Notice to applicant

Flowcharts for
EDA Chairman Decree 450 for the year 2023

Year 2024

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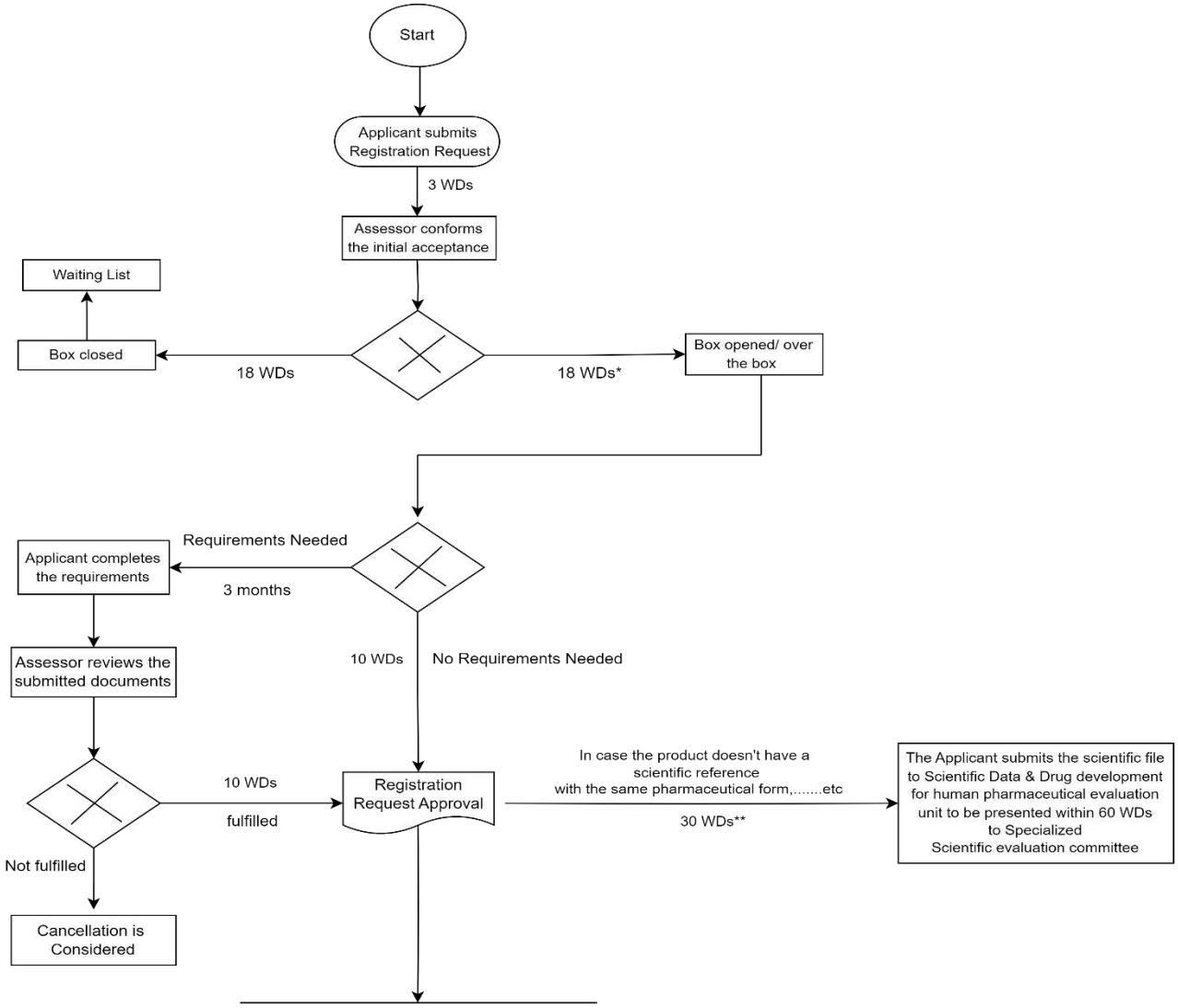
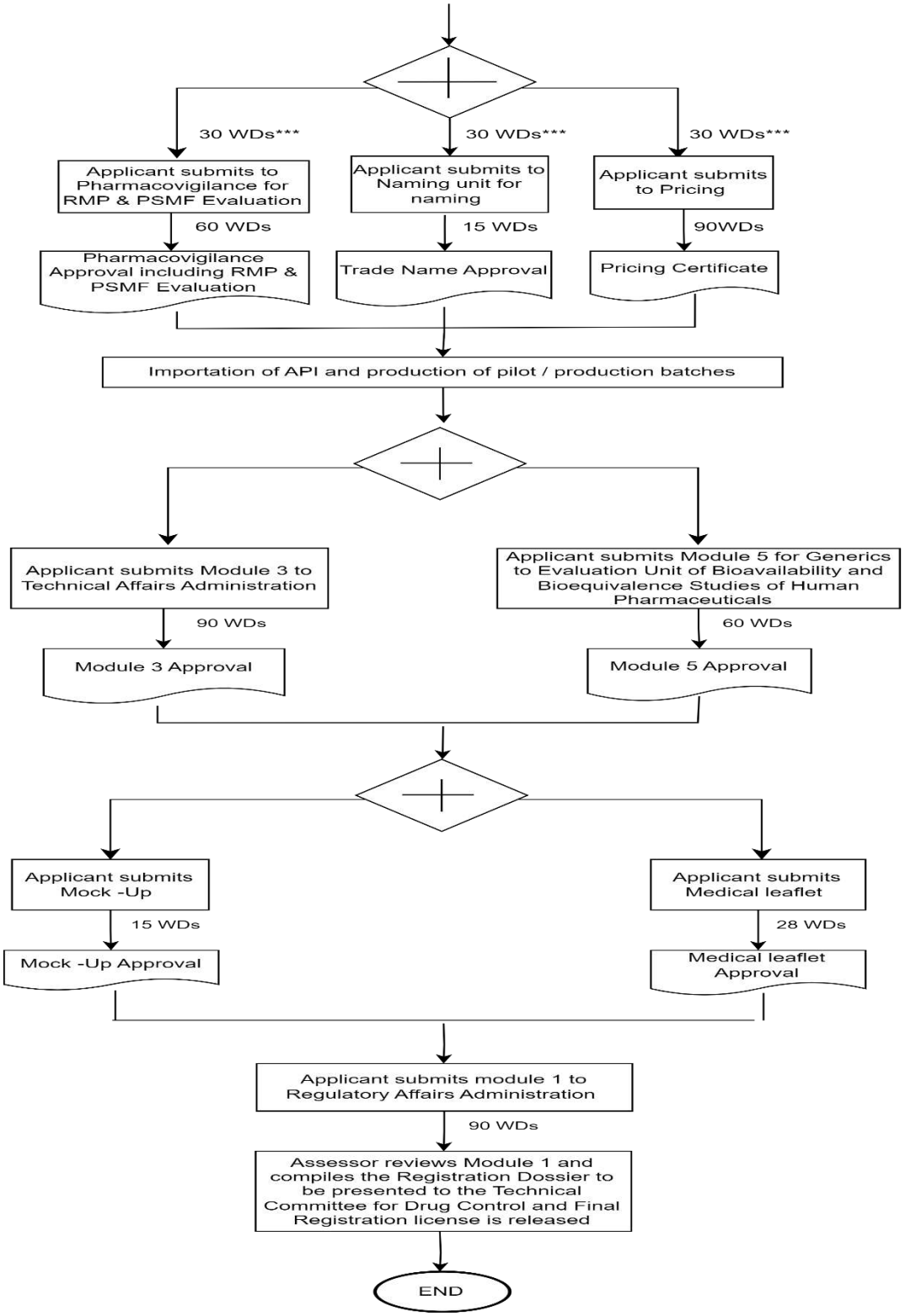
EDA Chairman Decree (450/2023) Flowchart for Locally Manufactured Generic Products with assessment timelines




30 WDs***
30 WDs***
30 WDs***
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 Module 3 to Technical Affairs Administration
Applicant submits Module 5 for Generics to Evaluation Unit of Bioavailability and Bioequivalence Studies of Human Pharmaceuticals
90 WDs
60 WDs
Module 3 Approval
Module 5 Approval
Applicant submits Mock -Up
Applicant submits Medical leaflet
15 WDs
28 WDs
Mock -Up Approval
Medical leaflet Approval
Applicant submits module 1 to Regulatory Affairs Administration
90 WDs
Assessor reviews Module 1 and compiles the Registration Dossier to be presented to the Technical Committee for Drug Control and Final Registration license is released
END

- Notes:

*In case of locally manufactured human pharmaceutical products intended for tender and export or for export only, the company shall be notified of the status of the product from the Box **within 15 working days** from the date of receiving the fulfilled and correct registration request.

- 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 **and** within 33 months from registration request approval (or from Specialized Scientific evaluation committee approval) in case of products registered for Export only.

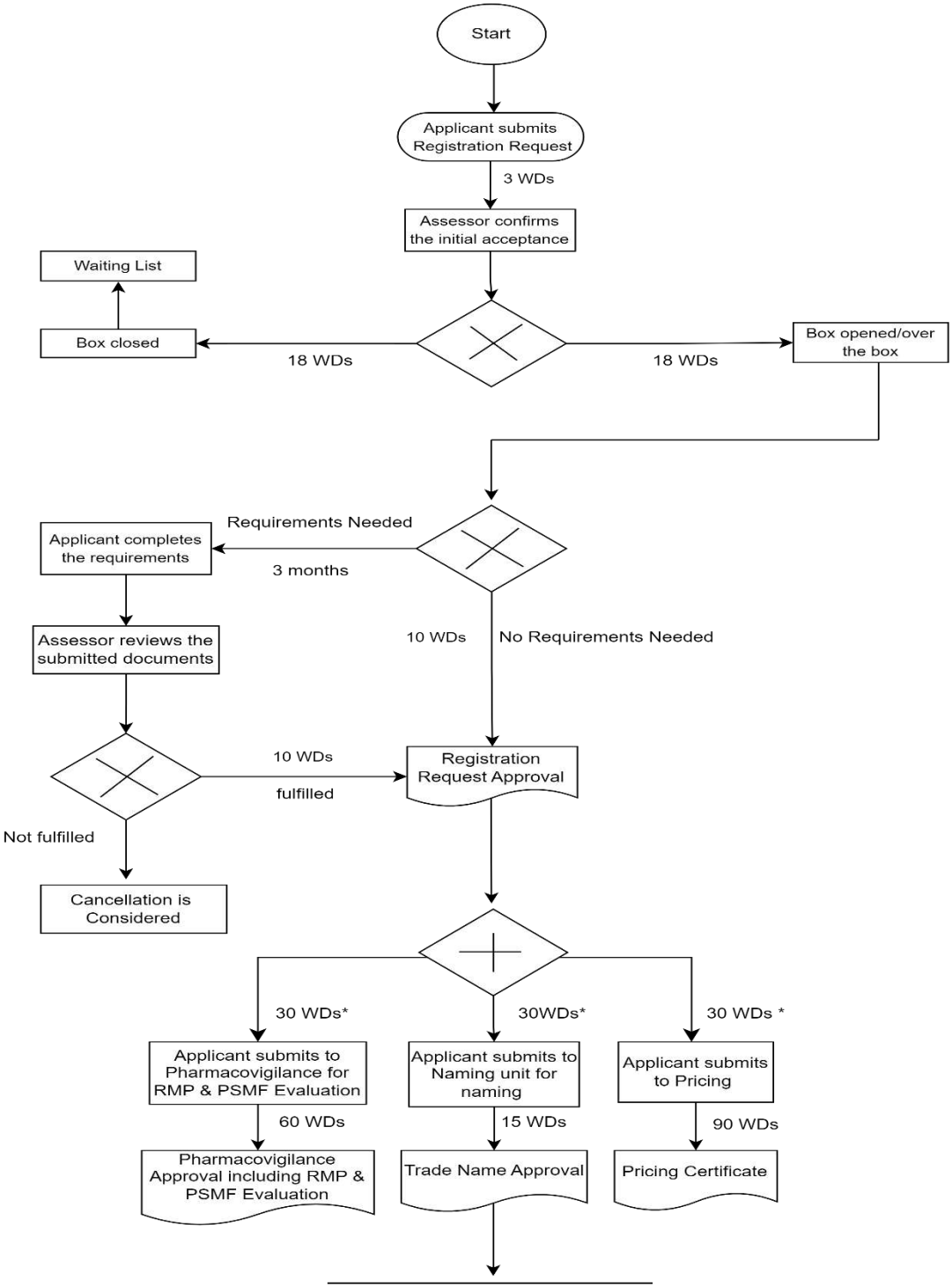
- The declared working days are the maximum time needed for the process to be completed.

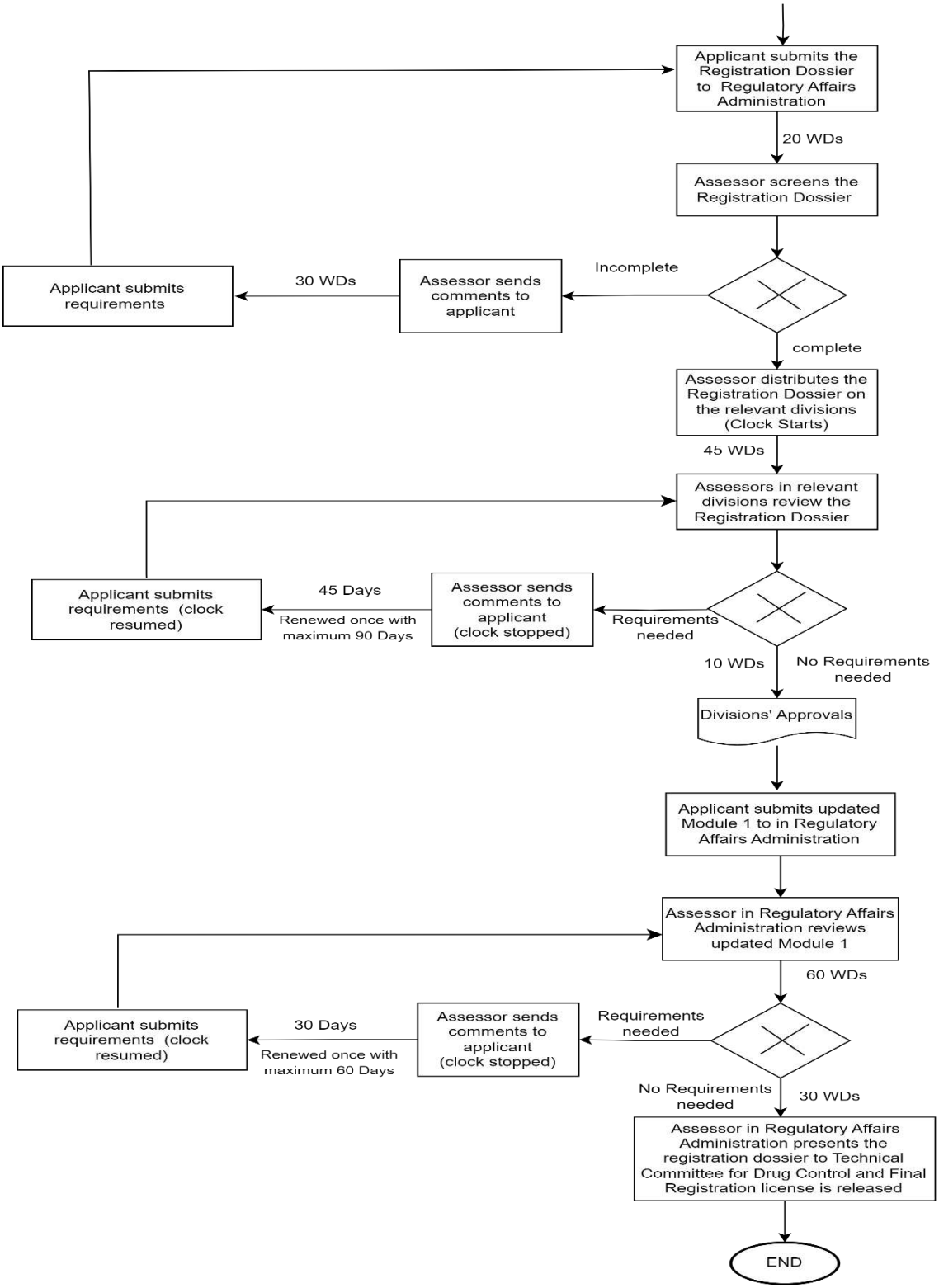
- Applicant Time:

**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).

EDA Chairman Decree (450/2023) Flowchart for Imported Products marketed in one of SRAs or WHO-Prequalified 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)
45 Days
Renewed once with maximum 90 Days
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approvals
Applicant submits updated Module 1 to in Regulatory Affairs Administration
Assessor in Regulatory Affairs Administration reviews updated Module 1
60 WDs
Requirements needed
Assessor sends comments to applicant (clock stopped)
30 Days
Renewed once with maximum 60 Days
Applicant submits requirements (clock resumed)
No Requirements needed
30 WDs
Assessor in Regulatory Affairs Administration presents the registration dossier to Technical Committee for Drug Control and Final Registration license is released
END

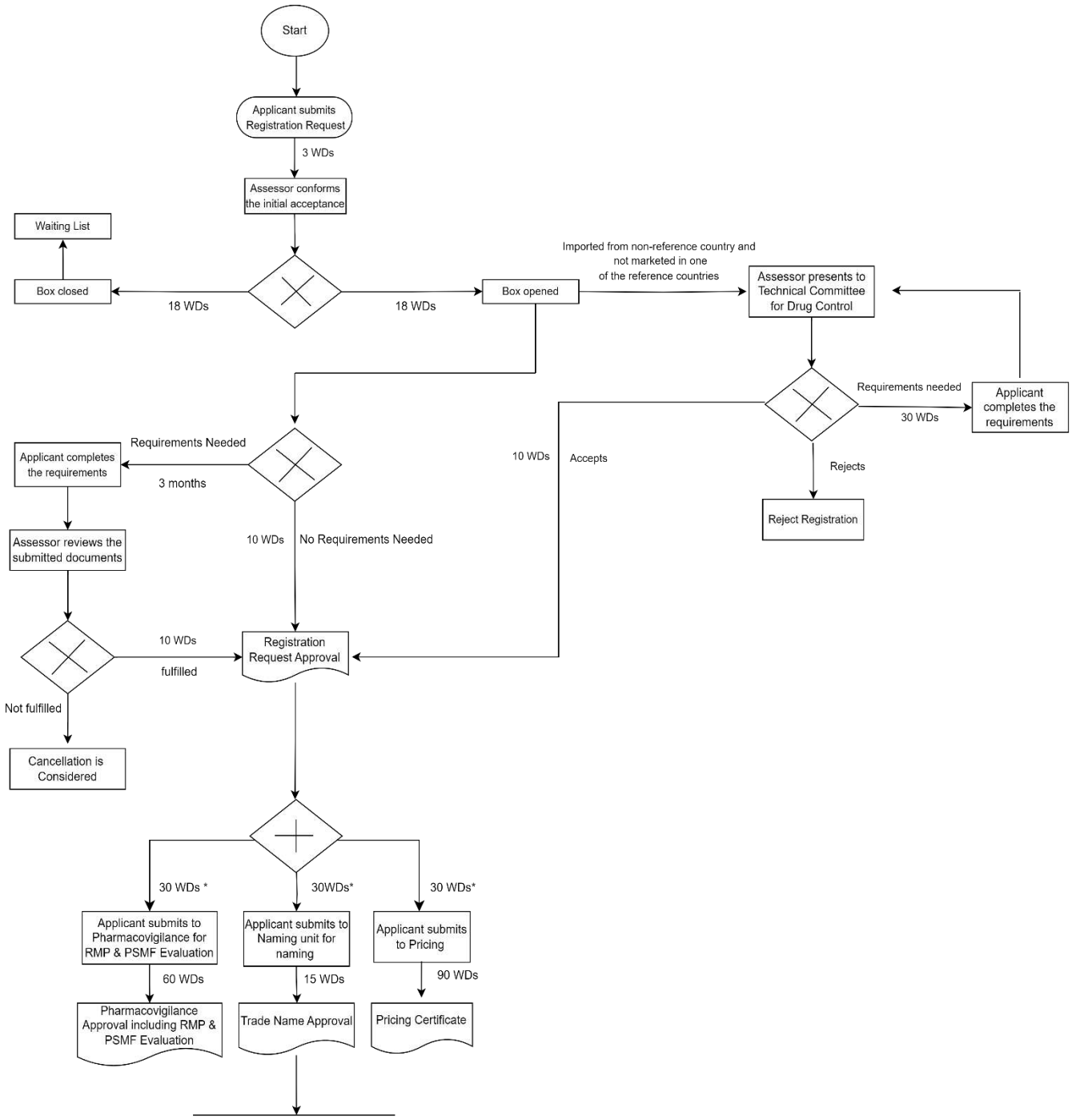
- Applicant Time:

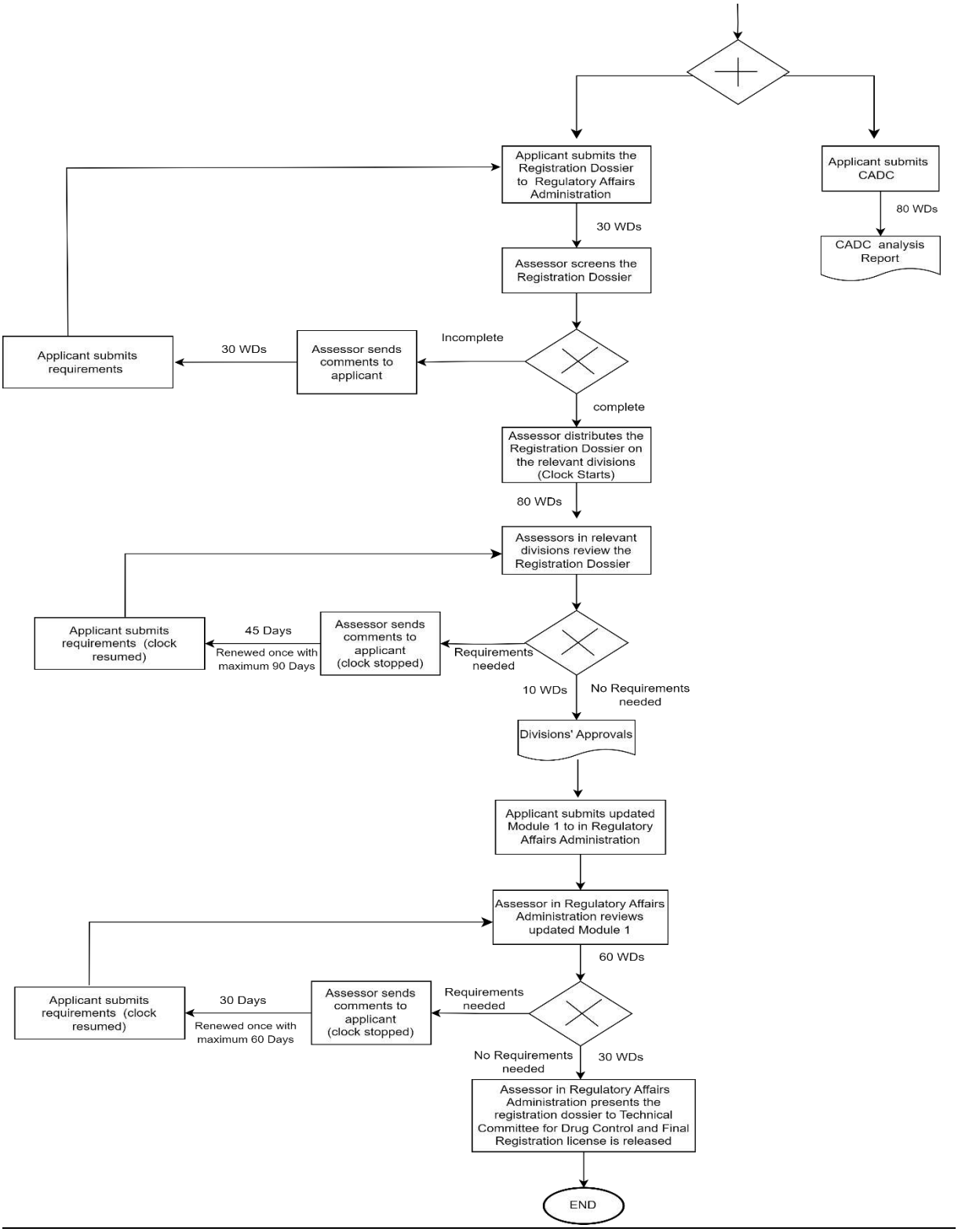
  * Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from registration request approval

  - 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 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)
45 Days
Renewed once with maximum 90 Days
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approvals
Applicant submits updated Module 1 to in Regulatory Affairs Administration
Assessor in Regulatory Affairs Administration reviews updated Module 1
60 WDs
Requirements needed
Assessor sends comments to applicant (clock stopped)
30 Days
Renewed once with maximum 60 Days
Applicant submits requirements (clock resumed)
No Requirements needed
30 WDs
Assessor in Regulatory Affairs Administration presents the registration dossier to Technical Committee for Drug Control and Final Registration license is released
END

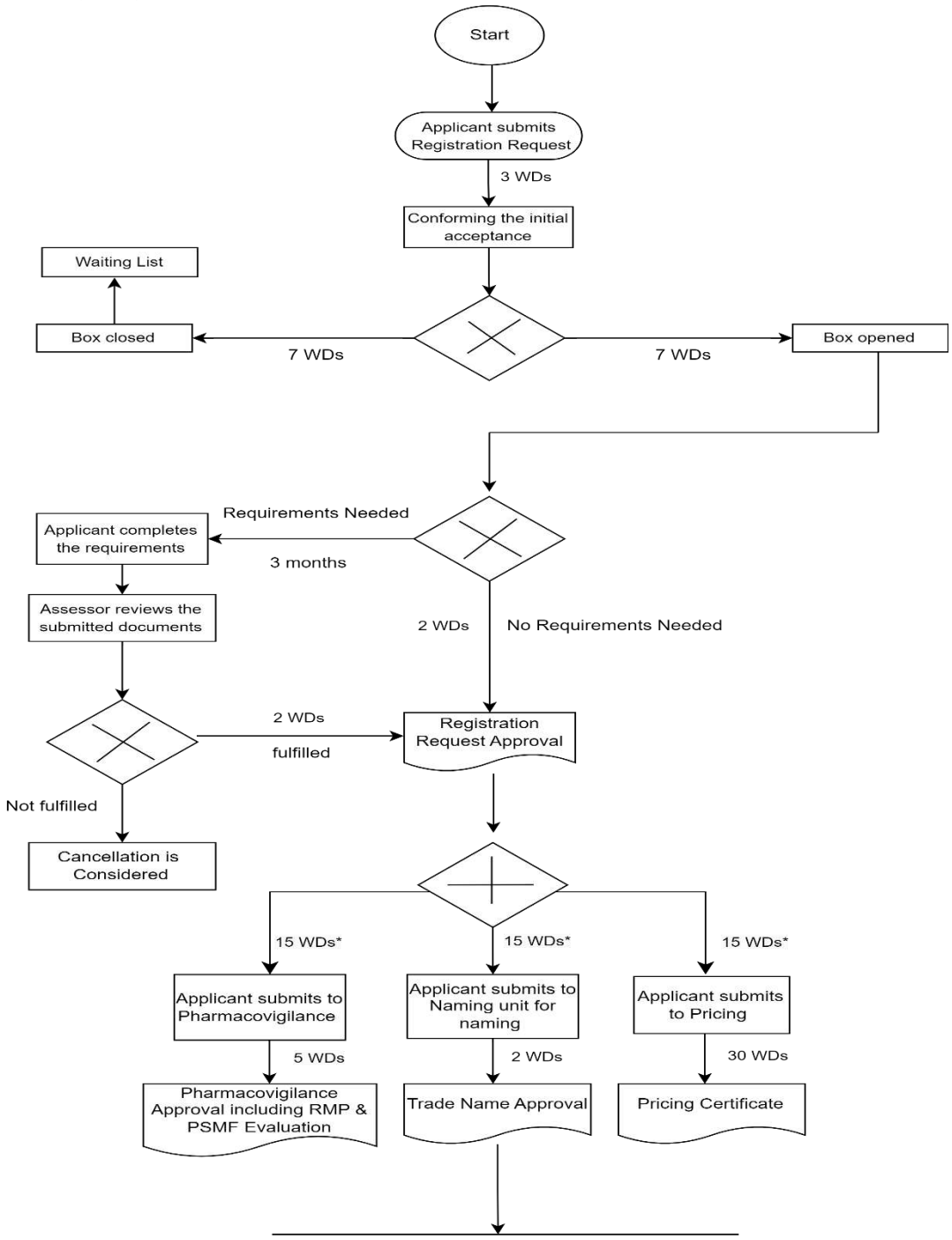
- Applicant Time:

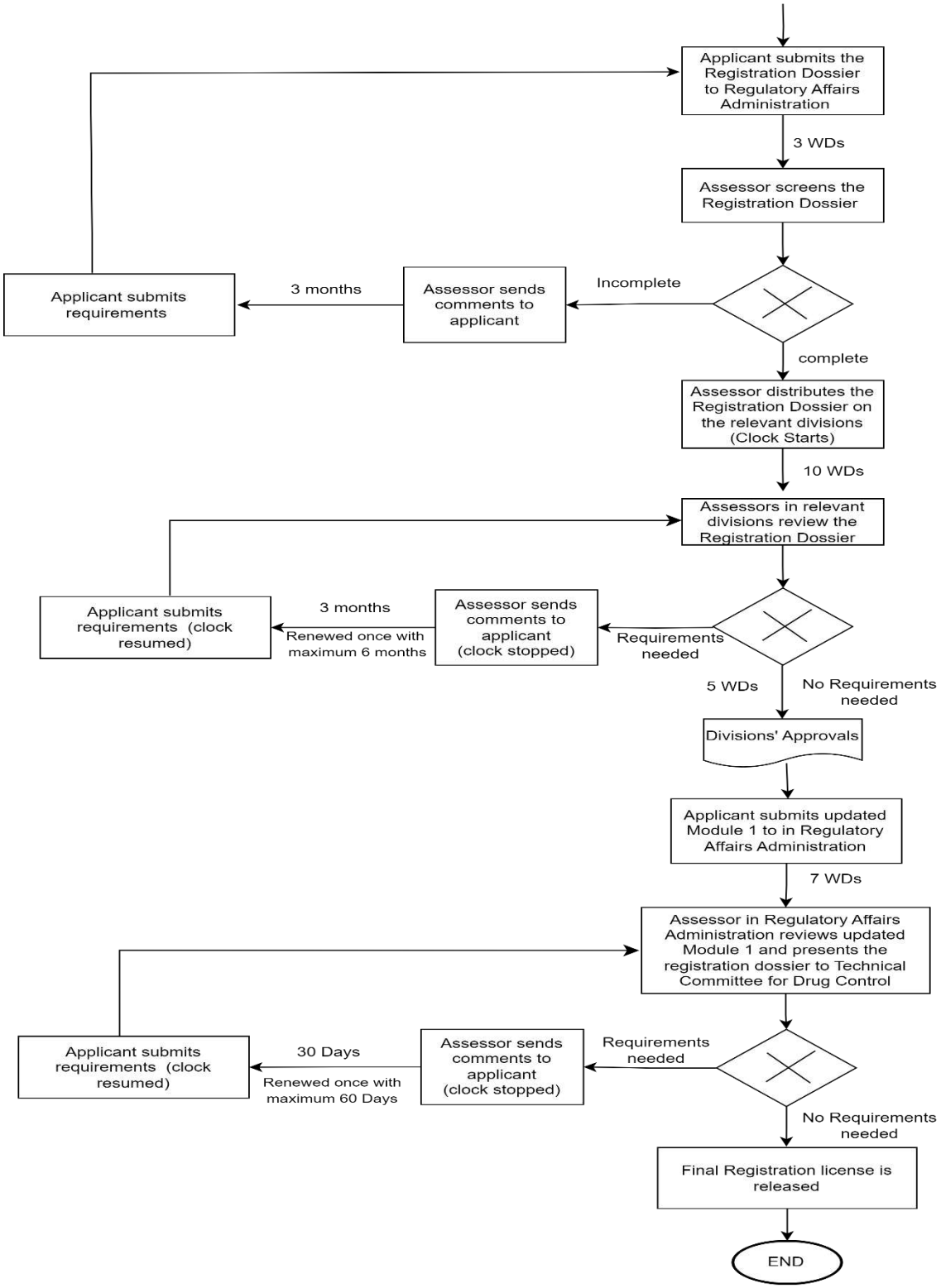
  * Applicant submits to naming unit, pharmacovigilance and pricing within 30 WDs from registration request approval

  - 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)




Applicant submits the Registration Dossier to Regulatory Affairs Administration
3 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)
10 WDs
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor sends comments to applicant (clock stopped)
3 months
Renewed once with maximum 6 months
Applicant submits requirements (clock resumed)
5 WDs
No Requirements needed
Divisions' Approvals
Applicant submits updated Module 1 to in Regulatory Affairs Administration
7 WDs
Assessor in Regulatory Affairs Administration reviews updated Module 1 and presents the registration dossier to Technical Committee for Drug Control
Requirements needed
Assessor sends comments to applicant (clock stopped)
30 Days
Renewed once with maximum 60 Days
Applicant submits requirements (clock resumed)
No Requirements needed
Final Registration license is released
END

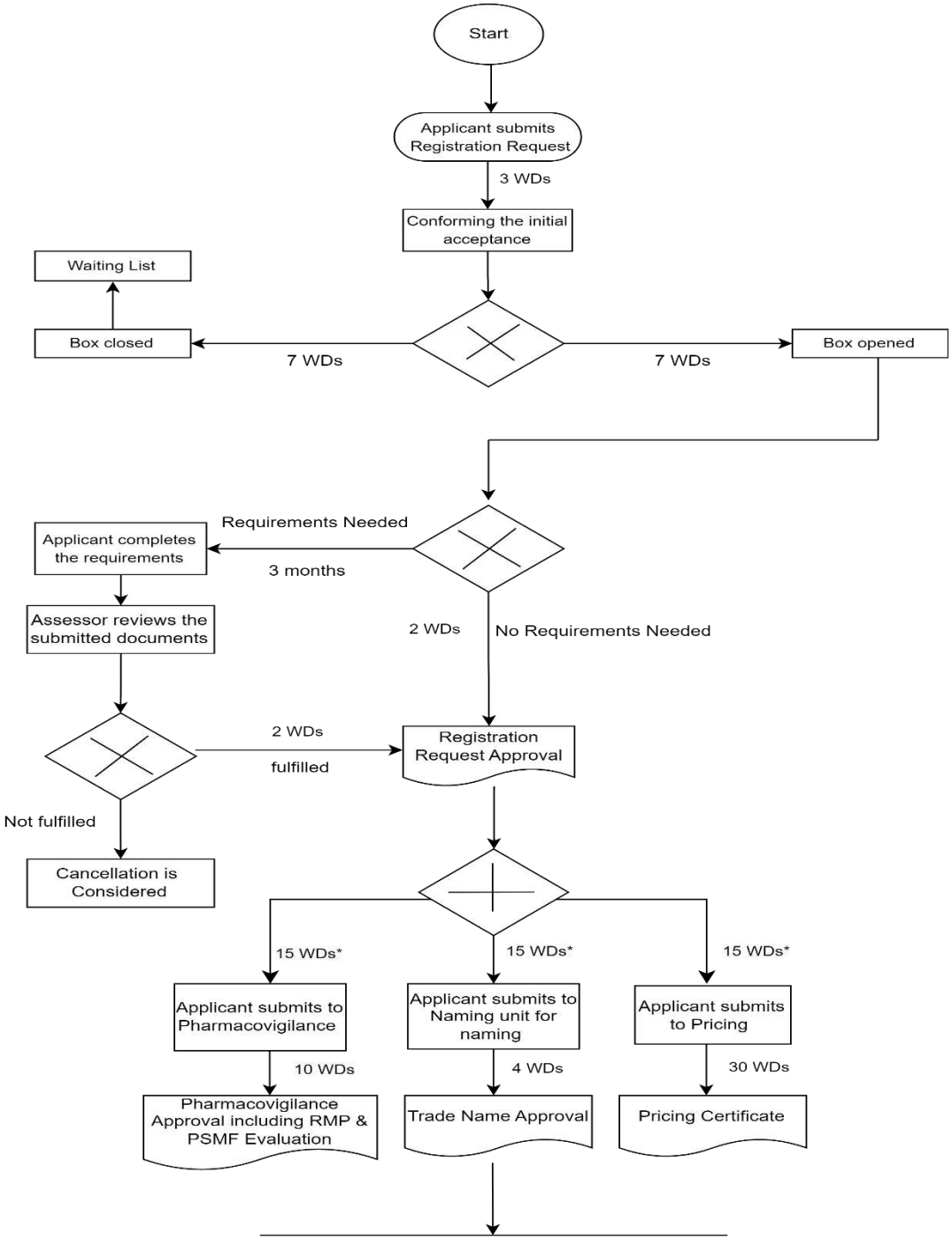
- Applicant Time:

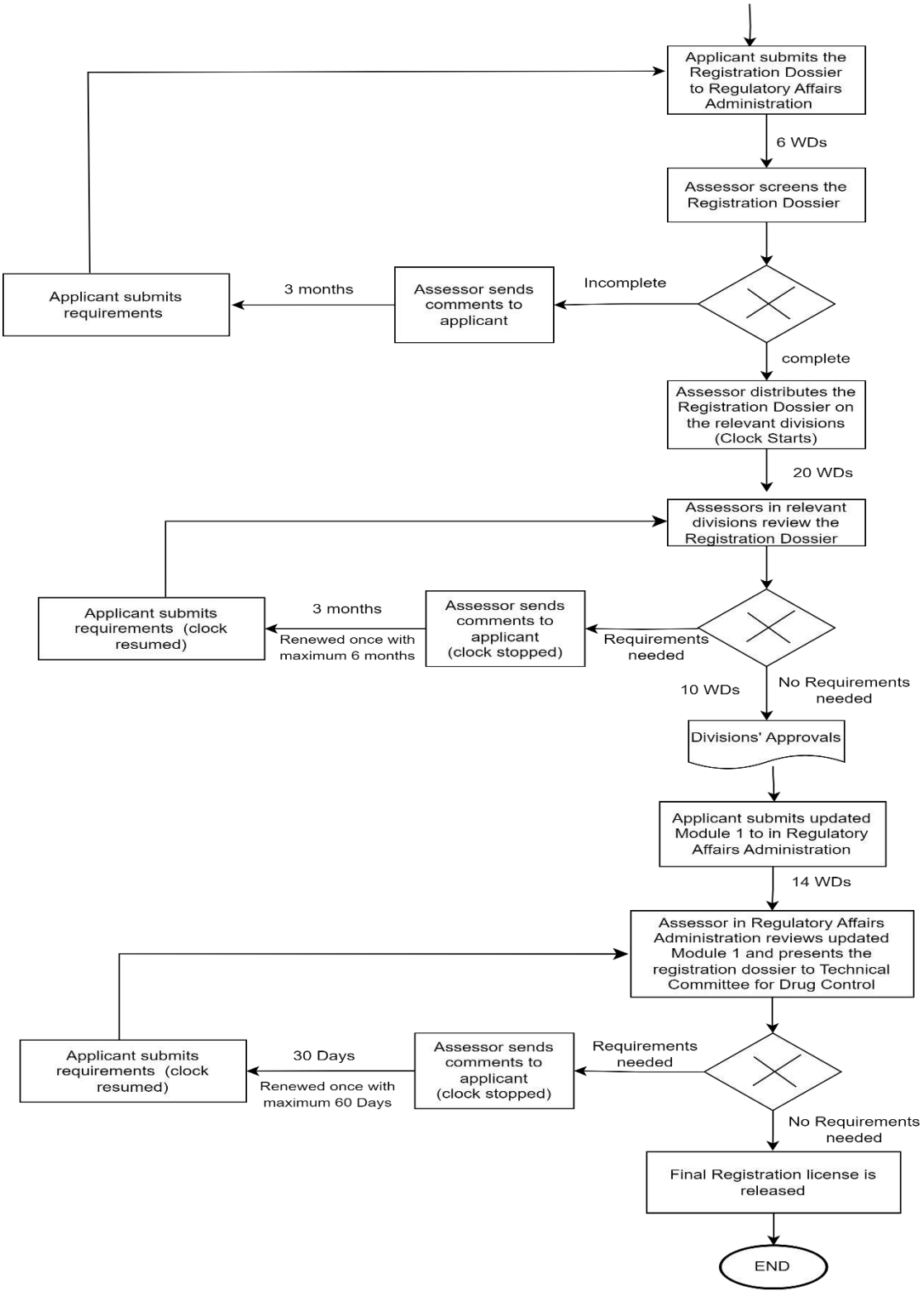
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval

  - Applicant has to submit the Registration Dossier within 30 WD from date of Trade Name 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 submits the Registration Dossier to Regulatory Affairs Administration
6 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)
20 WDs
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor sends comments to applicant (clock stopped)
3 months
Renewed once with maximum 6 months
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approvals
Applicant submits updated Module 1 to in Regulatory Affairs Administration
14 WDs
Assessor in Regulatory Affairs Administration reviews updated Module 1 and presents the registration dossier to Technical Committee for Drug Control
Requirements needed
Assessor sends comments to applicant (clock stopped)
30 Days
Renewed once with maximum 60 Days
Applicant submits requirements (clock resumed)
No Requirements needed
Final Registration license is released
END

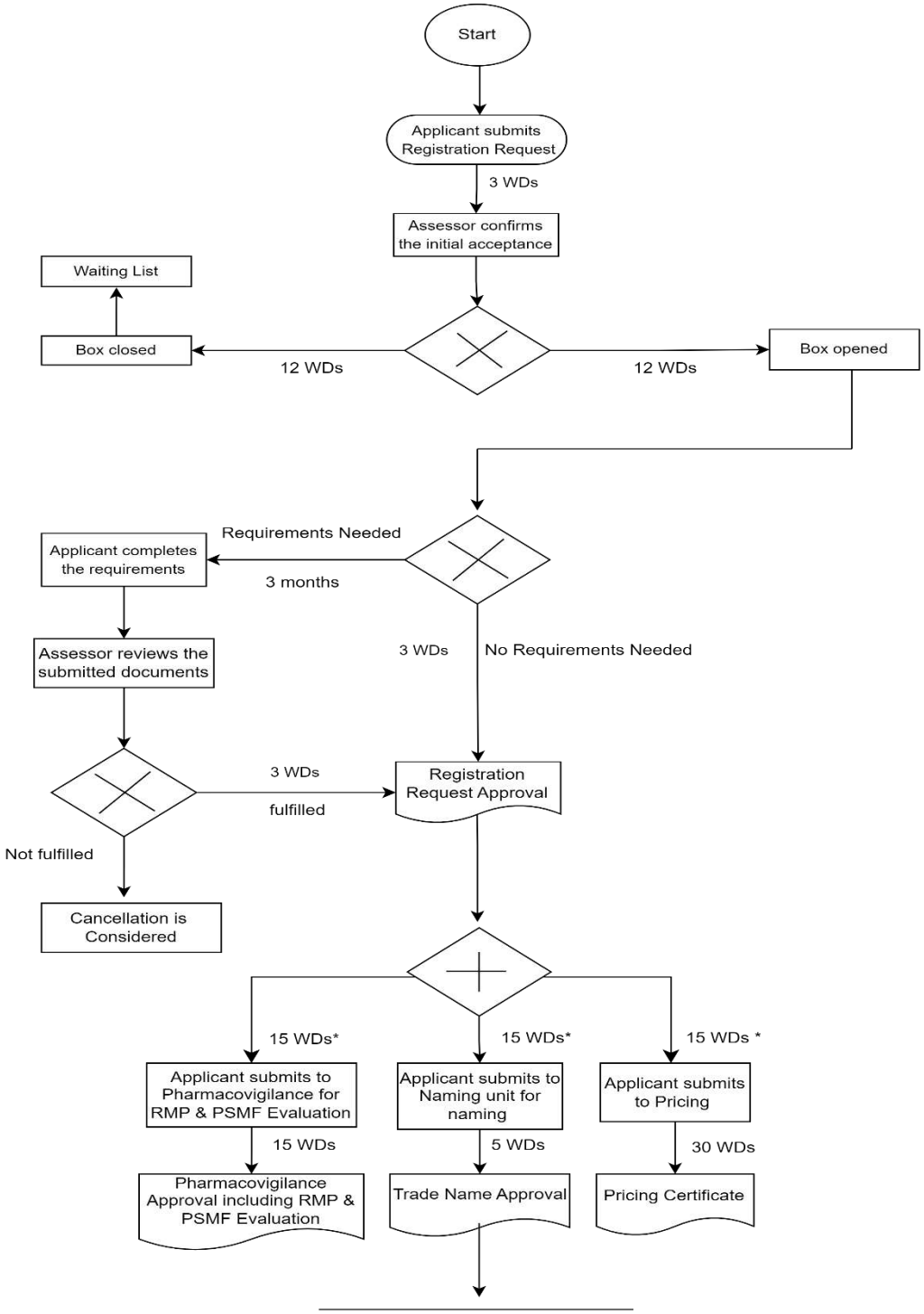
- Applicant Time:

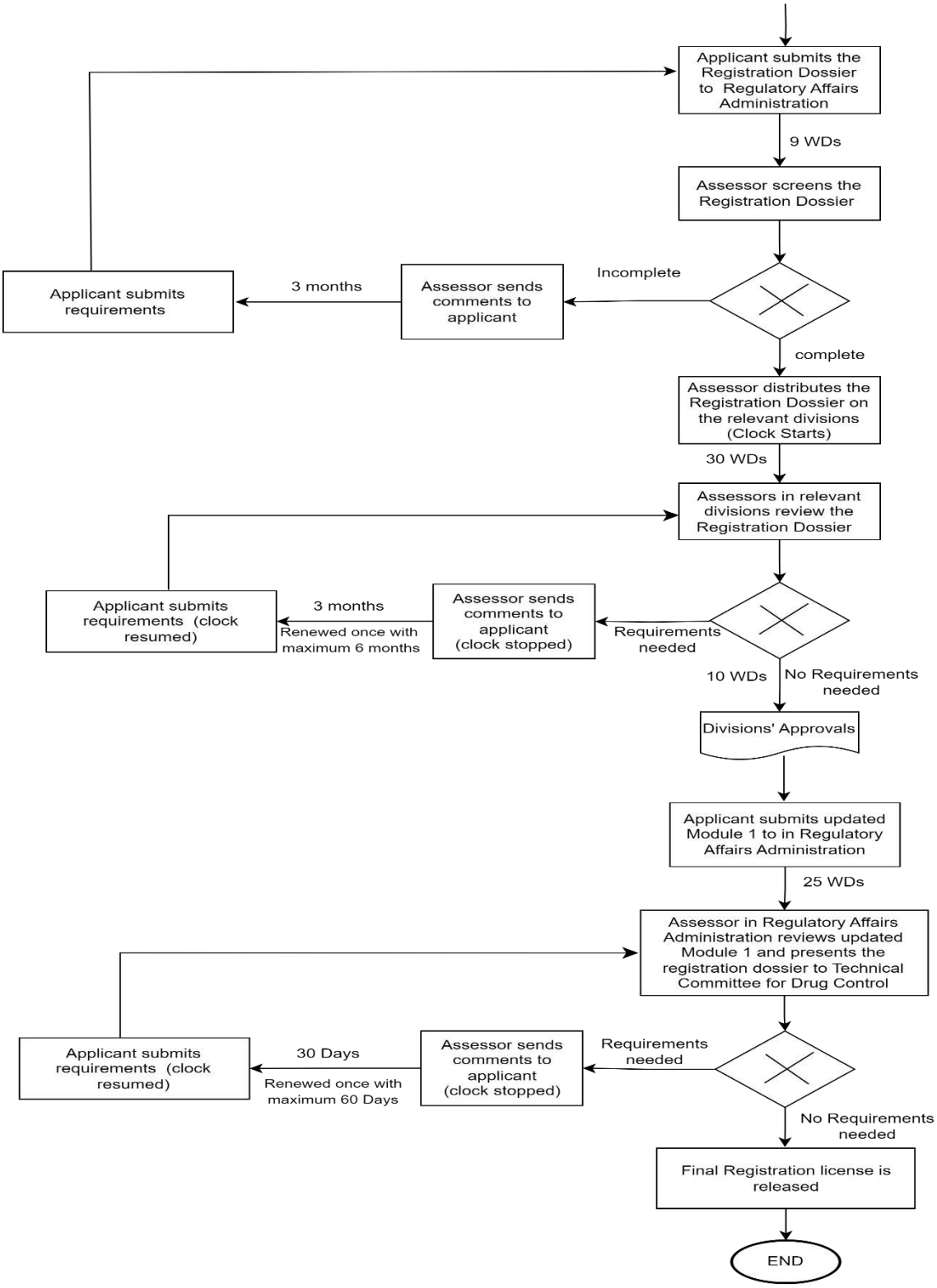
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval

  - Applicant has to submit the Registration Dossier within 30 WD from date of Trade Name 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 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
Renewed once with maximum 6 months
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approvals
Applicant submits updated Module 1 to in Regulatory Affairs Administration
25 WDs
Assessor in Regulatory Affairs Administration reviews updated Module 1 and presents the registration dossier to Technical Committee for Drug Control
Requirements needed
Assessor sends comments to applicant (clock stopped)
30 Days
Renewed once with maximum 60 Days
Applicant submits requirements (clock resumed)
No Requirements needed
Final Registration license is released
END

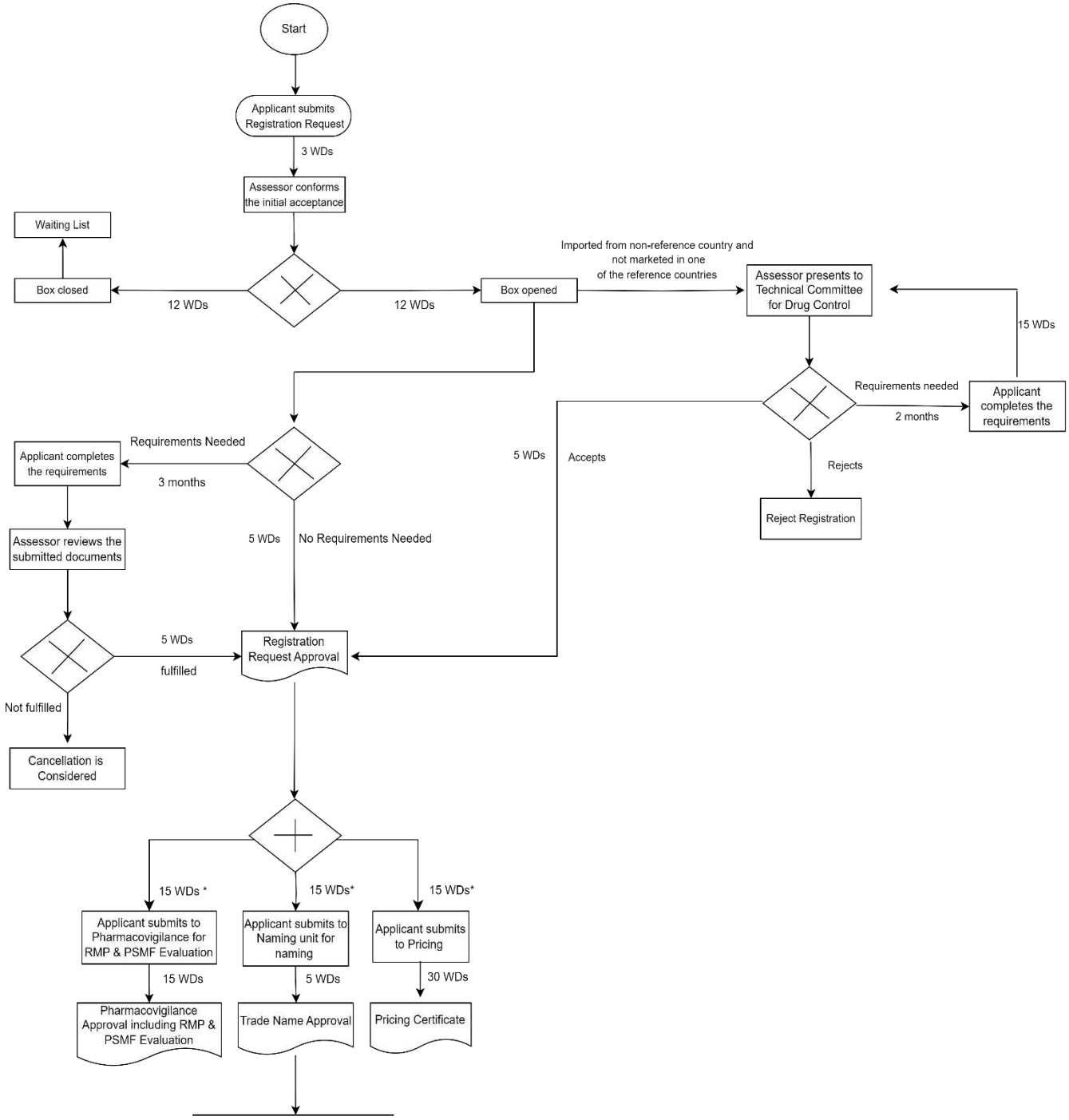
● Applicant Time:

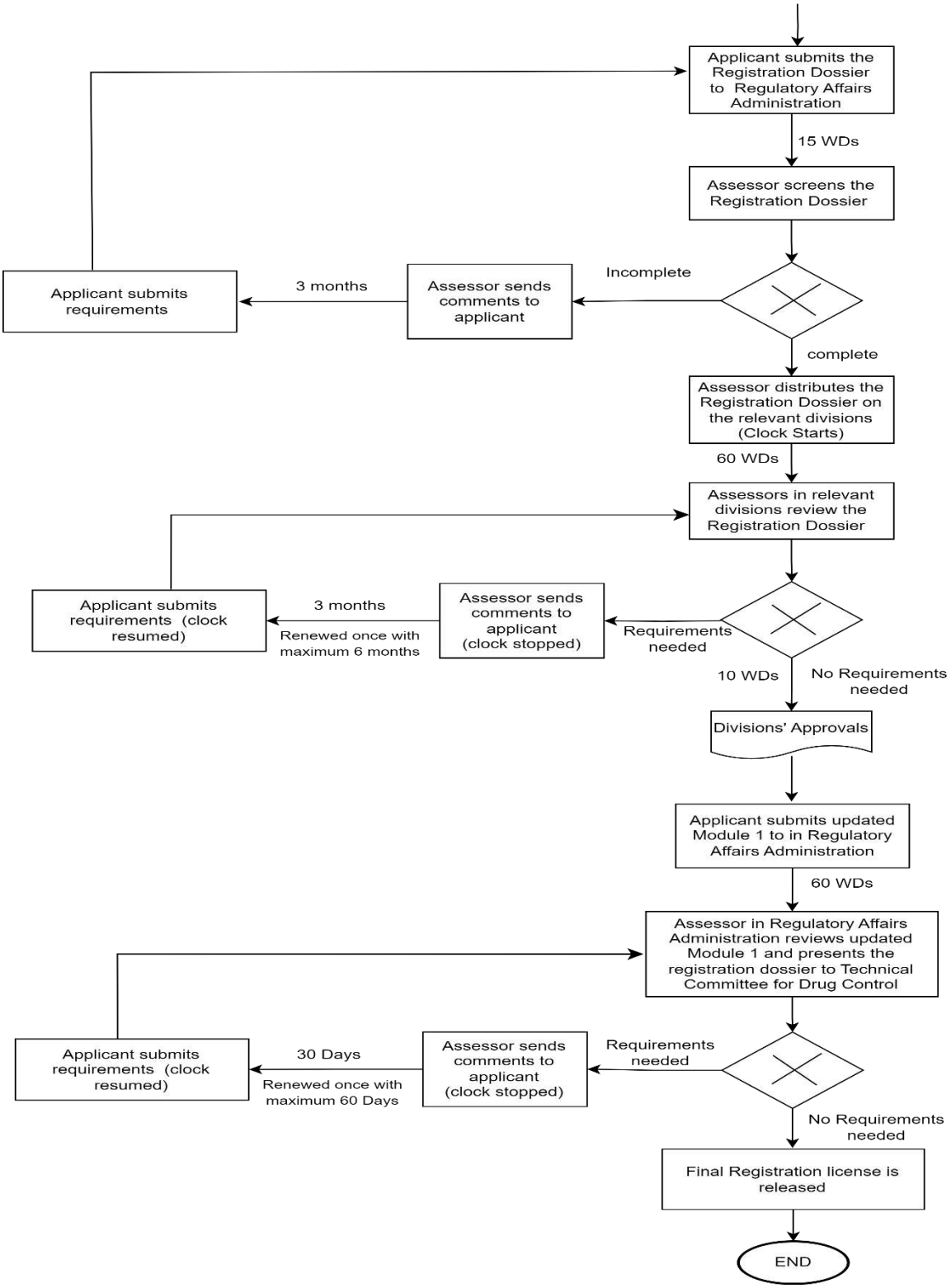
* Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval.

- Applicant has to submit the Registration Dossier within 2 months from Trade Name 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)



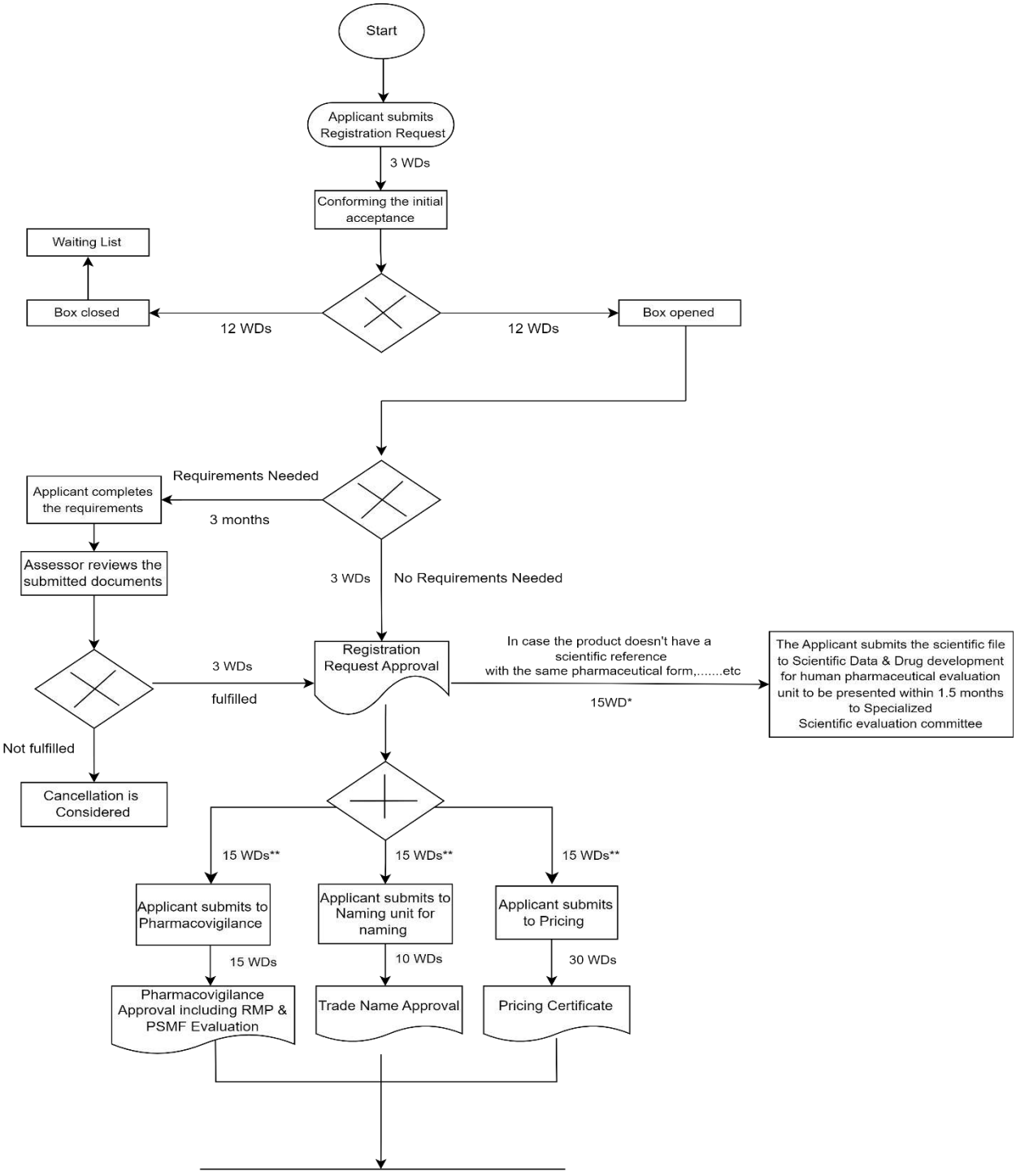

Applicant submits the Registration Dossier to Regulatory Affairs Administration
15 WDs
Assessor screens the Registration Dossier
Incomplete
Assessor sends comments to applicant
3 months
Applicant submits requirements
complete
Assessor distributes the Registration Dossier on the relevant divisions (Clock Starts)
60 WDs
Assessors in relevant divisions review the Registration Dossier
Requirements needed
Assessor sends comments to applicant (clock stopped)
3 months
Renewed once with maximum 6 months
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approvals
Applicant submits updated Module 1 to in Regulatory Affairs Administration
60 WDs
Assessor in Regulatory Affairs Administration reviews updated Module 1 and presents the registration dossier to Technical Committee for Drug Control
Requirements needed
Assessor sends comments to applicant (clock stopped)
30 Days
Renewed once with maximum 60 Days
Applicant submits requirements (clock resumed)
No Requirements needed
Final Registration license is released
END

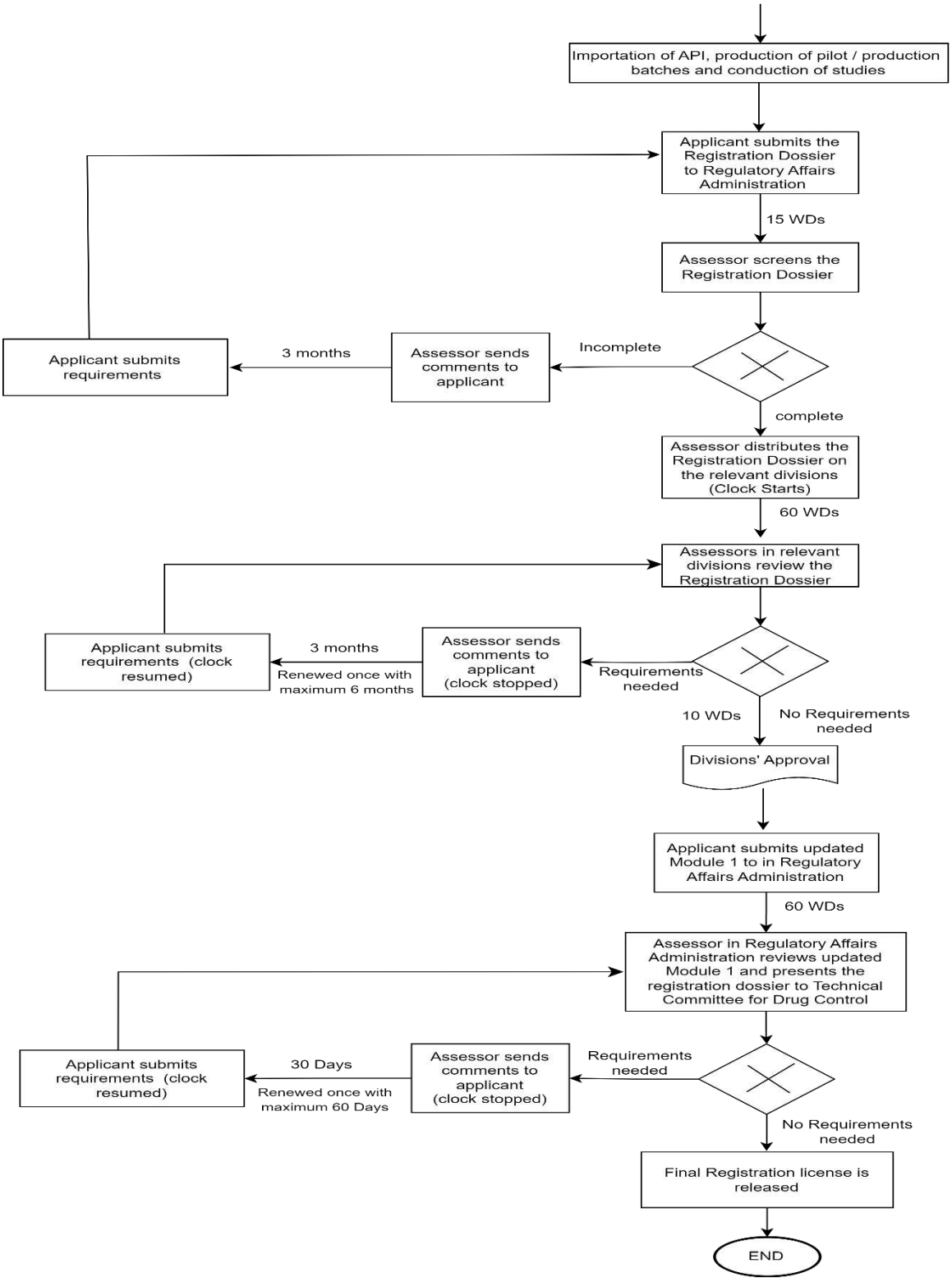
- Applicant Time:
  * Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval.

  - Applicant has to submit the Registration Dossier within 2 months from Trade Name 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, production of pilot / production batches and conduction of studies
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
Renewed once with maximum 6 months
Applicant submits requirements (clock resumed)
10 WDs
No Requirements needed
Divisions' Approval
Applicant submits updated Module 1 to in Regulatory Affairs Administration
60 WDs
Assessor in Regulatory Affairs Administration reviews updated Module 1 and presents the registration dossier to Technical Committee for Drug Control
Requirements needed
Assessor sends comments to applicant (clock stopped)
30 Days
Renewed once with maximum 60 Days
Applicant submits requirements (clock resumed)
No Requirements needed
Final Registration license is released
END

- Applicant Time:

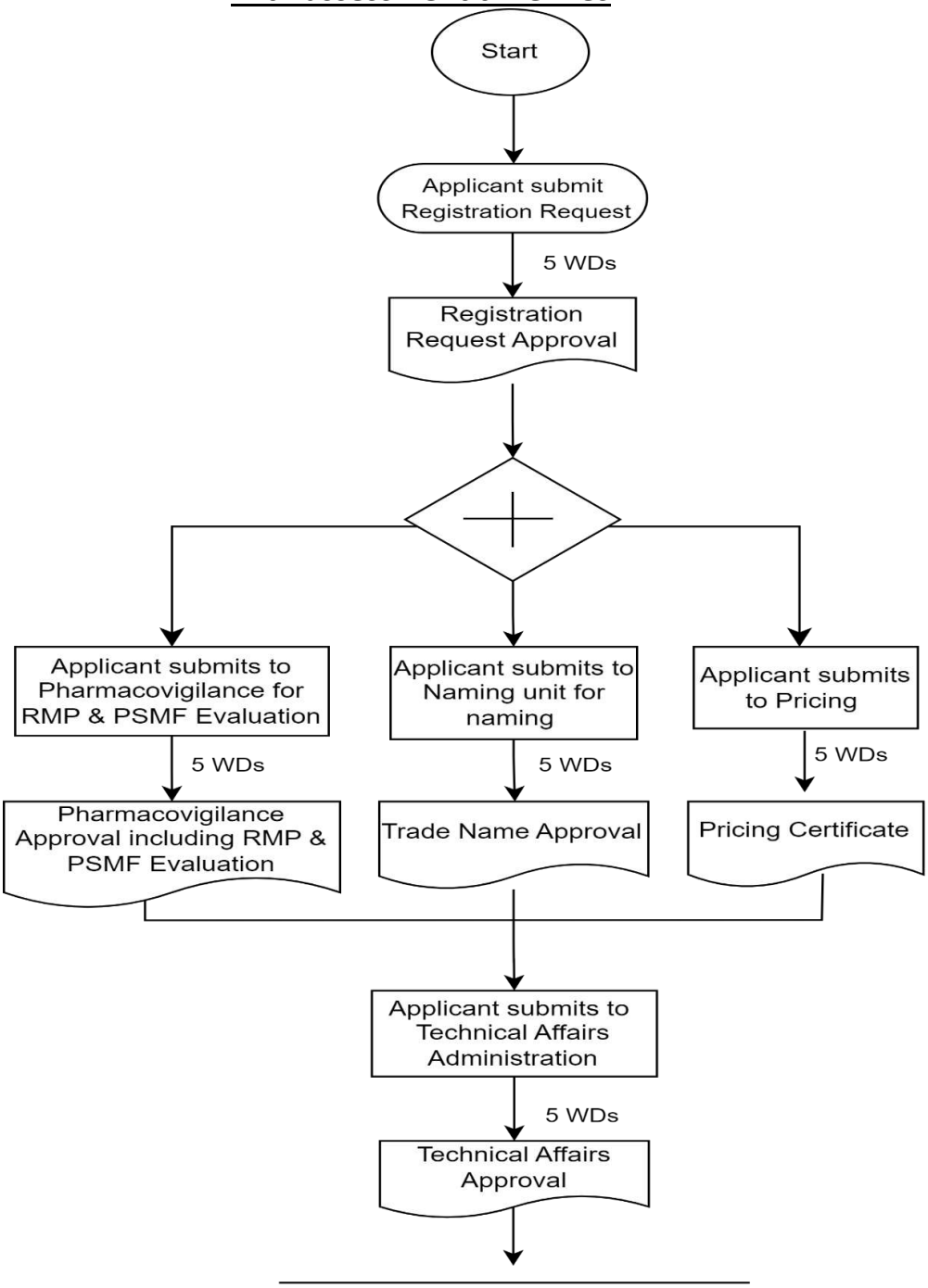
  * The Applicant submits the scientific file to Scientific Data & Drug development for human pharmaceutical evaluation unit within 15 WDs from registration request approval (Incase the product does not have a scientific reference with the same pharmaceutical form, concentration or route of administration).

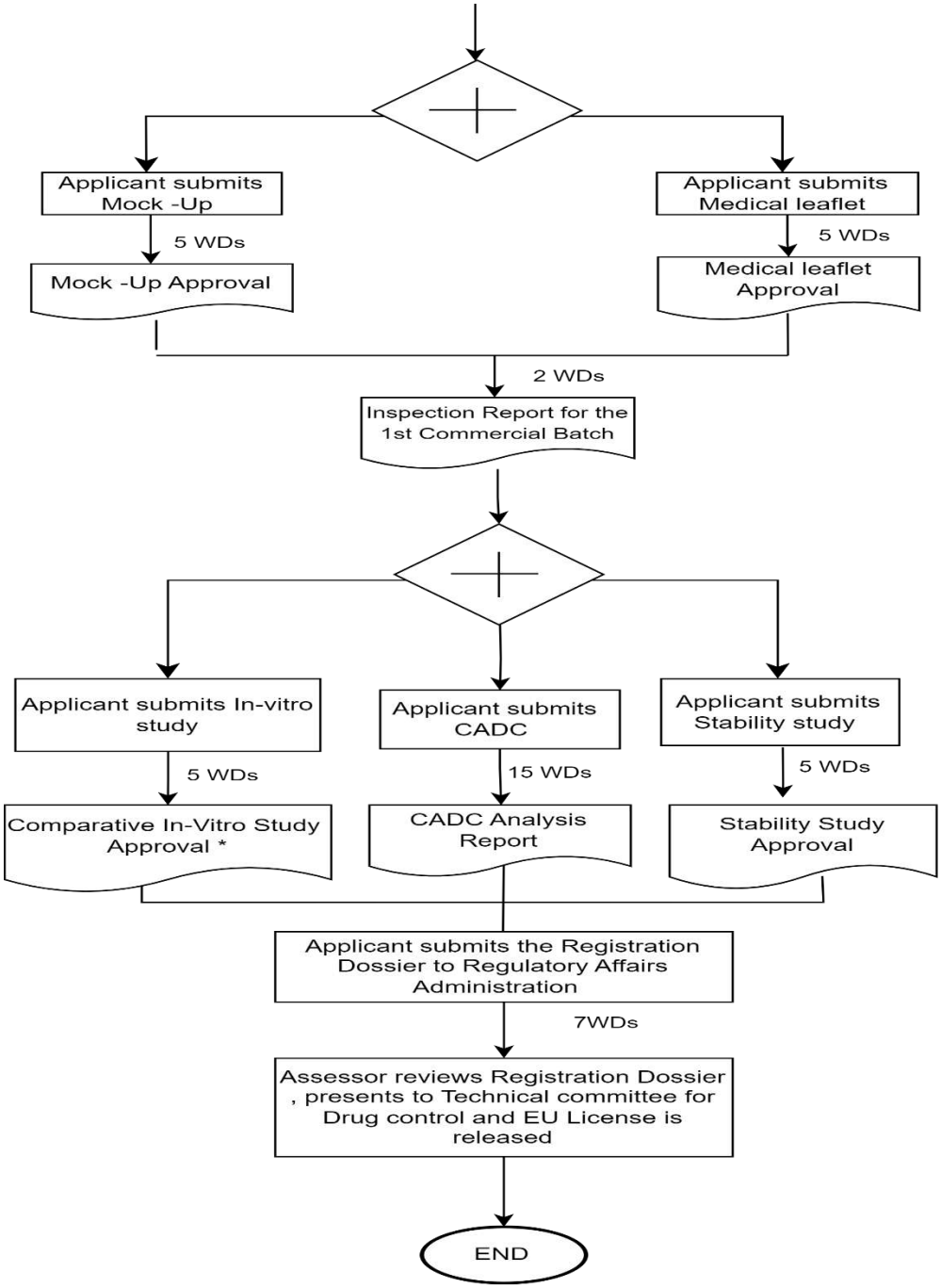
  ** Applicant submits to naming unit, pharmacovigilance and pricing within 15 WDs from registration request approval or specialized scientific evaluation approval.

  - 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

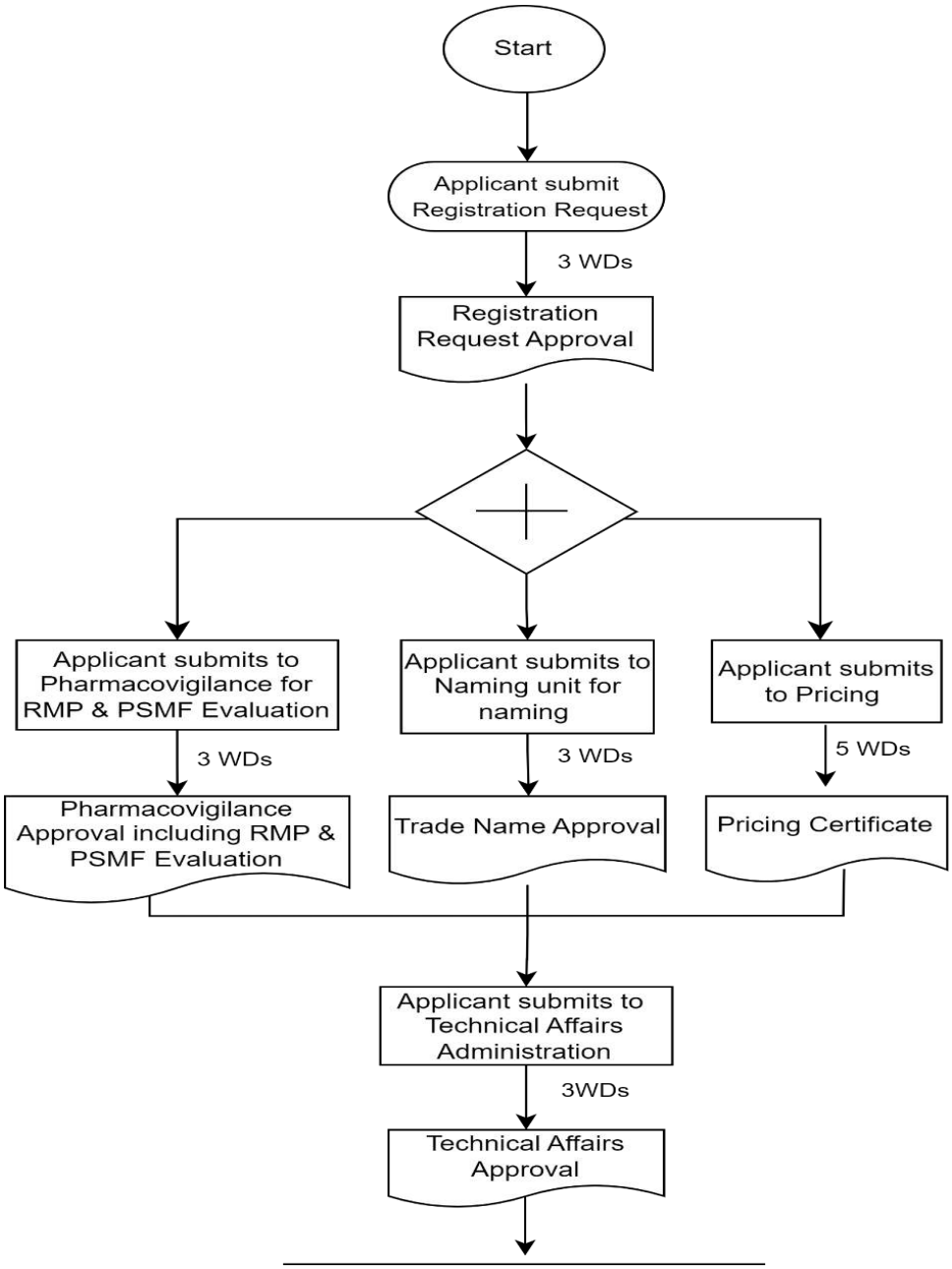


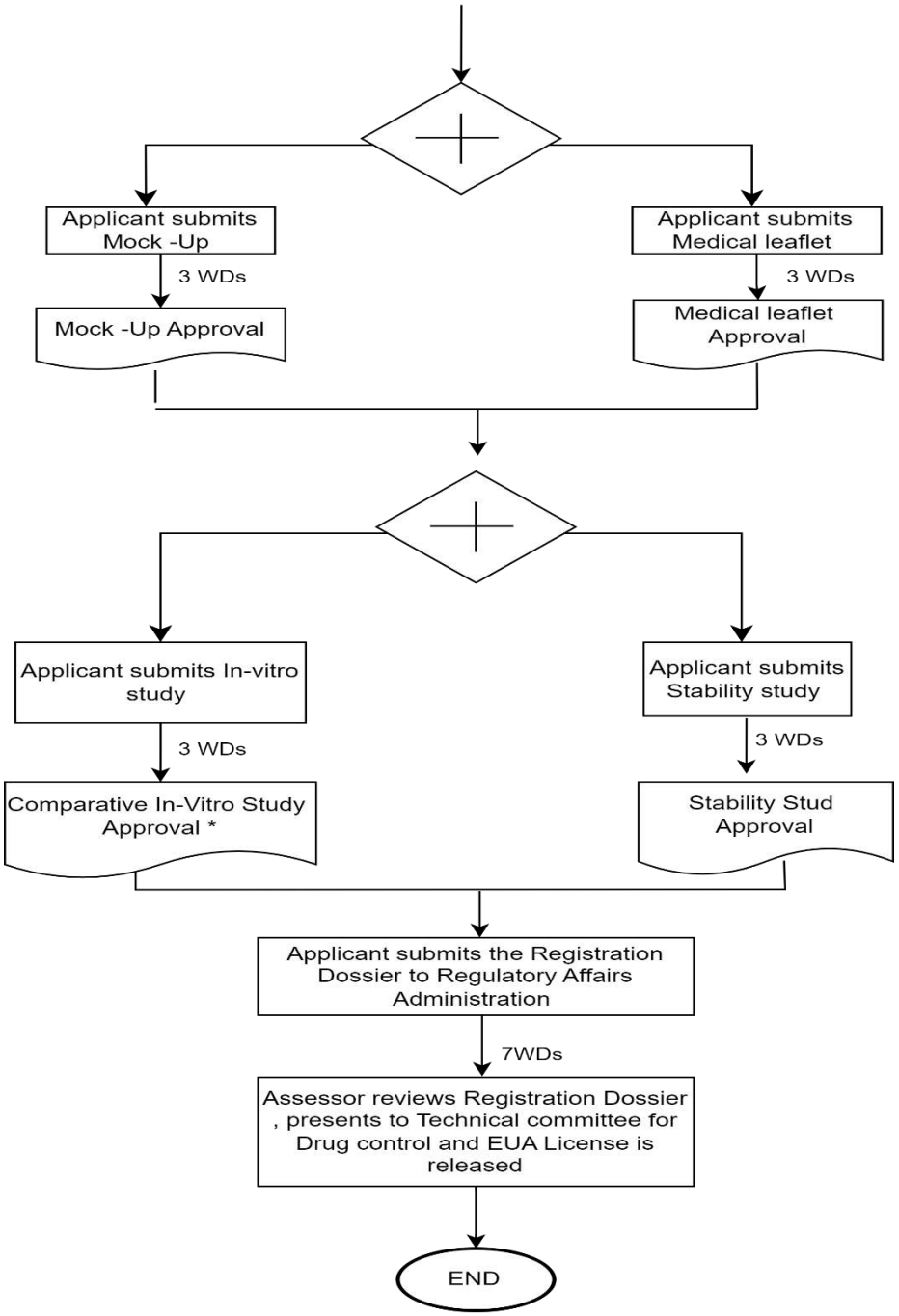


- Assessment timelines start from receiving complete files from applicants
- Total Assessment Timeline = maximum 44 WDs
  (without consideration of the time required for preparation of applicant's responses to requests).

*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)

Locally Manufactured Generic Products' Timeframes

EDA's Assessment Timeframe:

Application type	Application	Pricing +Naming+ PV	Screening &Evaluation
local Generic	31	90	208
local Generic (Fast Track)	18	30	145

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

Registration Assessment Time Frames Breakdowns:

	Procedure/Time Frame for Files submitted according to	Case I & III (Normal Track)			Case II (Fast Track)
		Module 3 (In Technical Affairs Administration)	**Module 5** (In Bioequivalence Unit)	**Module 1** (In Regulatory Affairs Administration)	
1	**Screening** (1)	15 WDs	5 WDs		15 WDs
2	**Technical Evaluation** (2)	1st Evaluation and sending letter of comments. = 40 WDs Review of 1st Suppl. Doc.= 15 WDs Review of 2nd Suppl. Doc.= 15 WDs	1st Evaluation and sending letter of comments. = 40 WDs Review of 1st Suppl. Doc.= 5 WDs Review of 2nd 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
3	**Approval Release from complete dossier**	5 WDs	5 WDs		10 WDs
4	**Final Review of Registration Dossier**			1st Evaluation and sending letter of comments. = 30 WDs Review of 1st Suppl. Doc.= 15 WDs Review of 2nd Suppl. Doc.= 15 WDs	60 WDs
5	**Presentation to Technical Committee and MA release**			30 WDs	

(1) **Screening:** Review of the technical study by the relevant division (in Normal Track) / review of the registration dossier by Administration of Regulatory Affairs of Human Pharmaceutical Products (in Fast Track) to check its completeness to proceed to the technical assessment process or not.

(2) **Technical Evaluation:** Detailed technical review and assessment of the technical study.

Applicants Completions Time Frames Breakdowns:

	Division	Case I & III (Normal Track)	Case II (Fast Track)	
1	**Bioequivalence Unit**	The company is committed to submitting the completions within **30 days** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **60 days**.	**All relevant Divisions involved in the Assessment**	The company is committed to submitting the completions within **3 months** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **6 months**.
2	**Technical Affairs Administration**	The company is committed to submitting the completions within **45 days** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **90 days**.		
3	**Regulatory Affairs Administration**	The company is committed to submitting the completions within **30 days** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **60 days**.	The company is committed to submitting the completions within **30 days** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **60 days**.	

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

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	165
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	74
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	145

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

Registration Assessment Time Frames Breakdowns:

	Procedure/Time Frame for Files submitted according to	Case I & III (Normal Track)		Case II (Fast Track)			
		Imported from Reference Country	Imported from Non- Reference Country and Not marketed in Reference Country	Track A	Track B	Track C Imported from reference country	Track C Imported from non-reference country & not marketed in reference country
1	**Screening** (1)	20 WDs	30 WDs	3 WDs	6 WDs	9 WDs	15 WDs
2	**Distribution and Technical Assessment** (2)	1st Evaluation and sending letter of comments. = 25 WDs Review of 1st Suppl. Doc. = 10 WDs Review of 2nd Suppl. Doc. = 10 WDs	1st Evaluation and sending letter of comments. = 40 WDs Review of 1st Suppl. Doc. = 20 WDs Review of 2nd Suppl. Doc. = 20 WDs	1st Evaluation and sending letter of comments. = 6 WDs Review of 1st Suppl. Doc. = 2 WDs Review of 2nd Suppl. Doc. = 2 WDs	1st Evaluation and sending letter of comments. = 12 WDs Review of 1st Suppl. Doc. = 4 WDs Review of 2nd Suppl. Doc. = 4 WDs	1st Evaluation and sending letter of comments. = 20 WDs Review of 1st Suppl. Doc. = 5 WDs Review of 2nd 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
3	**Approval Release from complete dossier**	10 WDs	10 WDs	5 WDs	10 WDs	10 WDs	10 WDs
4	**Final Review of Registration Dossier**	1st Evaluation and sending letter of comments. = 30 WDs Review of 1st Suppl. Doc. = 15 WDs Review of 2nd Suppl. Doc. = 15WDs	1st Evaluation and sending letter of comments. = 30 WDs Review of 1st Suppl. Doc. = 15 WDs Review of 2nd Suppl. Doc. = 15WDs	7 WDs	14 WDs	25 WDs	60 WDs
5	**Presentation to Technical Committee and MA release**	30 WDs	30 WDs				

(1) **Screening:** Review of the registration dossier by Administration of Regulatory Affairs of Human Pharmaceutical Products to check its completeness to proceed to the technical assessment process or not.

(2) **Technical Evaluation:** Detailed technical review and assessment of the registration dossier.

Applicant completions Time Frames Breakdowns:

	Division	Case I & III (Normal Track)	Case II (Fast Track)
1	**All relevant Divisions involved in the Assessment**	The company is committed to submitting the completions within **45 days** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **90 days**.	The company is committed to submitting the completions within **3 months** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **6 months**.
3	**Regulatory Affairs Administration**	The company is committed to submitting the completions within **30 days** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **60 days**.	The company is committed to submitting the completions within **30 days** from the date of sending the completions, **renewed once**, provided that the total completion period doesn't exceed **60 days**.

***In the event that the total deadline for required completion is exceeded, the company is obligated 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)