Notice to applicant

Flowcharts for
EDA Chairman Decree 450 for the year 2023

Year 2024

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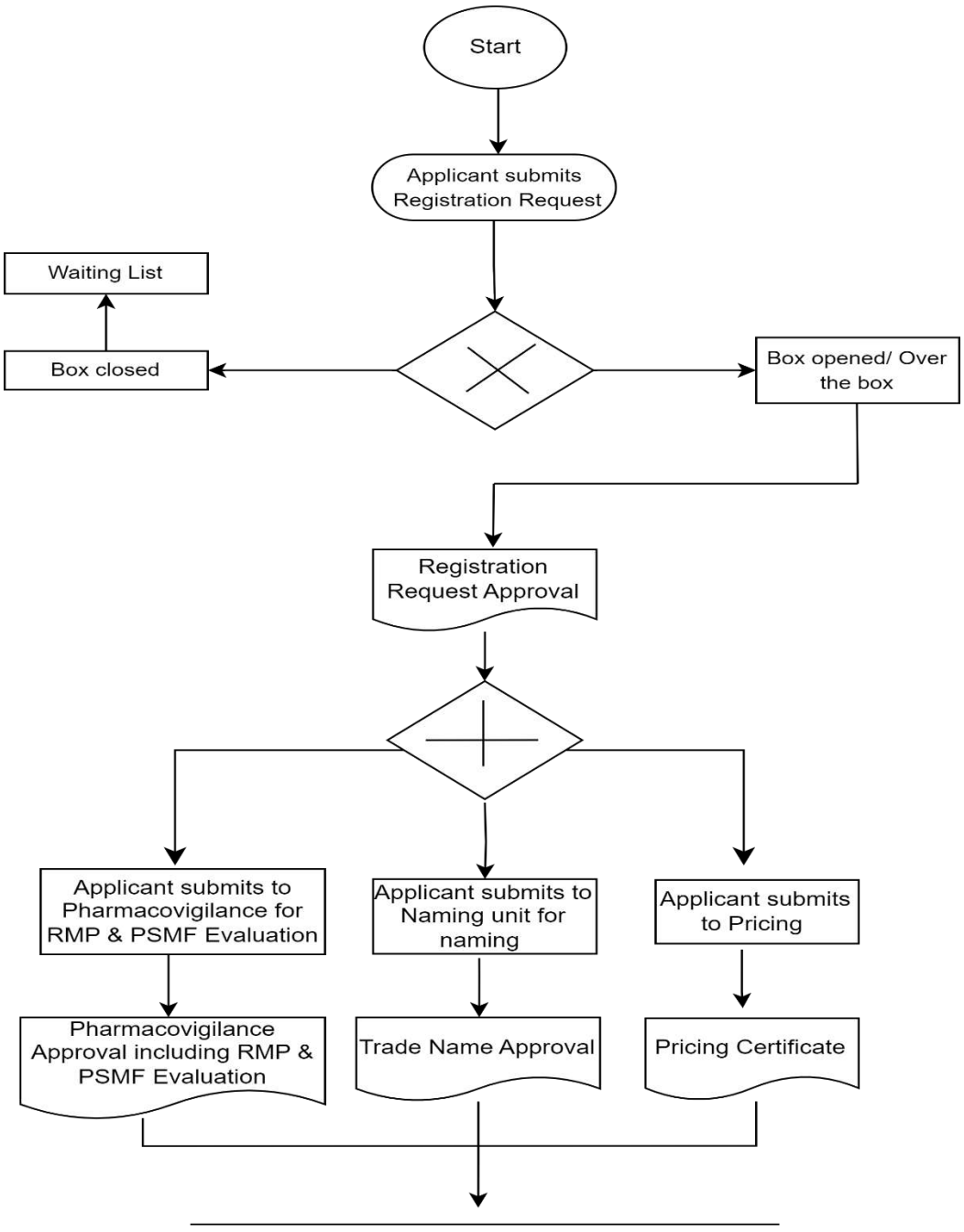
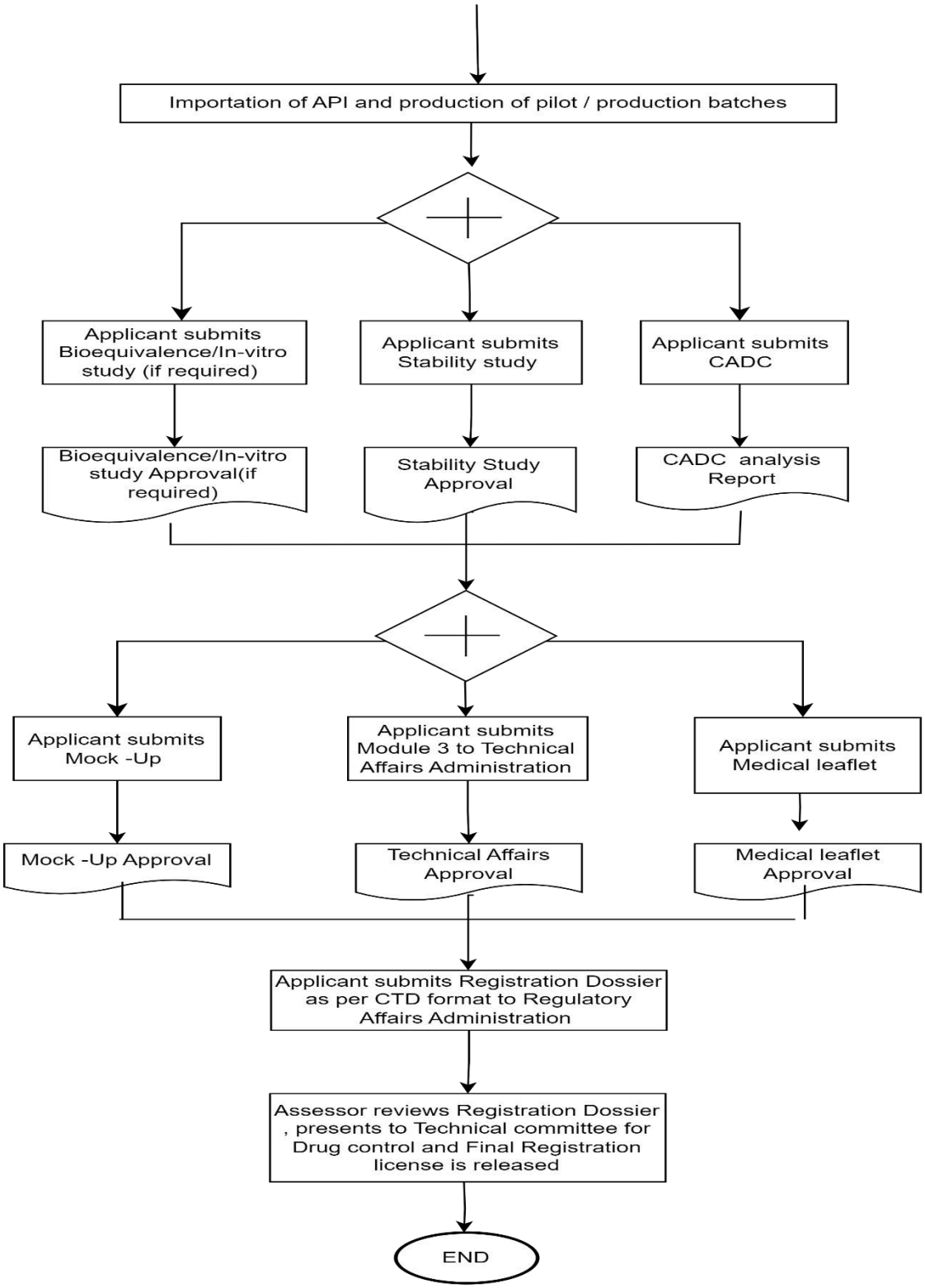
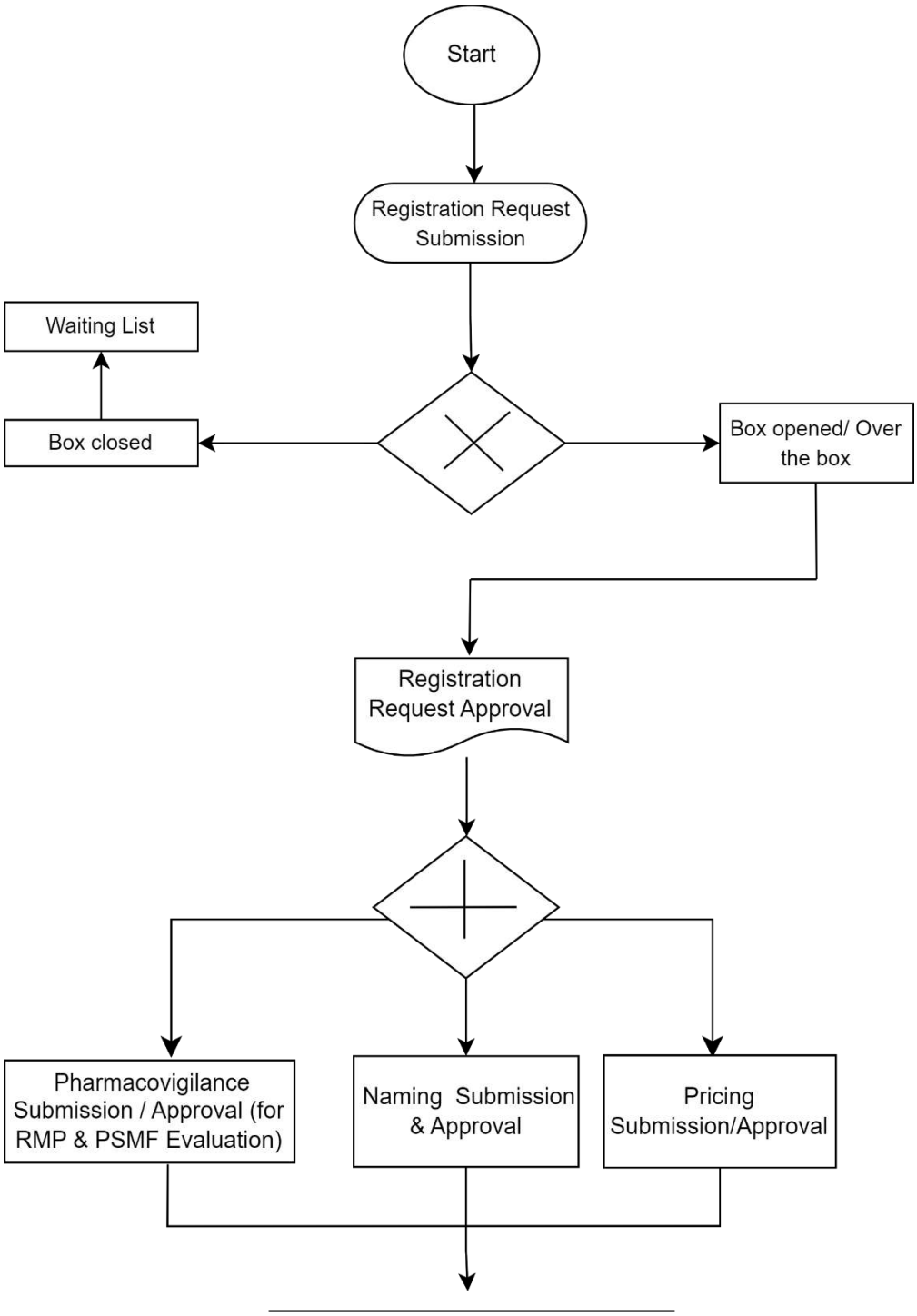
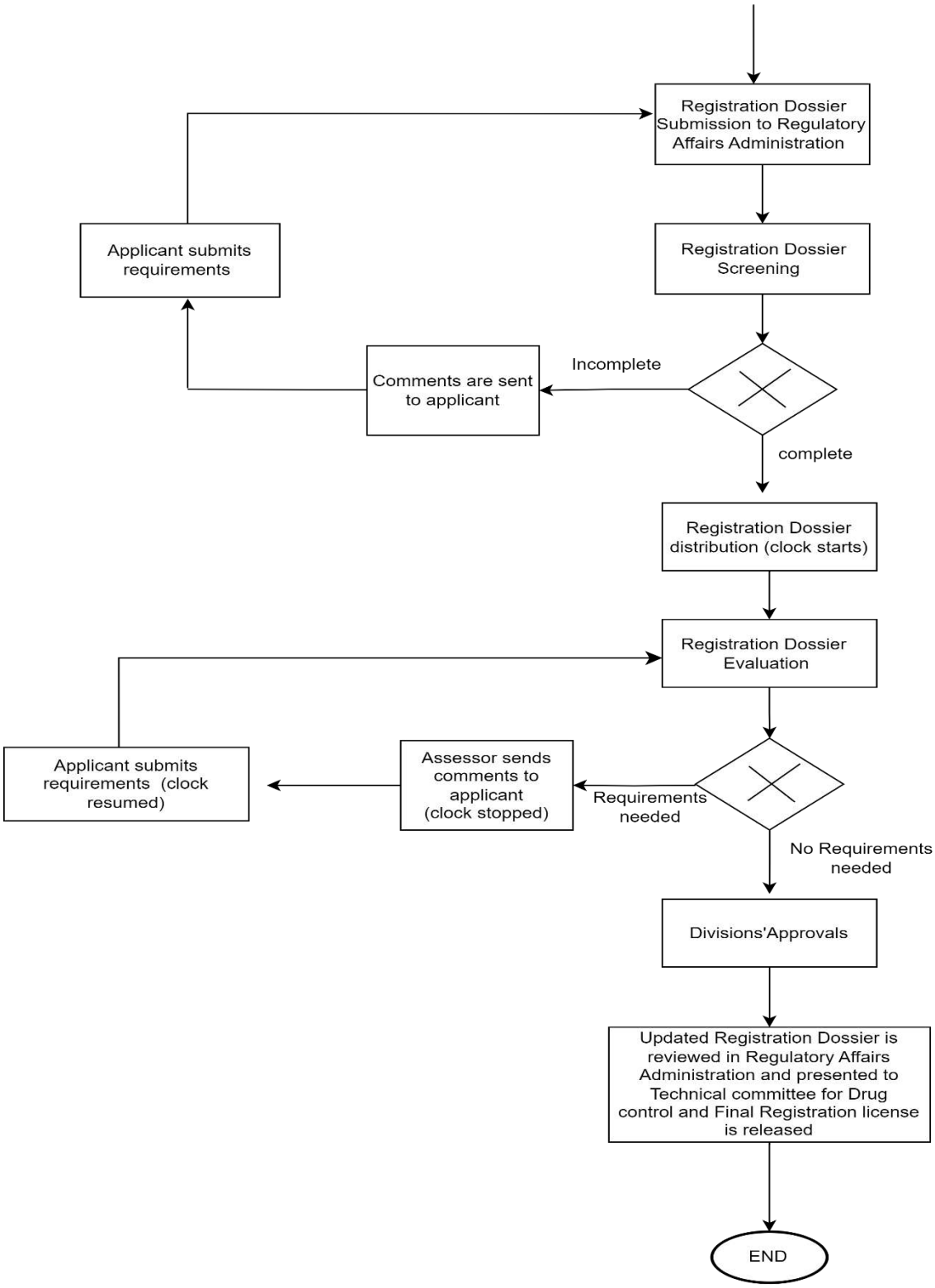
EDA Chairman Decree (450/2023) Rolling Submission General Flowchart



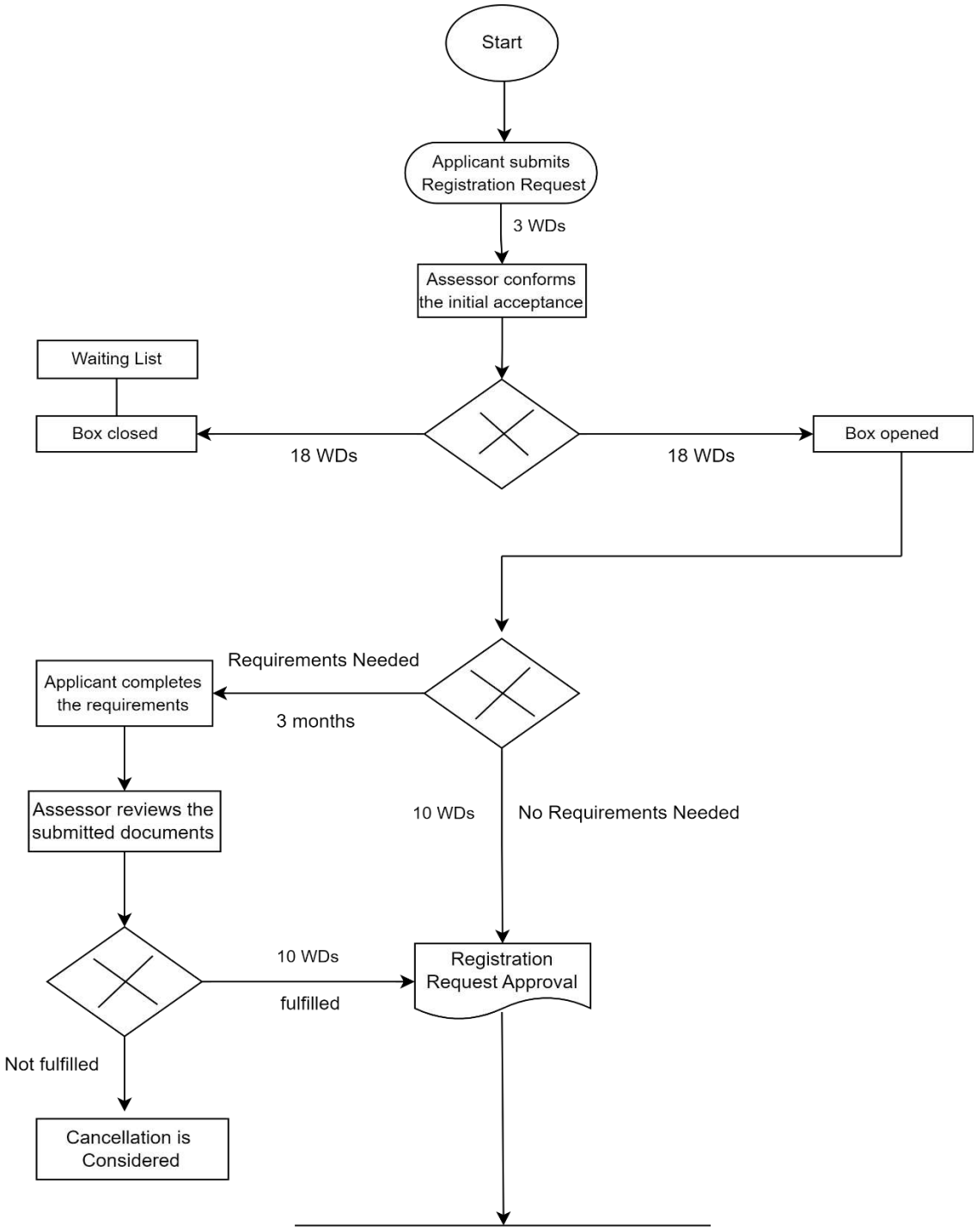

Importation of API and production of pilot / production batches
Applicant submits Bioequivalence/In-vitro study (if required)
Applicant submits Stability study
Applicant submits CADC
Bioequivalence/In-vitro study Approval(if required)
Stability Study Approval
CADC analysis Report
Applicant submits Mock -Up
Applicant submits Module 3 to Technical Affairs Administration
Applicant submits Medical leaflet
Mock -Up Approval
Technical Affairs Approval
Medical leaflet Approval
Applicant submits Registration Dossier as per CTD format to Regulatory Affairs Administration
Assessor reviews Registration Dossier , presents to Technical committee for Drug control and Final Registration license is released
END

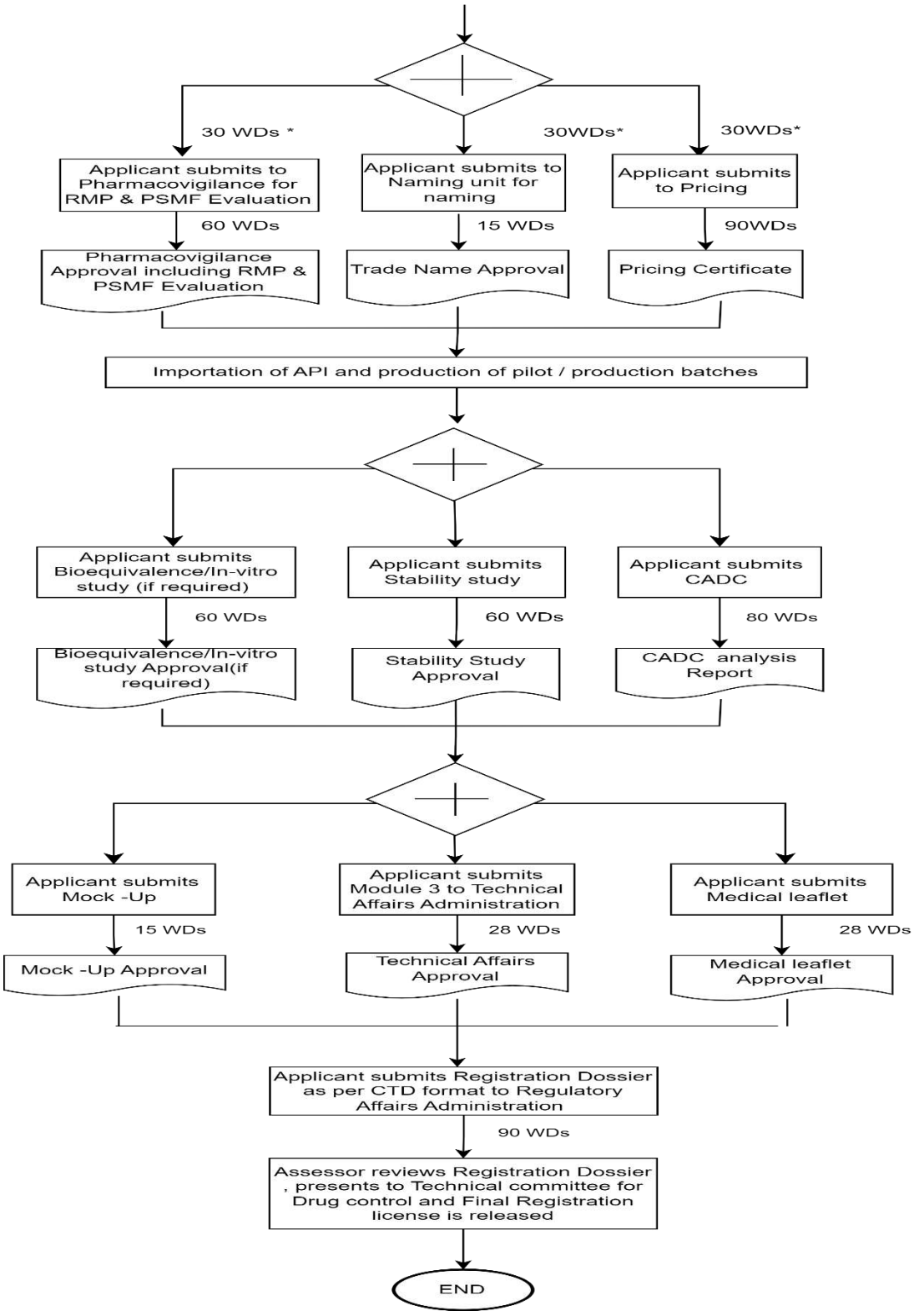
EDA Chairman Decree (450/2023) One Submission General Flowchart




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
Updated Registration Dossier is reviewed in Regulatory Affairs Administration and presented to Technical committee for Drug control and Final Registration license is released
END

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



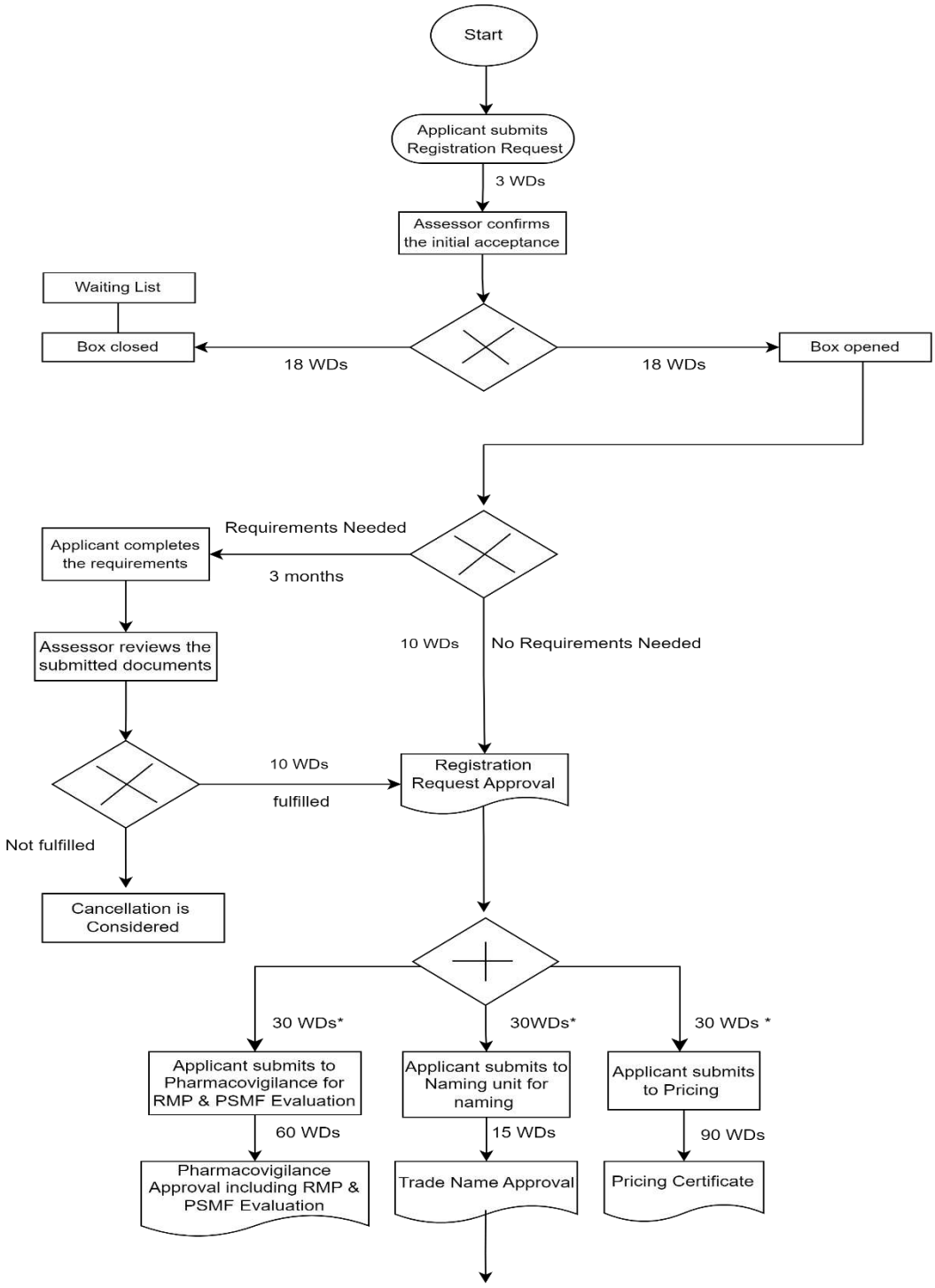

30 WDs *
30WDs*
30WDs*
Applicant submits to Pharmacovigilance for RMP & PSMF Evaluation
Applicant submits to Naming unit for naming
Applicant submits to Pricing
60 WDs
15 WDs
90WDs
Pharmacovigilance Approval including RMP & PSMF Evaluation
Trade Name Approval
Pricing Certificate
Importation of API and 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 Registration Dossier as per CTD format to Regulatory Affairs Administration
90 WDs
Assessor reviews Registration Dossier , presents to Technical committee for Drug control and Final Registration license is released
END

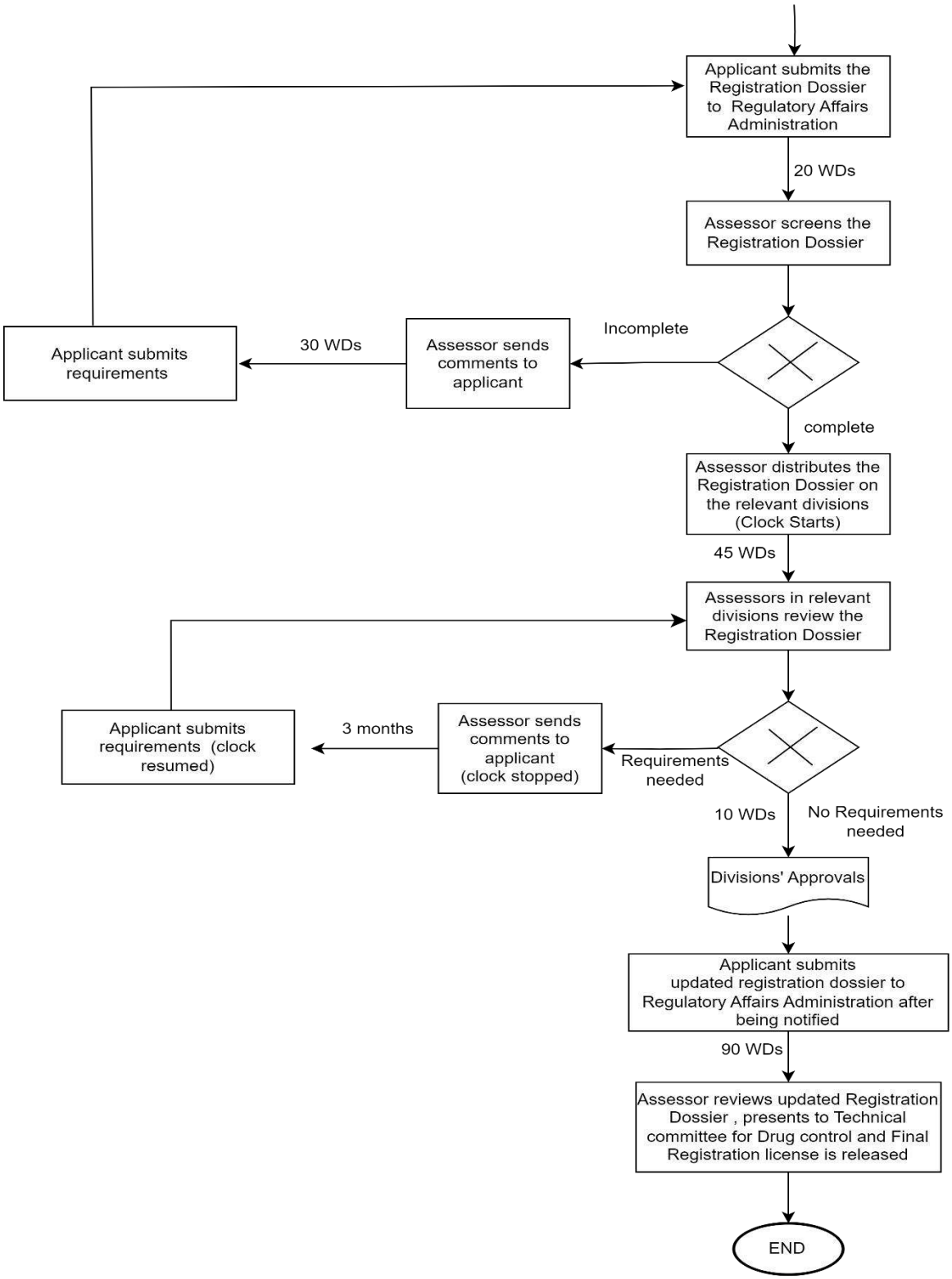
- Applicant Time:
  *Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from registration request approval
  - Applicant has to submit the Registration Dossier within 33 months from date of pharmacovigilance approval or first pricing certificate whichever is the latest.

- EDA Time:
  Application = 31WDs, Rolling submission = 198WDs, Registration Dossier = 90WDs
  Target Assessment Time= maximum 319 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

- 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) Case I Flowchart for Imported Products from Reference Country with assessment timelines

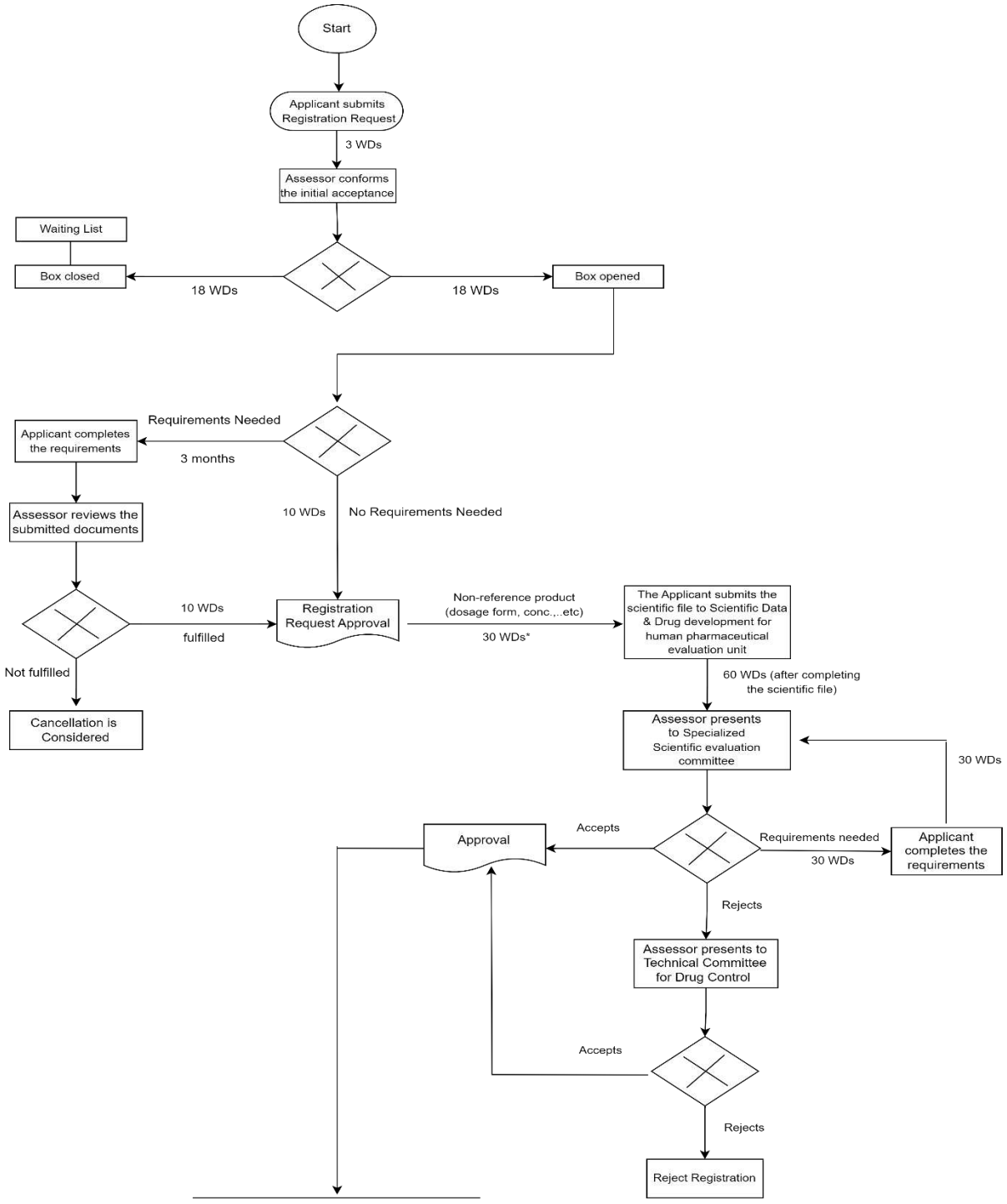


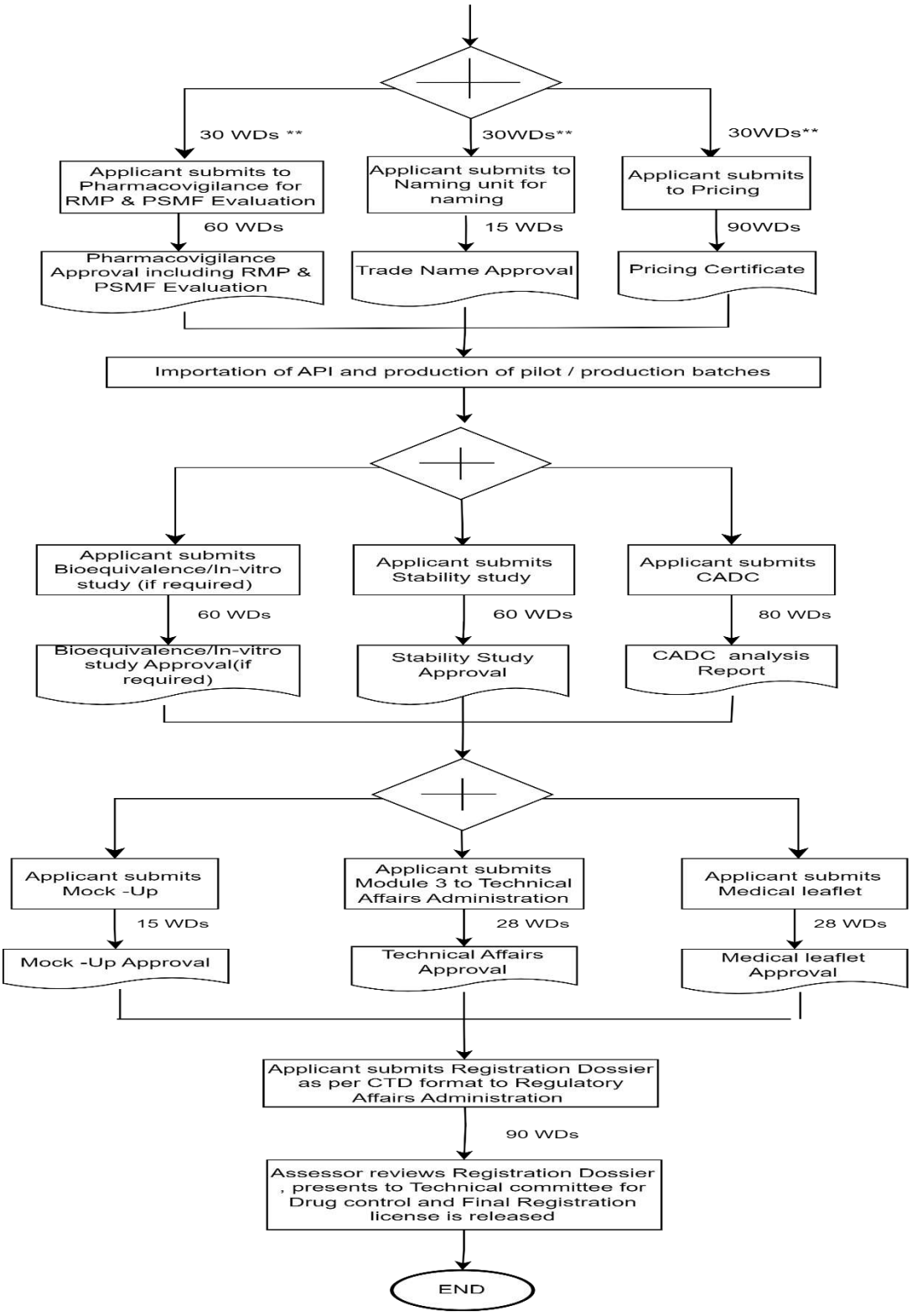

Applicant submits the Registration Dossier to Regulatory Affairs Administration
20 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
30 WDs
Applicant submits requirements
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
45 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 registration dossier to Regulatory Affairs Administration after being notified
90 WDs
Assessor reviews updated Registration Dossier , presents 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 Registration Dossier within 6 months from date of pharmacovigilance approval or first pricing certificate whichever is the latest.
- EDA Time:
  Application & screening = 141 WDs, Registration Dossier = 145 WDs
  Target Assessment Time= maximum 286 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

- In case of importation from reference country, Applicant may import and analyze the product (CADC lab analysis) before issuing MA.
- The declared working days are the maximum time needed for the process to be completed.

EDA Chairman Decree (450/2023) Case I Flowchart for Locally Manufactured Non-Reference 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 Registration Dossier as per CTD format to Regulatory Affairs Administration
90 WDs
Assessor reviews Registration Dossier , presents 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 30 WDs from registration request approval.

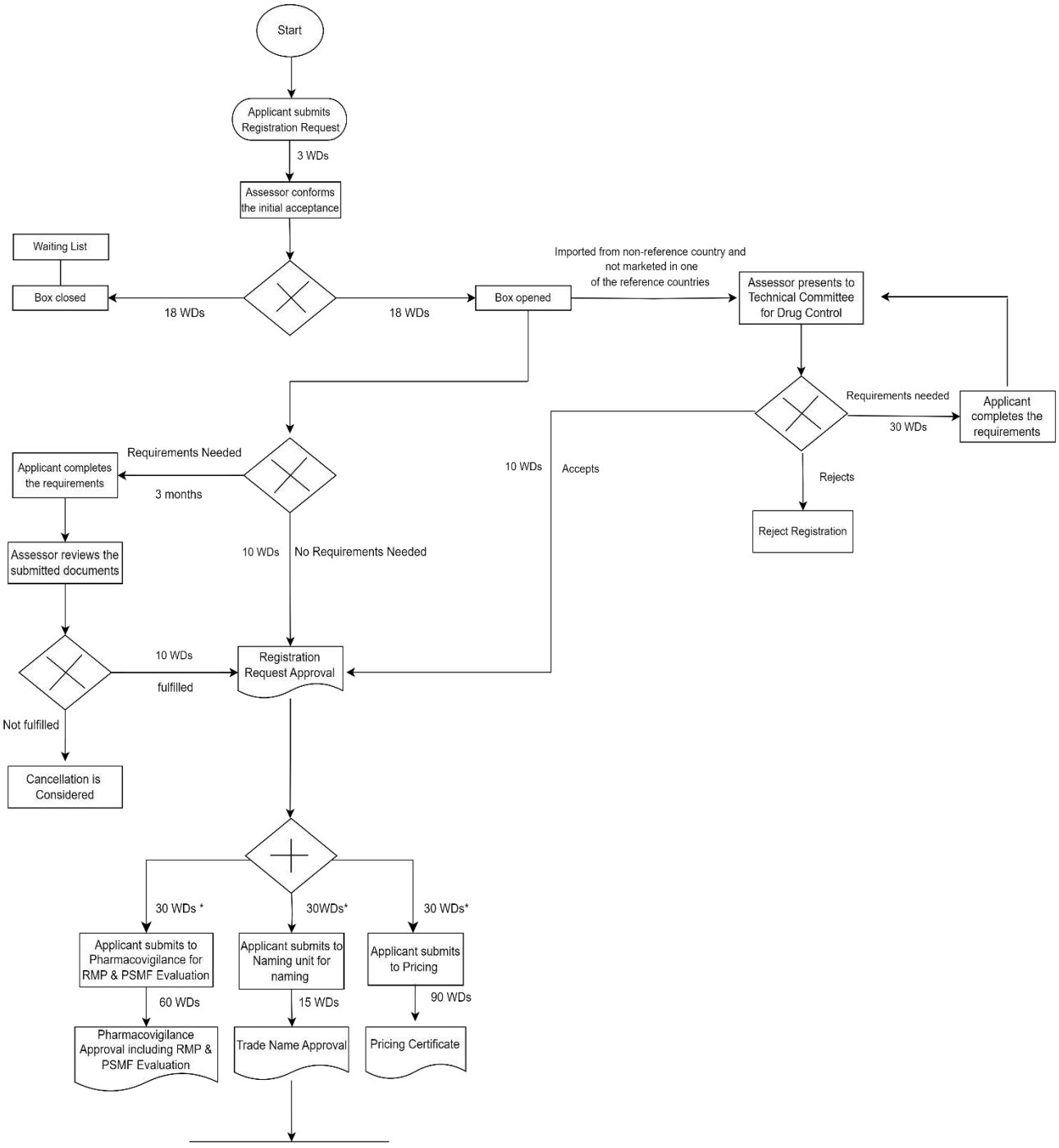
** Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from Specialized Scientific evaluation committee approval.

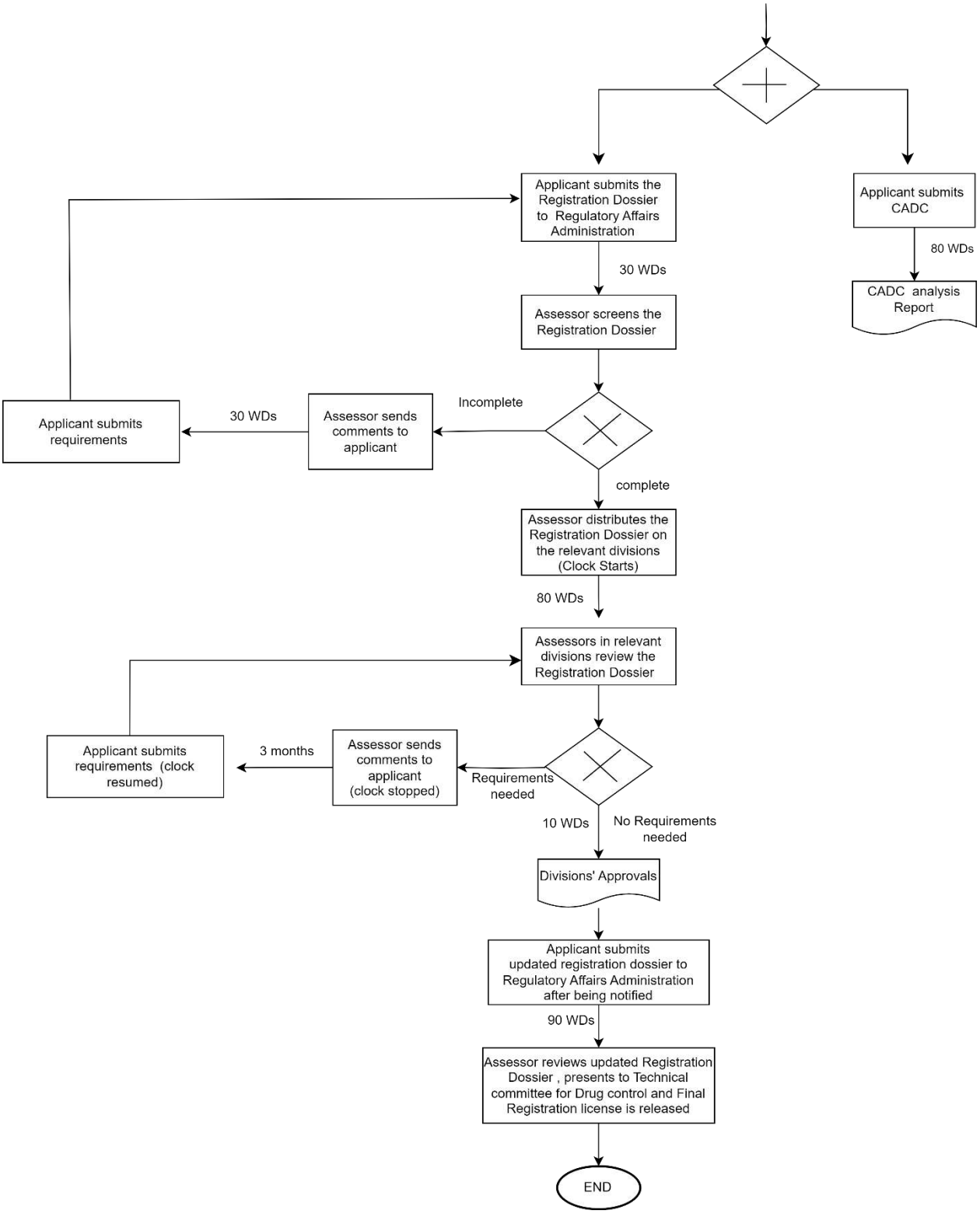
- Applicant has to submit the Registration Dossier within 33 months from date of pharmacovigilance approval or first pricing certificate whichever is the latest.

- EDA Time:
  Application = 91WDs, Rolling submission = 198WDs, Registration Dossier = 90WDs
  Target Assessment Time= maximum 379 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

- 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.

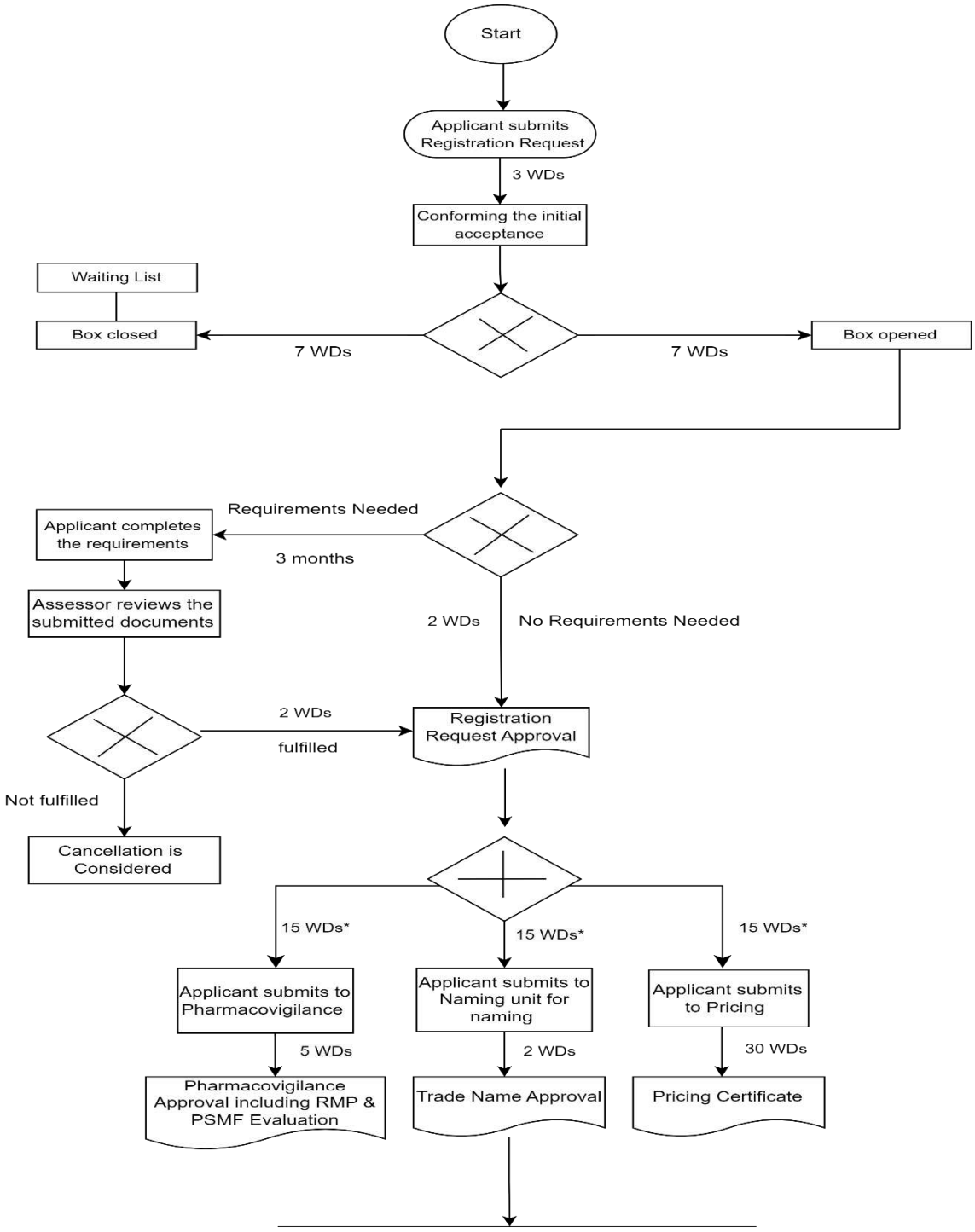
EDA Chairman Decree (450/2023) Case I Flowchart for Imported Products from non-reference country and not marketed in one of reference countries with assessment timelines

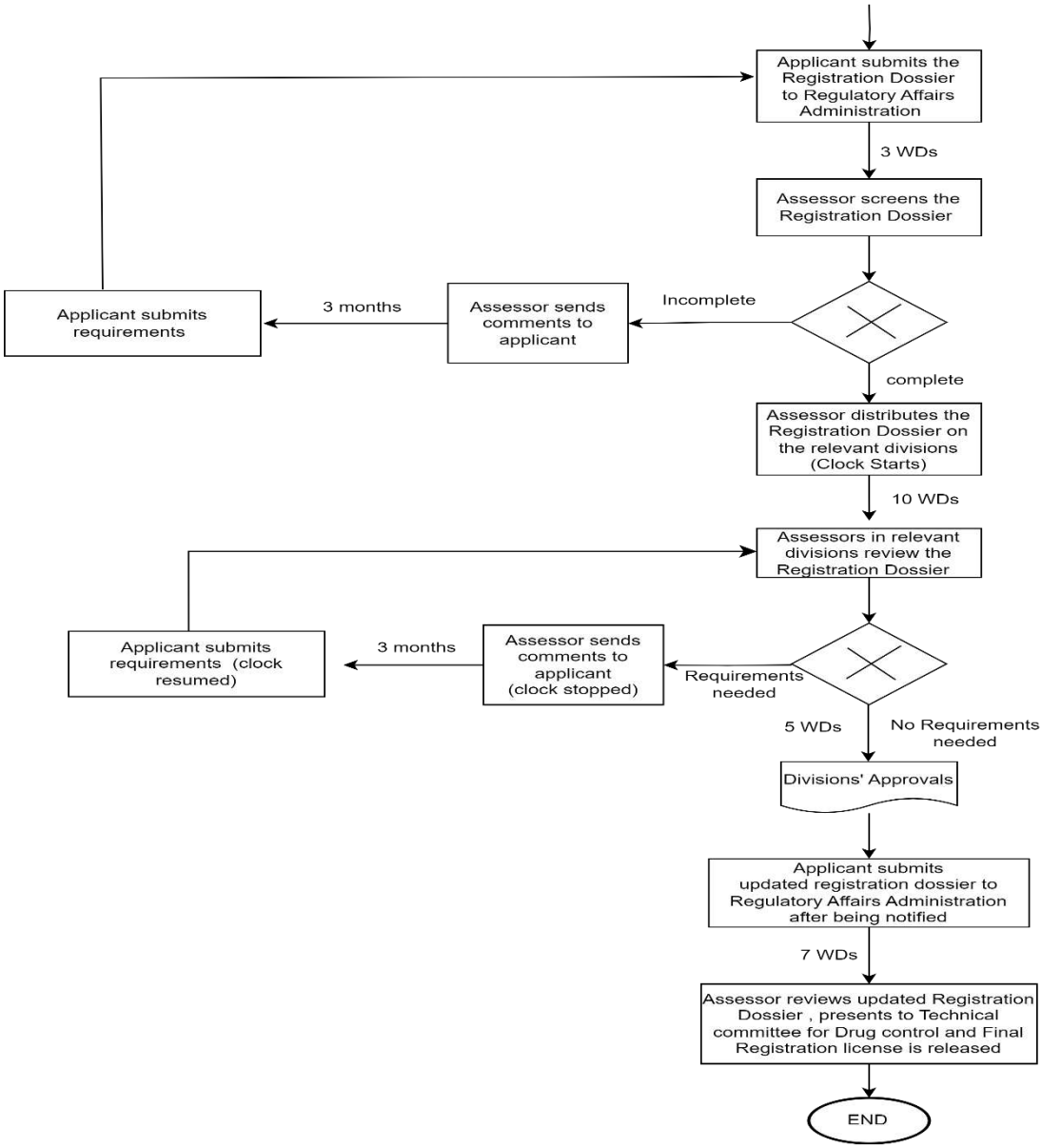



Applicant submits the Registration Dossier to Regulatory Affairs Administration
Applicant submits CADC
80 WDs
CADC analysis Report
30 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
30 WDs
Applicant submits requirements
complete
Assessor distributes the Registration 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 registration dossier to Regulatory Affairs Administration after being notified
90 WDs
Assessor reviews updated Registration Dossier , presents 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 Registration Dossier within 6 months from date of pharmacovigilance approval or first pricing certificate whichever is the latest.
- EDA Time:
  Application & screening = 151, Registration Dossier = 180 WDs
  Target Assessment Time= maximum 331 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).
- The declared working days are the maximum time needed for the process to be completed.

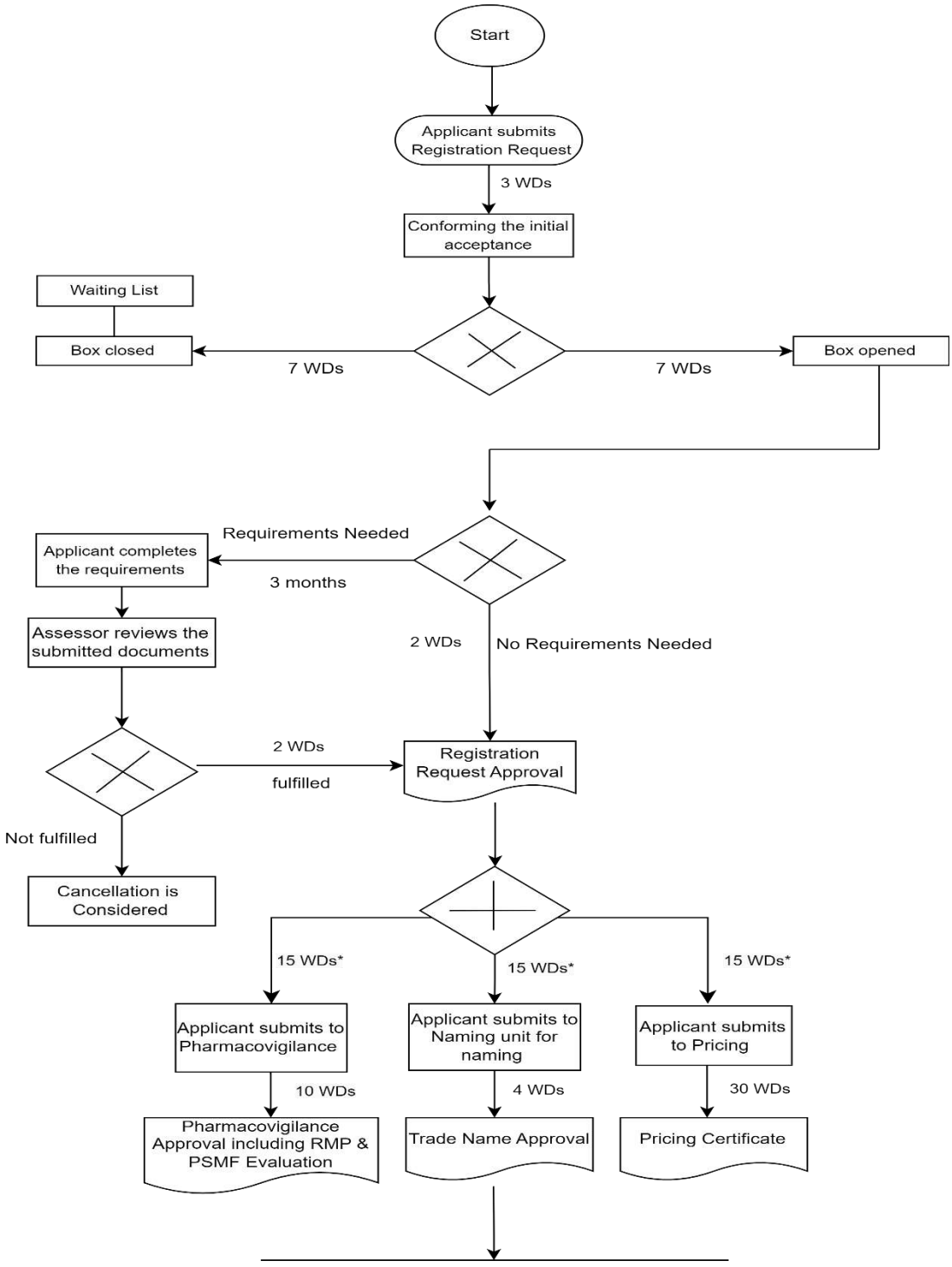
EDA Chairman Decree (450/2023) Case II- Track A Flowchart with assessment timelines

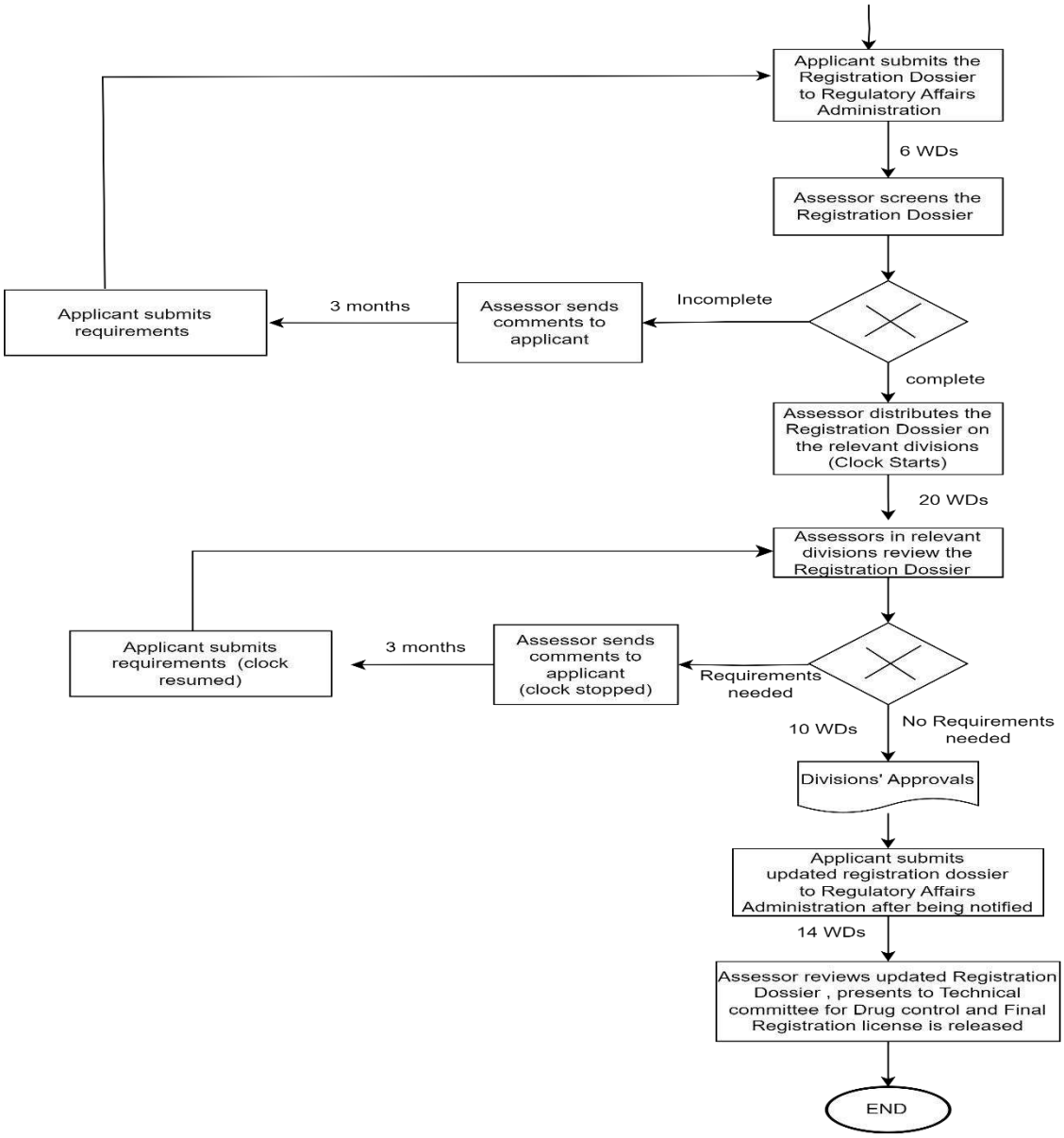




- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval
  - Applicant has to submit the Registration Dossier within 30 WD from date of registration request approval
- EDA Time:
  Application & screening= 17 WDs, Registration Dossier = 22 WDs
  Target Assessment Time= maximum 39 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).
- The declared working days are the maximum time needed for the process to be completed.

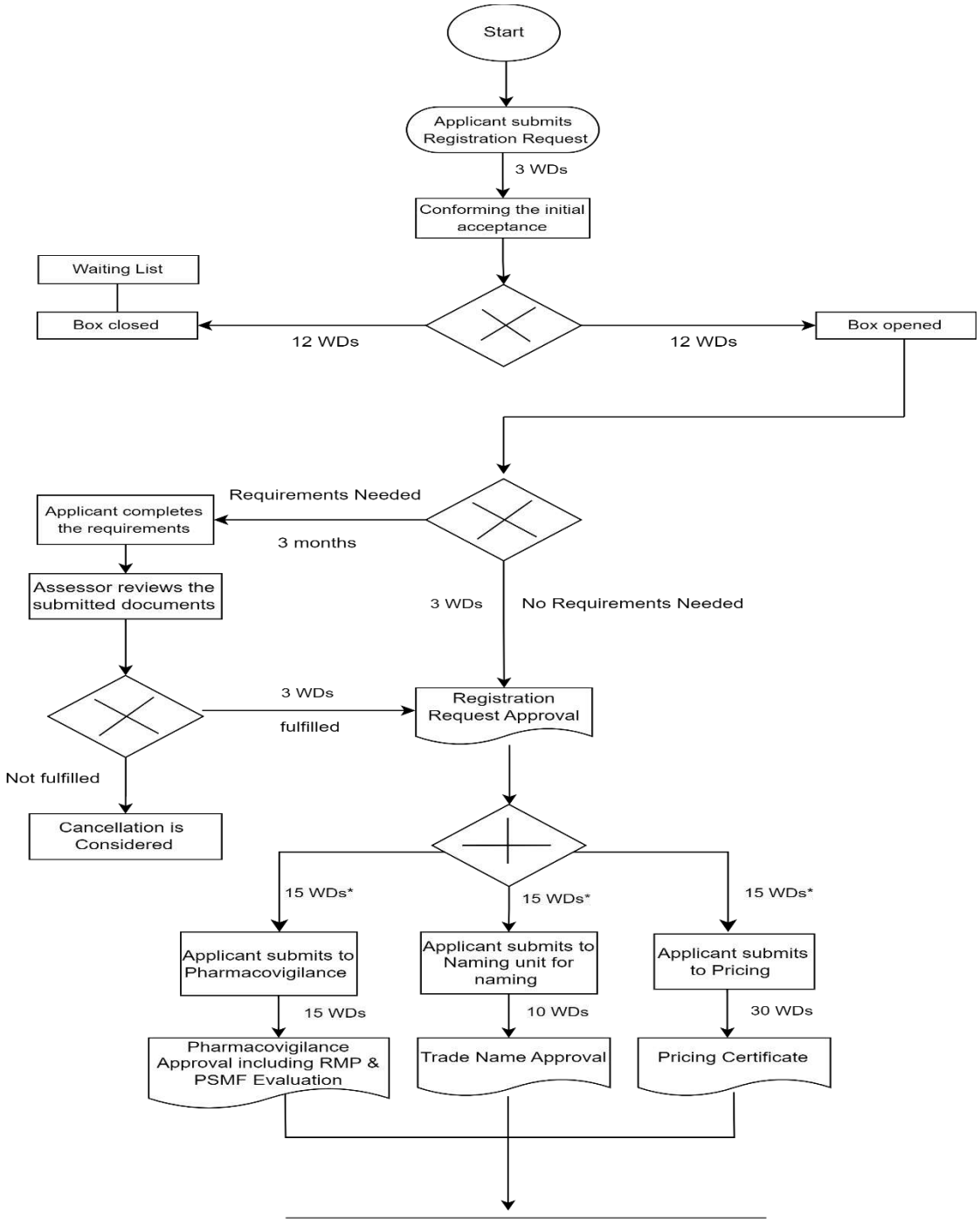
EDA Chairman Decree (450/2023) Case II- Track B Flowchart with assessment timelines

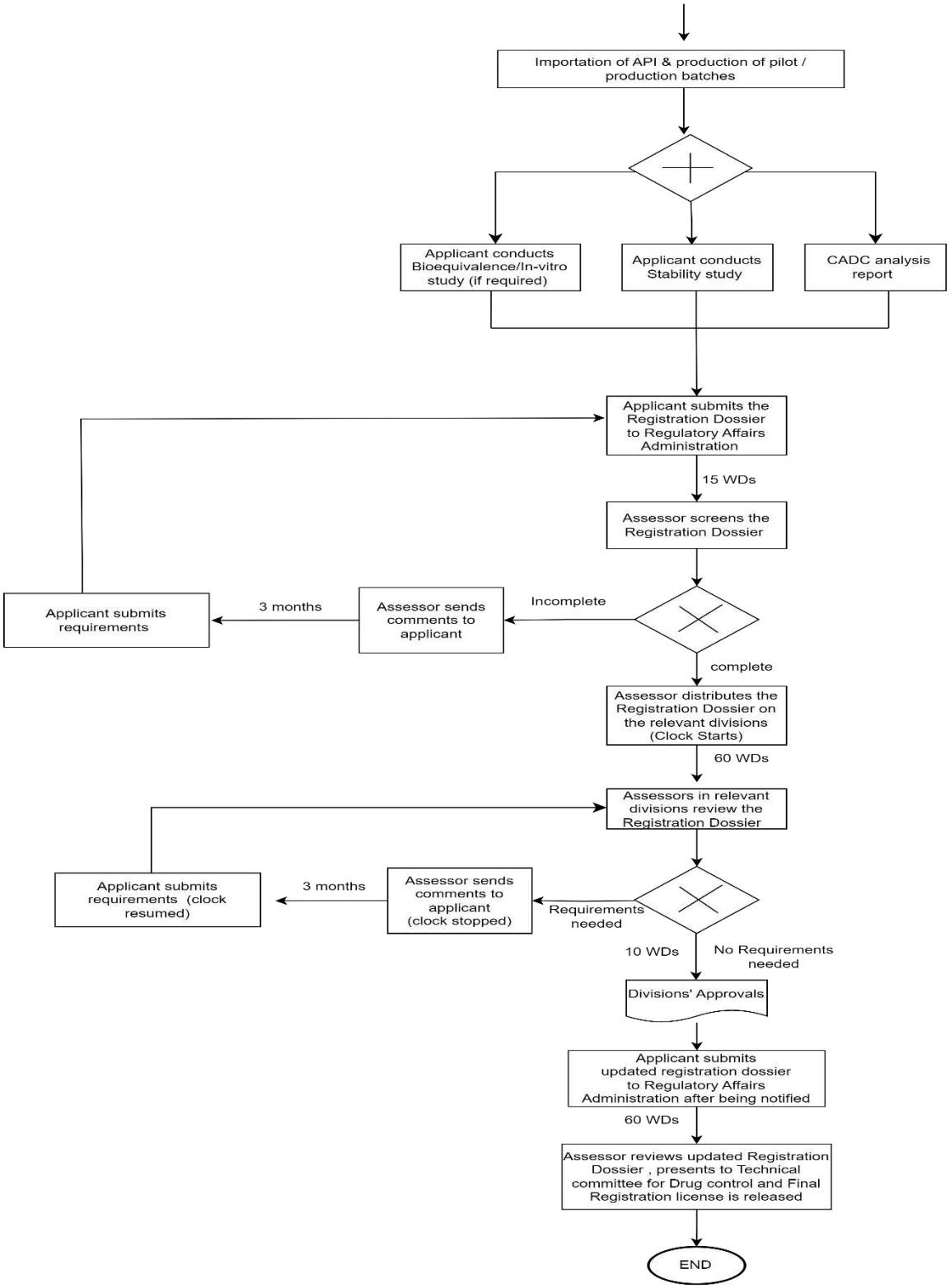




- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval
  - Applicant has to submit the Registration Dossier within 30 WD from date of registration request approval
- EDA Time:
  Application & screening= 22 WDs, Registration Dossier = 44 WDs
  Target Assessment Time= maximum 66 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).
- The declared working days are the maximum time needed for the process to be completed.

EDA Chairman Decree (450/2023) Case II- Track C Flowchart for Locally Manufactured Reference Products with assessment timelines

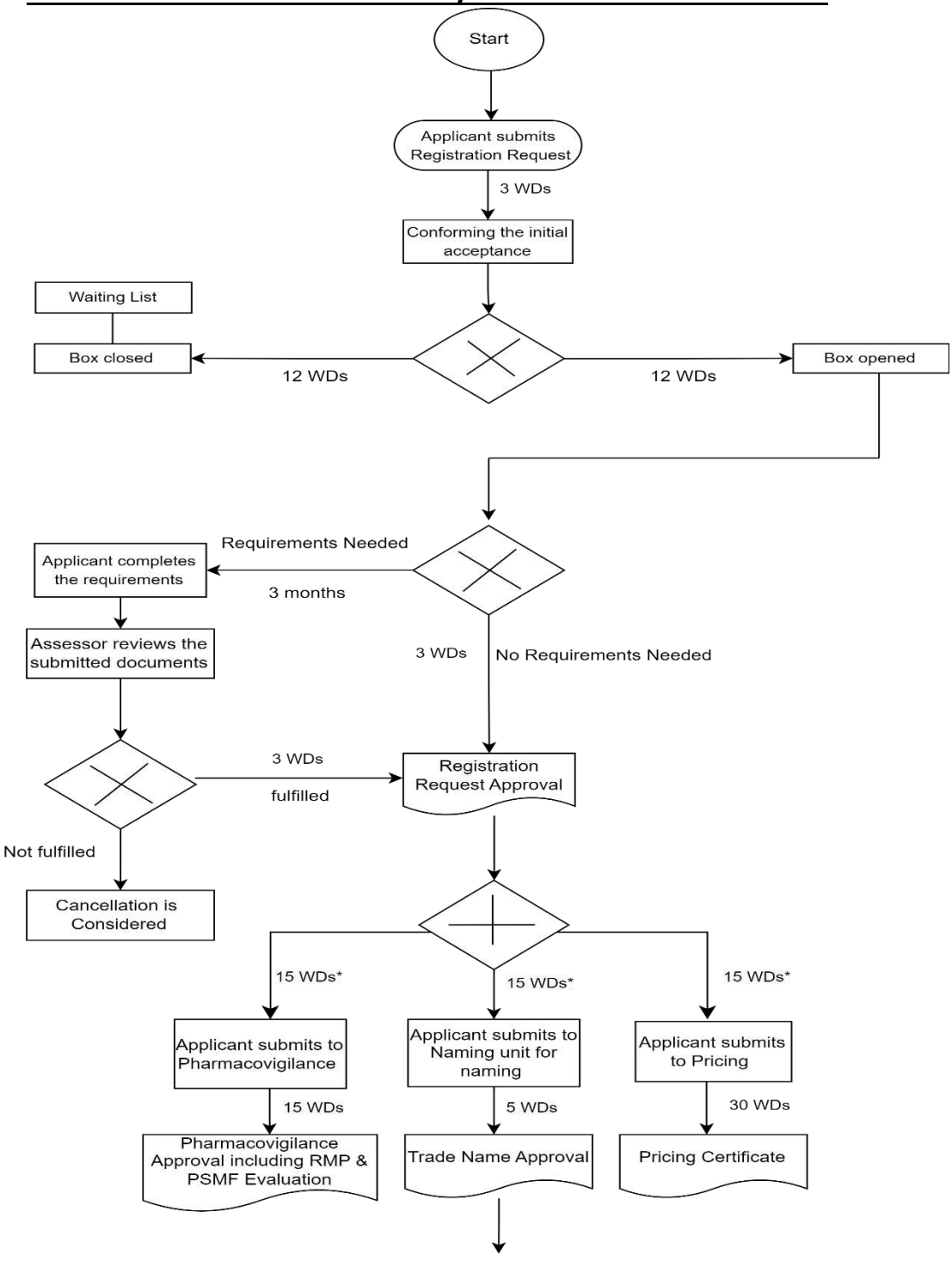


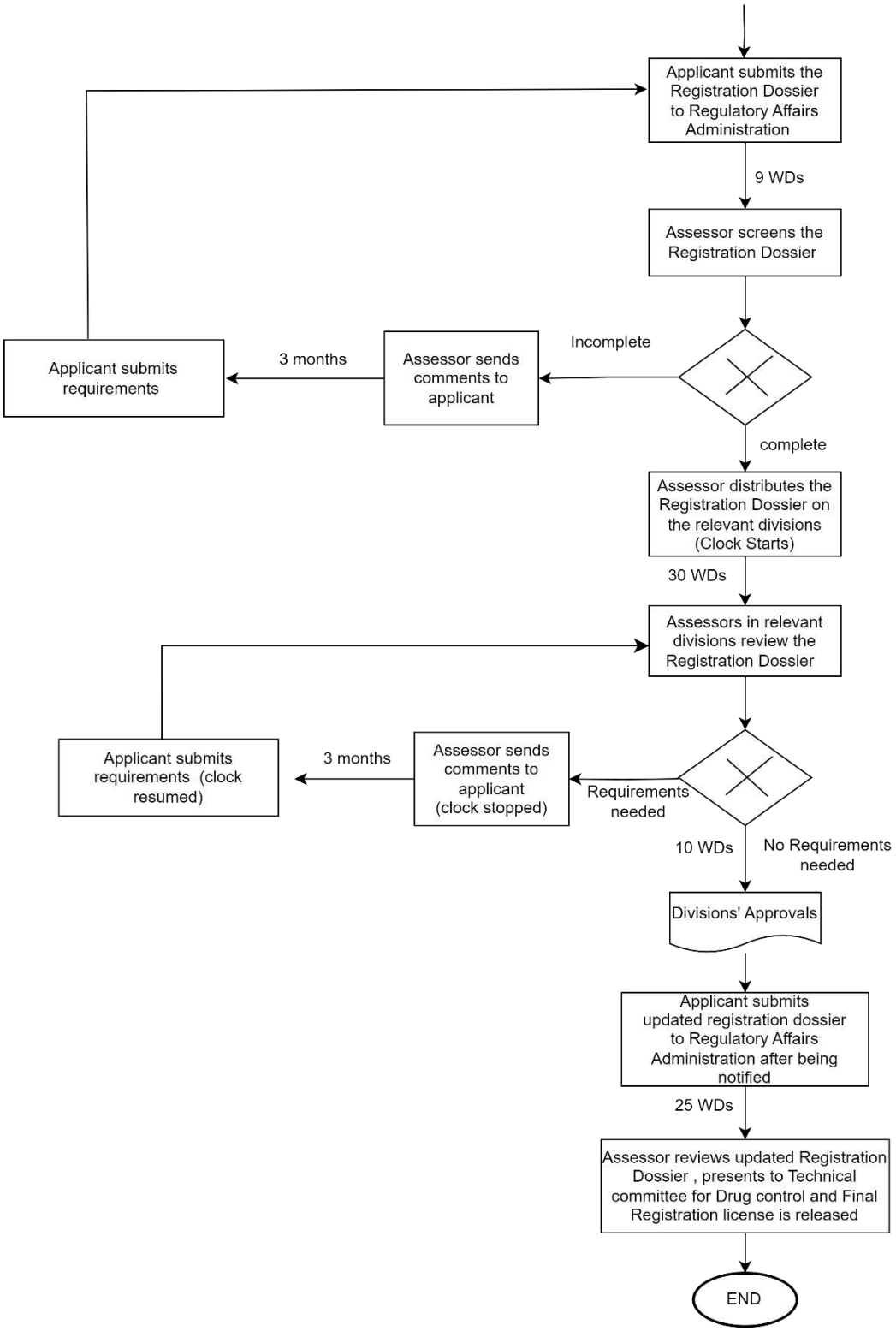

Importation of API & production of pilot / production batches
Applicant conducts Bioequivalence/In-vitro study (if required)
Applicant conducts Stability study
CADC analysis report
Applicant submits the Registration Dossier to Regulatory Affairs Administration
15 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
3 months
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
Assessor sends comments to applicant (clock stopped)
3 months
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approvals
Applicant submits updated registration dossier to Regulatory Affairs Administration after being notified
60 WDs
Assessor reviews updated Registration Dossier , presents to Technical committee for Drug control and Final Registration license is released
END

- 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 33 WDs from date of first pricing certificate
- EDA Time:
  Application & screening= 63 WDs, Registration Dossier = 130 WDs
  Target Assessment Time= maximum 193 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

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

EDA Chairman Decree (450/2023) Case II- Track C Flowchart for Imported Products from Reference country with assessment timelines



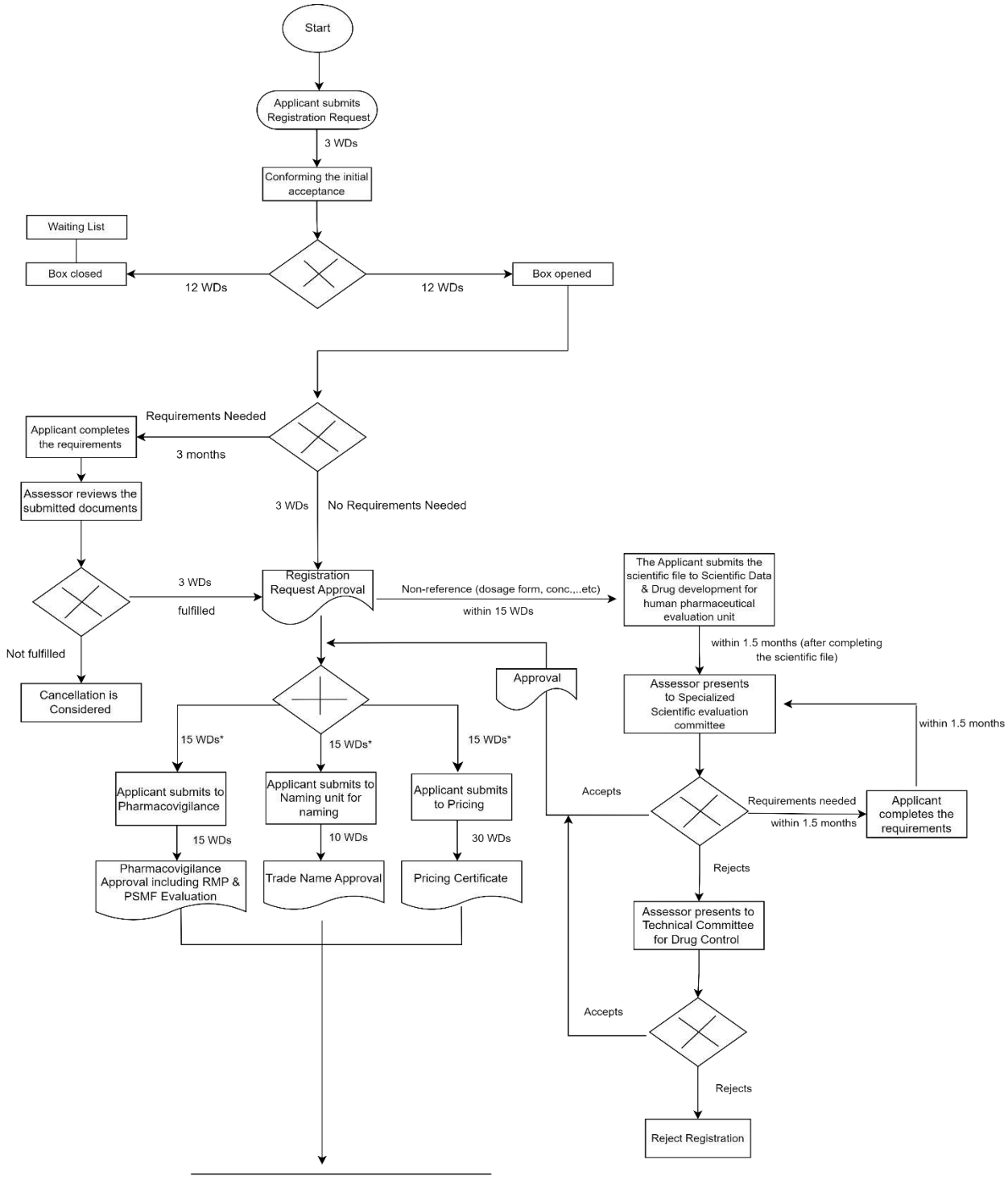

Applicant submits the Registration Dossier to Regulatory Affairs Administration
9 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
3 months
Applicant submits requirements
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
30 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 registration dossier to Regulatory Affairs Administration after being notified
25 WDs
Assessor reviews updated Registration Dossier , presents to Technical committee for Drug control and Final Registration license is released
END

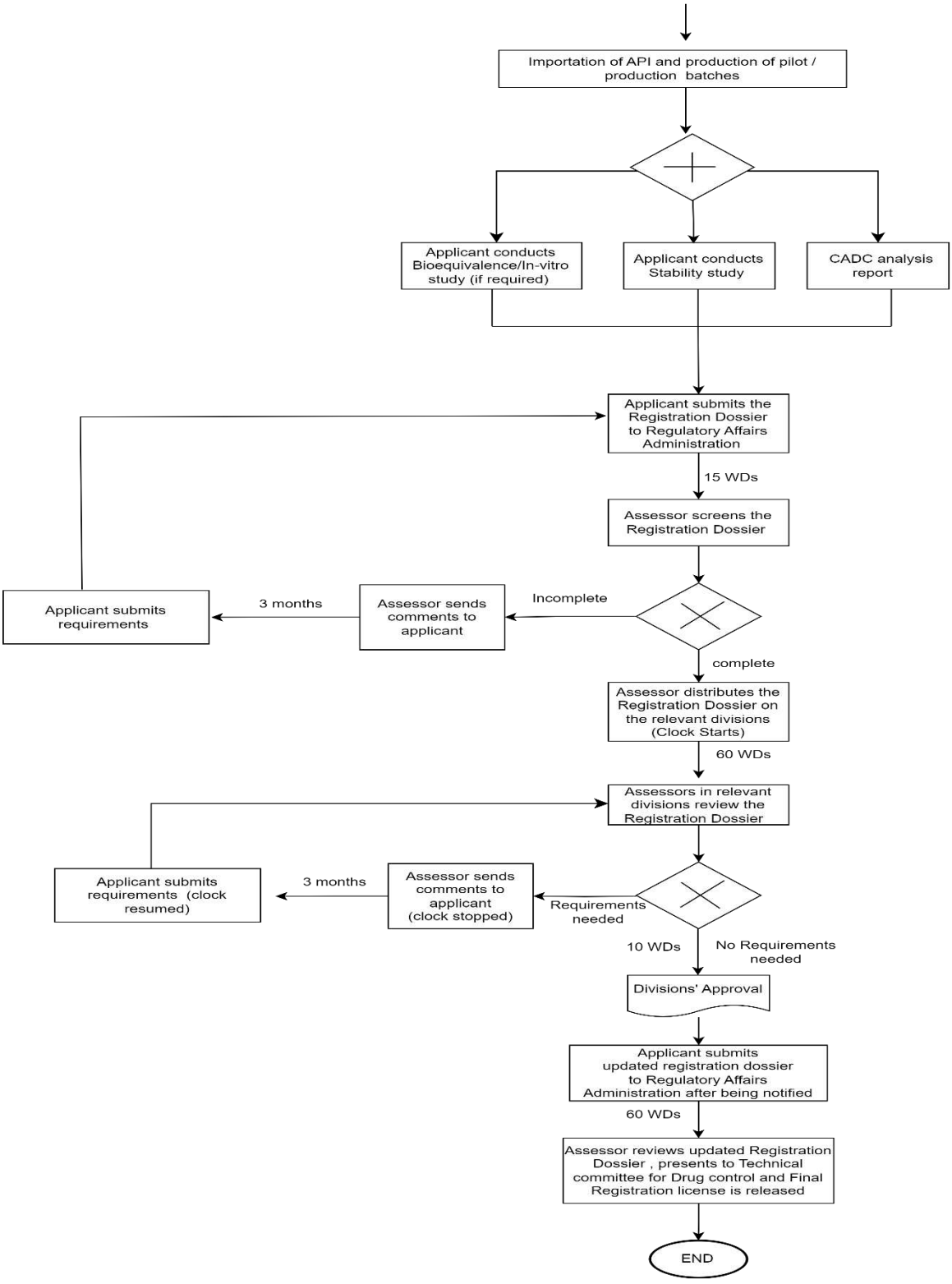
- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval.
  - Applicant has to submit the Registration Dossier within 2 months from Registration Request Approval

- EDA Time:
  Application & screening= 32 WDs, Registration Dossier = 65 WDs
  Target Assessment Time= maximum 97 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

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

EDA Chairman Decree (450/2023) Case II- Track C Flowchart for Locally Manufactured Non-Reference Products with assessment timelines

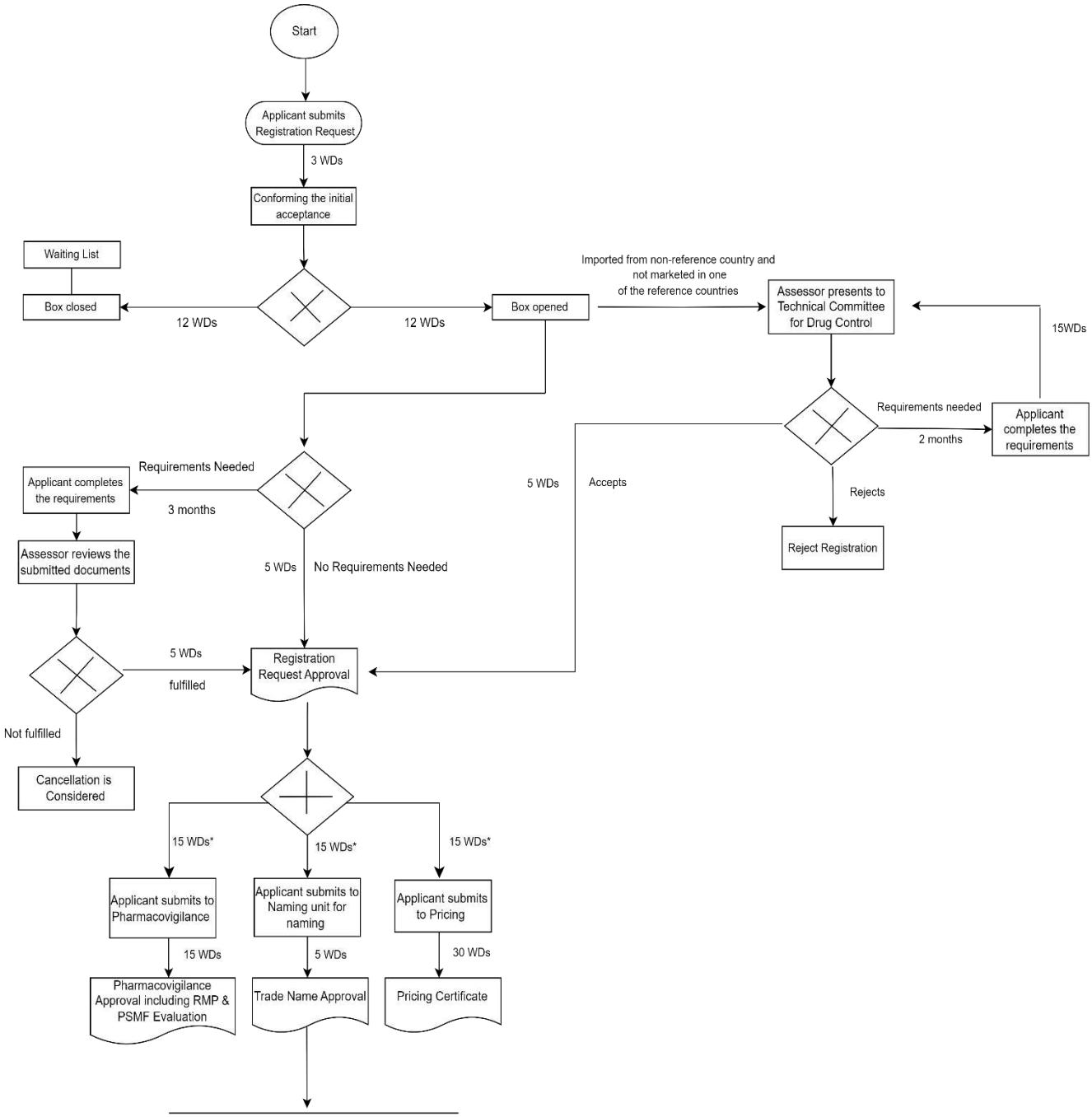



Importation of API and production of pilot / production batches
Applicant conducts Bioequivalence/In-vitro study (if required)
Applicant conducts Stability study
CADC analysis report
Applicant submits the Registration Dossier to Regulatory Affairs Administration
15 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
3 months
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
Assessor sends comments to applicant (clock stopped)
3 months
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approval
Applicant submits updated registration dossier to Regulatory Affairs Administration after being notified
60 WDs
Assessor reviews updated Registration Dossier , presents to Technical committee for Drug control and Final Registration license is released
END

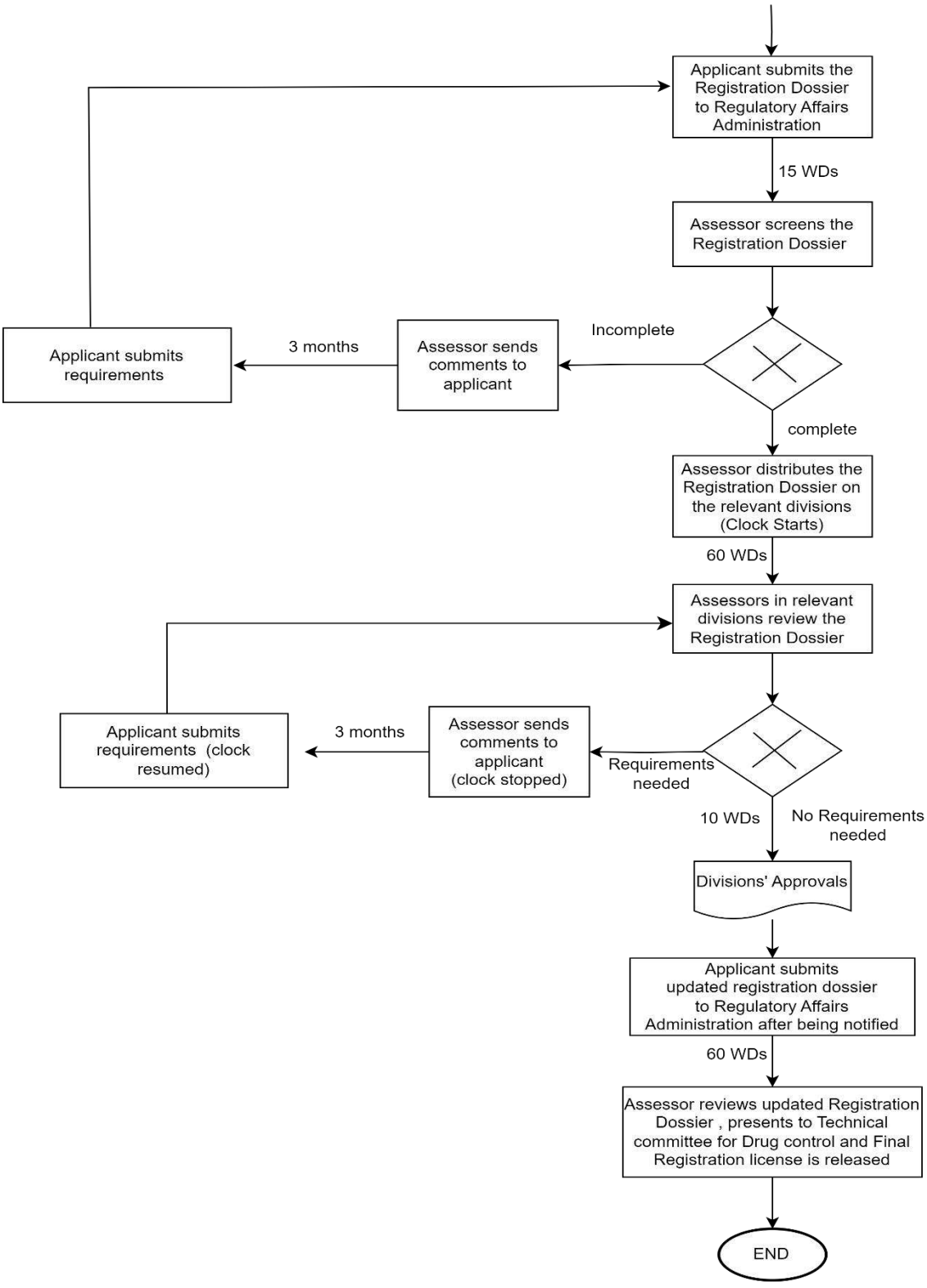
- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from Specialized Scientific evaluation committee.
  - Applicant has to submit the Registration Dossier within 33 WDs from date of first pricing certificate.
- EDA Time:
  Application & screening= 96 WDs, Registration Dossier = 130 WDs
  Target Assessment Time= maximum 226 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

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

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



Notice to applicant

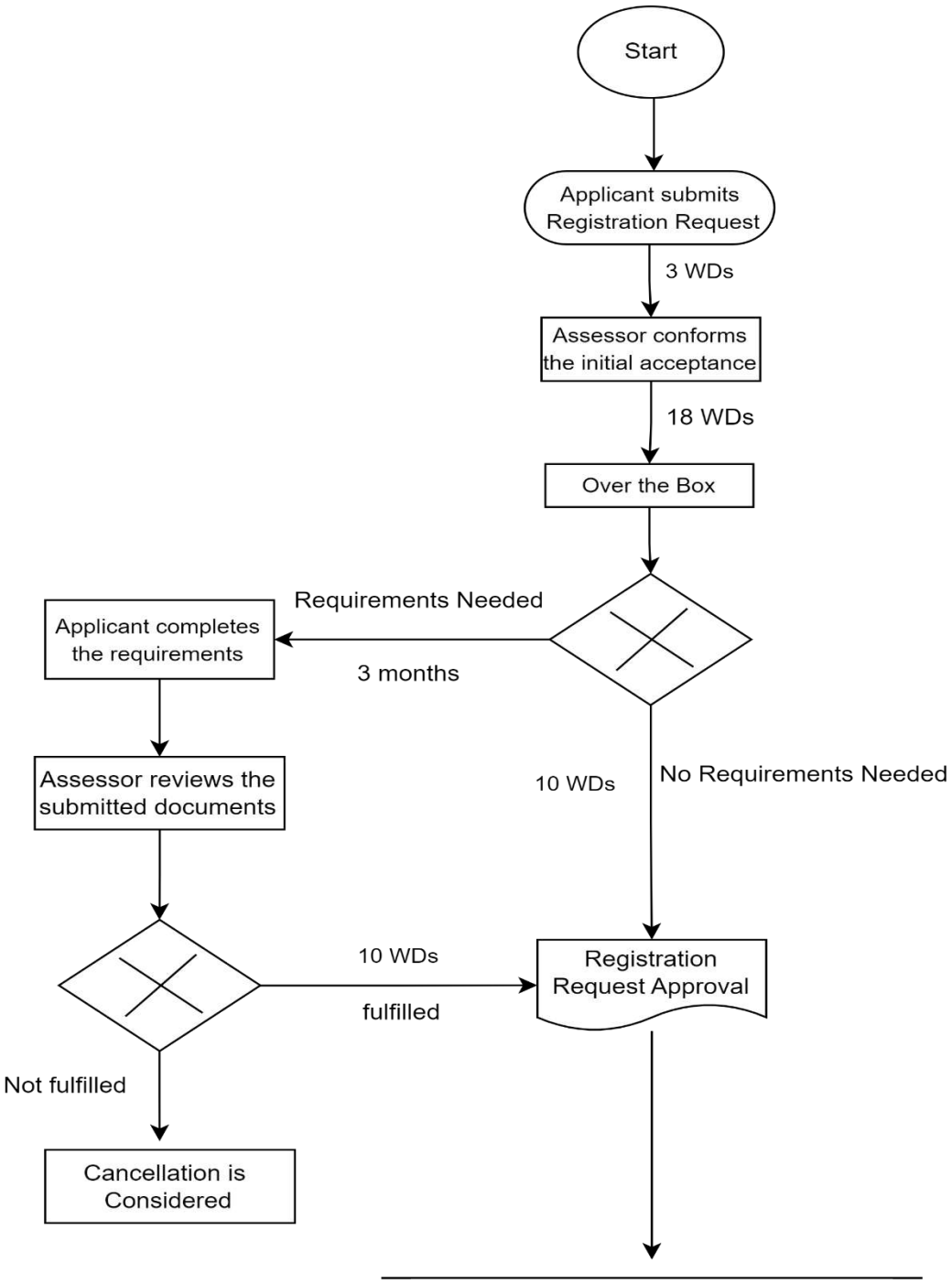


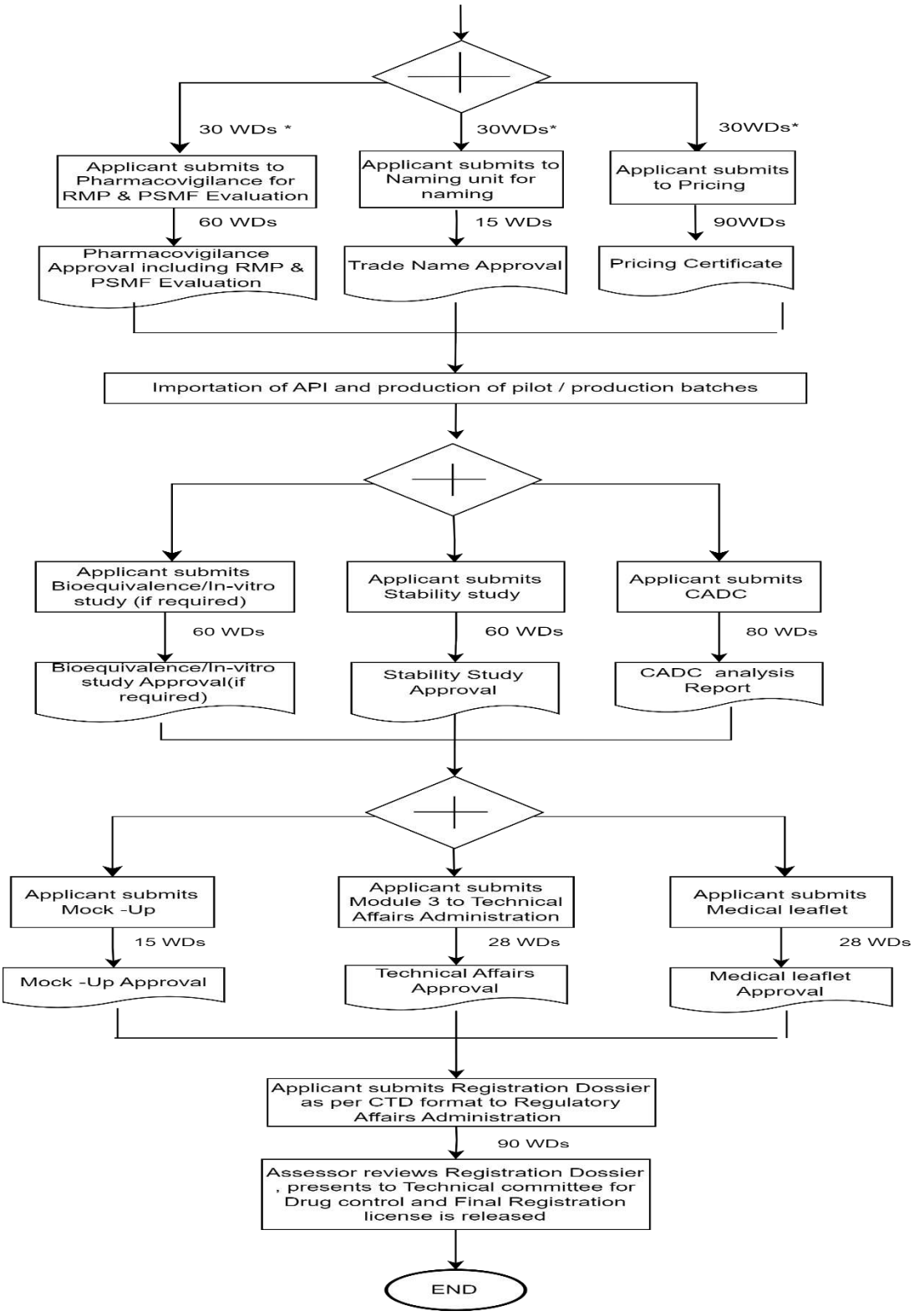
- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval.
  - Applicant has to submit the Registration Dossier within 2 months from Registration Request Approval

- EDA Time:
  Application & screening= 40 WDs, Registration Dossier = 130 WDs
  Target Assessment Time= maximum 170 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

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

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

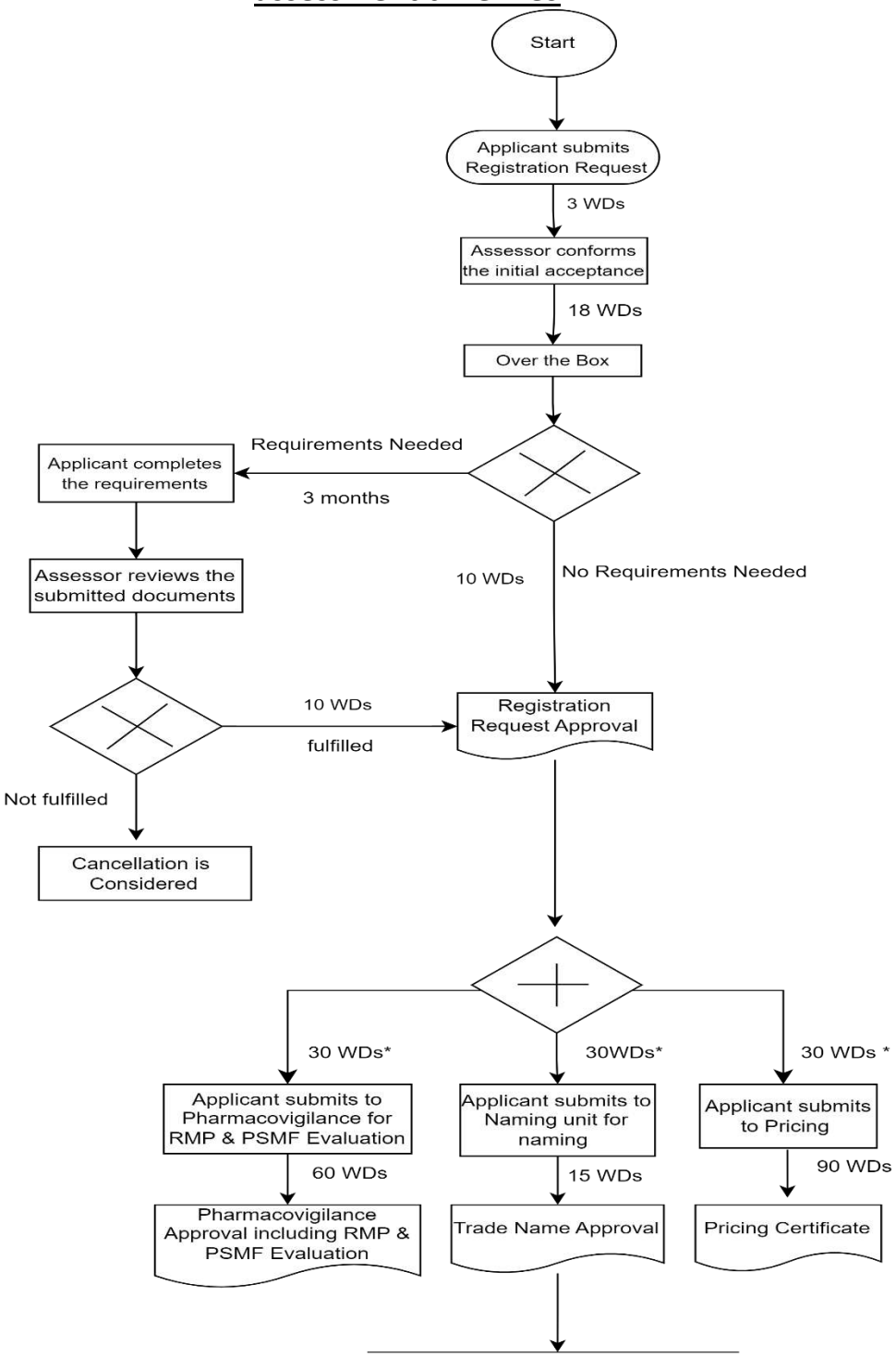


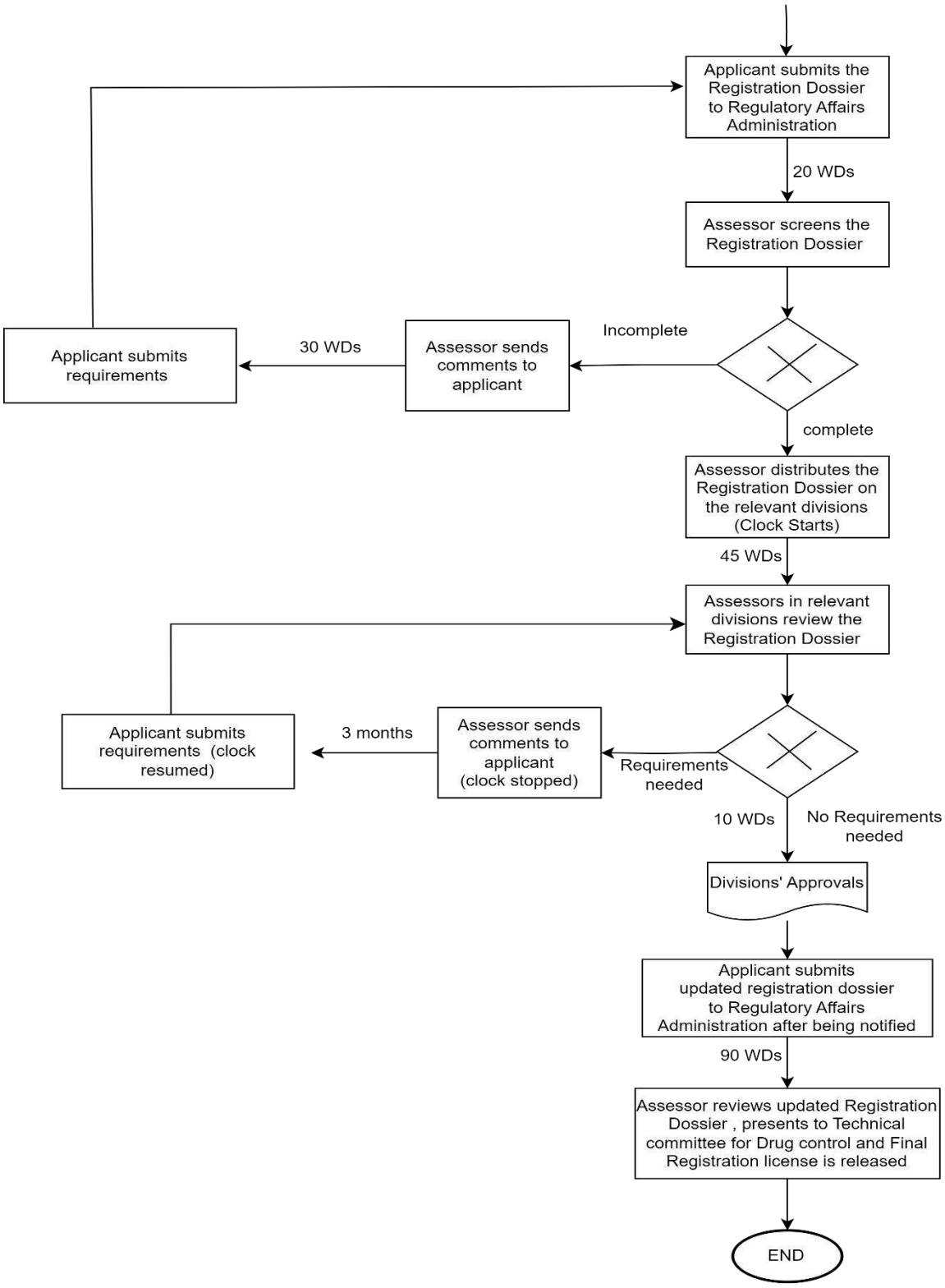

30 WDs *
30WDs*
30WDs*
Applicant submits to Pharmacovigilance for RMP & PSMF Evaluation
Applicant submits to Naming unit for naming
Applicant submits to Pricing
60 WDs
15 WDs
90WDs
Pharmacovigilance Approval including RMP & PSMF Evaluation
Trade Name Approval
Pricing Certificate
Importation of API and 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 Registration Dossier as per CTD format to Regulatory Affairs Administration
90 WDs
Assessor reviews Registration Dossier , presents 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 Registration Dossier within 33 months (except Track A: 21 months) from date of pharmacovigilance approval or first pricing certificate whichever is the latest.
- EDA Time:
  Application = 31WD, Rolling submission = 198WD, Registration Dossier = 90WD
  Target Assessment Time= maximum 319 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

- 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) Case III- Flowchart for Imported Products with assessment timelines

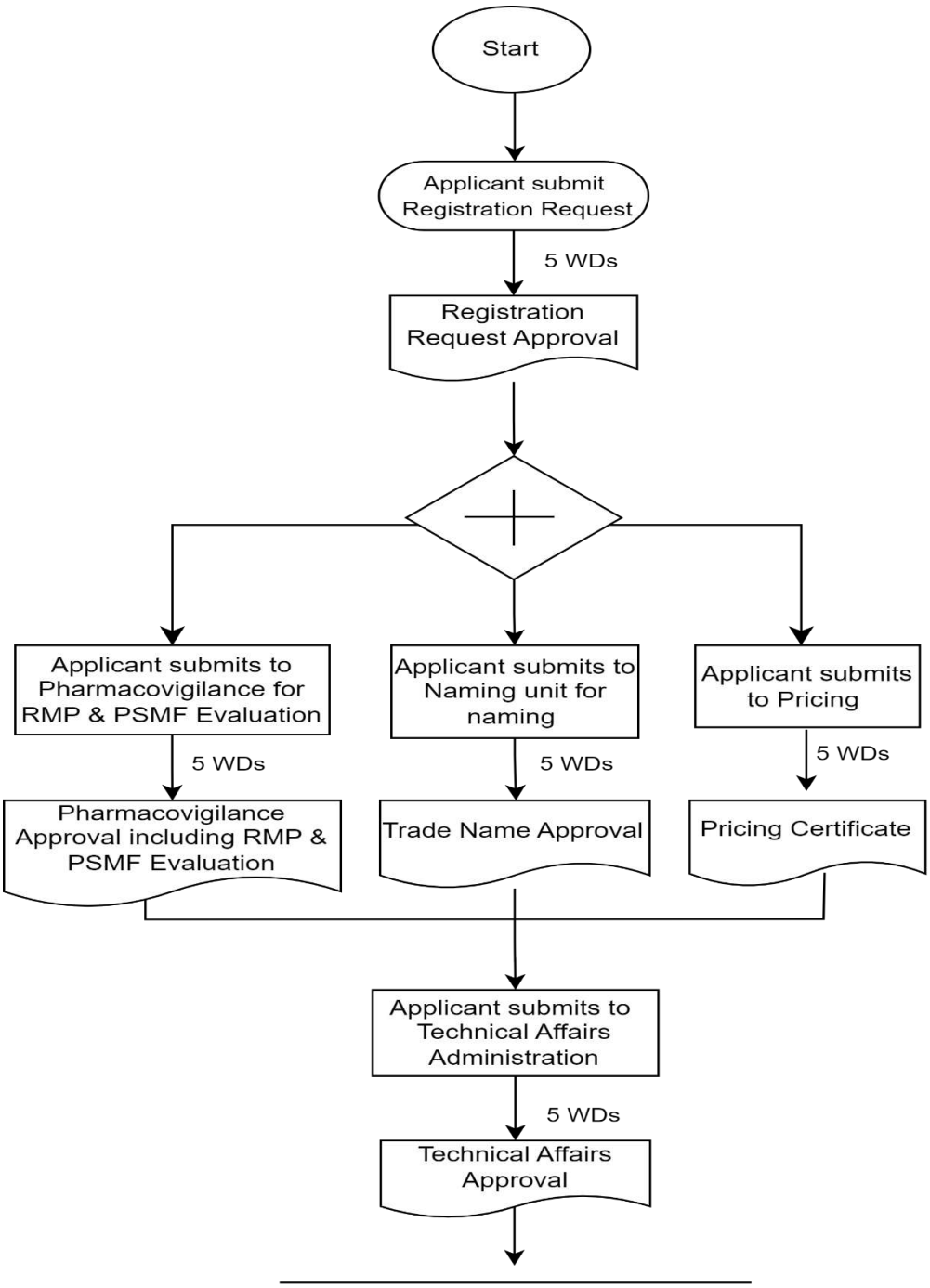


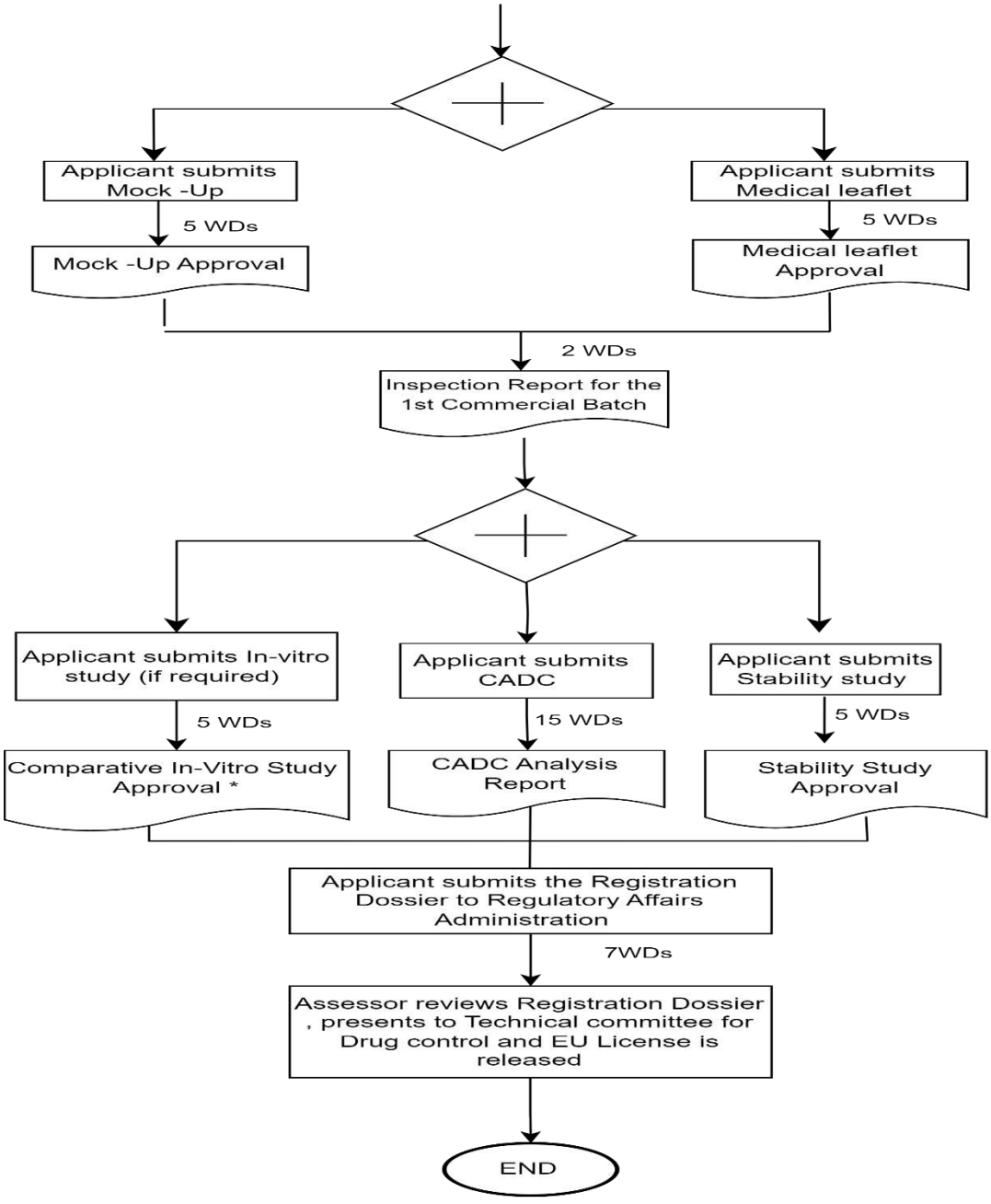

Applicant submits the Registration Dossier to Regulatory Affairs Administration
20 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
30 WDs
Applicant submits requirements
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
45 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 registration dossier to Regulatory Affairs Administration after being notified
90 WDs
Assessor reviews updated Registration Dossier , presents 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 Registration Dossier within 6 months from date of pharmacovigilance approval or first pricing certificate whichever is the latest.
- EDA Time:
  Application & screening = 141 WDs, Registration Dossier = 145 WDs
  Target Assessment Time= maximum 286 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

- In case of importation from reference country, Applicant may import and analyze the product (CADC lab analysis) before issuing MA.
- The declared working days are the maximum time needed for the process to be completed.

Emergency Use Approval of Locally Manufactured Products Flowchart with assessment timelines

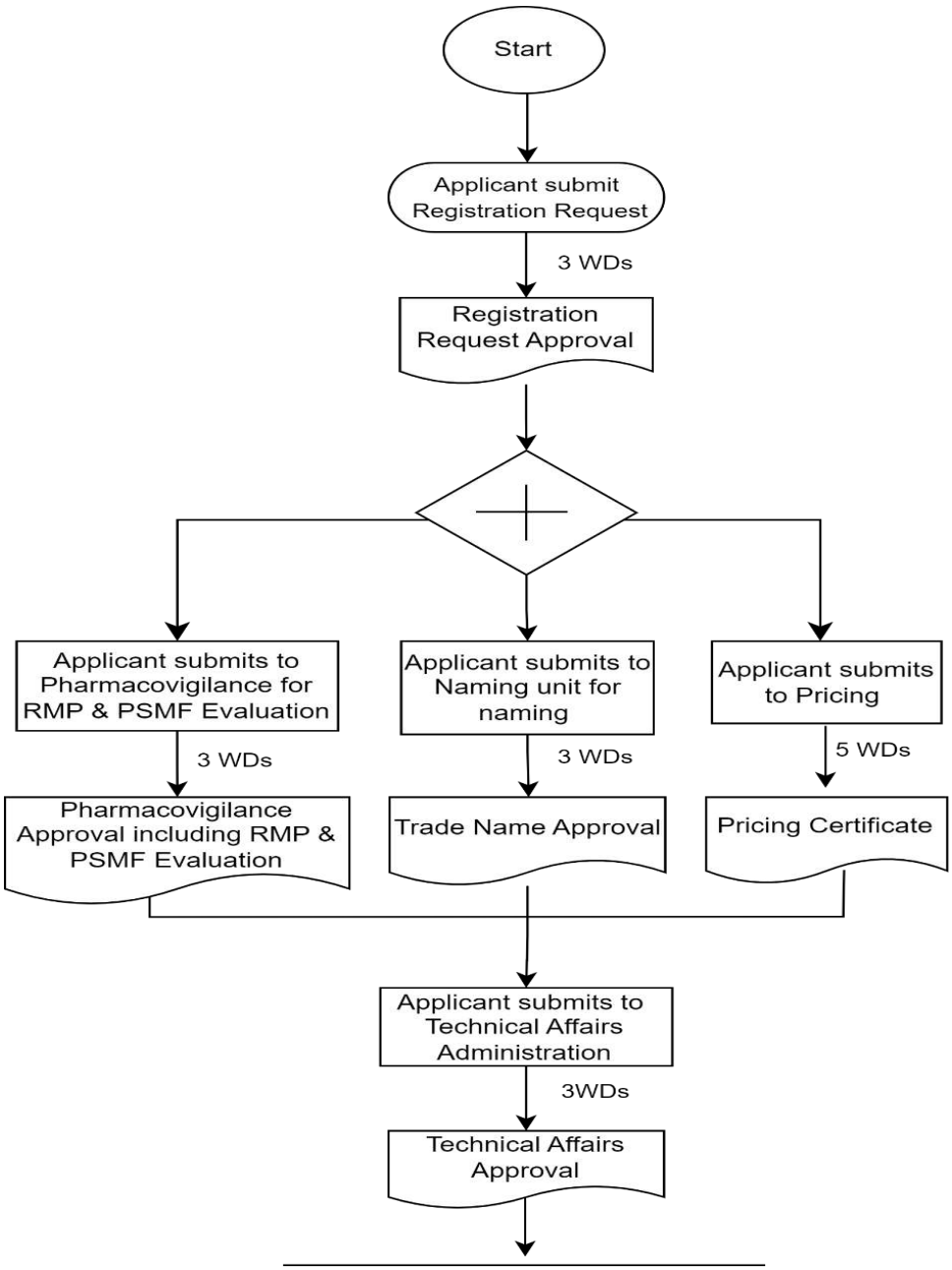


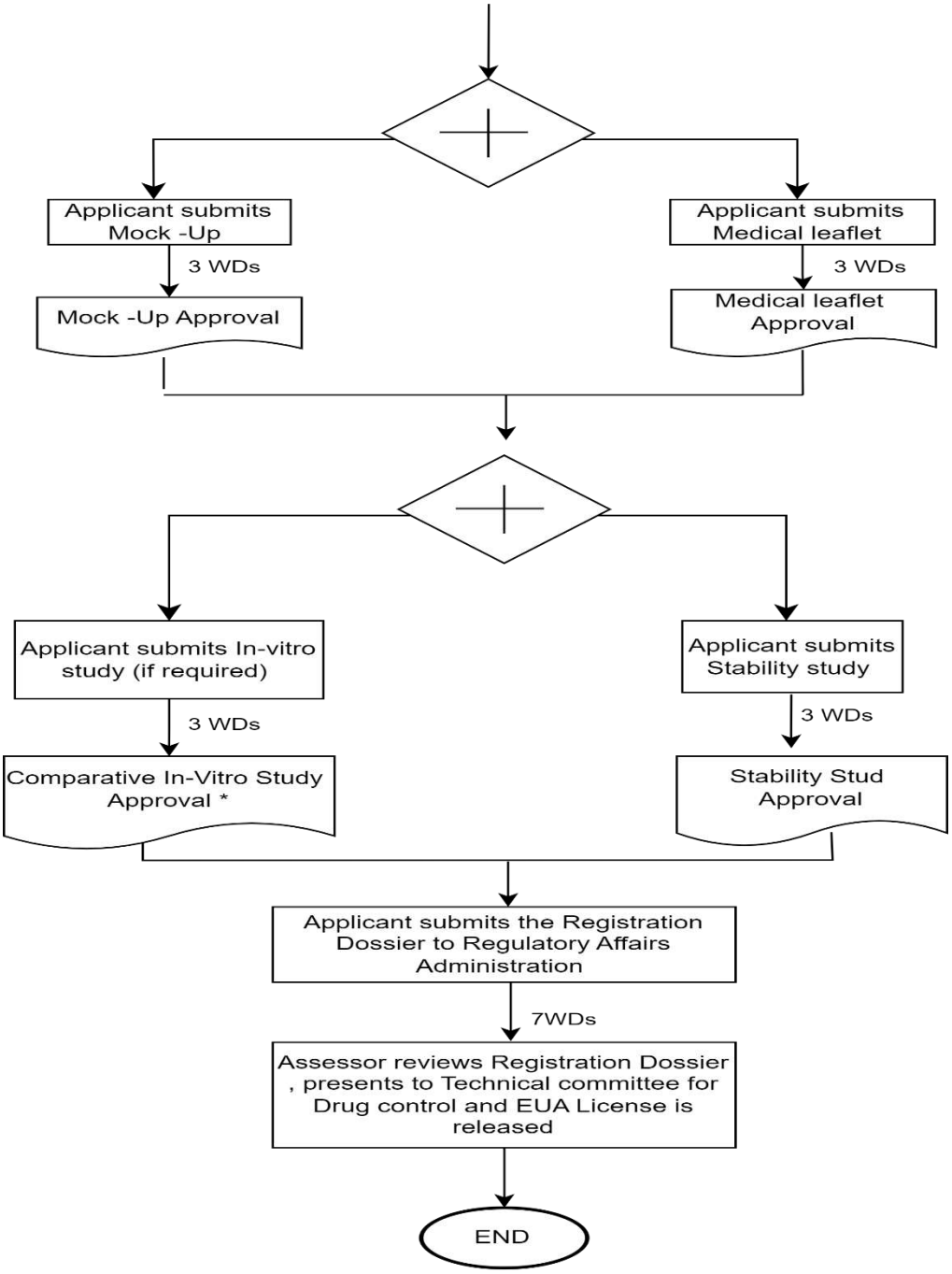


- Assessment timelines start from receiving complete files from applicants
- Total Assessment Timeline = maximum 44 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

*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).

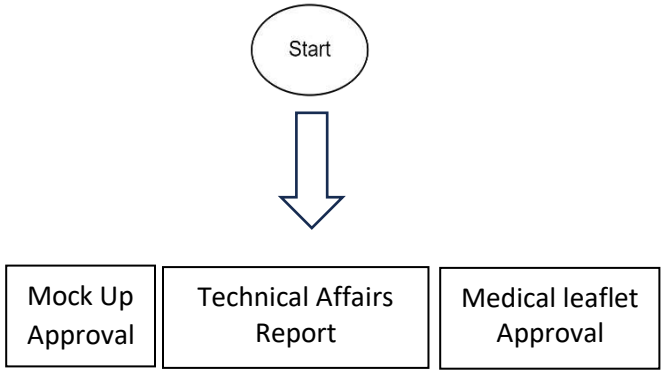
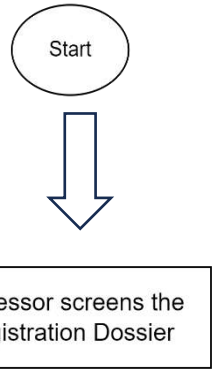
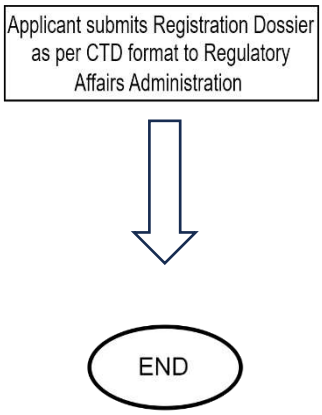
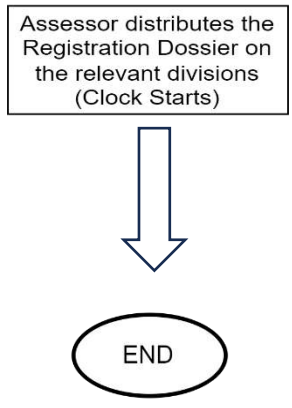
*Bioequivalence study approval is a condition for the commercial batch release (if applicable)

Abbreviations:

- RMP: Risk Management Plan
- PSMF: Pharmacovigilance System Master File
- WD: Working Days

General Notes:

Timeline Calculation:

Rolling Submission	One Submission
Application & rolling submission = 	**Application & Screening =** 
Registration Dossier = 	**Registration Dossier =** 

EDA Timeframe:

EDA timeframe is from **START** to **END** (without consideration of the time required for preparation of applicant's responses to requests).

EDA Timeframe		
	Local	Imported
Case I		
	Reference	
	319 WDs	286 WDs
	Non- Reference	
	379 WDs	331 WDs
Case II		
Track A		39 WDs
Track B		66 WDs
Track C	Reference	
	193 WDs	97 WDs
	Non- Reference	
	226 WDs	170 WDs
Case III		
	Reference	
	319 WDs	286 WDs
Emergency		
	44 WDs	24 WDs

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)