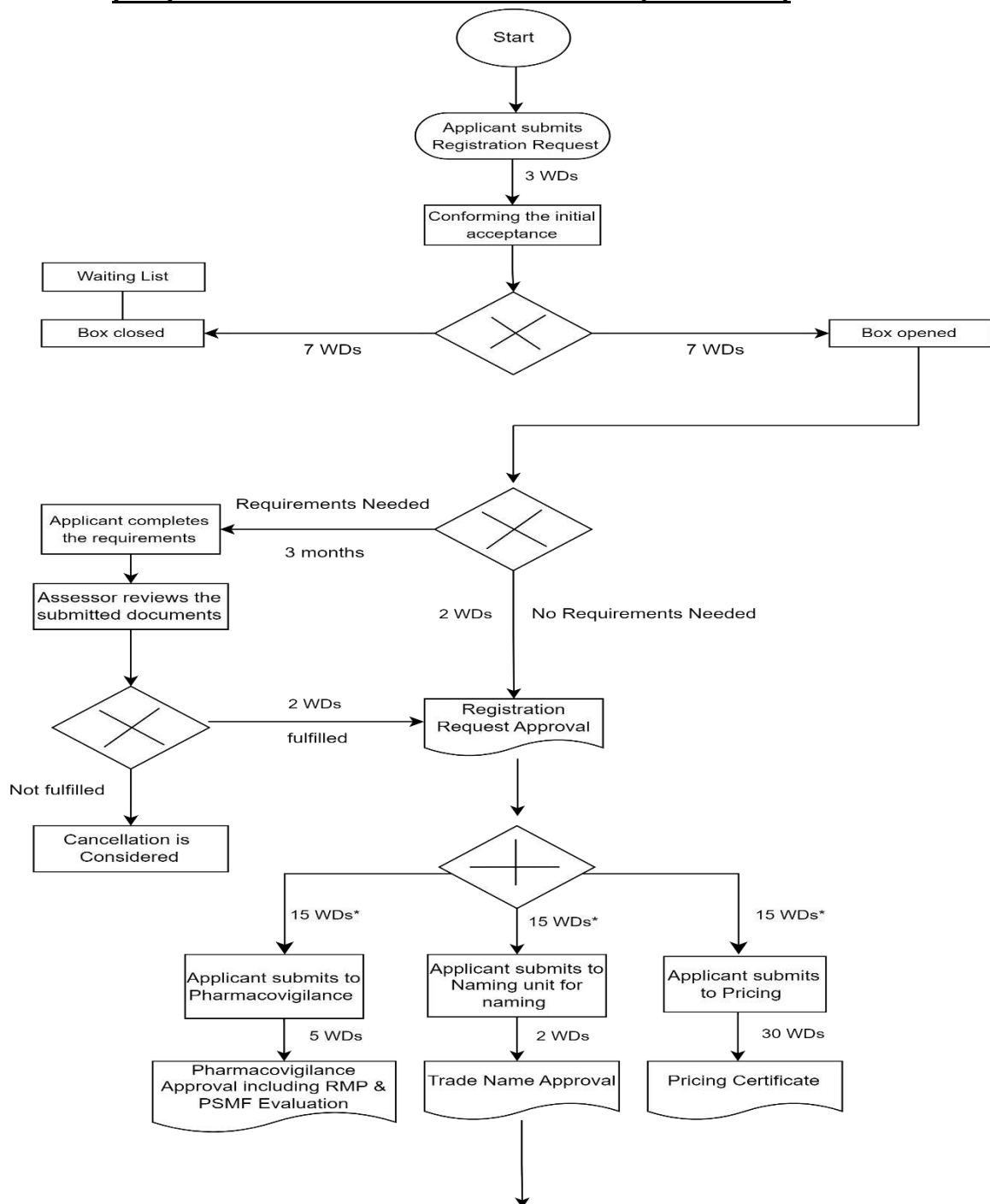


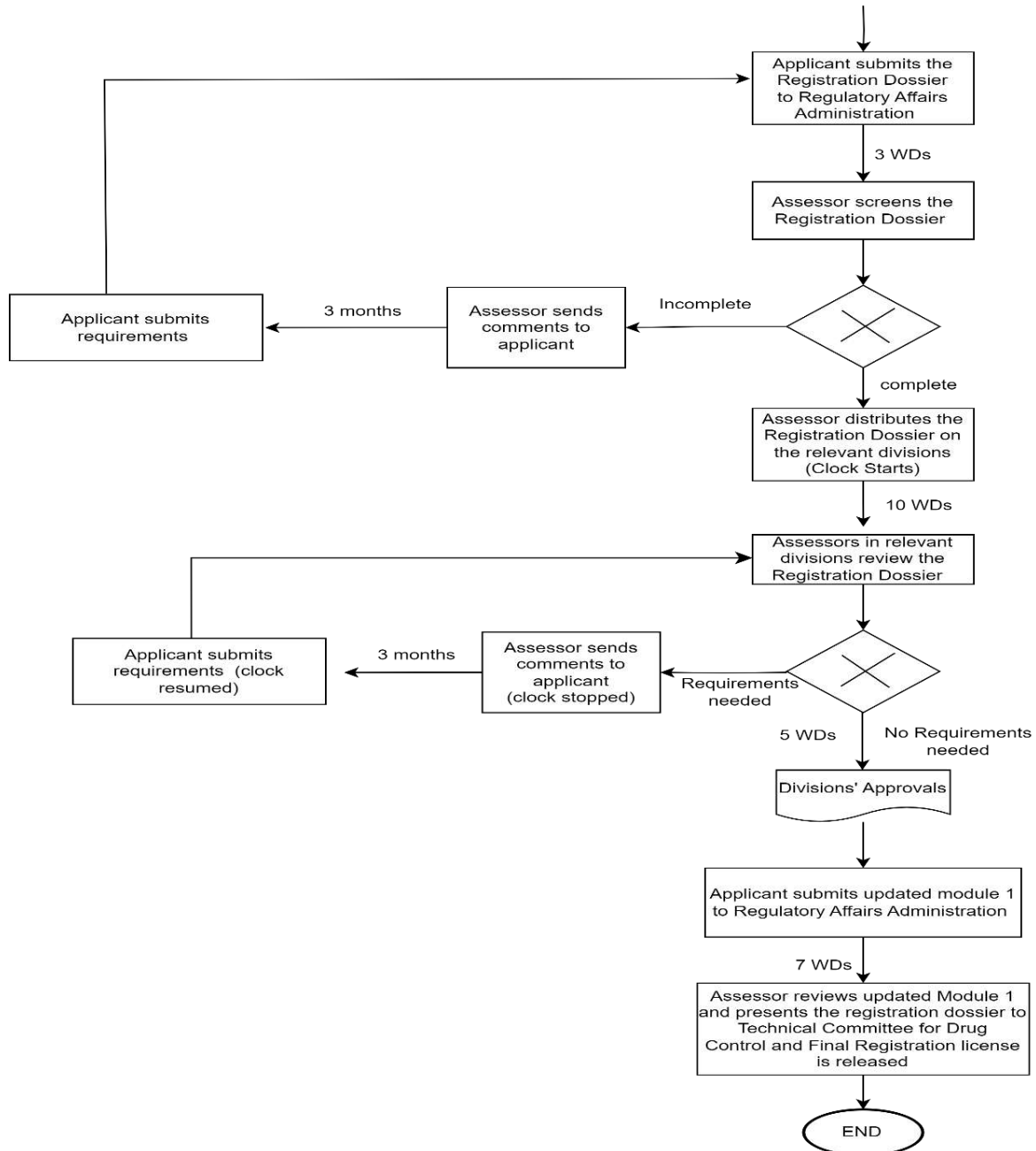




- Applicant Time:
 - * Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from registration request approval
 - Applicant has to submit the updated Module 1 within 6 months from date of pharmacovigilance approval or first pricing certificate whichever is the latest.
- The declared working days are the maximum time needed for the process to be completed.

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)





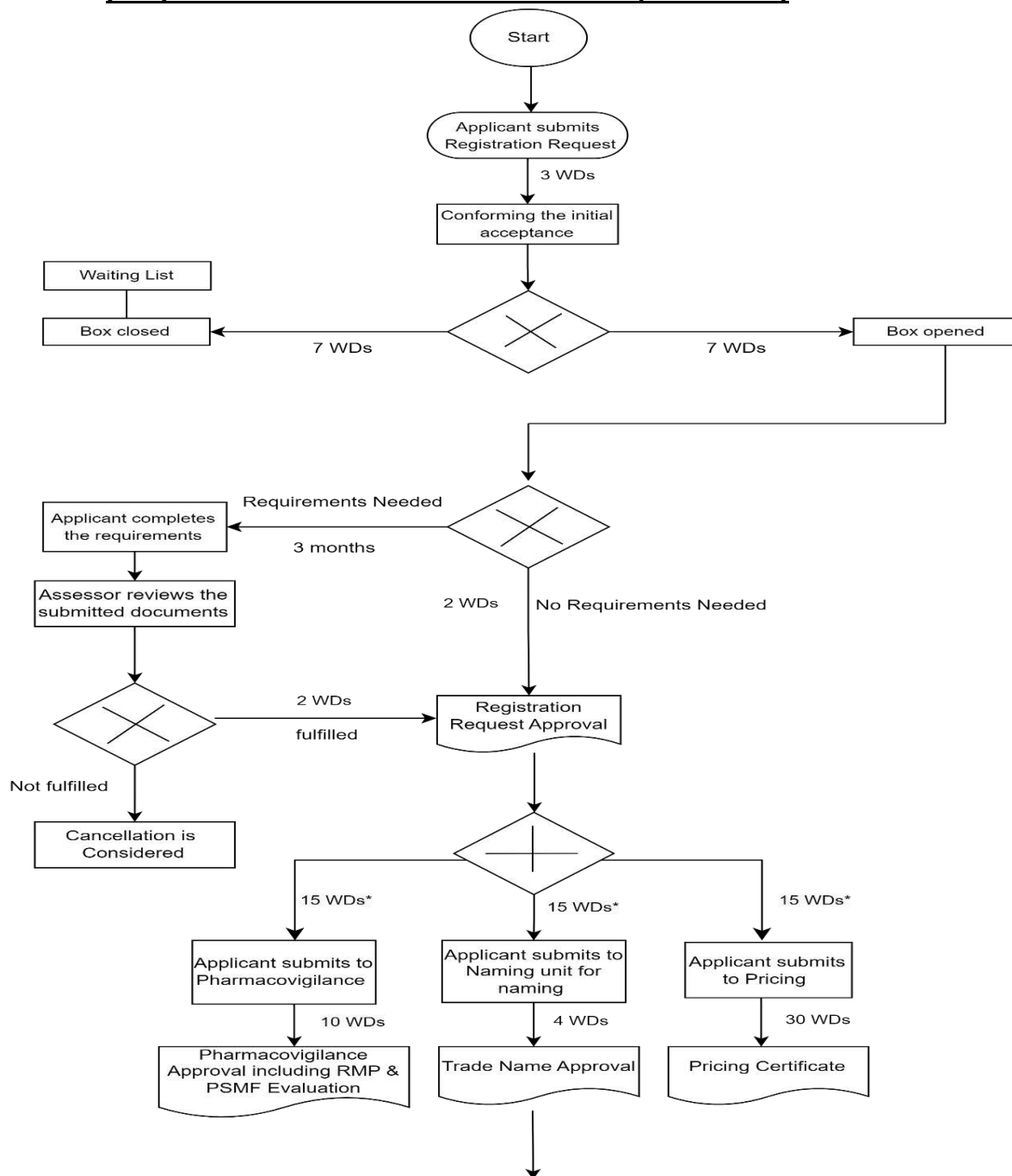
- Applicant Time:

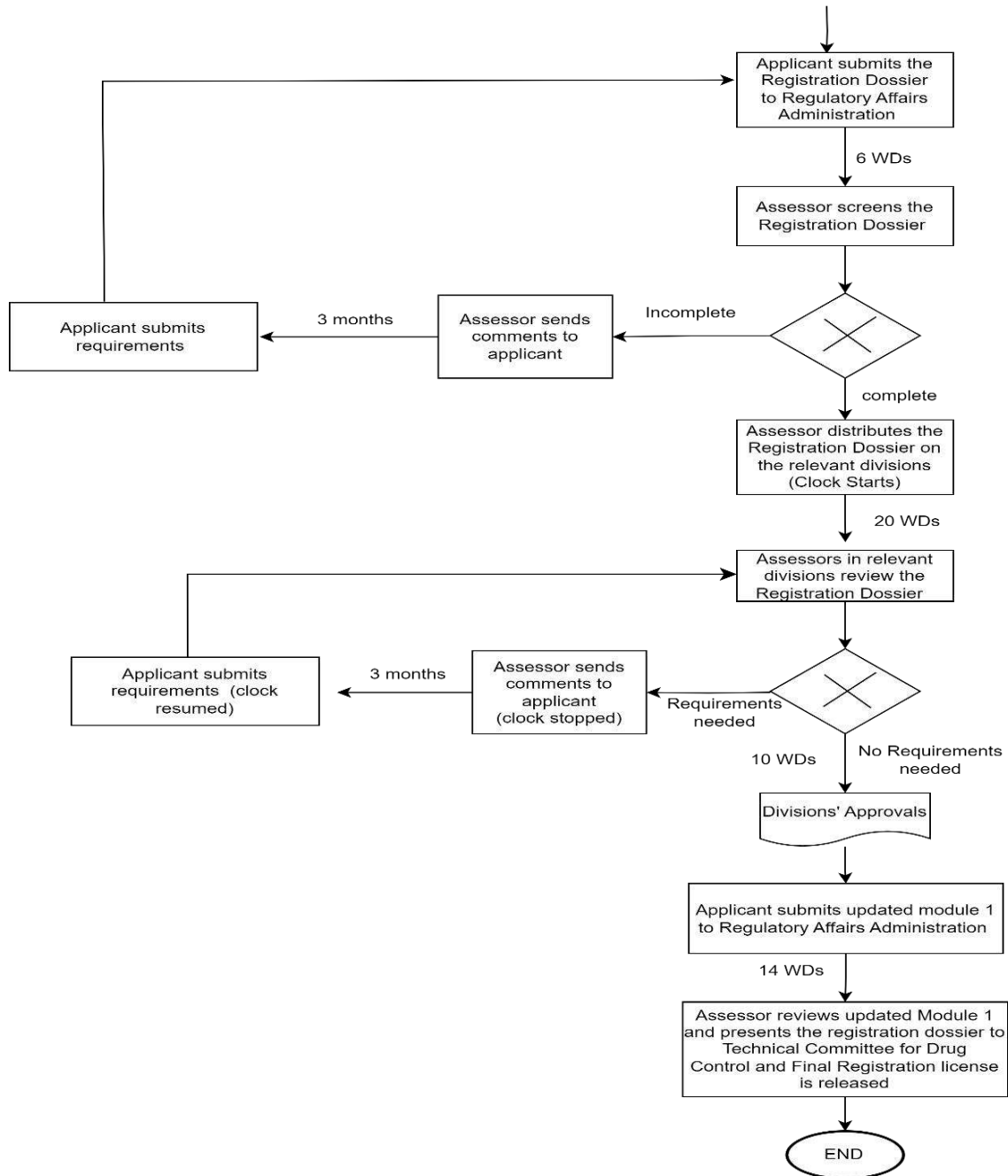
- * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval

- Applicant has to submit the Registration Dossier within 30 WD from date of registration request approval

- The declared working days are the maximum time needed for the process to be completed.

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)





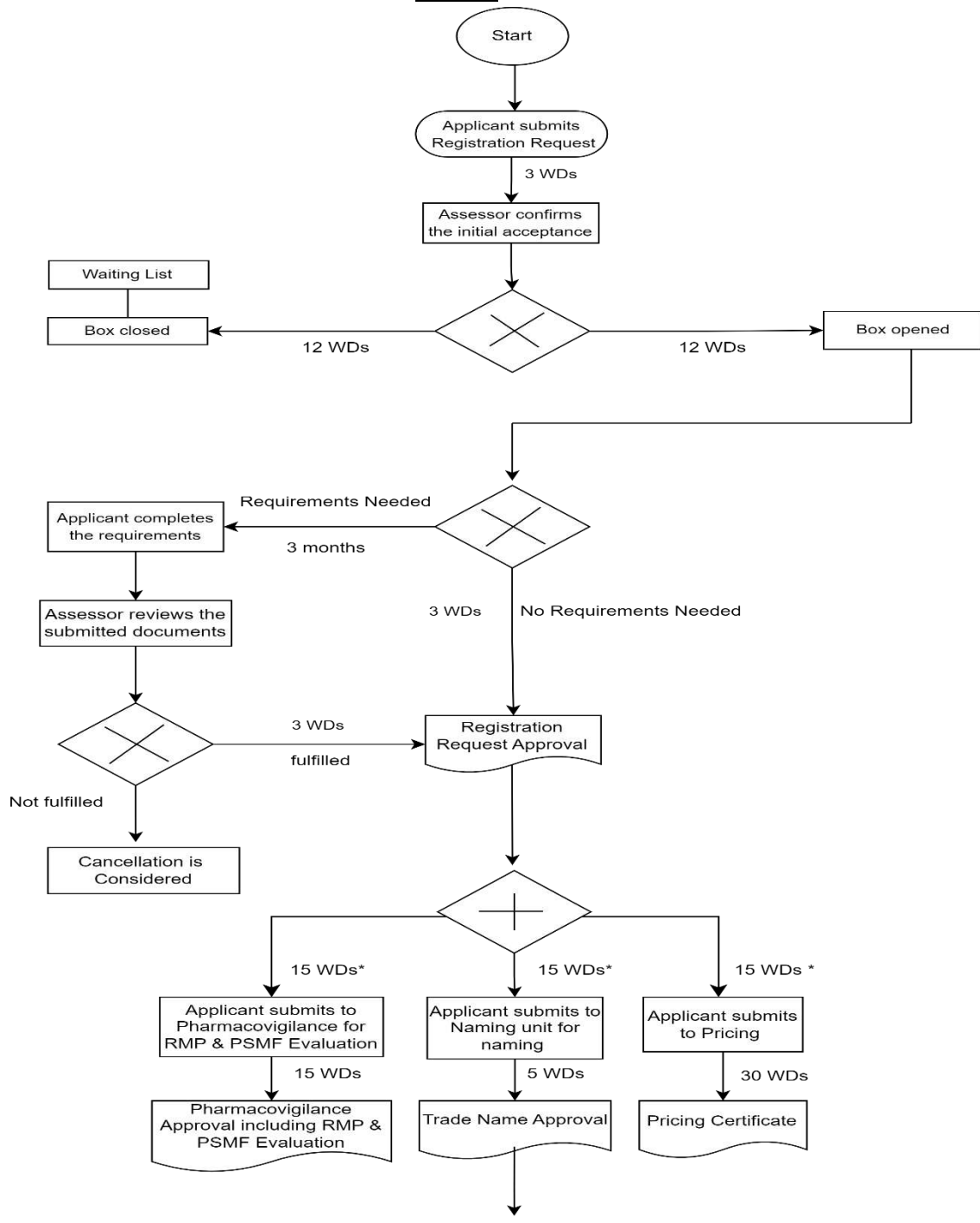
- Applicant Time:

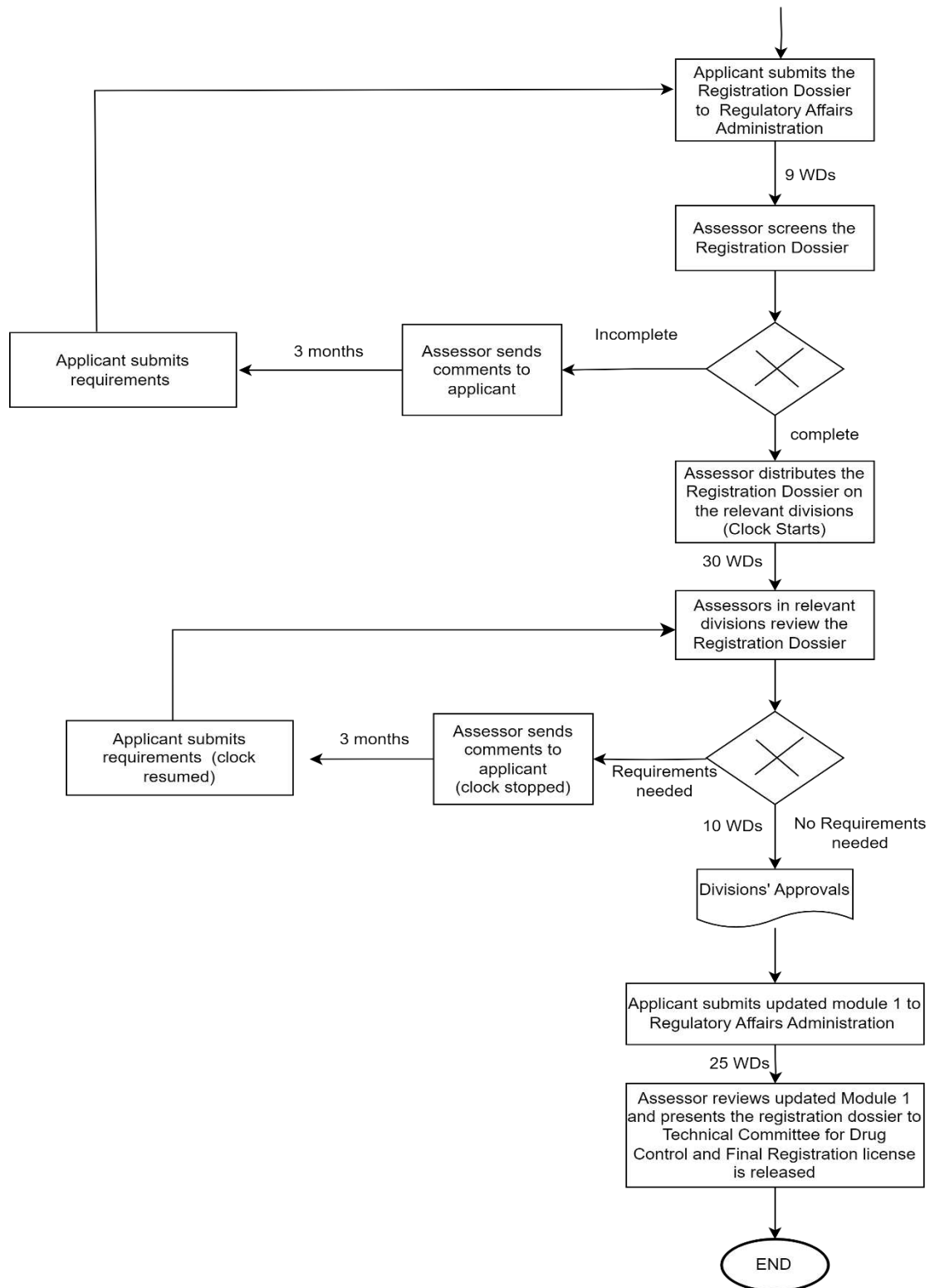
- * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval

- Applicant has to submit the Registration Dossier within 30 WD from date of registration request approval

- The declared working days are the maximum time needed for the process to be completed.

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



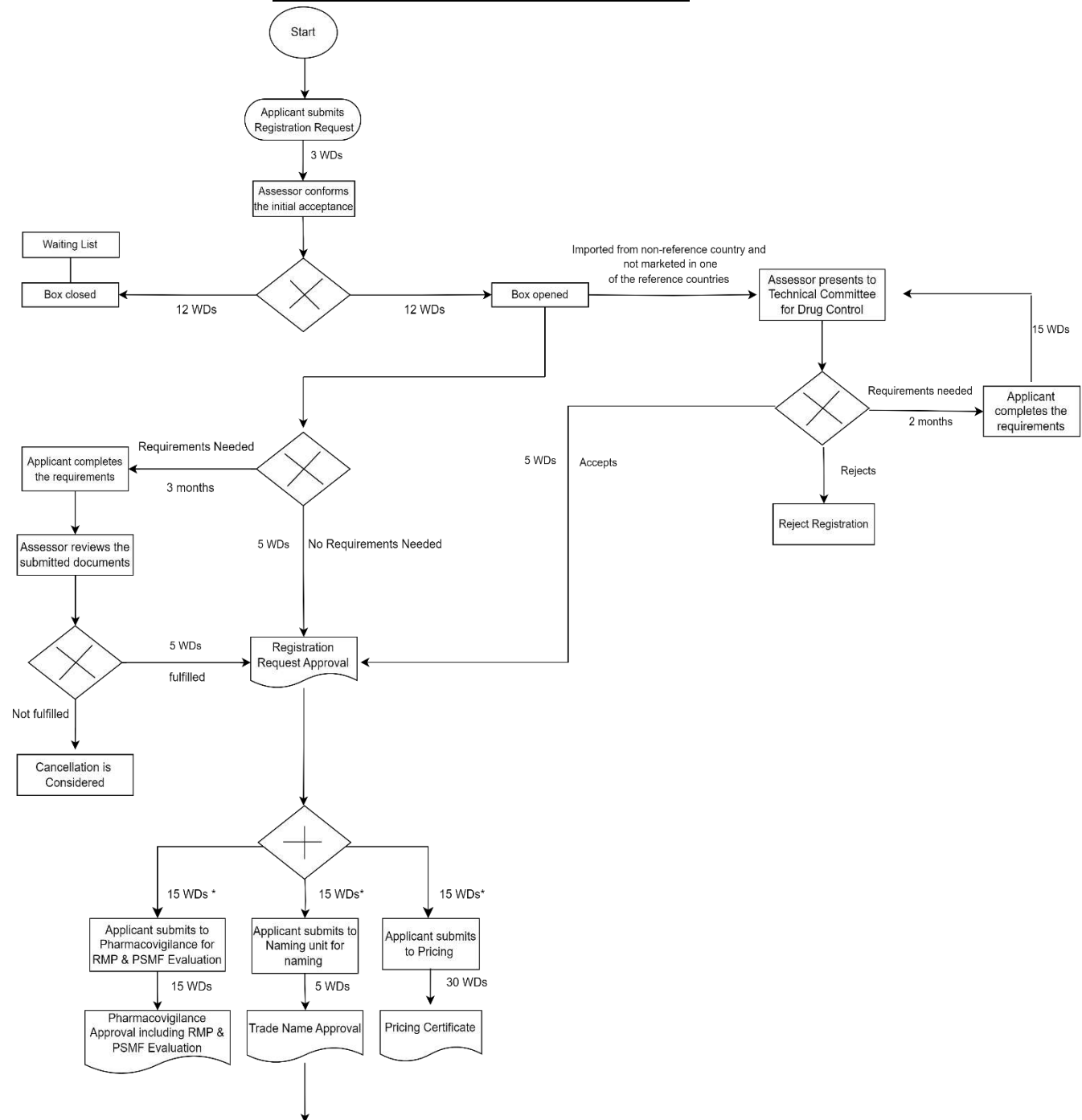


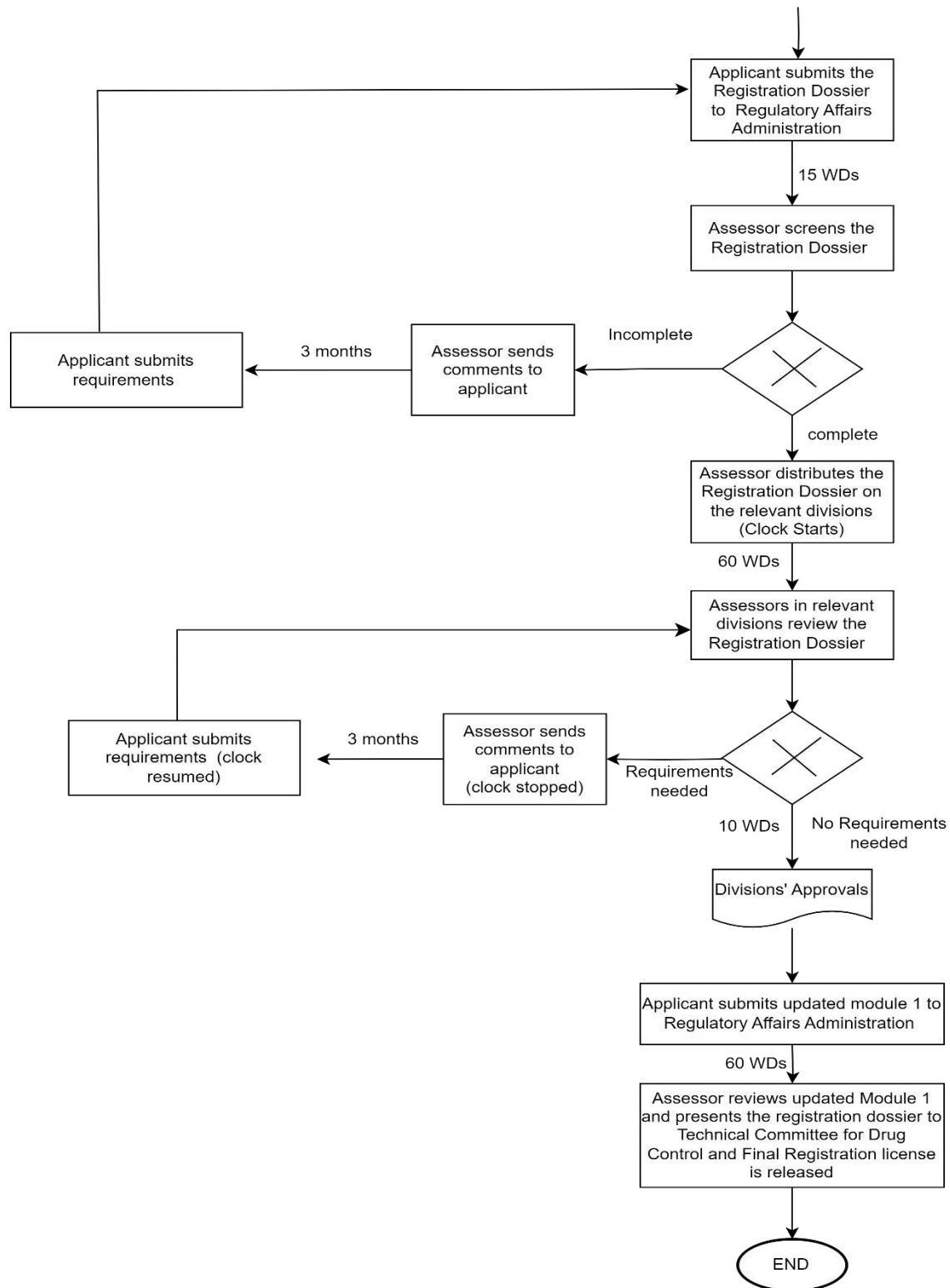


● Applicant Time:

- * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval.
- Applicant has to submit the Registration Dossier within 2 months from Registration Request Approval
- The declared working days are the maximum time needed for the process to be completed.

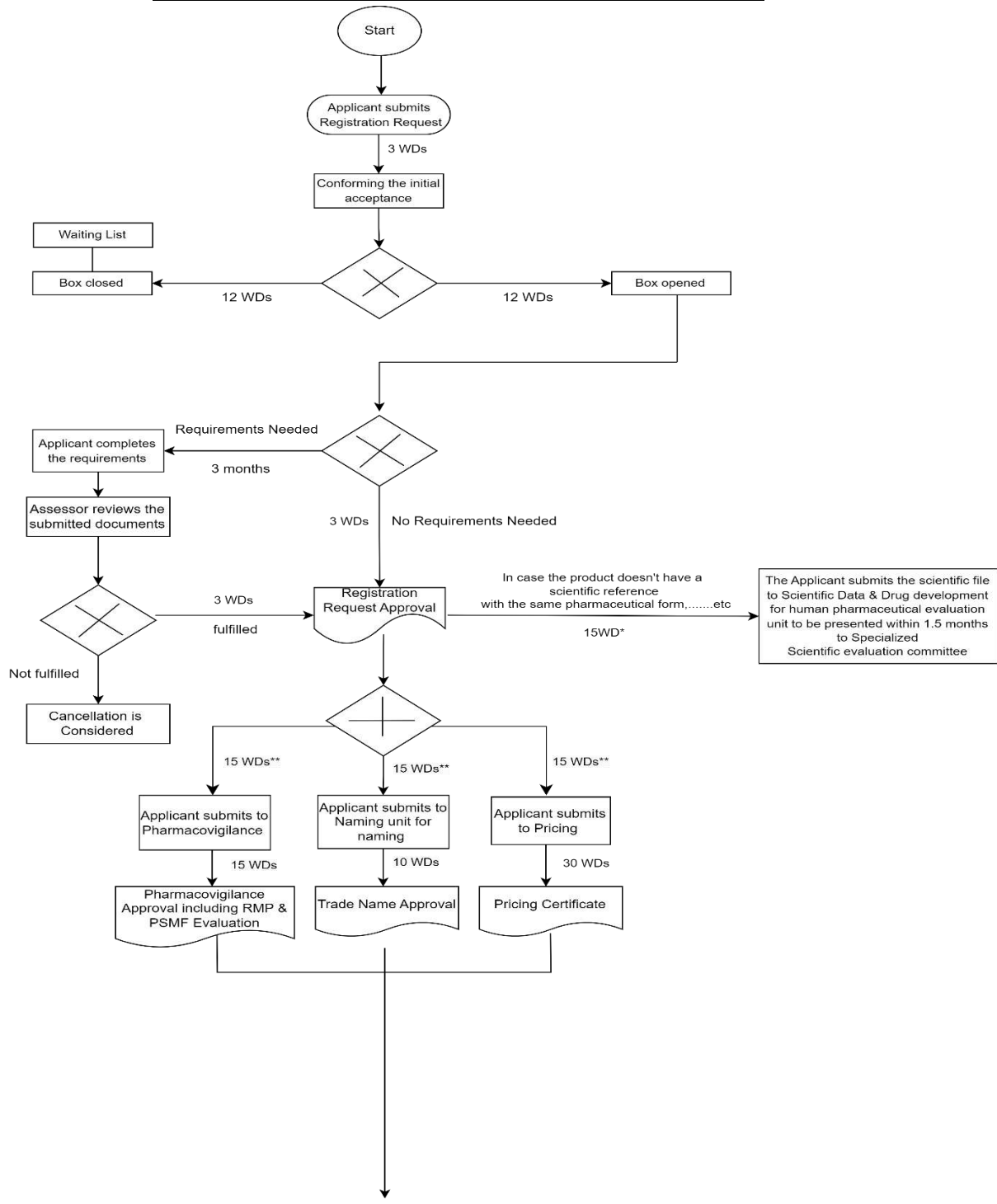
EDA Chairman Decree (450/2023) Flowchart for Imported Products from non-reference country and not marketed in one of reference countries with assessment timelines (Fast Track)

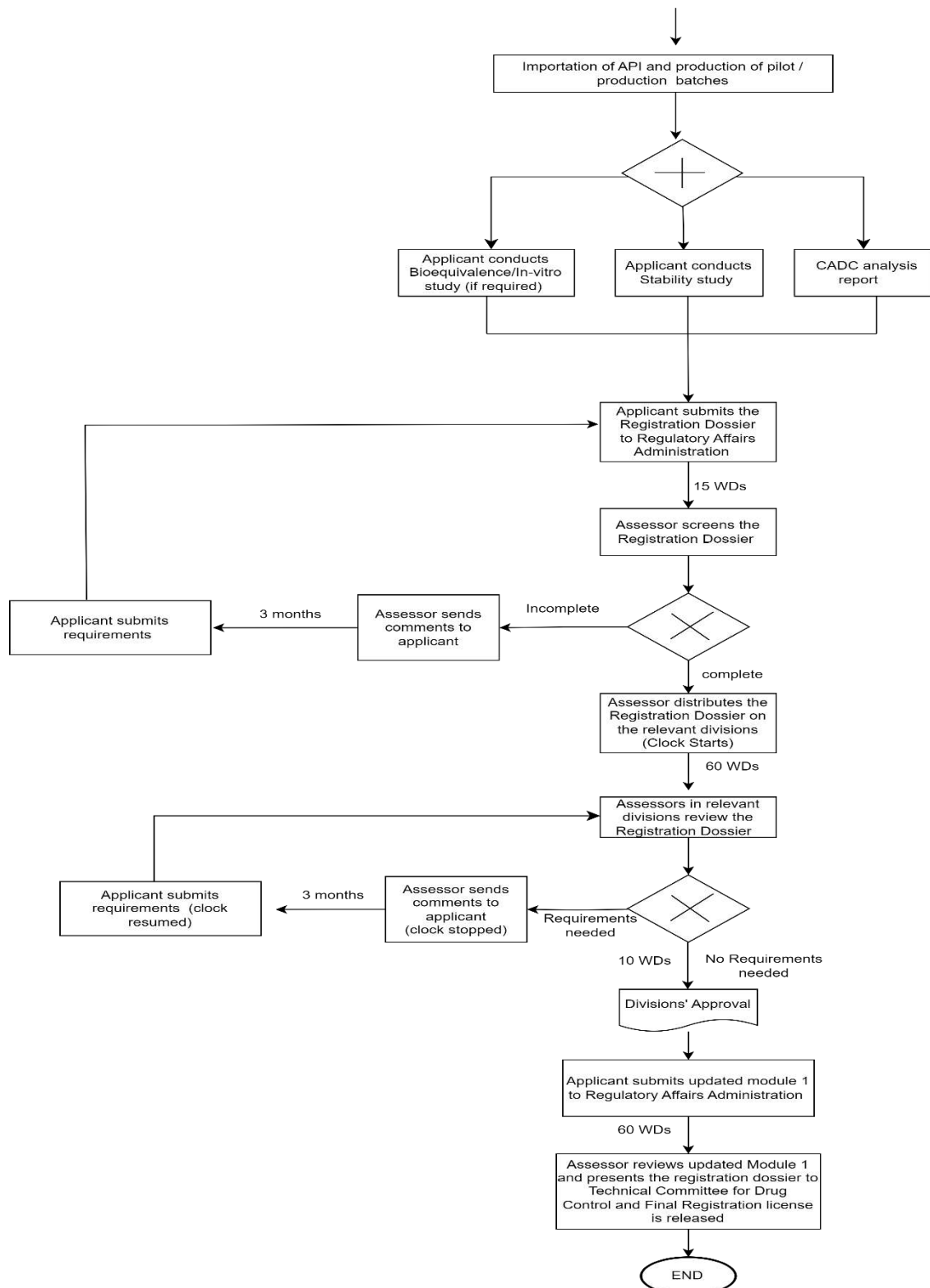




- Applicant Time:
 - * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval.
 - Applicant has to submit the Registration Dossier within 2 months from Registration Request Approval
- The declared working days are the maximum time needed for the process to be completed.

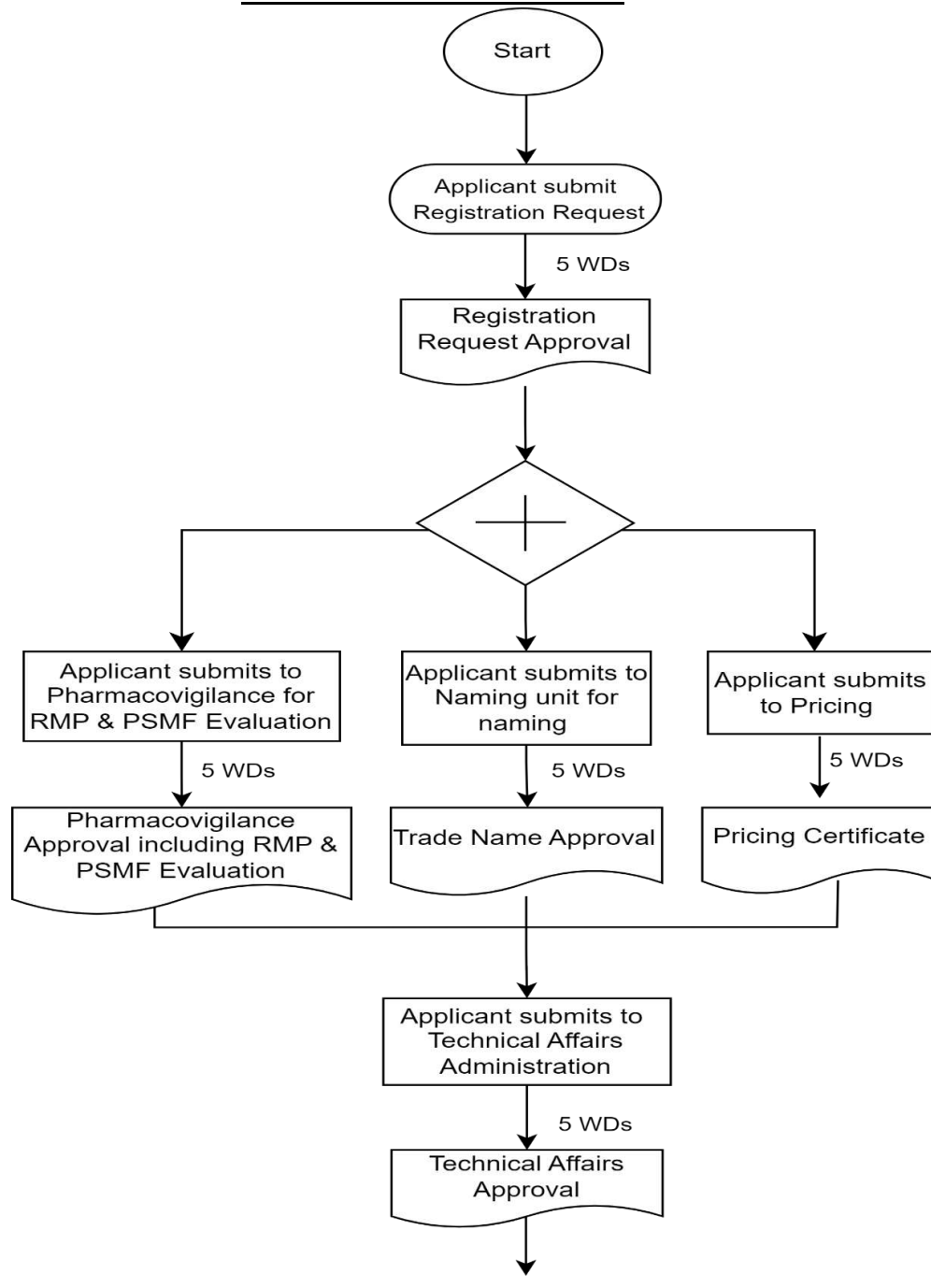
EDA Chairman Decree (450/2023) Flowchart for Locally Manufactured Generic Products with assessment timelines (Fast Track)

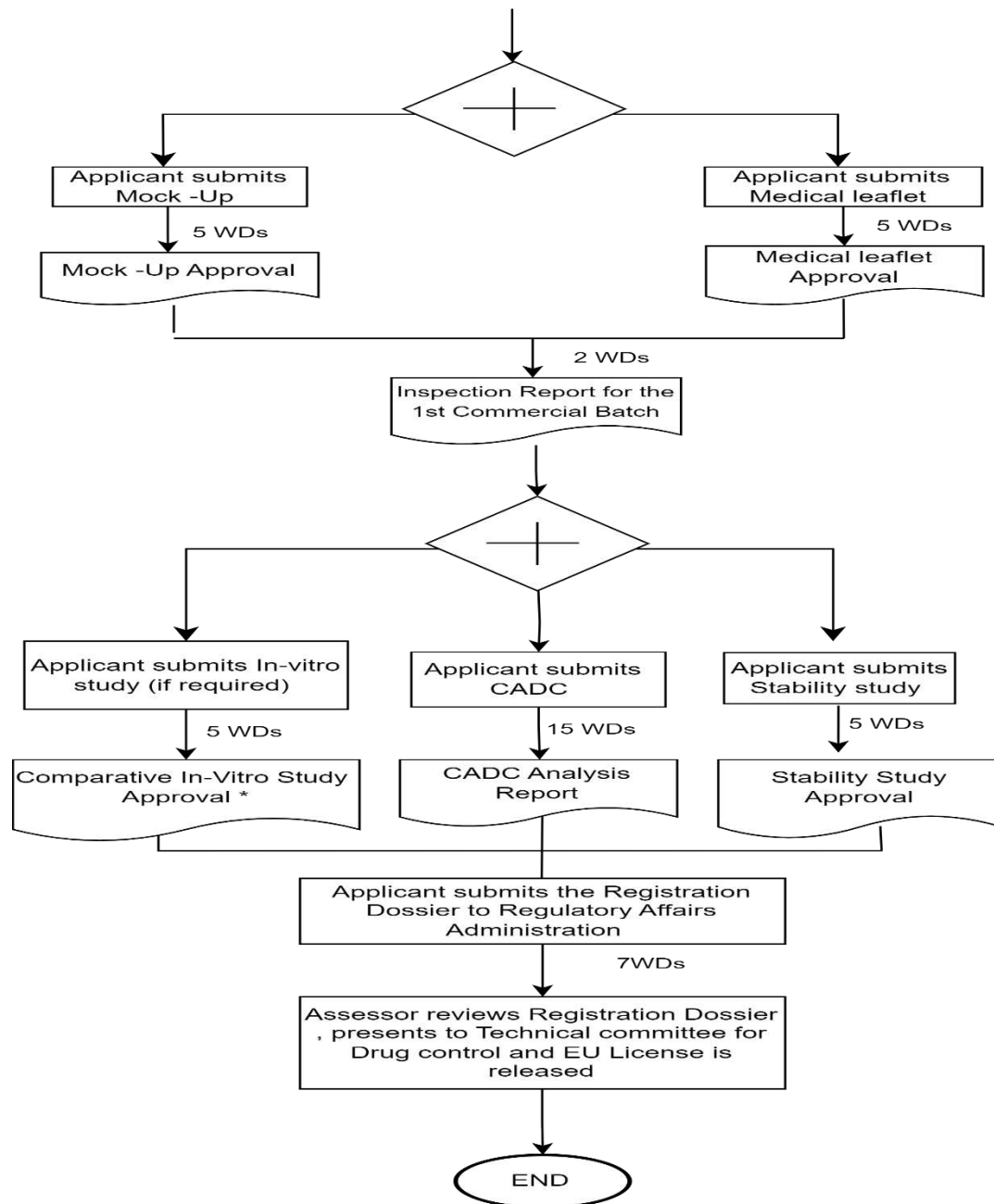




- Applicant Time:
 - * The Applicant submits the scientific file to Scientific Data & Drug development for human pharmaceutical evaluation unit within 15 WDs from registration request approval (Incase the product does not have a scientific reference with the same pharmaceutical form, concentration or route of administration).
 - ** Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval or specialized scientific evaluation approval.
- Applicant has to submit the Registration Dossier within 33 WDs from date of first pricing certificate
- The declared working days are the maximum time needed for the process to be completed.

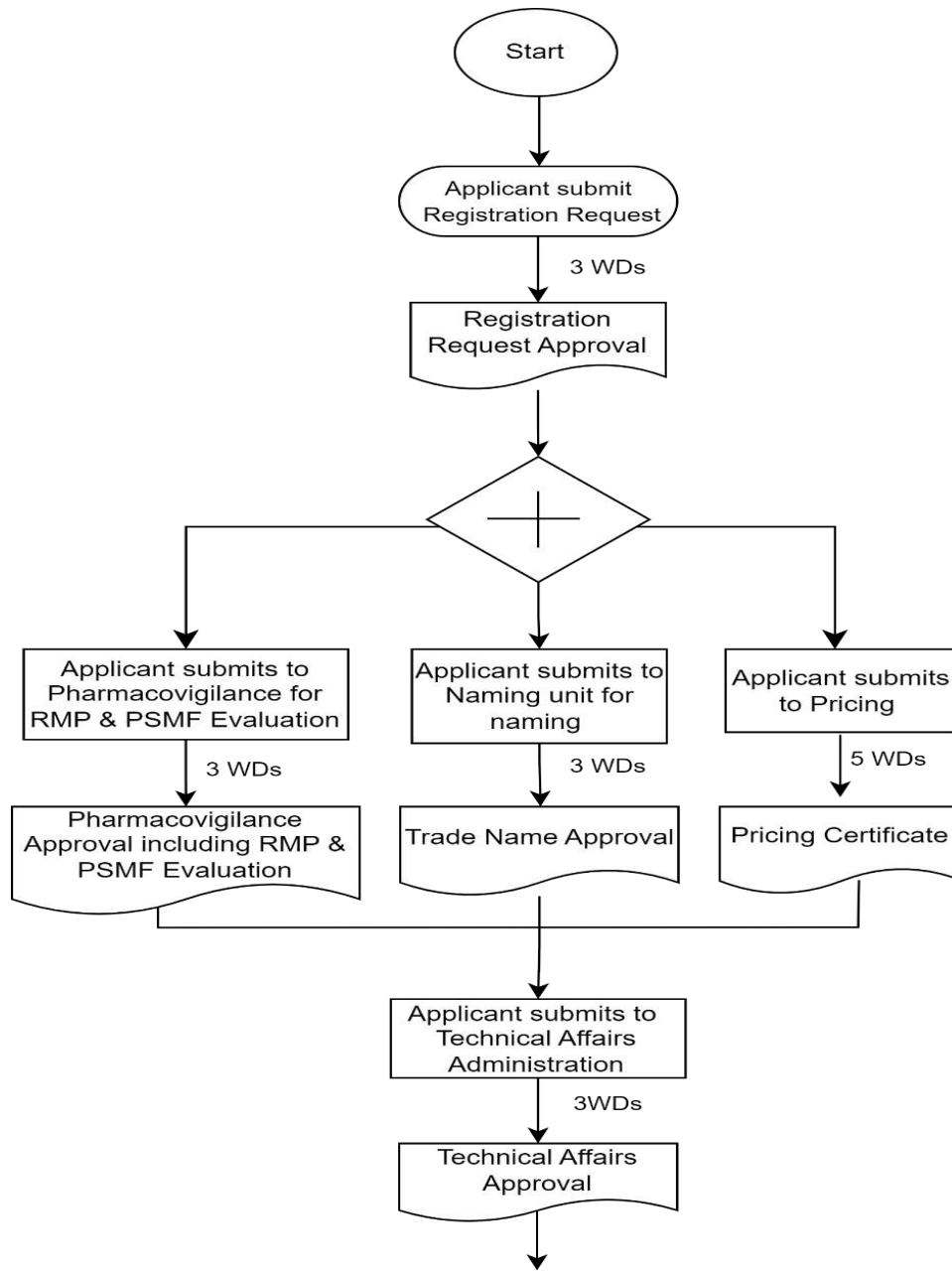
Emergency Use Approval of Locally Manufactured Generic Products Flowchart with assessment timelines

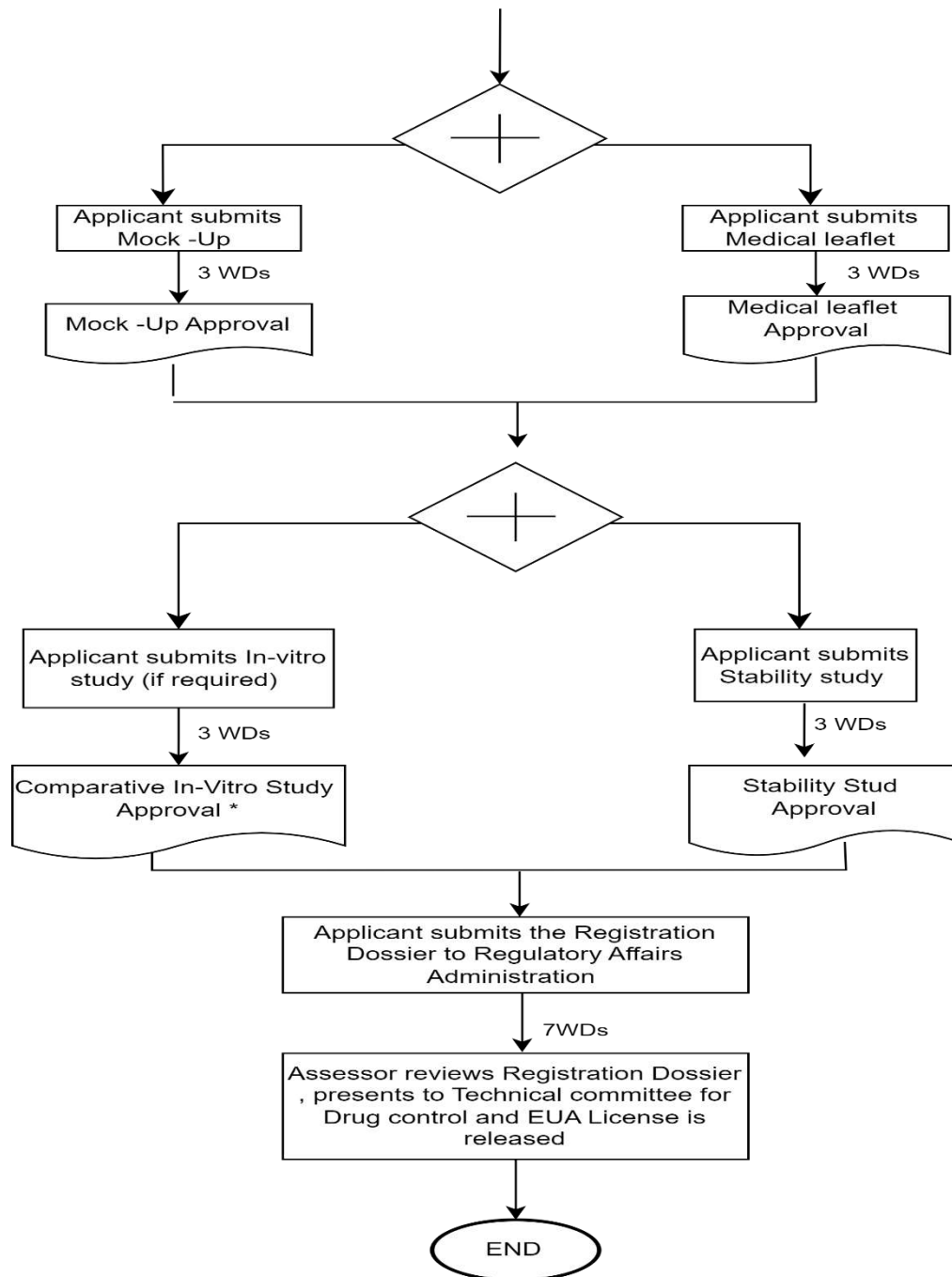




- Assessment timelines start from receiving complete files from applicants
- Total Assessment Timeline = maximum 44 WDs
(without consideration of the time required for preparation of applicant's responses to requests).
- *Bioequivalence study approval is a condition for the commercial batch release (if 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)

EDA's Assessment Timeframes:

Assessment Timeframe for Locally Manufactured Generic products:

Application type	Application	Pricing +Naming+ PV	Screening &Evaluation
local Generic	31	90	198
local Generic (Fast Track)	18	30	145

Assessment Timeframe for Imported Products:

Application type	Application	Pricing +Naming+ PV	Screening &Evaluation
Imported Products marketed in one of SRAs or WHO-Prequalified	31	90	165
Imported from non-reference country and not marketed in one of the reference countries	31 (After reviewing site master file and quality module and inspection on the factory abroad)	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	74
Imported from non-reference country and not marketed in one of the reference countries (Fast Track)	20 (After reviewing site master file and quality module and inspection on the factory abroad)	45	130

*The timeline mentioned above does not include the time needed for the applicant to fulfill the comments.

Abbreviations:

- RMP: Risk Management Plan
- PSMF: Pharmacovigilance System Master File
- WD: Working Days
- SRA: Stringent regulatory authority

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 (page 3-6)
4	4/8/2024	Clarification of EDA's Assessment Timeframes (page 33)