Notice to applicant

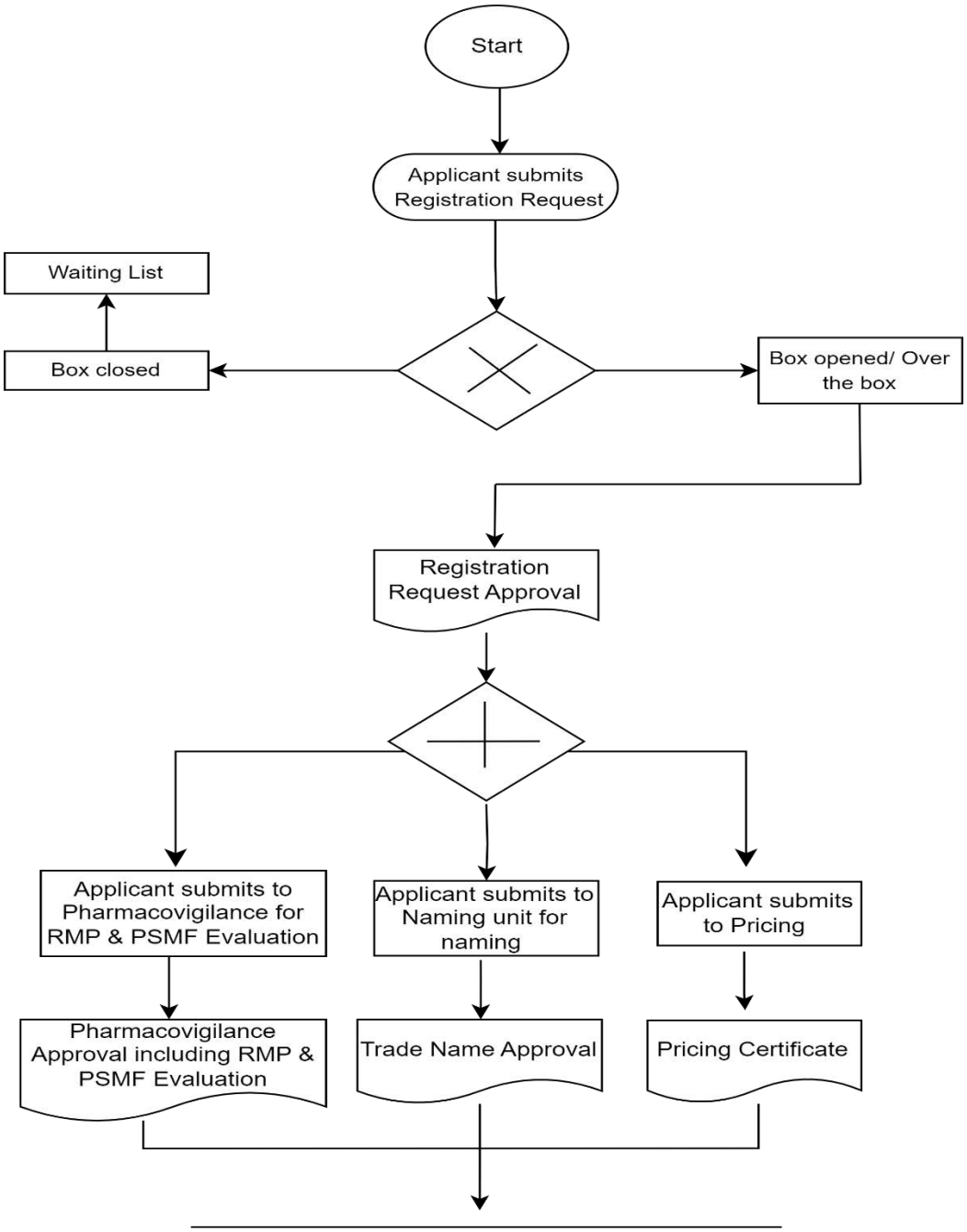
# Flowcharts for
# EDA Chairman Decree 450 for the year 2023

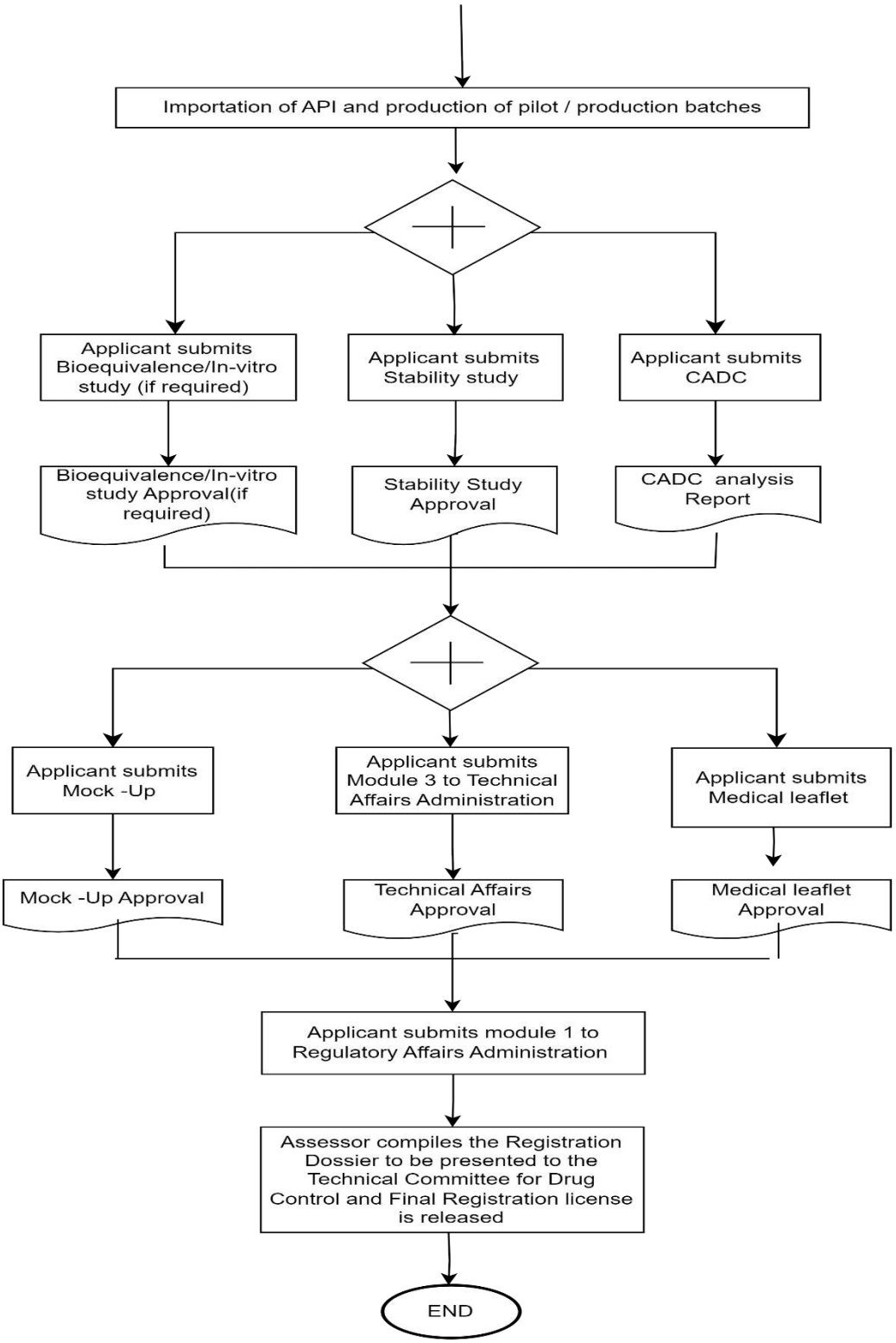
## Year 2024

**Code: EDREX:NP.CAPP.064**
**Version No: 4**
**Issue Date: 4/8/2024**
**Effective date: 4/8/2024**

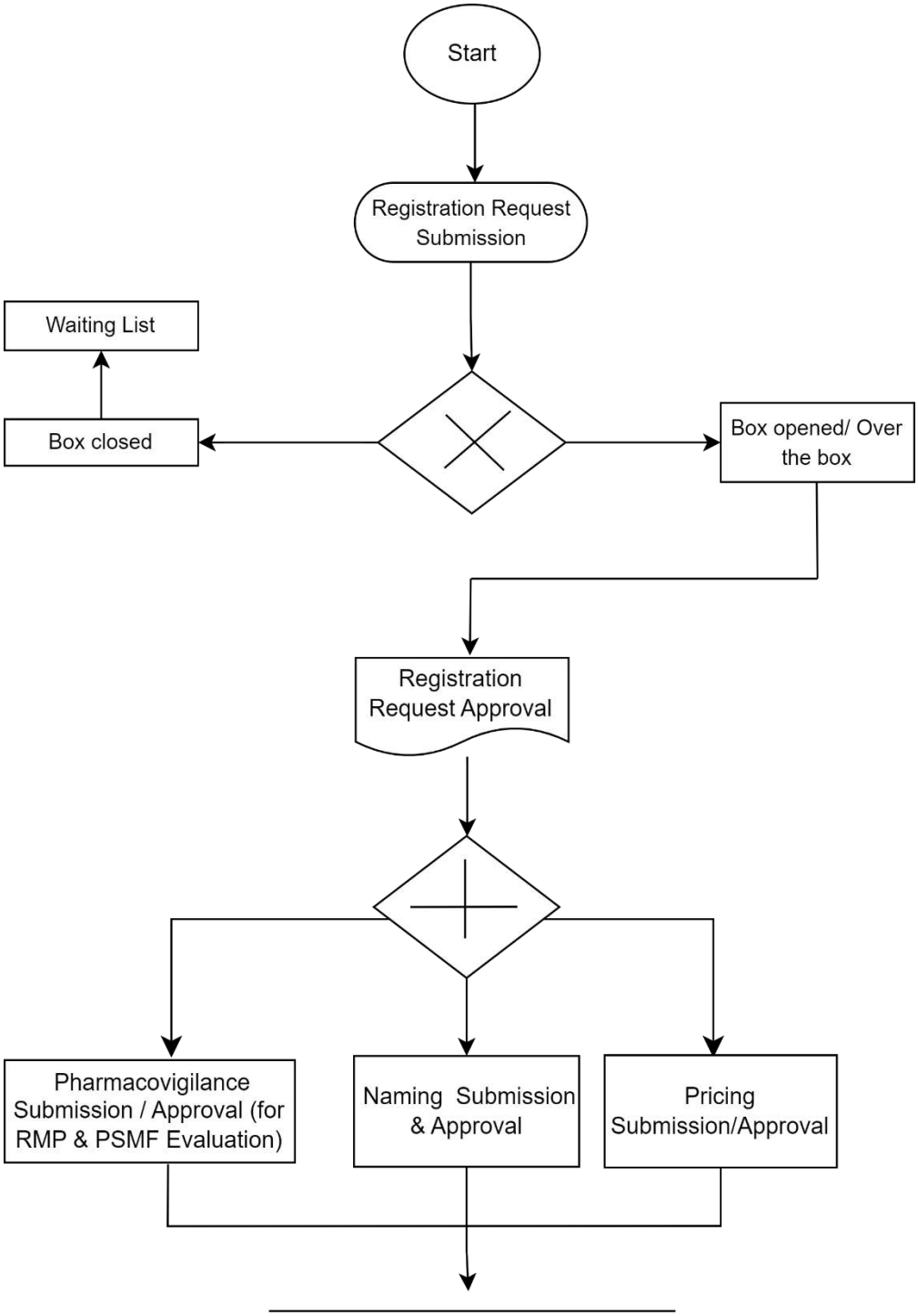
# 1 Table of Contents

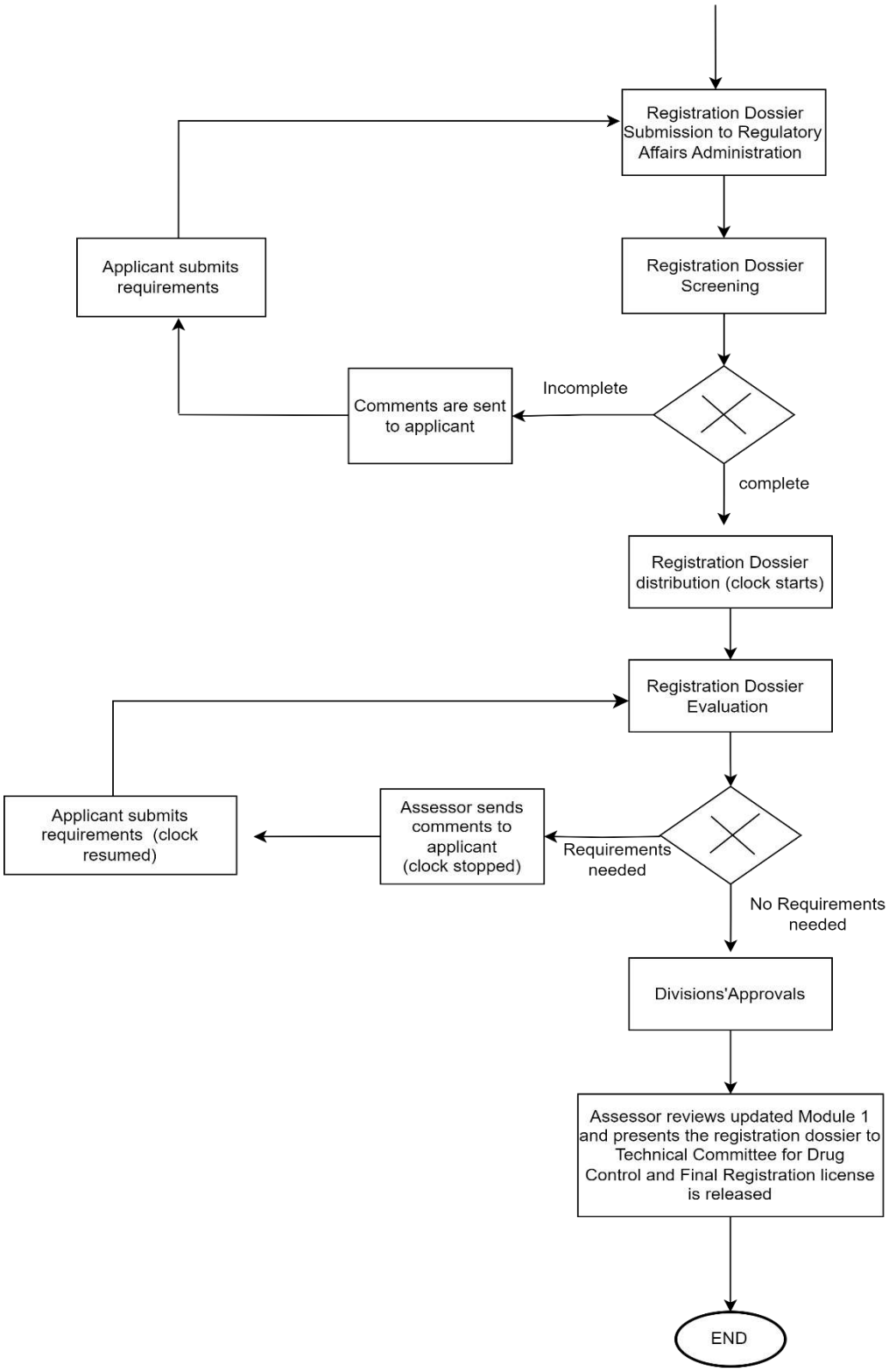
# EDA Chairman Decree (450/2023) Rolling Submission General Flowchart



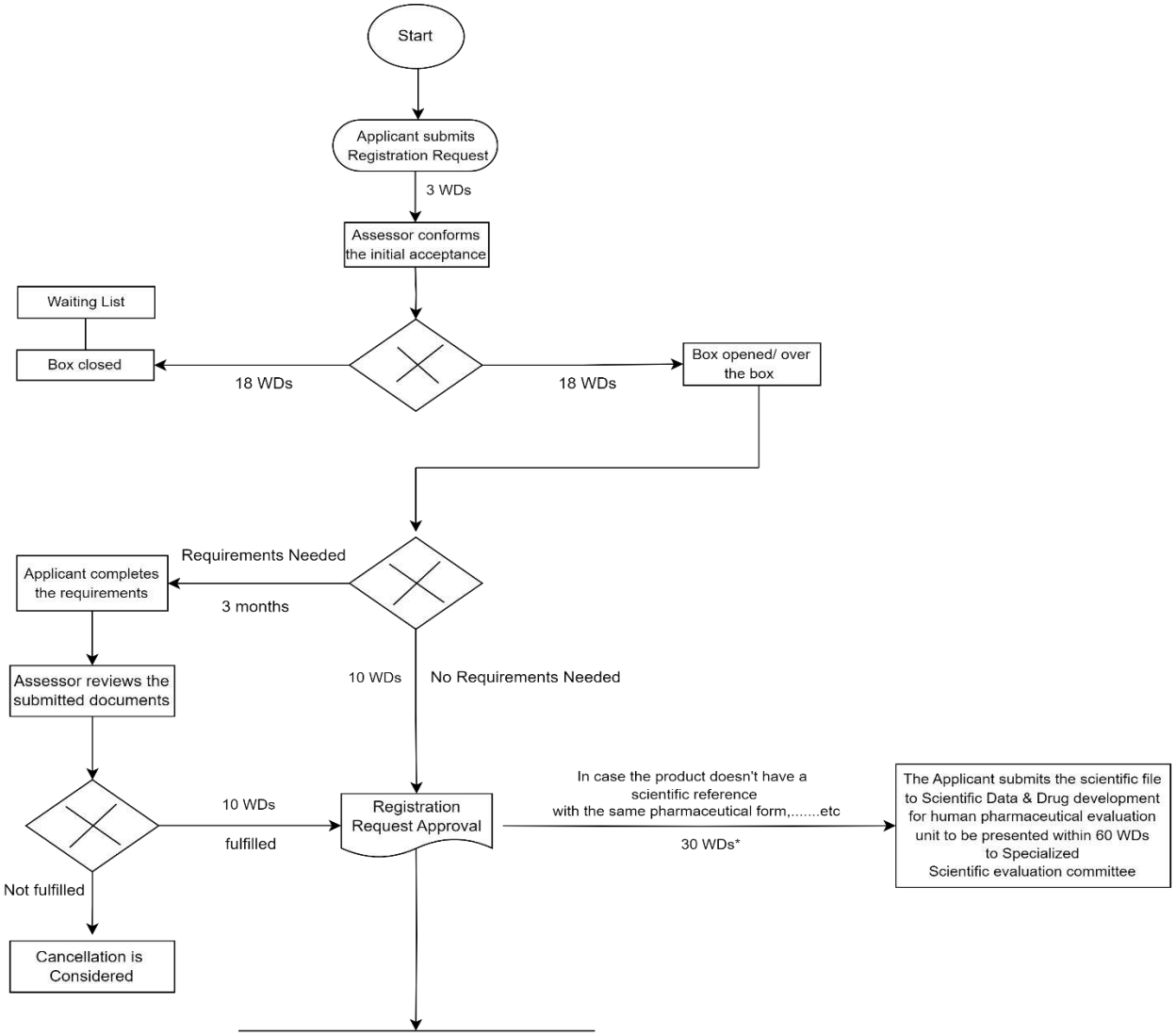

Importation of API and production of pilot / production batches
Applicant submits Bioequivalence/In-vitro study (if required)
Applicant submits Stability study
Applicant submits CADC
Bioequivalence/In-vitro study Approval(if required)
Stability Study Approval
CADC analysis Report
Applicant submits Mock -Up
Applicant submits Module 3 to Technical Affairs Administration
Applicant submits Medical leaflet
Mock -Up Approval
Technical Affairs Approval
Medical leaflet Approval
Applicant submits module 1 to Regulatory Affairs Administration
Assessor compiles the Registration Dossier to be presented to the Technical Committee for Drug Control and Final Registration license is released
END

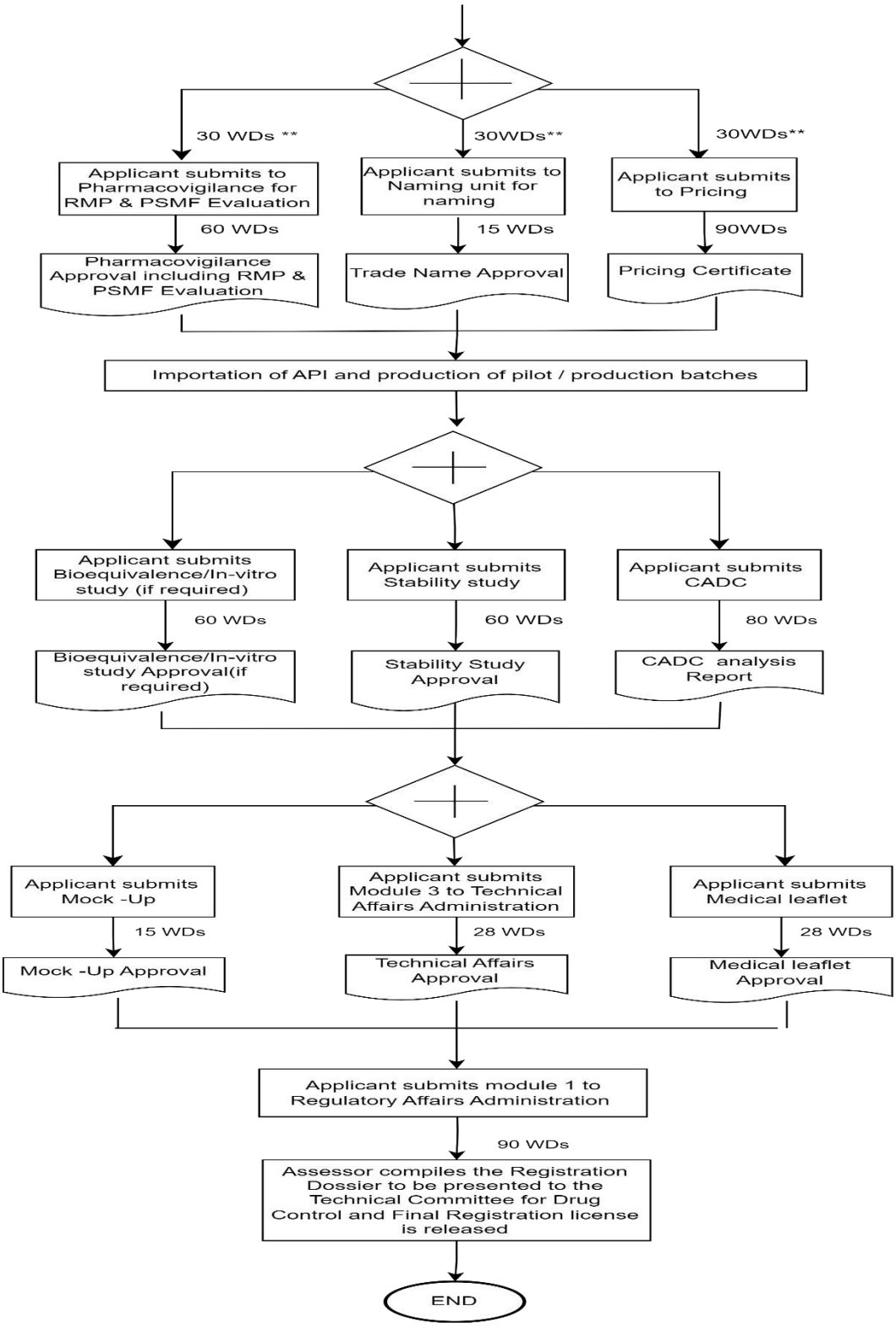
## EDA Chairman Decree (450/2023) One Submission General Flowchart




Registration Dossier Submission to Regulatory Affairs Administration
Registration Dossier Screening
Incomplete
Comments are sent to applicant
Applicant submits requirements
complete
Registration Dossier distribution (clock starts)
Registration Dossier Evaluation
Requirements needed
Assessor sends comments to applicant (clock stopped)
Applicant submits requirements (clock resumed)
No Requirements needed
Divisions'Approvals
Assessor reviews updated Module 1 and presents the registration dossier to Technical Committee for Drug Control and Final Registration license is released
END

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




30 WDs **
30WDs**
30WDs**
Applicant submits to Pharmacovigilance for RMP & PSMF Evaluation
Applicant submits to Naming unit for naming
Applicant submits to Pricing
60 WDs
15 WDs
90WDs
Pharmacovigilance Approval including RMP & PSMF Evaluation
Trade Name Approval
Pricing Certificate
Importation of API and production of pilot / production batches
Applicant submits Bioequivalence/In-vitro study (if required)
Applicant submits Stability study
Applicant submits CADC
60 WDs
60 WDs
80 WDs
Bioequivalence/In-vitro study Approval(if required)
Stability Study Approval
CADC analysis Report
Applicant submits Mock -Up
Applicant submits Module 3 to Technical Affairs Administration
Applicant submits Medical leaflet
15 WDs
28 WDs
28 WDs
Mock -Up Approval
Technical Affairs Approval
Medical leaflet Approval
Applicant submits module 1 to Regulatory Affairs Administration
90 WDs
Assessor compiles the Registration Dossier to be presented to the Technical Committee for Drug Control and Final Registration license is released
END

- Applicant Time:

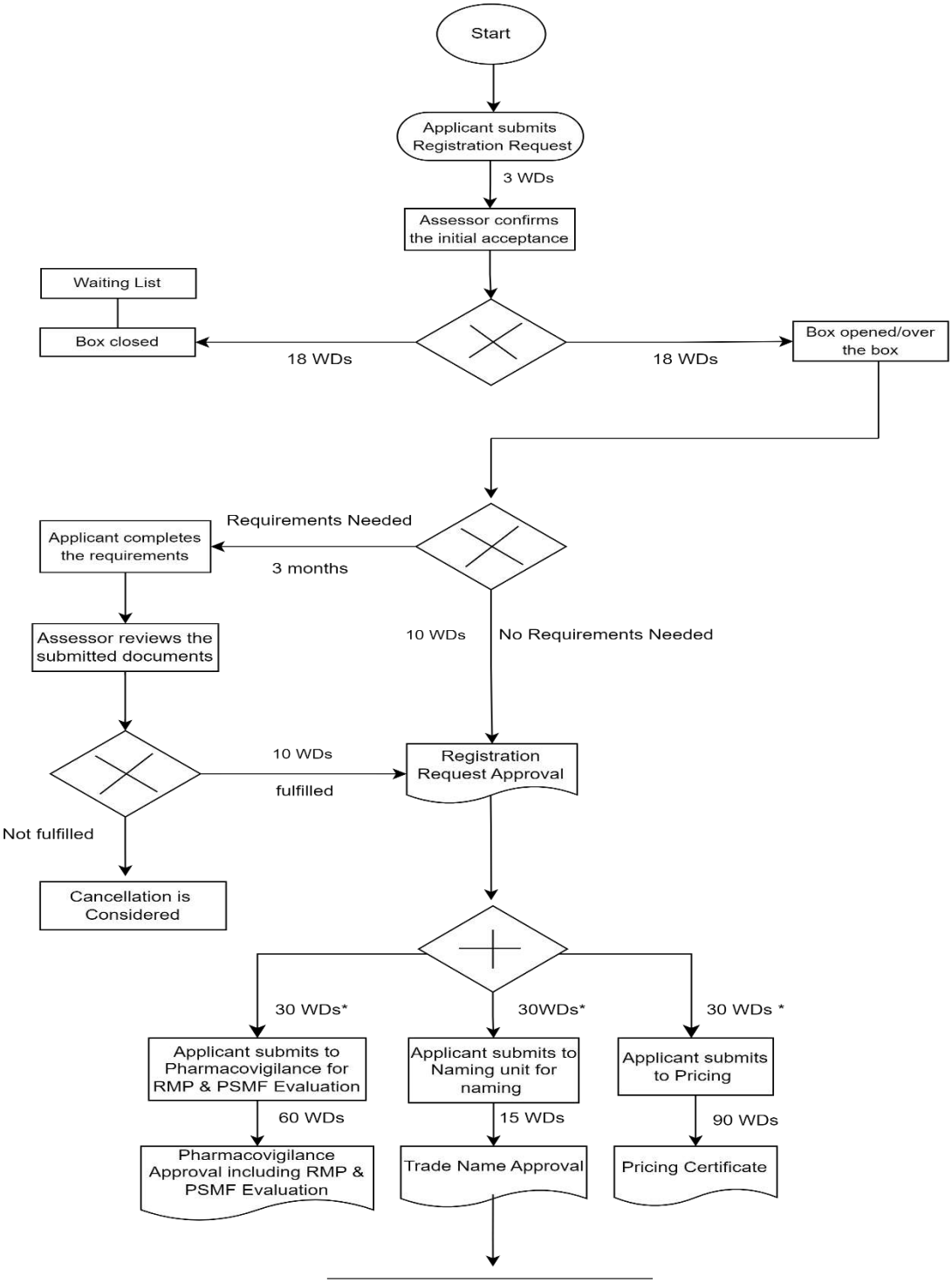
*The Applicant submits the scientific file to Scientific Data & Drug development for human pharmaceutical evaluation unit within 30 WDs from registration request approval (Incase the product does not have a scientific reference with the same pharmaceutical form, concentration or method of administration).

** 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



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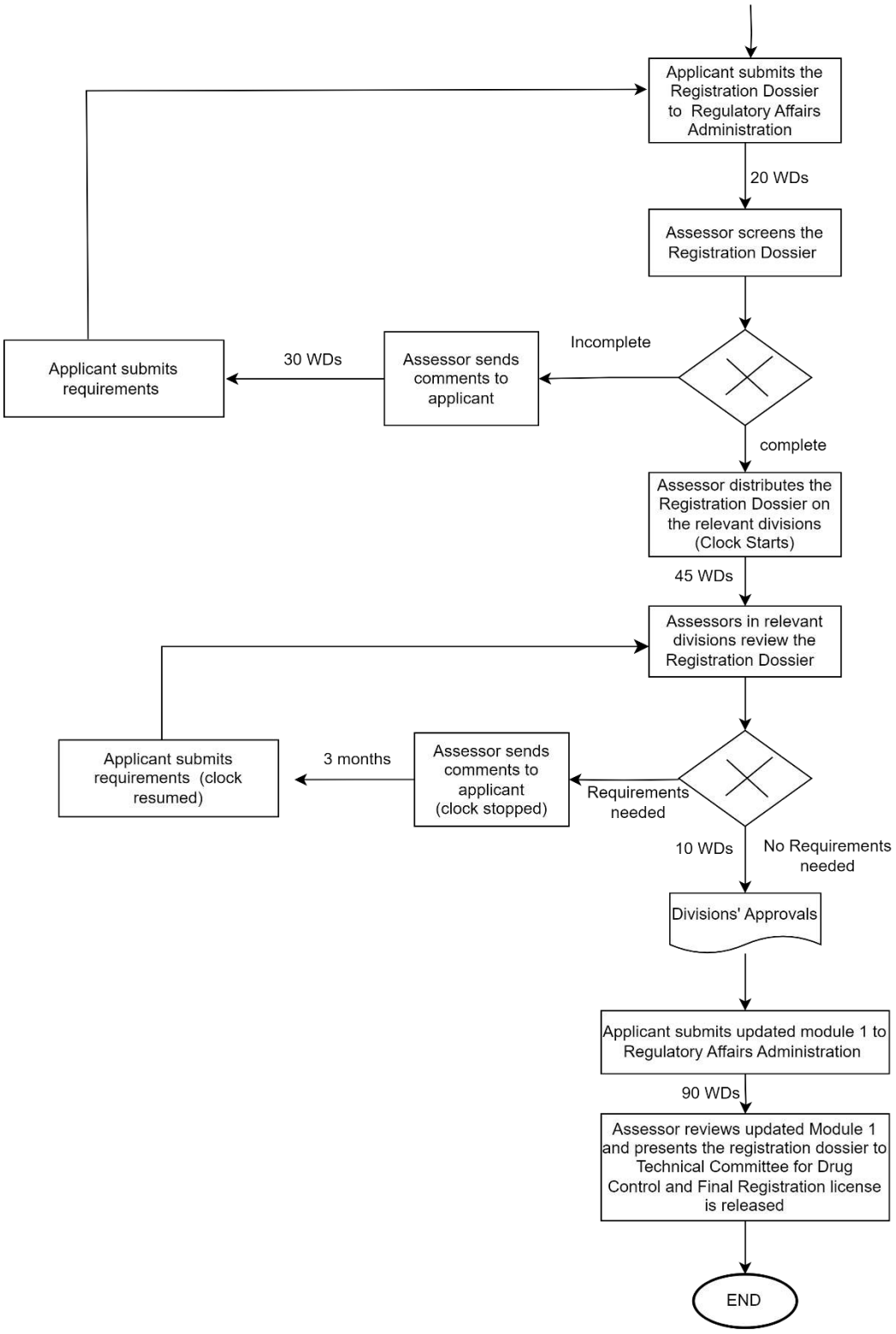
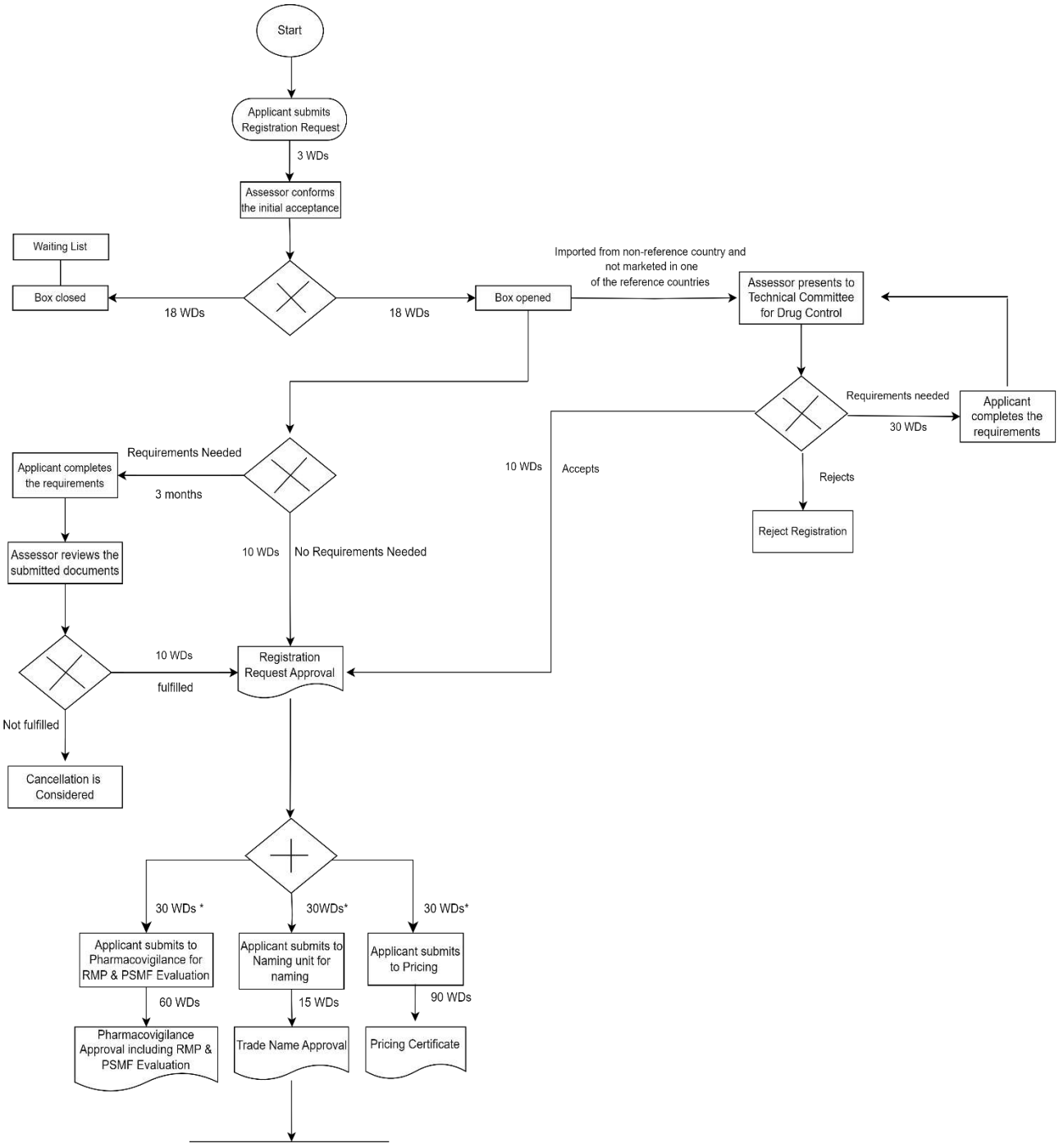


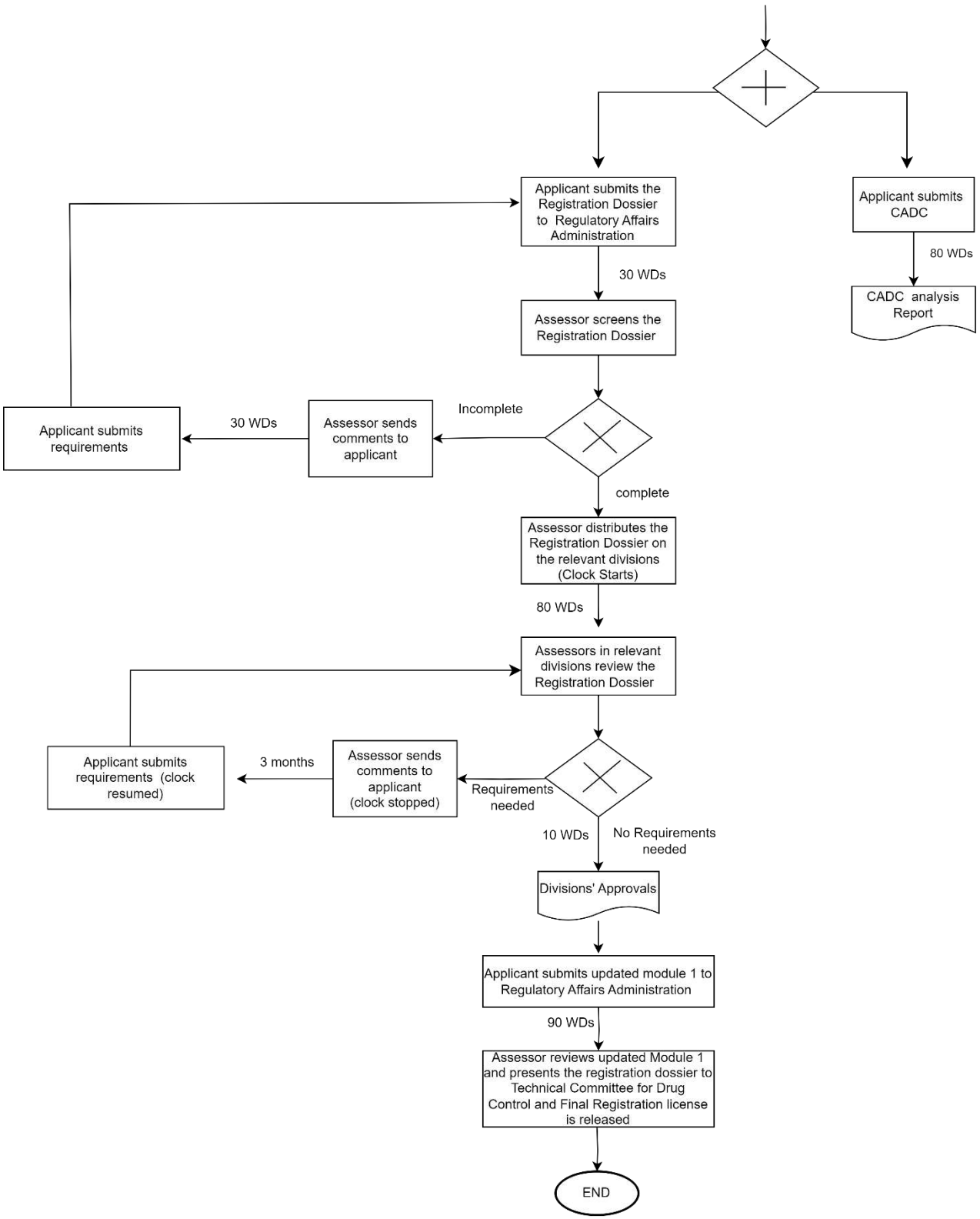
- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from registration request approval

  - 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



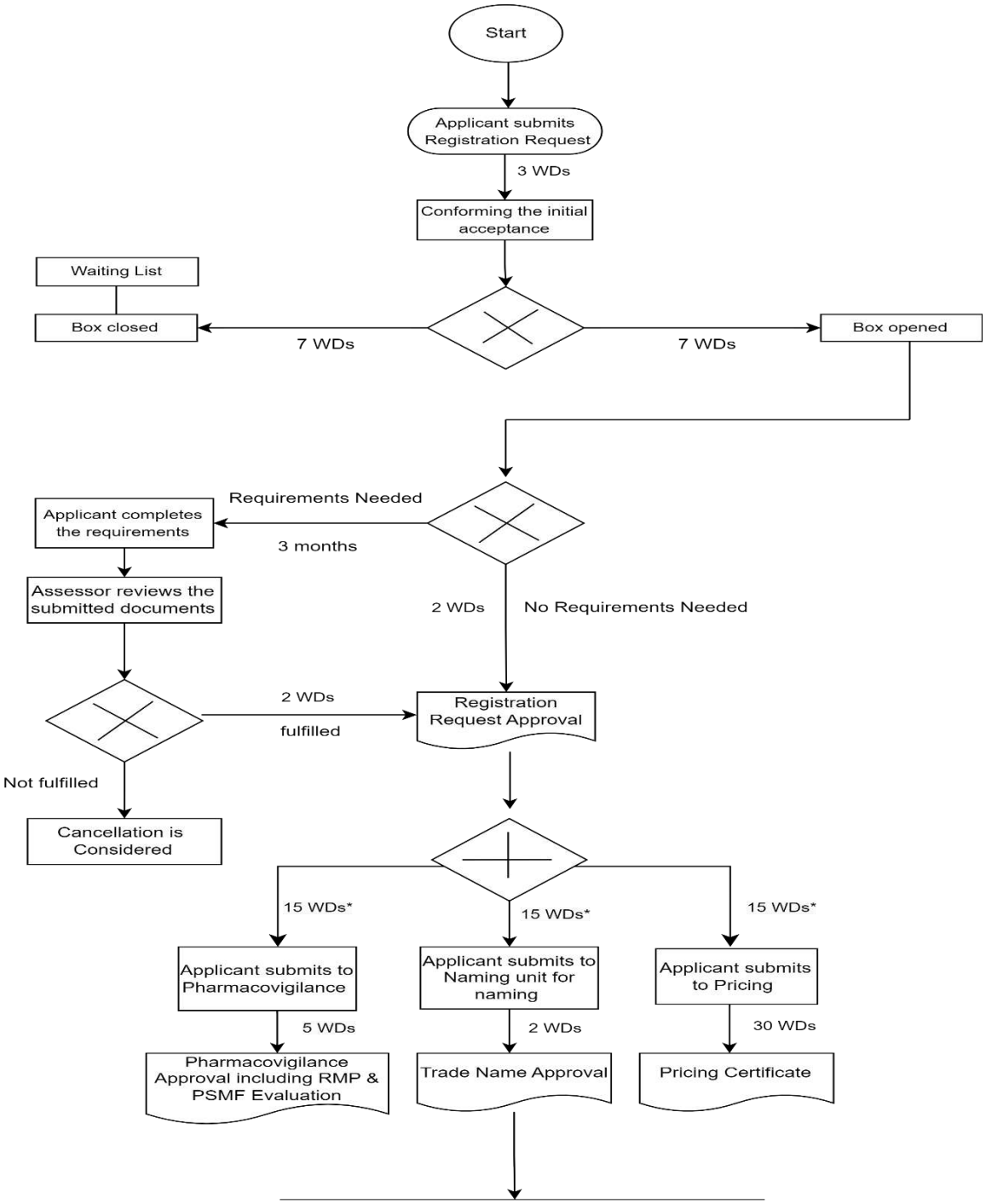

Applicant submits the Registration Dossier to Regulatory Affairs Administration
Applicant submits CADC
80 WDs
CADC analysis Report
30 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
30 WDs
Applicant submits requirements
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
80 WDs
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor sends comments to applicant (clock stopped)
3 months
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approvals
Applicant submits updated module 1 to Regulatory Affairs Administration
90 WDs
Assessor reviews updated Module 1 and presents the registration dossier to Technical Committee for Drug Control and Final Registration license is released
END

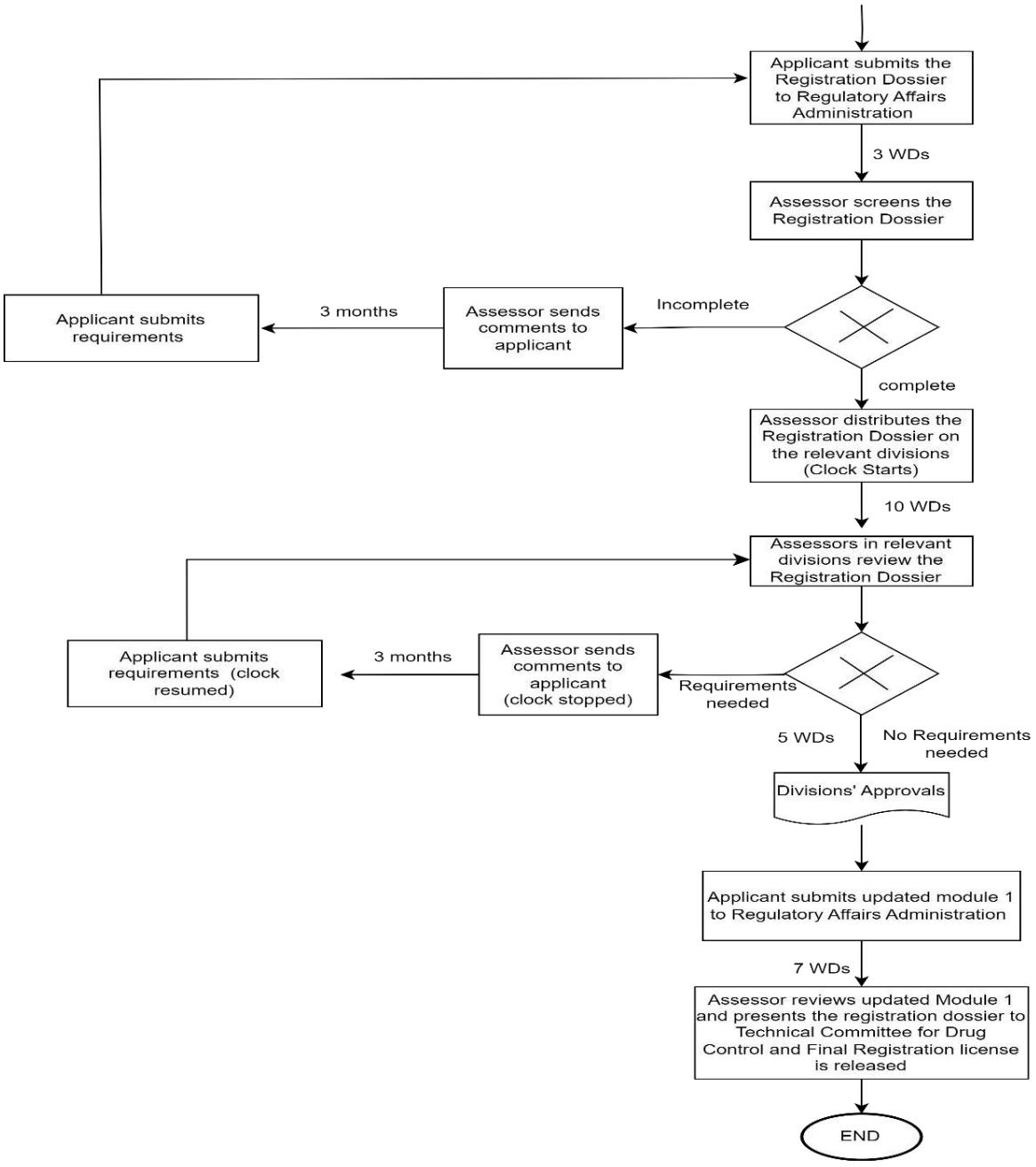
- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from registration request approval

  - 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)

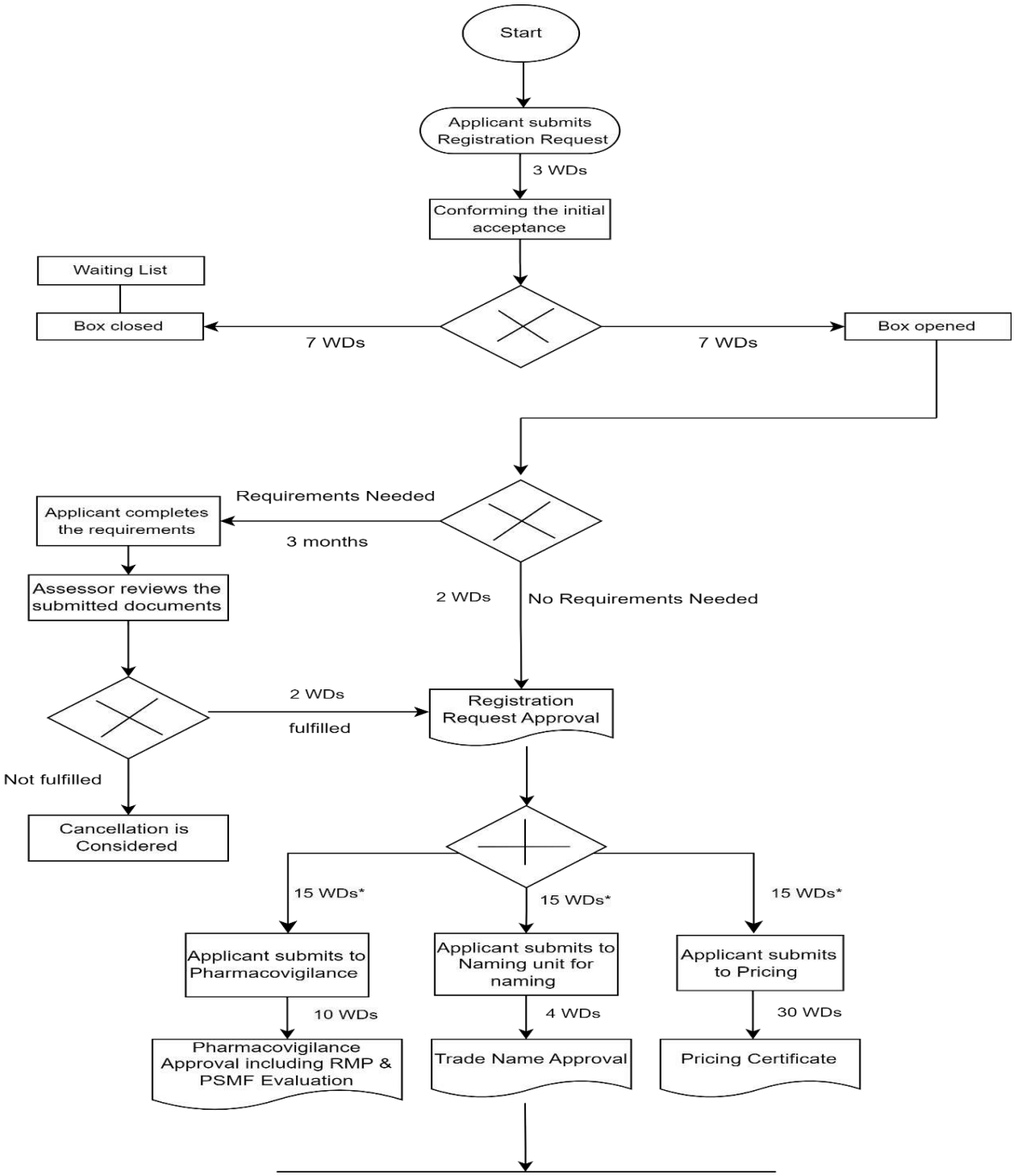


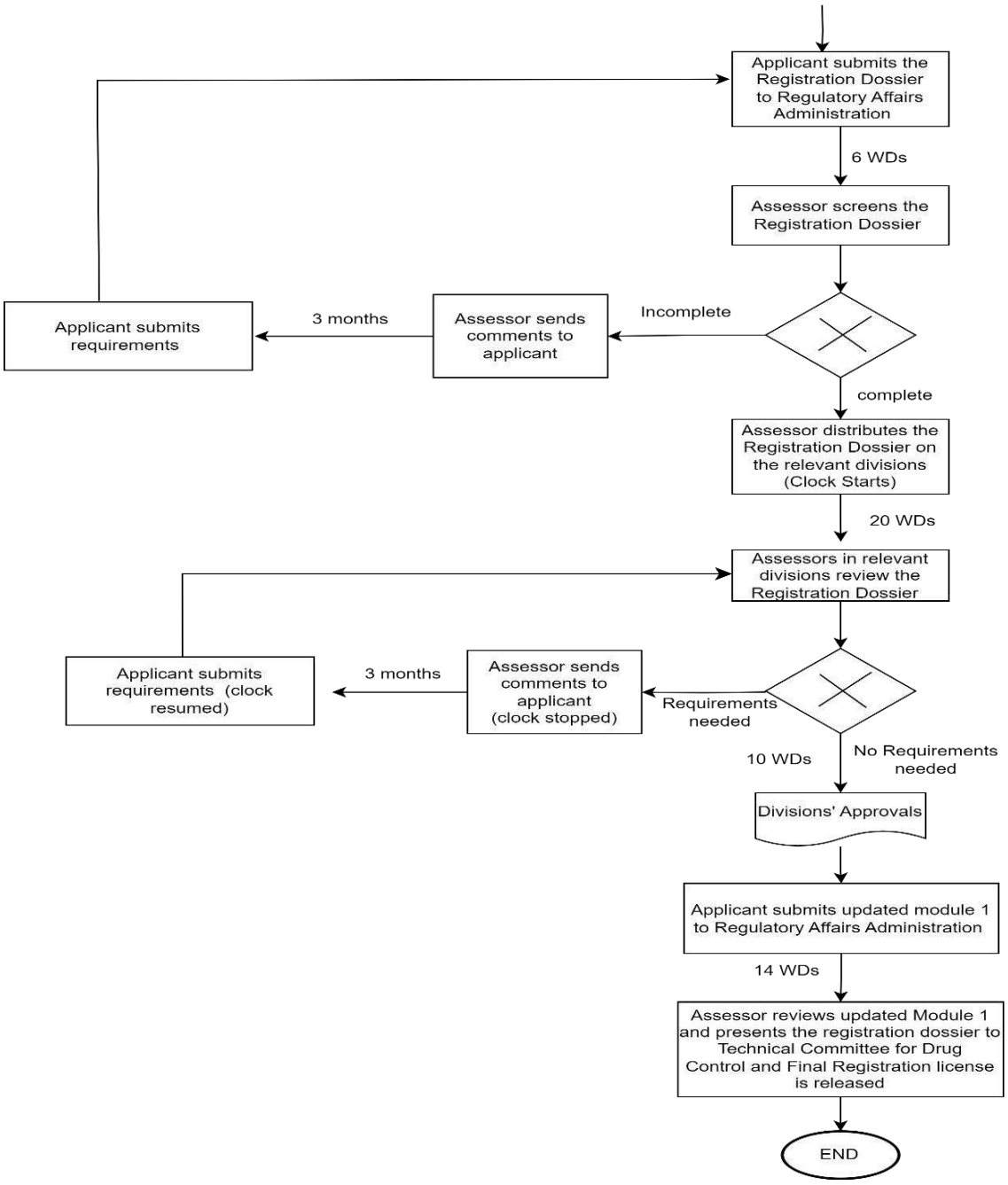



- <u>Applicant Time:</u>
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval

  - 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)



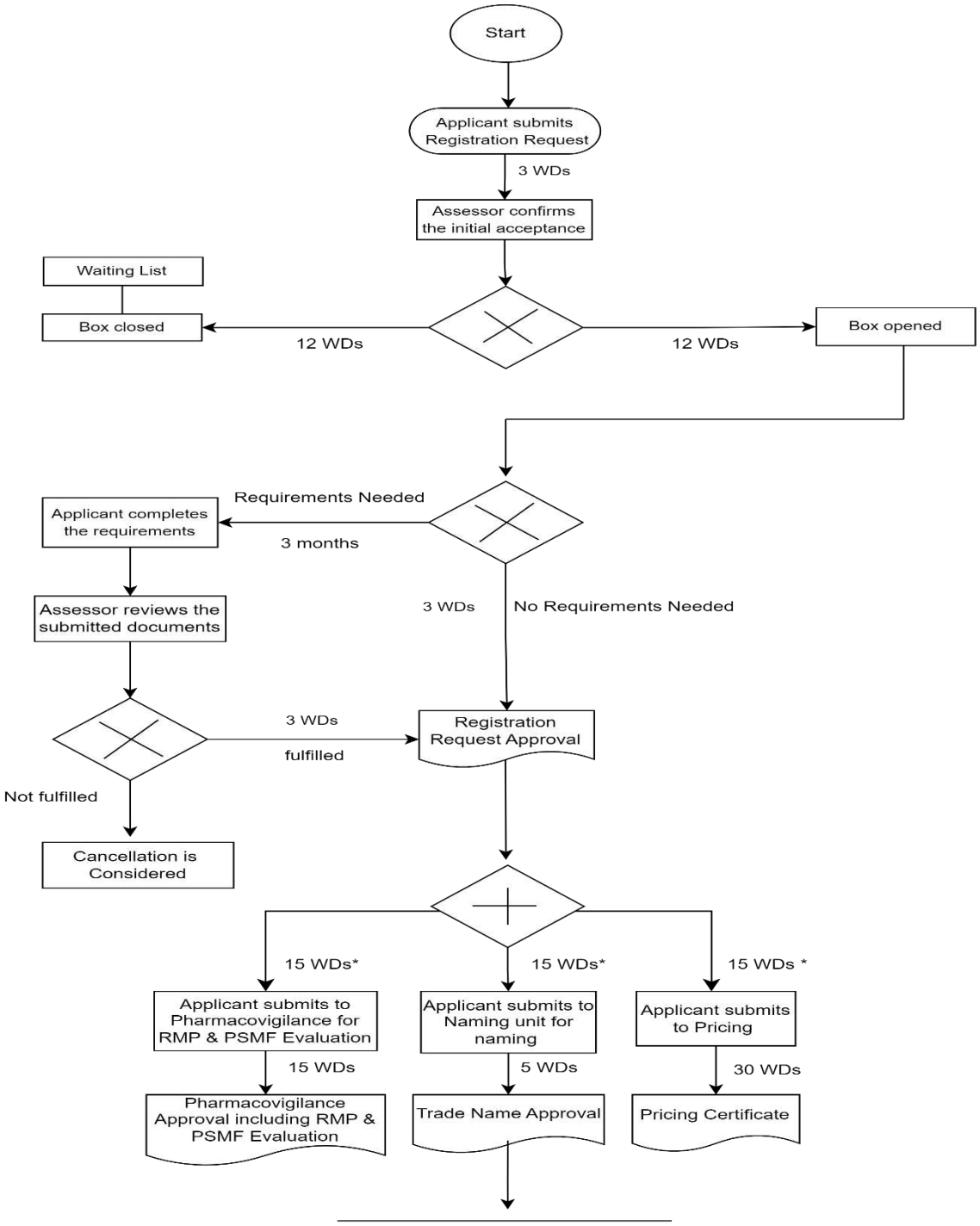



- Applicant Time:

  * 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)



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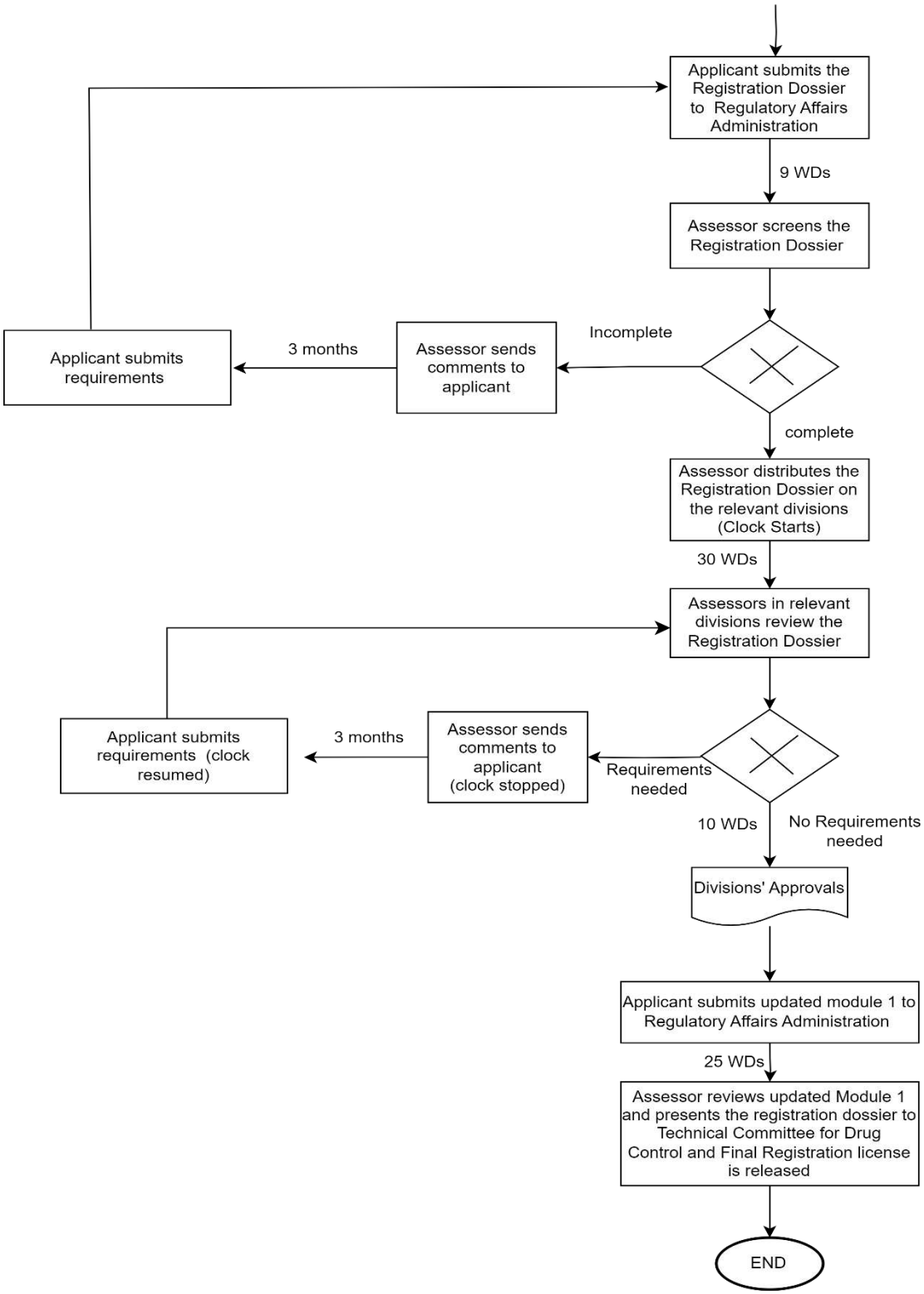


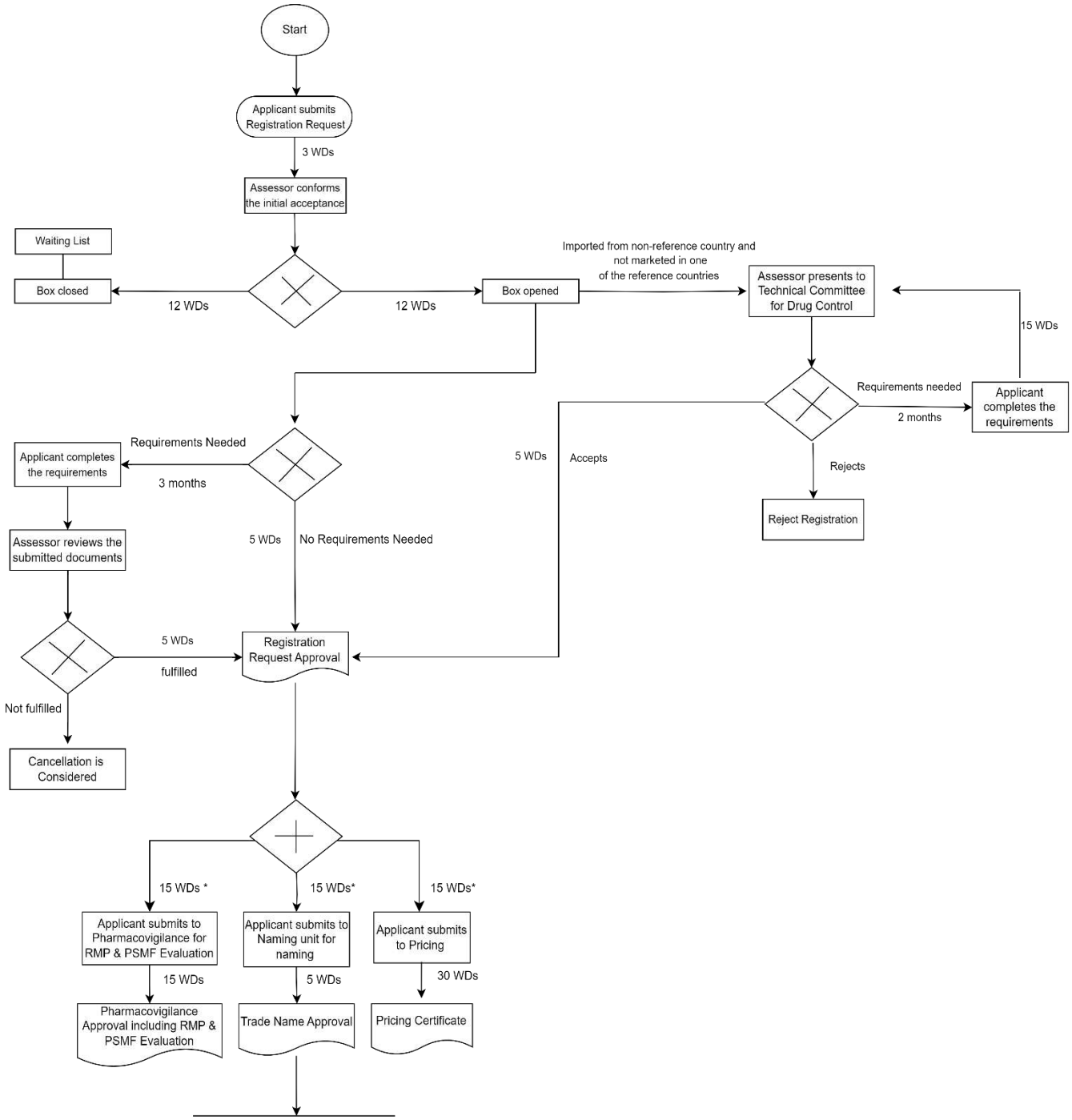
● Applicant Time:

* 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)



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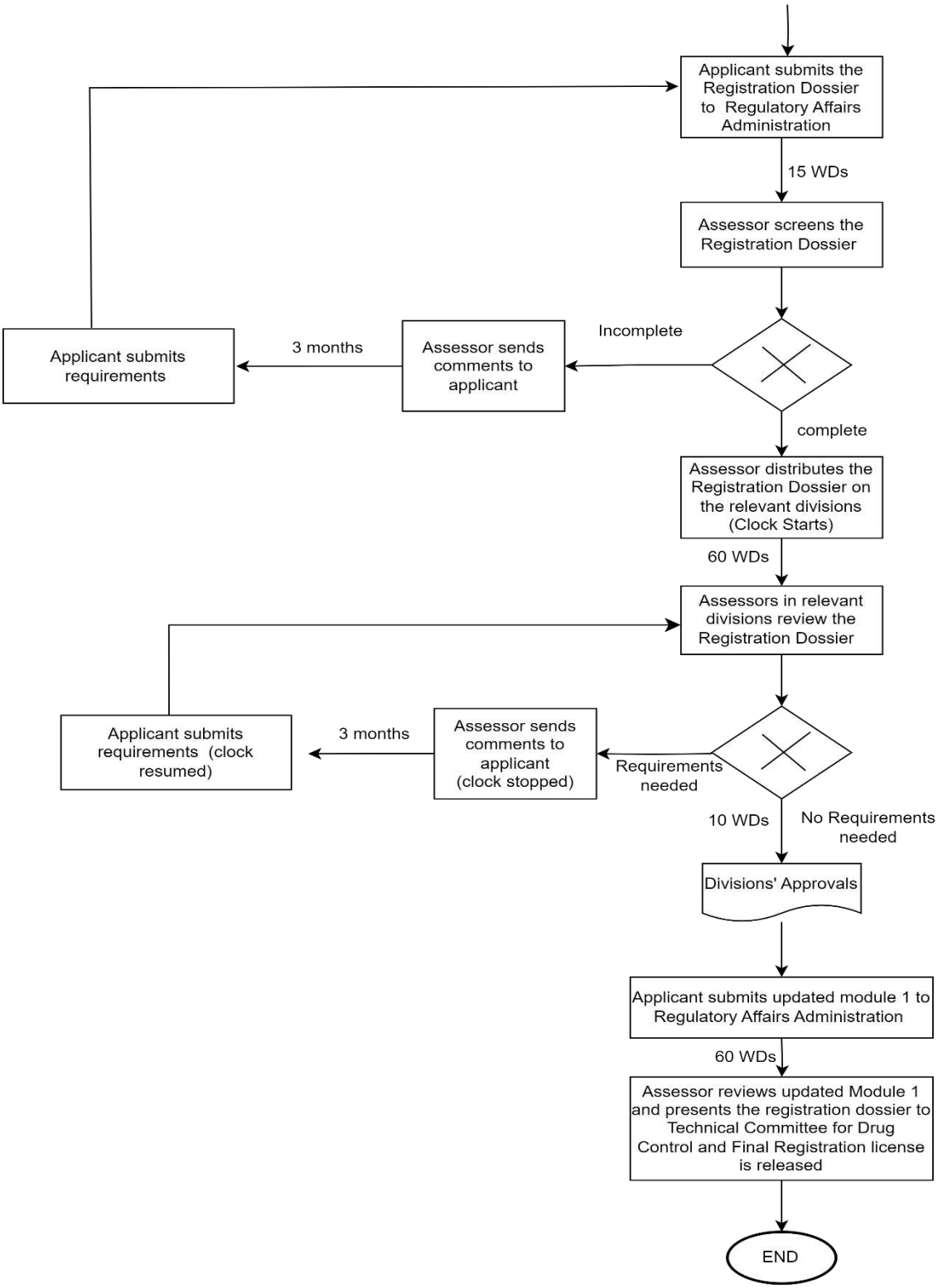
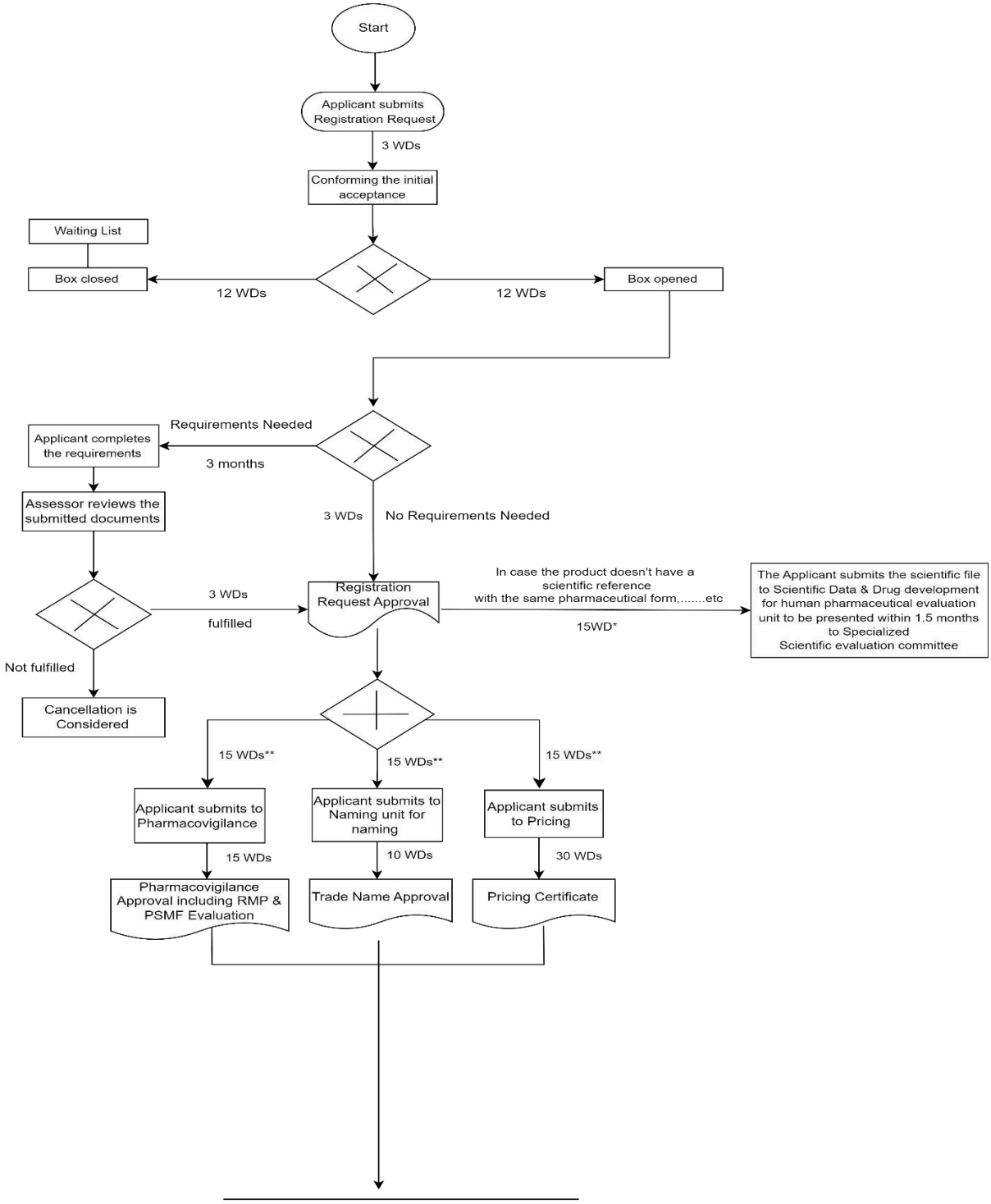
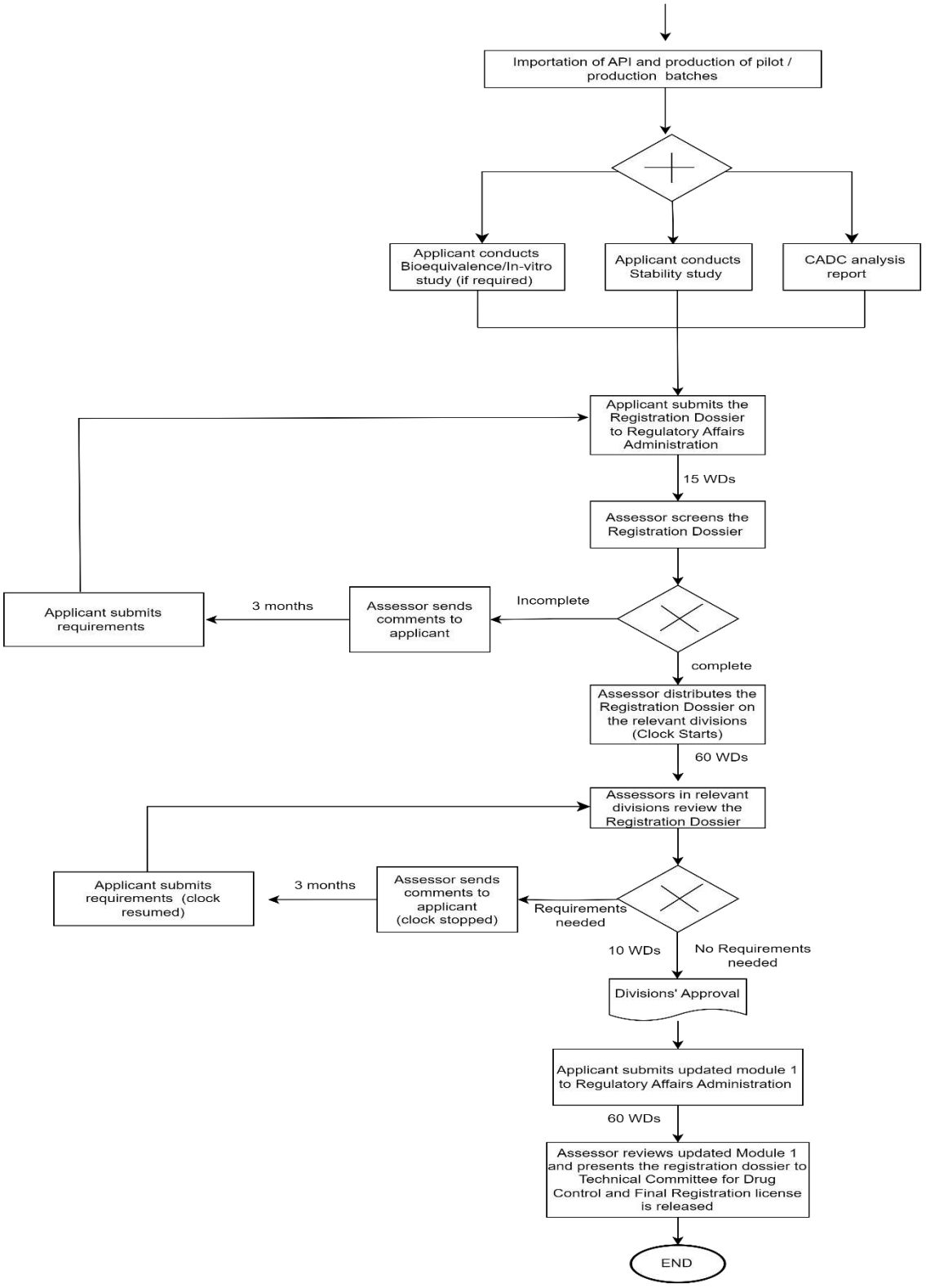


- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval.
  - Applicant has to submit the Registration Dossier within 2 months from Registration Request Approval

- 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)



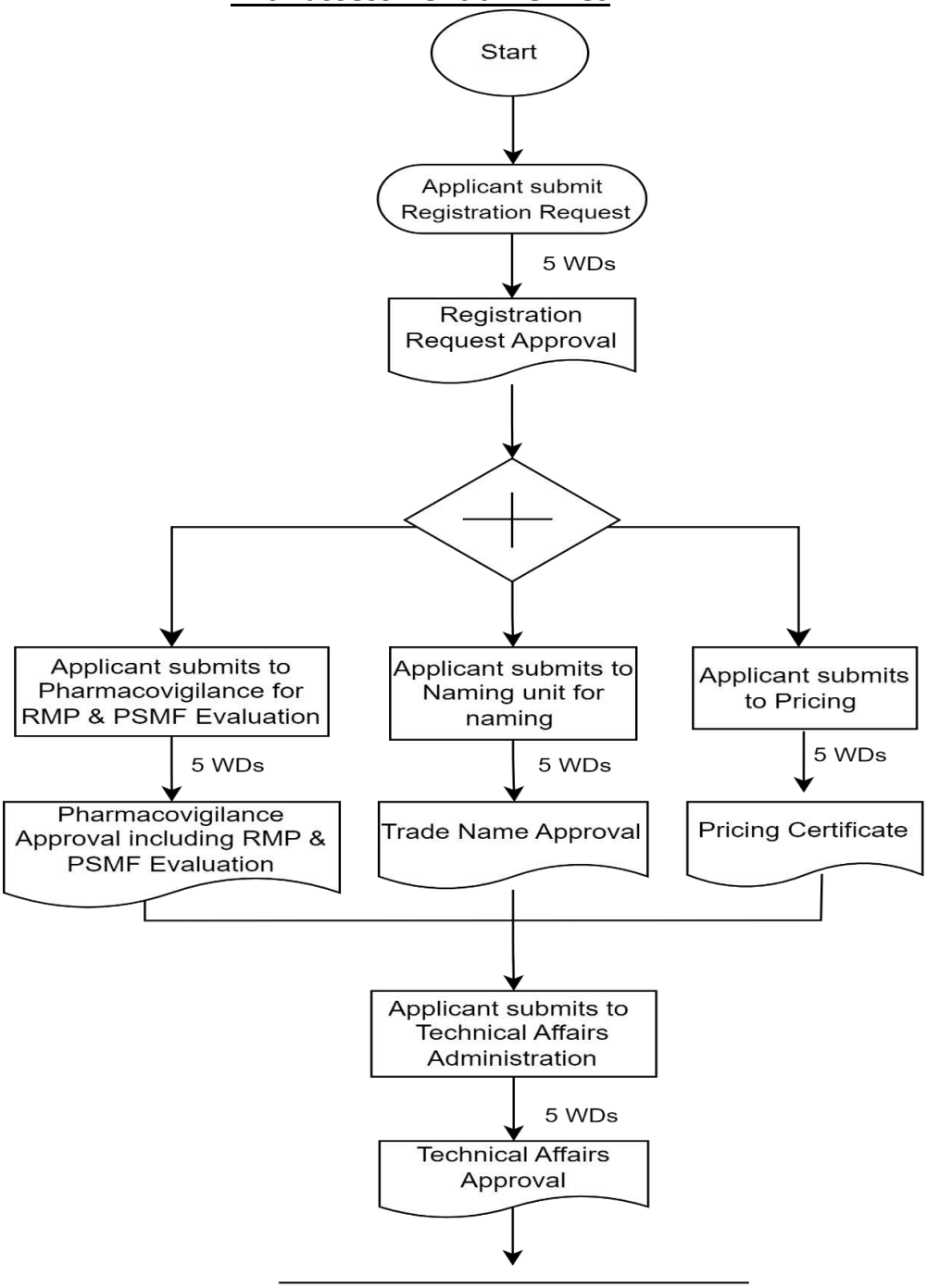

Importation of API and production of pilot / production batches
Applicant conducts Bioequivalence/In-vitro study (if required)
Applicant conducts Stability study
CADC analysis report
Applicant submits the Registration Dossier to Regulatory Affairs Administration
15 WDs
Assessor screens the Registration Dossier
Incomplete
3 months
Assessor sends comments to applicant
Applicant submits requirements
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
60 WDs
Assessors in relevant divisions review the Registration Dossier
Requirements needed
3 months
Assessor sends comments to applicant (clock stopped)
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approval
Applicant submits updated module 1 to Regulatory Affairs Administration
60 WDs
Assessor reviews updated Module 1 and presents the registration dossier to Technical Committee for Drug Control and Final Registration license is released
END

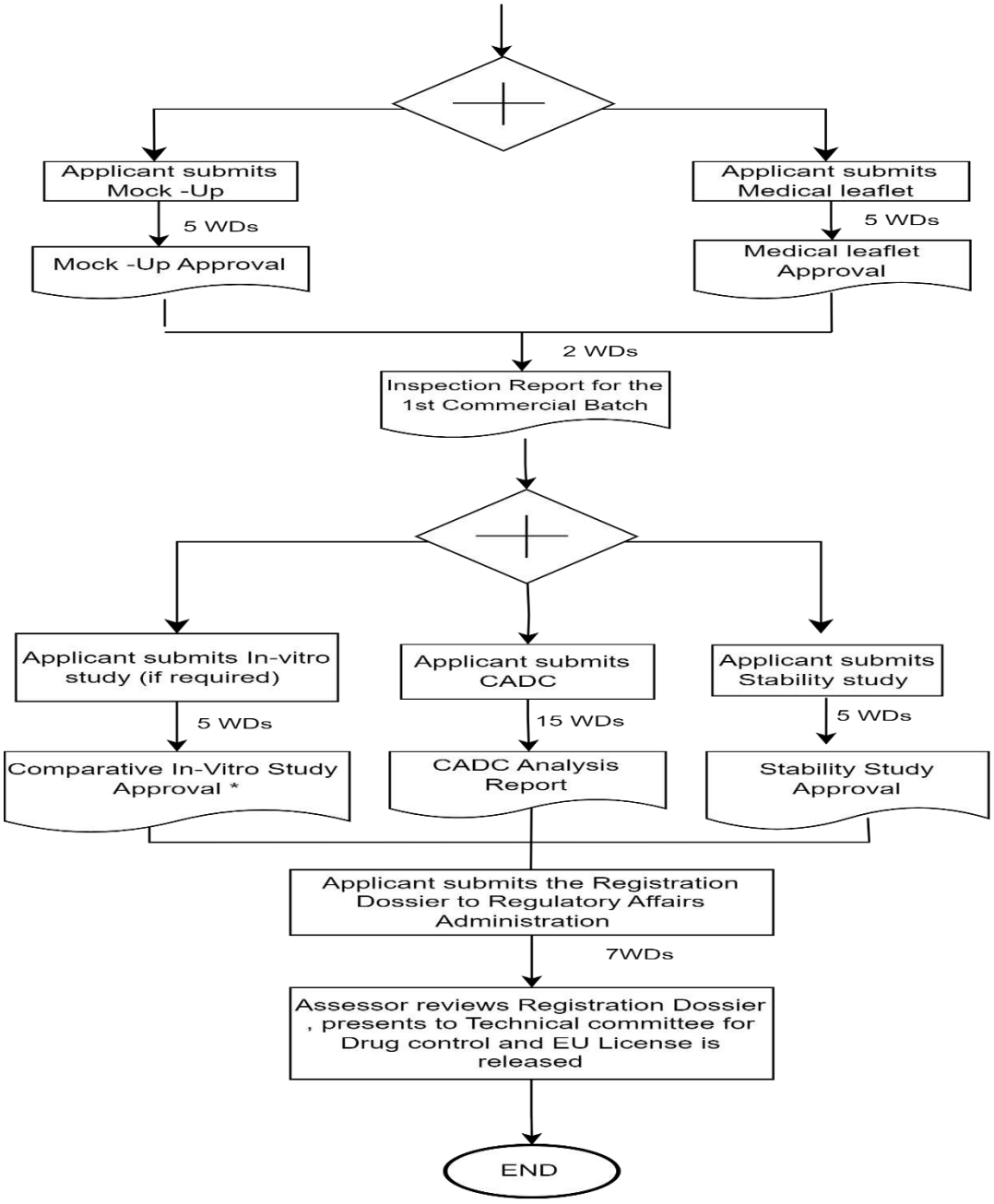
- Applicant Time:
  * The Applicant submits the scientific file to Scientific Data & Drug development for human pharmaceutical evaluation unit within 15 WDs from registration request approval (Incase the product does not have a scientific reference with the same pharmaceutical form, concentration or 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

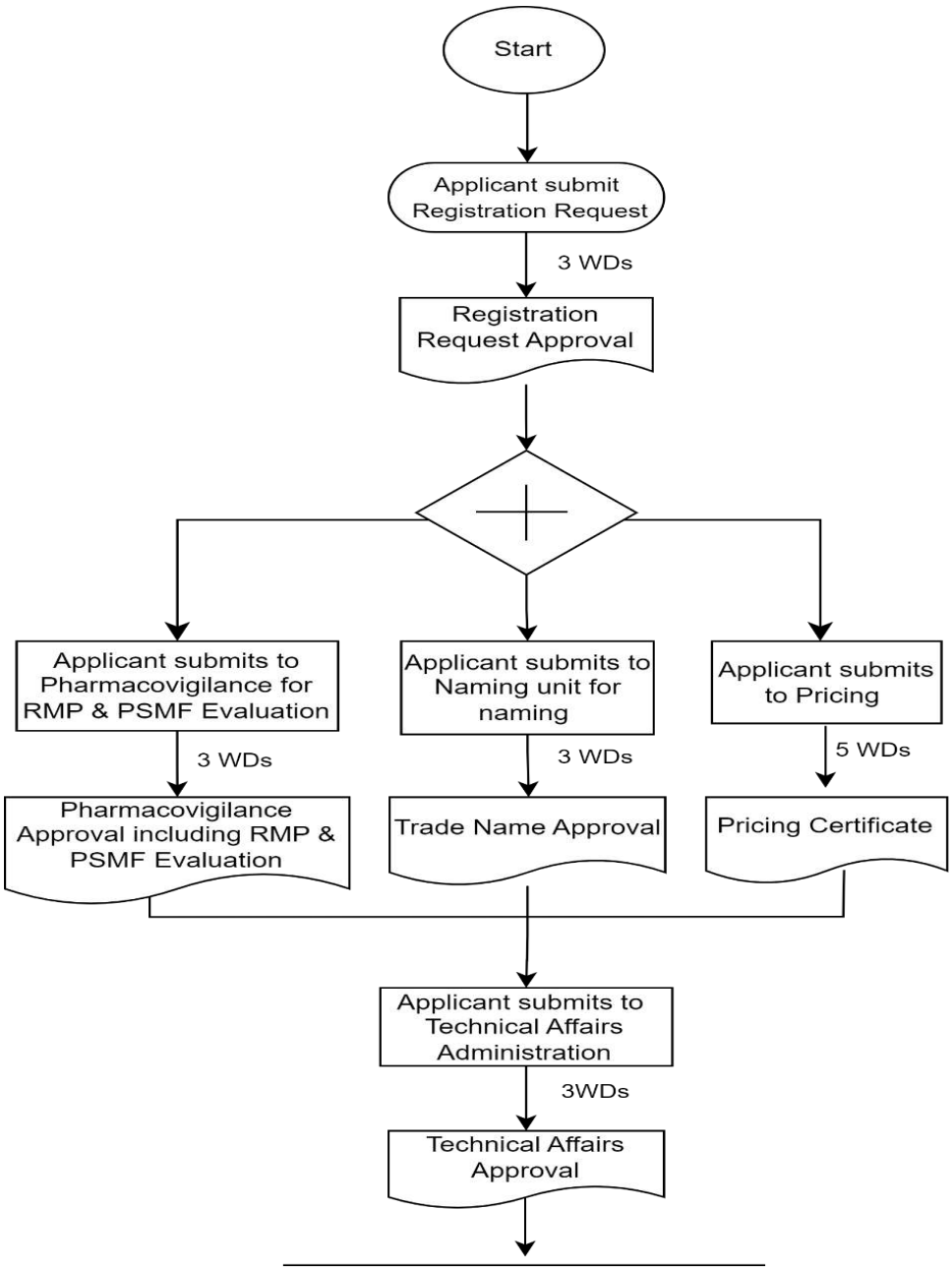


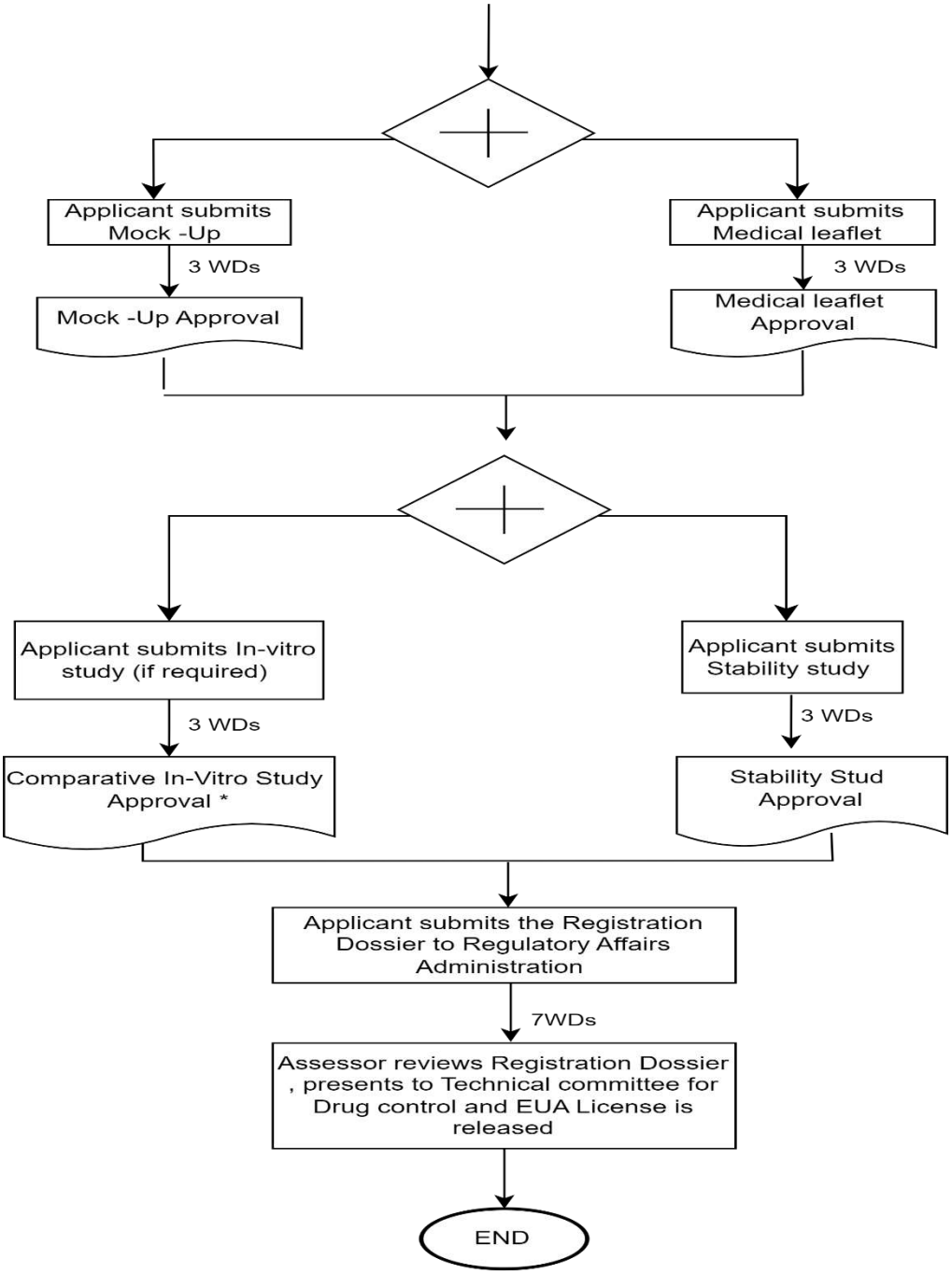



- Assessment timelines start from receiving complete files from applicants
- Total Assessment Timeline = maximum 44 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

*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) | 30 | 145 |

***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 in rolling submission "The applicant submits Module 1 to Regulatory Affairs administration" (page 4 and page 8)<br>• Clarification of EDA's Assessment Timeframes (page 33) |