



Submission Procedures for Registration Dossiers

A Step-by-Step Overview

Administration of Human Pharmaceuticals Regulatory Affairs

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Scope

Fast Track submission

**EDA Chairman decree 450/2023 CASE
2 and 820/2016**

Normal Track submission

**EDA Chairman decree 450/2023 CASE 1 and
CASE 3 (Track A) imported only**



FAST TRACK

The Updated Submission Procedures for Registration Dossiers on Decree 820/2016 and 450/2023 Case II

A Step-by-Step Overview

Administration of Human Pharmaceuticals Regulatory Affairs

Fast Track submission

EDA Chairman decree 450/2023 CASE 2

Regulating the registration of human pharmaceutical products, which must fall into one of the following categories :

Track (A)

approved by both the U.S. Food and Drug Administration "FDA" and the European Medicines Agency "EMA", in addition to a stringent regulatory authority (SRA)/WHO Prequalified

Track (B)

approved by either the U.S. Food and Drug Administration "FDA" or the European Medicines Agency "EMA", in addition to a stringent regulatory authority (SRA))/WHO Prequalified

Track (C)

- (I) Imported products from Reference country
- (II) Imported products from Non-Reference country
- (III) Local Products

Submission Step 1



Submission of Full Registration Dossier for Evaluation from different Departments

- The initial submission of Full CTD Modules to the Human Pharmaceutical Regulatory Affairs Administration will occur subsequent to the following steps:
1-Obtaining Box approval (Registration request approval) and Naming approval
2-Submission to the Pricing and Pharmacovigilance departments (*). (Submit a screenshot as evidence of submission)

Note :

(*)According to decree 820/2016, PV documents will be submitted within the full registration dossier.

- The Required documents for the Leaflet and layout were Submitted according to their own submission guidance.

STEP 2 : Screening by Administration Of Human Pharmaceutical Regulatory Affairs



Completed

The registration Dossier will be distributed to relevant departments (Clock Starts)



In-completed

Rejection with comments will be sent to applicant and the applicant must fulfill the comments and re-submit the full registration dossier as **new submission again** in maximum period of **3 months**





STEP 3 Technical Evaluation

In Case Of Acceptance

The administration of Human Pharmaceutical Regulatory Affairs sends the registration Dossier to different departments for technical evaluation.
In the case of additional comments required from the company(**Clock Stop**), a maximum period of **three months** is granted to submit the required documents as supplementary for each departments.

Upon Fulfilling all Requirements

**All Technical Approvals will be Issued within the
published timeframe**

STEP 4

Submission for Updated Module (I) after getting Approvals

After Obtaining all technical approvals, Pricing Certificate and PV approval , the applicant Must re-submit the updated Module I with approvals [on supplementary link](#)



FINAL STEP

Final Review and Committee Presentation

Administration Of Human Pharmaceutical Regulatory affairs will review the Final registration Dossier and present to The Technical Committee for Drug control for approval

In the case of additional comments from the company(**Clock Stop**), a maximum period of **three months** is granted to submit the required documents as supplementary .

**Then Issuance Of Registration License
After Technical Committee Approval**

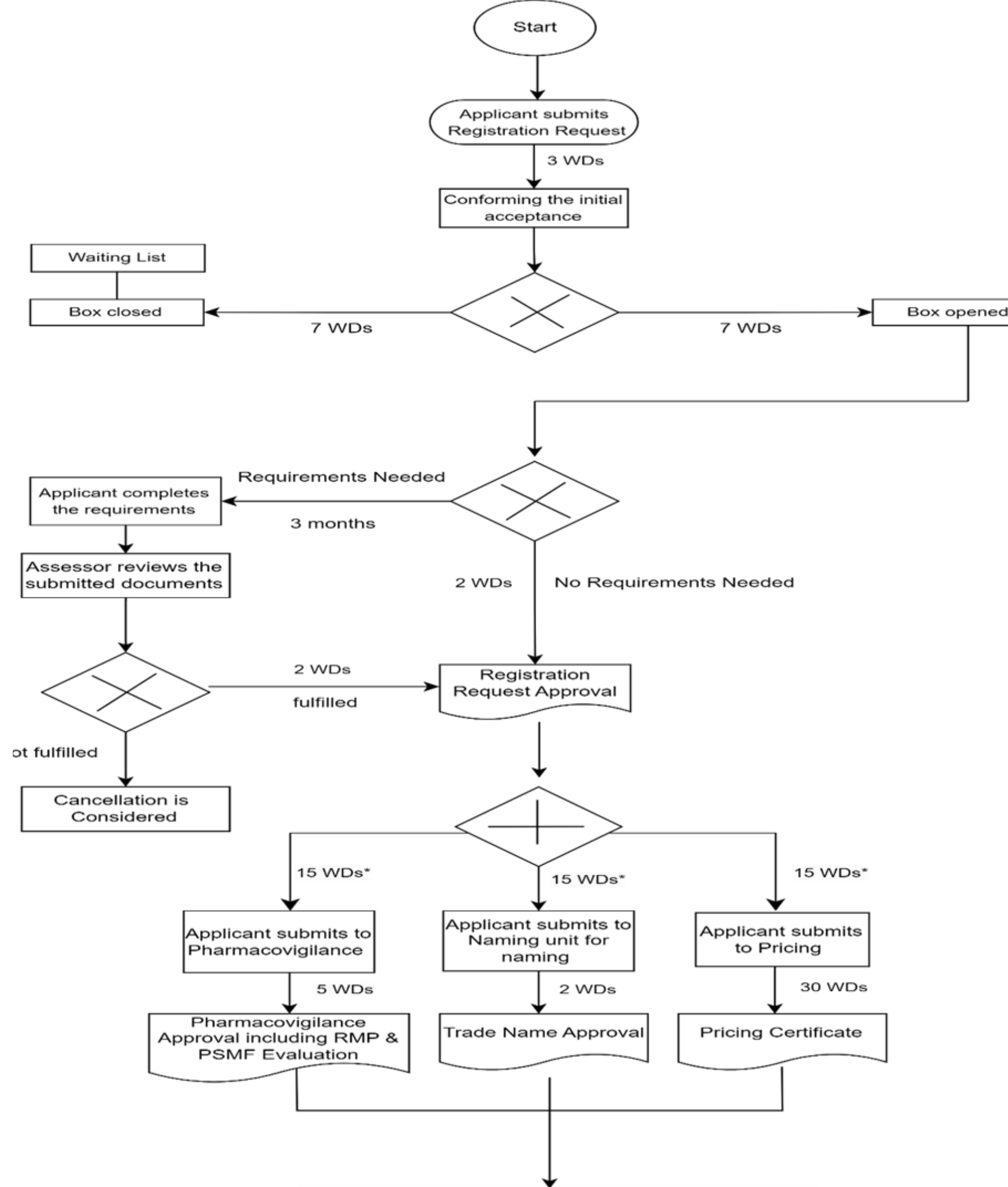
1

Full Registration
Dossier submitted for
Evaluation from
different Departments

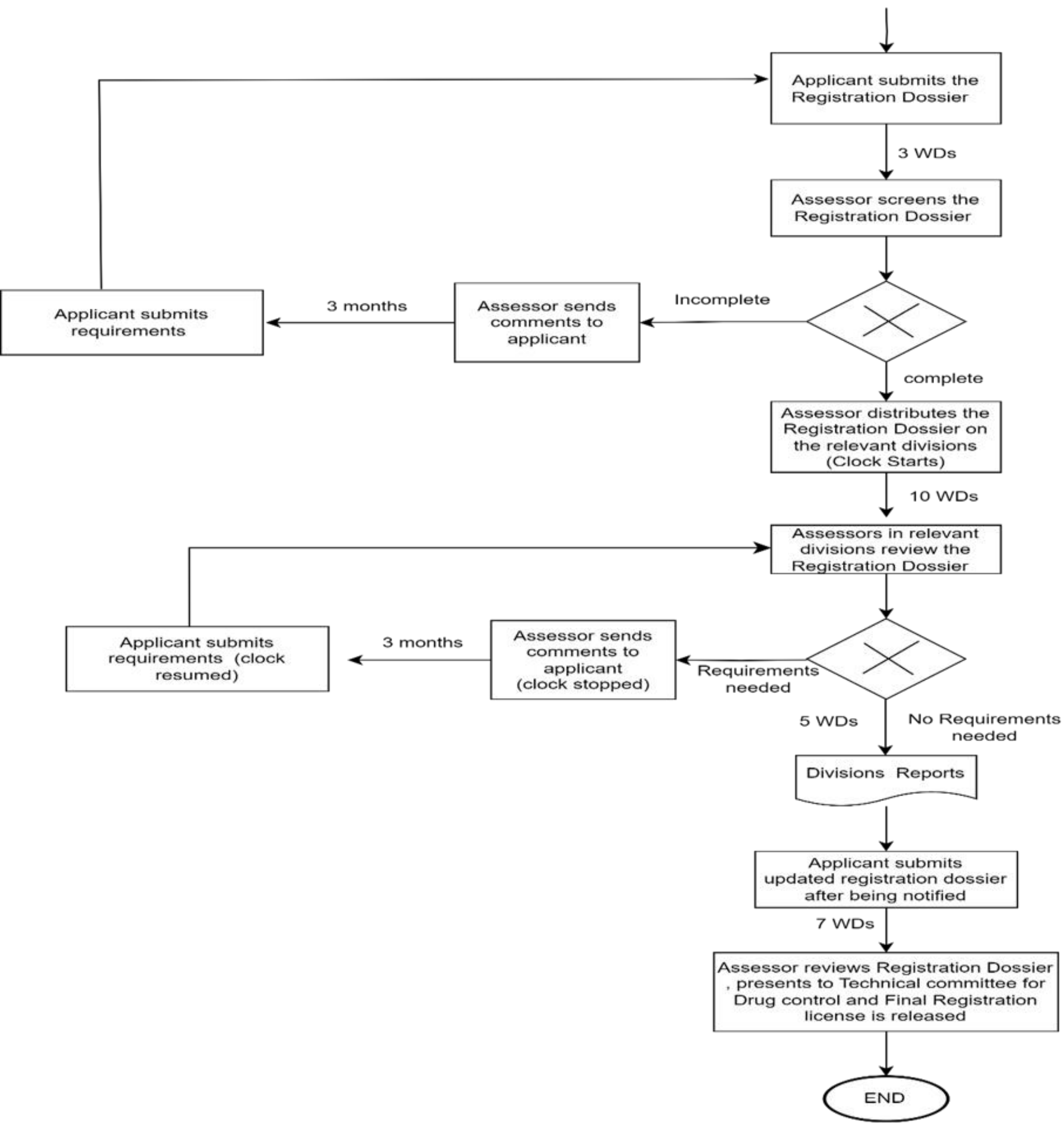
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Submission for
updated Module (I)
with approvals.

Summary of types of Submission to the administration of human pharmaceuticals regulatory affairs by the applicant.

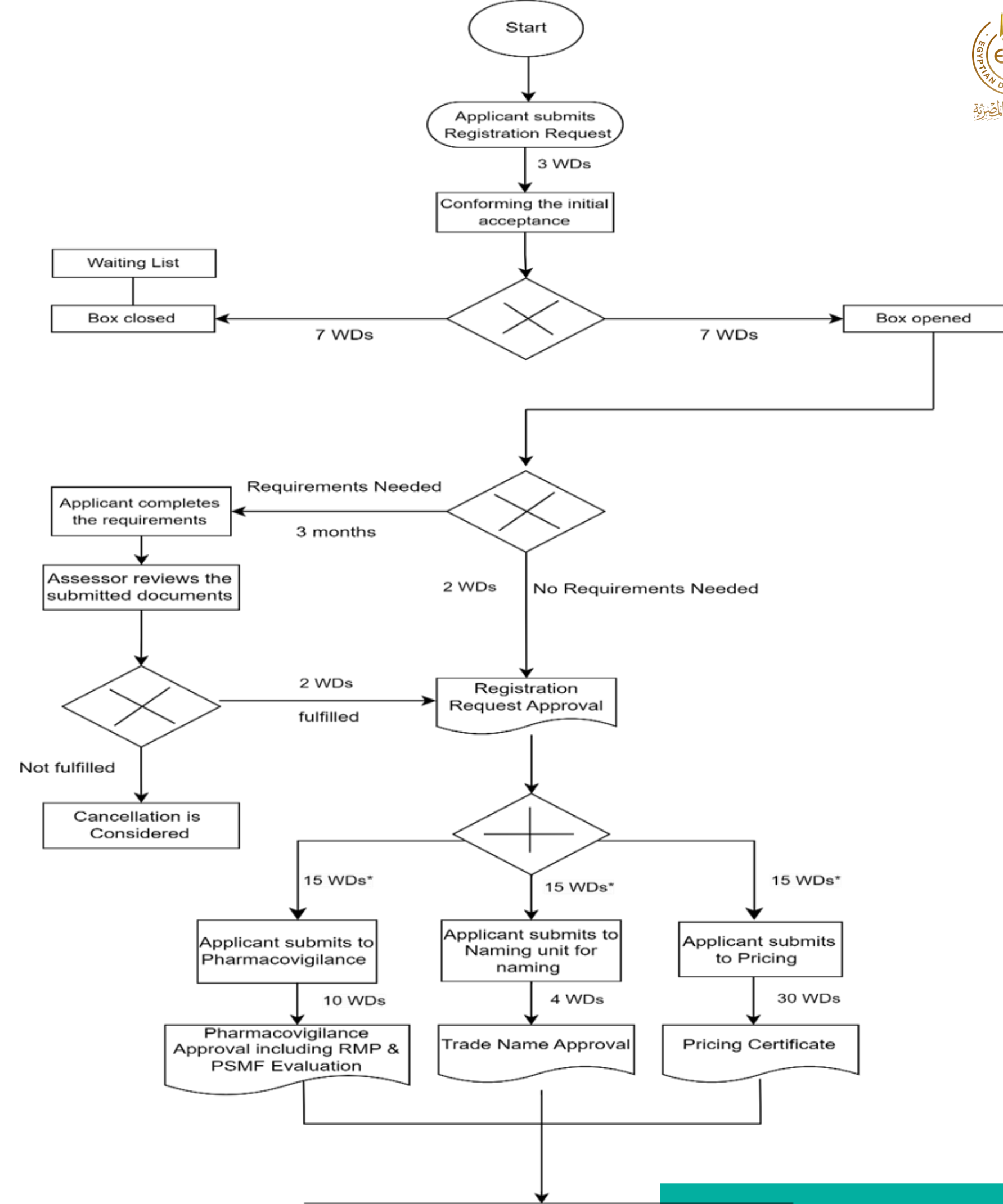


EDA Chairman Decree (450/2023) **Case II- Track A** Flowchart with assessment timelines

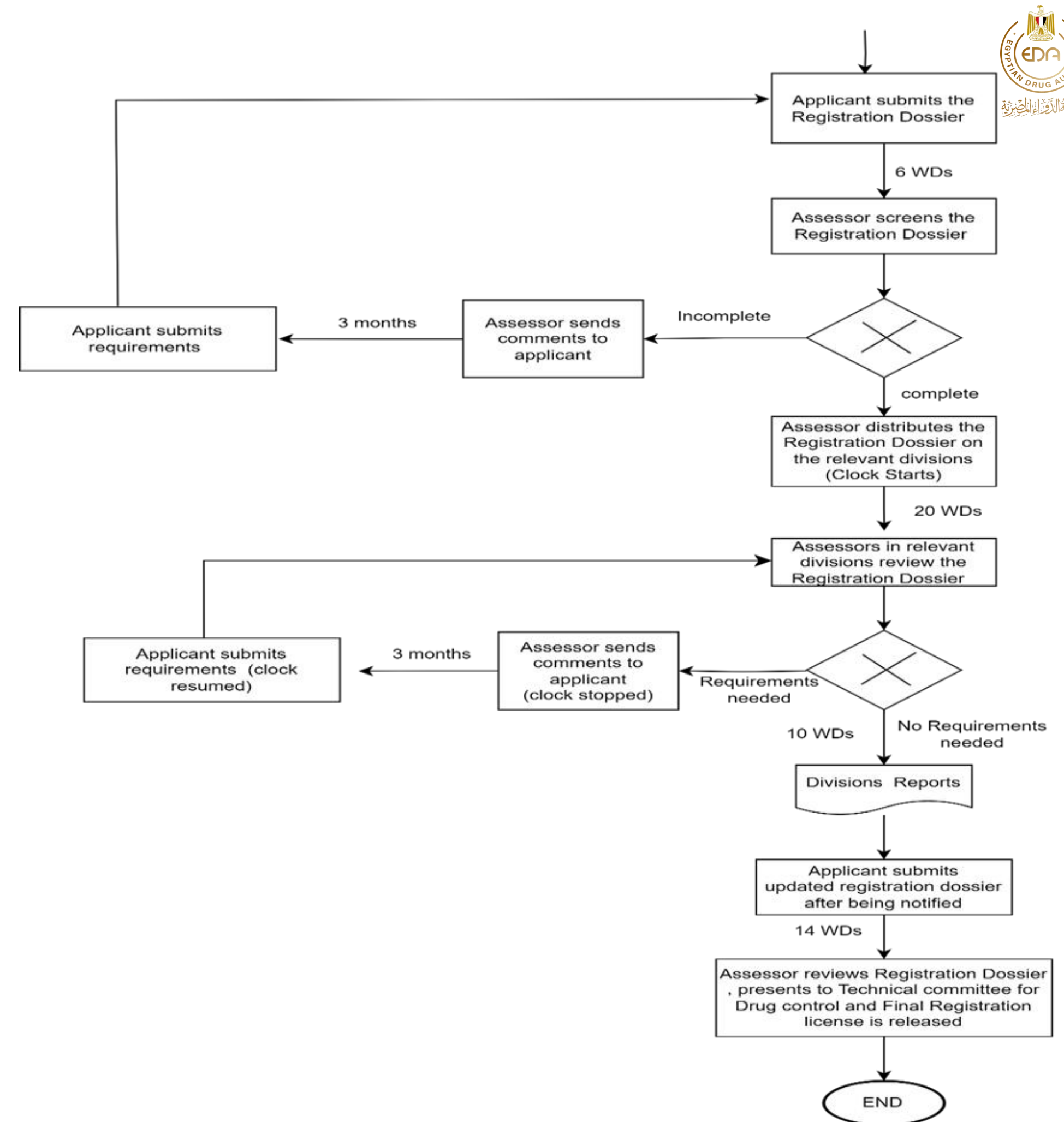


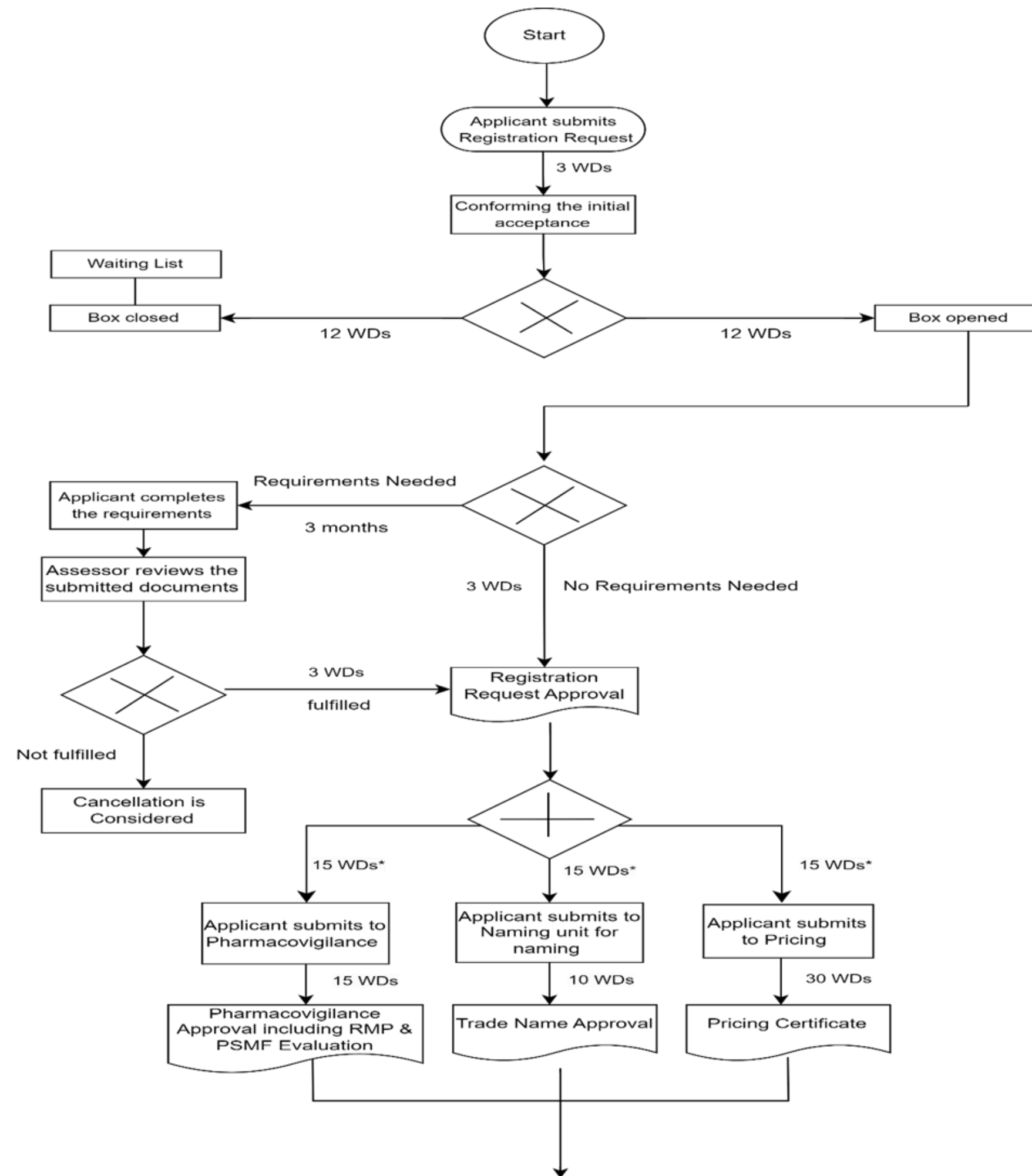
EDA Chairman Decree (450/2023) Case II- Track A Flowchart with assessment timelines

EDA CHAIRMAN DECREE (450/2023) **CASE II-** **TRACK B FLOWCHART** **WITH ASSESSMENT** **TIMELINES**

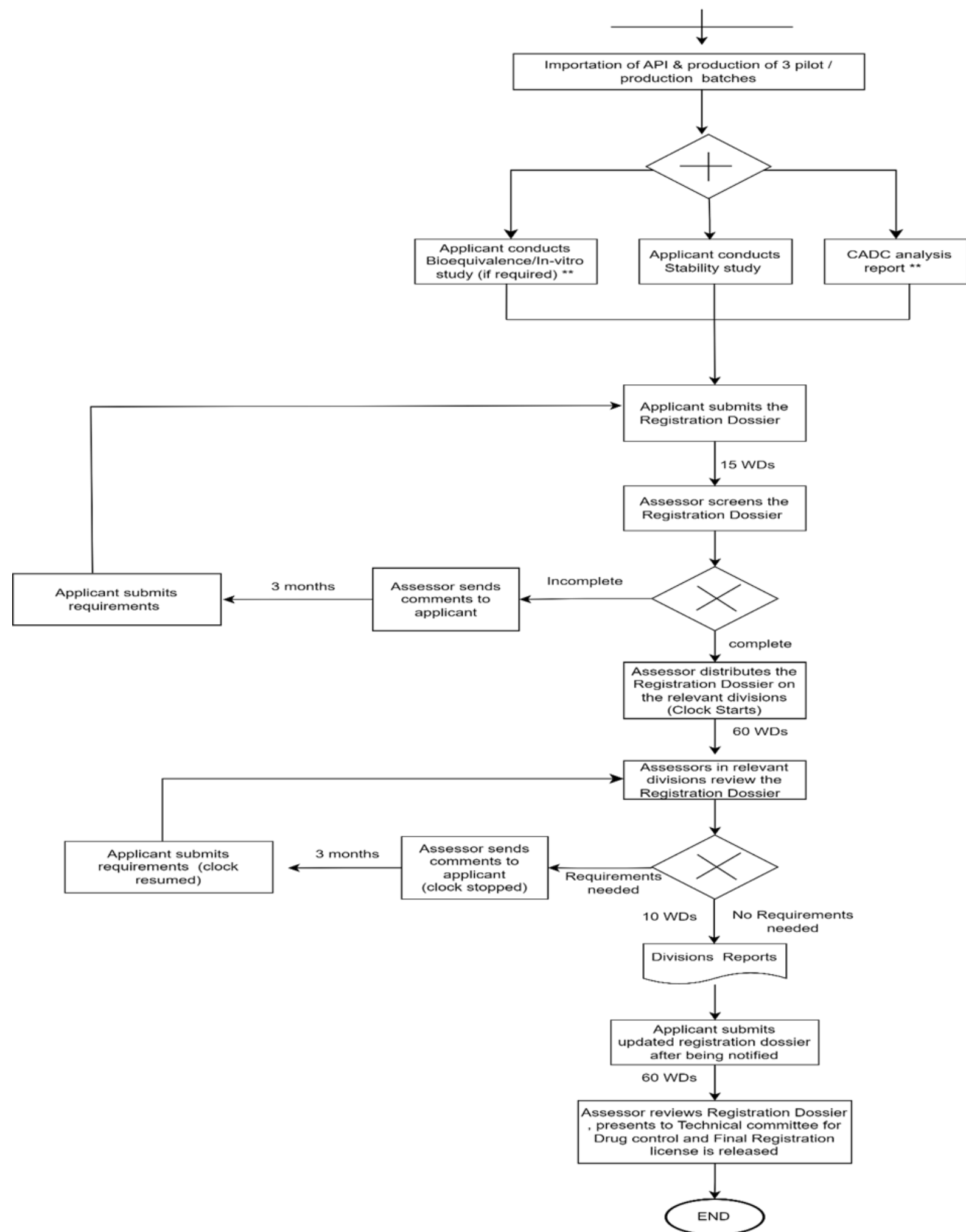


EDA CHAIRMAN DECREE (450/2023) **CASE II-** **TRACK B FLOWCHART** **WITH ASSESSMENT** **TIMELINES**



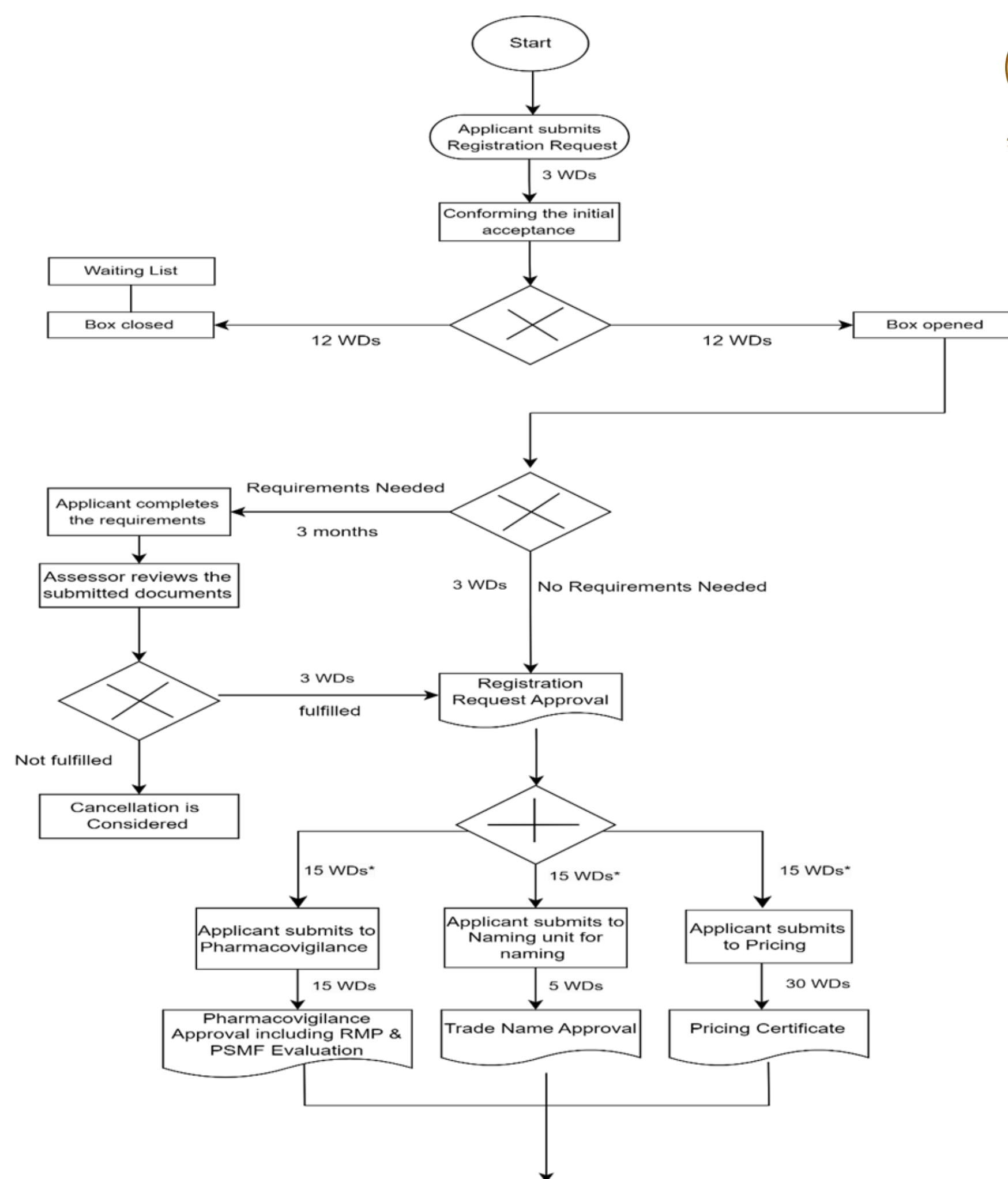


EDA Chairman Decree (450/2023) Case II- Track C Flowchart for Locally Manufactured Reference Products with assessment timelines

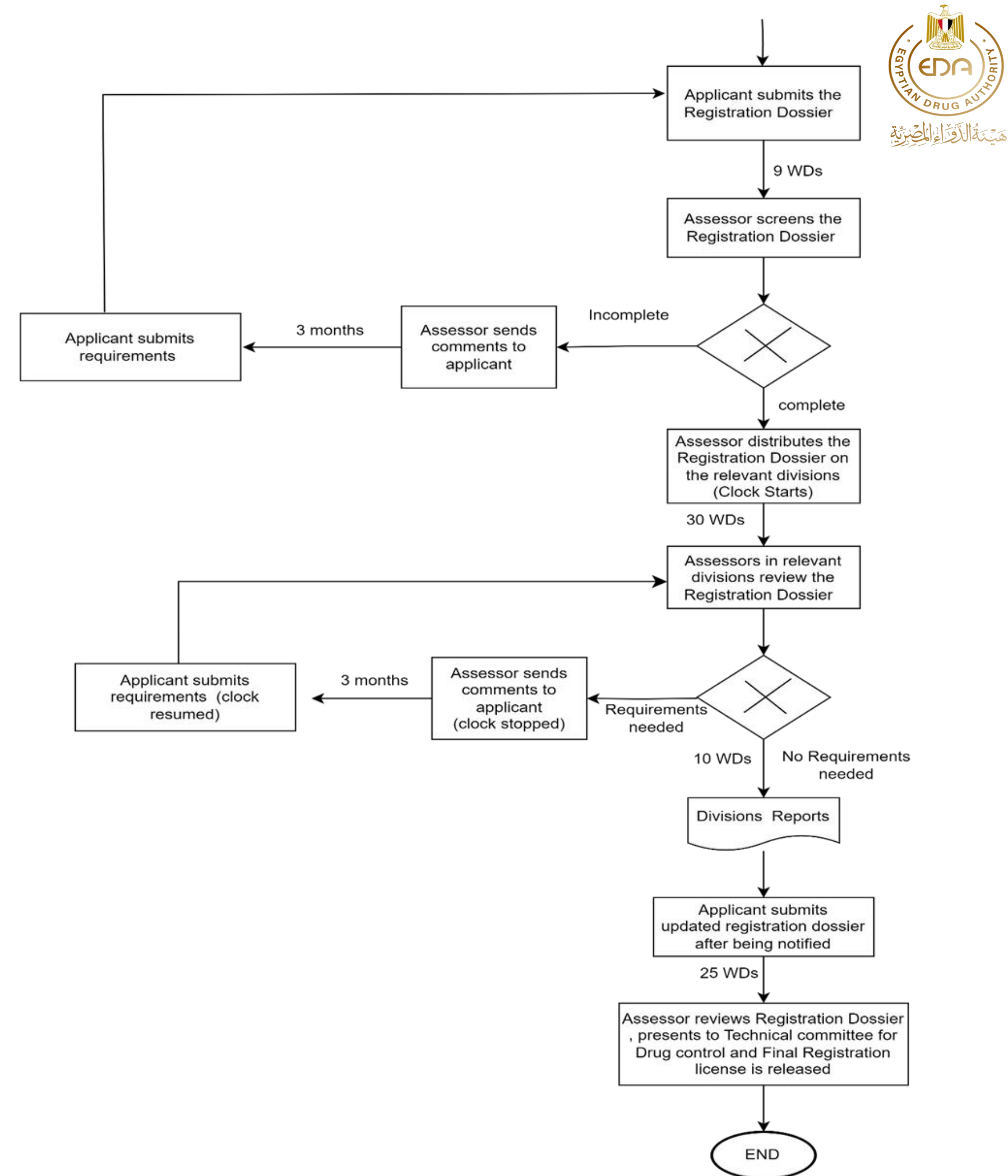


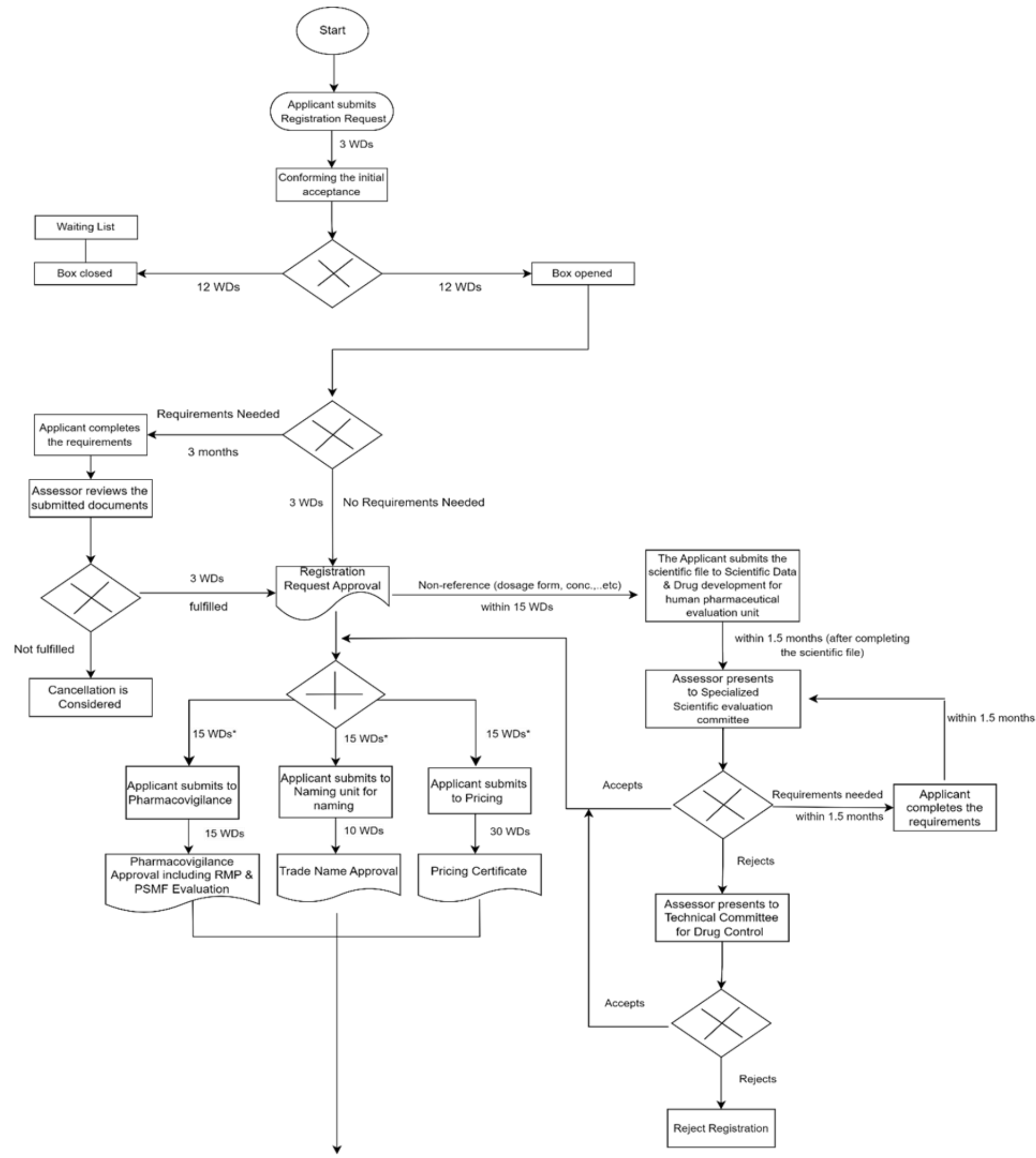
EDA Chairman Decree (450/2023) Case II- Track C Flowchart for Locally Manufactured Reference Products with assessment timelines

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

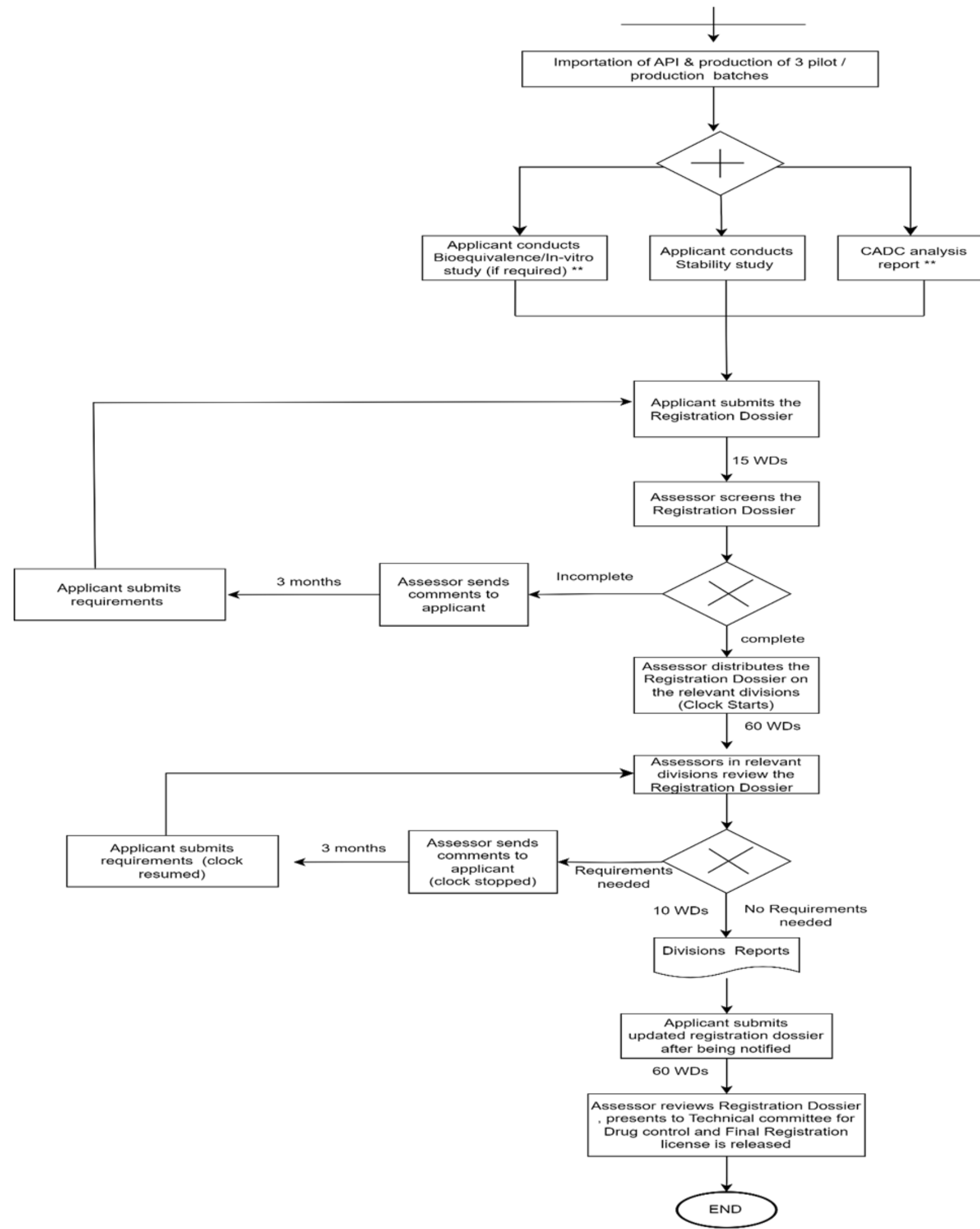


EDA Chairman Decree (450/2023) Case II- Track C Flowchart for Imported Products From Reference Countries with assessment timelines



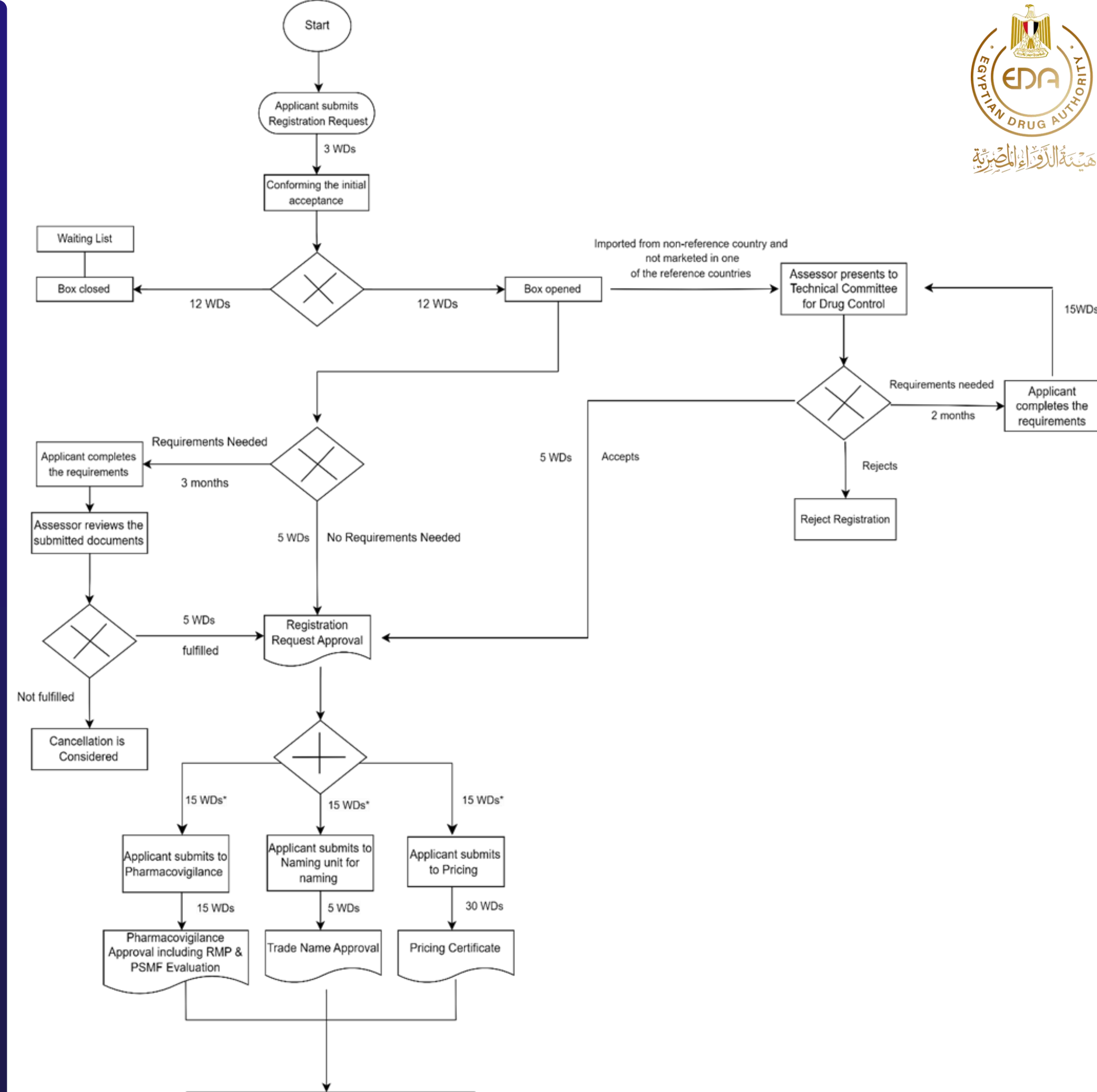


EDA Chairman Decree (450/2023) Case II- Track C Flowchart for **Locally Manufactured Non- Reference Products** with assessment timelines

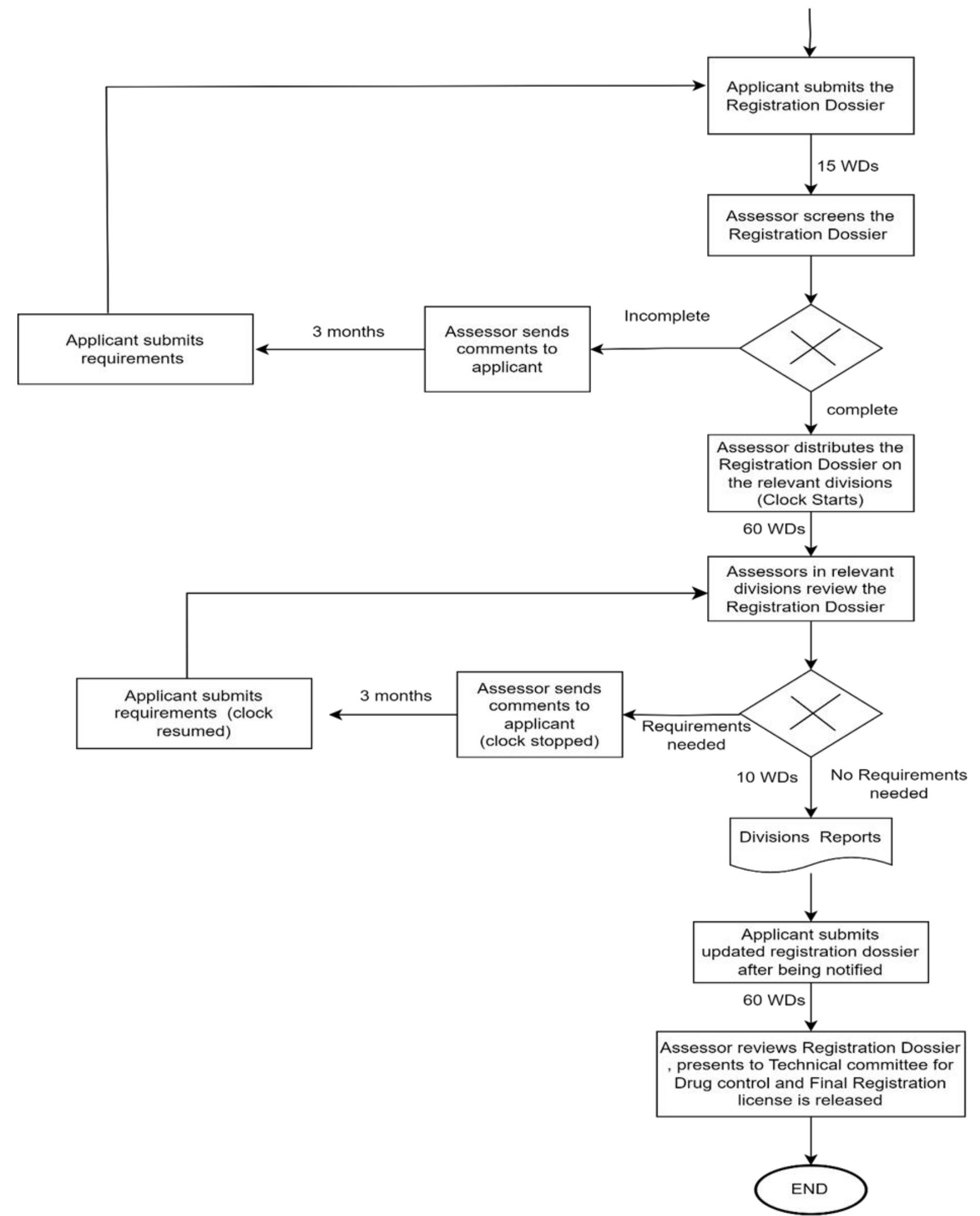


EDA Chairman Decree (450/2023) Case II- Track C Flowchart for **Locally Manufactured Non- Reference Products** with assessment timelines

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



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



EDA Timeframes



	Procedures	Timeline Related to	Timeline according to Ministerial decrees 820/2016				EDA Chairman decree (450/2023 (case 2))			
	Case or Track		<u>EMA & FDA</u>	<u>EMA or FDA</u>	<u>Imported (CTD)</u>	<u>Local (CTD)</u>	<u>Track A</u>	<u>Track B</u>	<u>Track C (Imported from Reference country)</u>	<u>Track C (Imported from non- Reference and not marketed in Reference country & Local)</u>
1	Screening	EDA	Within 3 WDs	Within 6 WDs	Within 15 WDs	Within 15 WDs	Within 3 WDs	Within 6 WDs	Within 9 WDs	Within 15 WDs
2	Distribution and Technical evaluation from related departments	EDA	3 WDs	6 WDs	20 WDs	20 WDs	10 WDs	20 WDs	30 WDs	60 WDs
3	Release of approval from related departments	EDA	10 WDs	20 WDs	3 months	3 months	5 WDs	10 WDs	10 WDs	10 WDs
4	Final Revision of Registration Dossier, Present to Technical committee & license release	EDA	7 WDs	14 WDs	2 months	2 months	7 WDs	14 WDs	25 WDs	60 WDs
5	Total time for registration* (months)	EDA	1	2	6	6	1	2	3	6

Form Name	Link
Submission Link for Registration Dossier according to EDA Chairman Decree 450/2023 Case (2) or Ministerial Decree 820/2016	https://forms.gle/3fXxGBq5WMvWqW4A7
Supplementary Documents For EDA Chairman Decree Case (2) or Ministerial Decree 820/2016 For Updating Module 1 & For Supplementary documents after final Review	https://forms.gle/SAAxy2BsmRz4NXT9

Submission Procedures for Registration Dossiers on Decree 450/2023 Case 1 & Case 3 Track A (IMPORTED ONLY)

NORMAL TRACK

A Step-by-Step Overview

Submission Step 1



Submission of Full Registration Dossier for Evaluation from different Departments

- The initial submission of Full CTD Modules to the Human Pharmaceutical Regulatory Affairs Administration will occur subsequent to the following steps:
1-Obtaining Box approval (Registration request approval) and Naming approval
2-Submission to the Pricing and Pharmacovigilance departments (*). (Submit a screenshot as evidence of submission)
- The Required documents for the Leaflet and layout were Submitted according to their own submission guidance.

STEP 2 : Screening by Administration Of Human Pharmaceutical Regulatory Affairs



Completed

The registration Dossier will be distributed to relevant departments (Clock Starts)



In-completed

Rejection with comments will be sent to applicant and the applicant must fulfill the comments and re-submit the full registration dossier as **new submission again** in maximum period of **30 WDs**





STEP 3 Technical Evaluation

In Case Of Acceptance

The administration of Human Pharmaceutical Regulatory Affairs sends the registration Dossier to different departments for technical evaluation.

In the case of additional comments required from the company(**Clock Stop**), a maximum period of **three months** is granted to submit the required documents as supplementary for each departments.

Upon Fulfilling all Requirements

**All Technical Approvals will be Issued within the
published timeframe**

STEP 4

Submission for Updated Module (I) after getting Approvals

After Obtaining all technical approvals, Pricing Certificate and PV approval , the applicant Must re-submit the updated Module I with approvals by maximum 6 months PV approval or pricing certificate whichever is later [on submission link](#)



FINAL STEP

Final Review and Committee Presentation

Administration Of Human Pharmaceutical Regulatory affairs will review the Final registration Dossier and present to The Technical Committee for Drug control for approval

In the case of additional comments from the company(**Clock Stop**), a maximum period of **60 Days** is granted to submit the required documents as supplementary .

**Then Issuance Of Registration License
After Technical Committee Approval**

1

Full Registration
Dossier submitted for
Evaluation from
different Departments

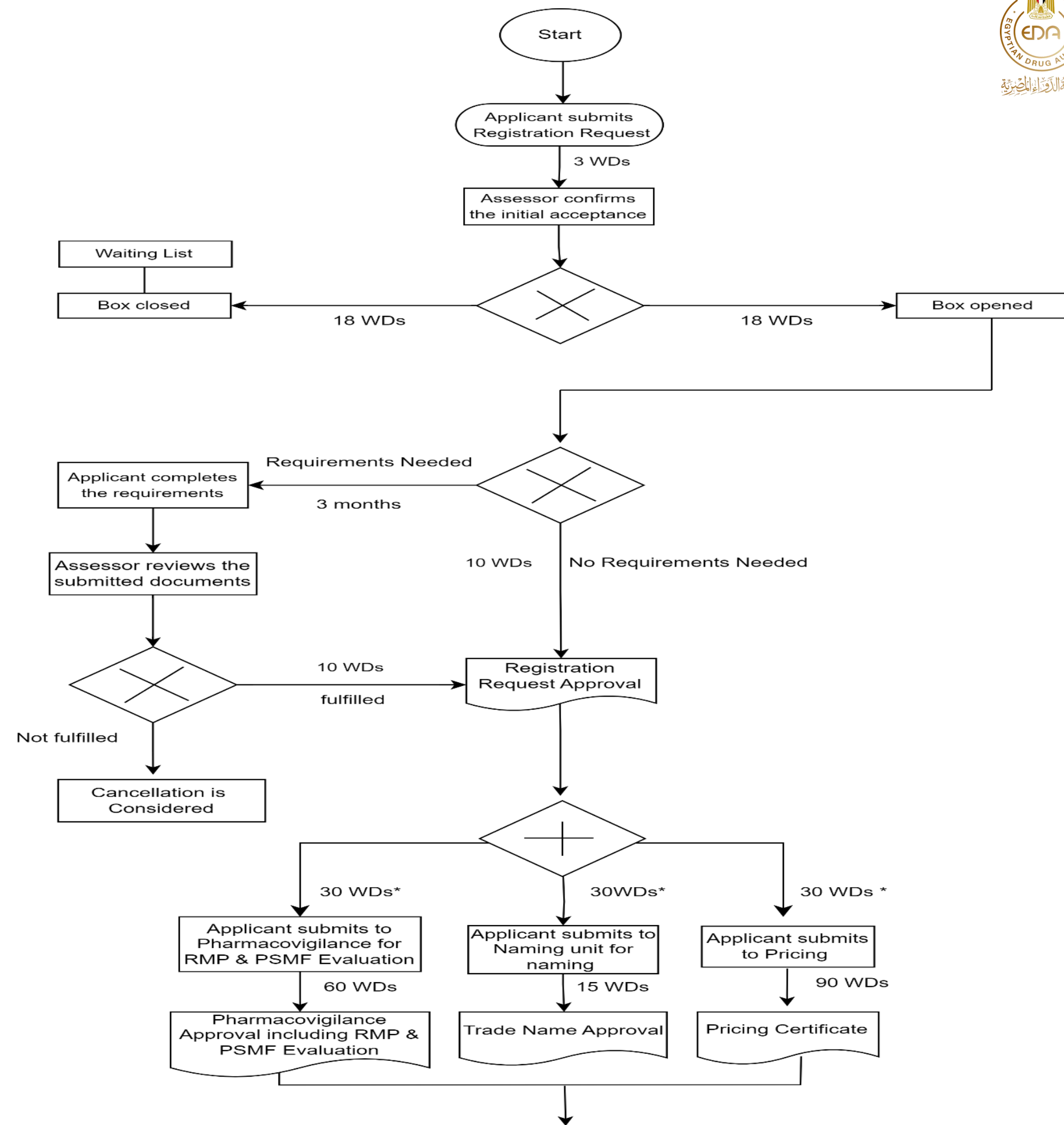
2

Submission for
updated Module (I)
with approvals.

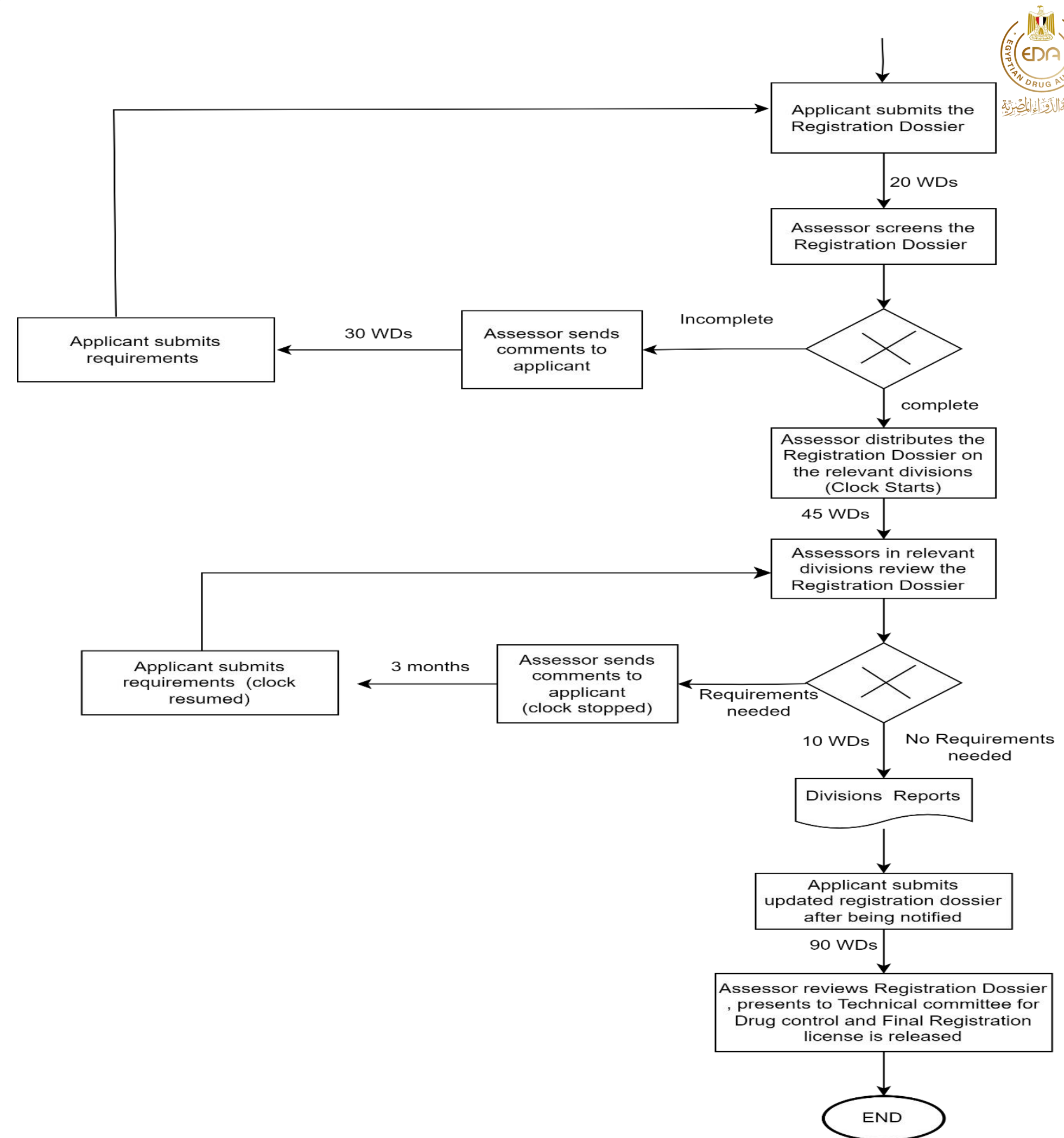
Summary of types of Submission to the administration of human pharmaceuticals regulatory affairs by the applicant.

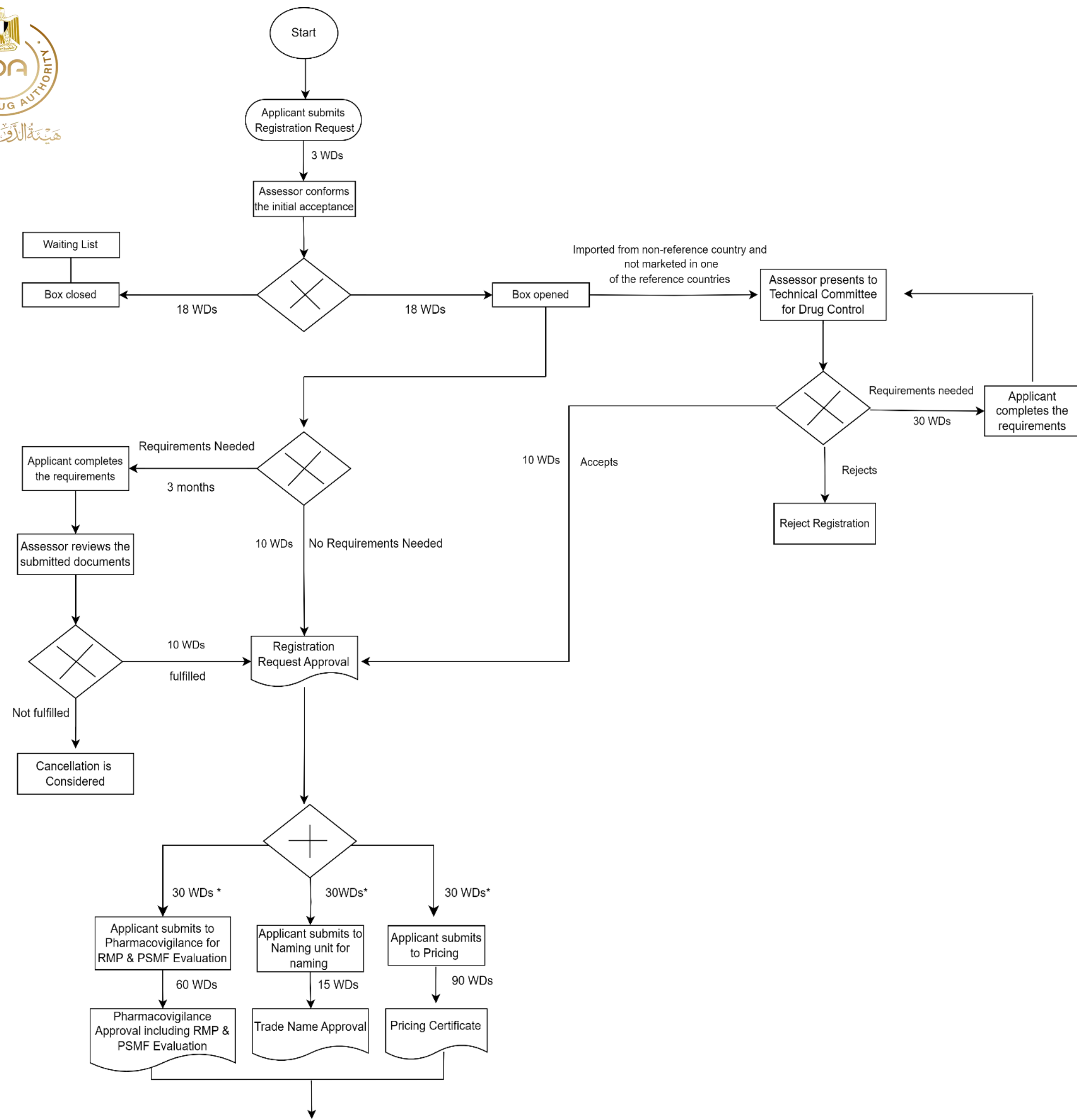
EDA Chairman Decree (450/2023) Case I

Flowchart for Imported Products from Reference Countries with assessment timelines



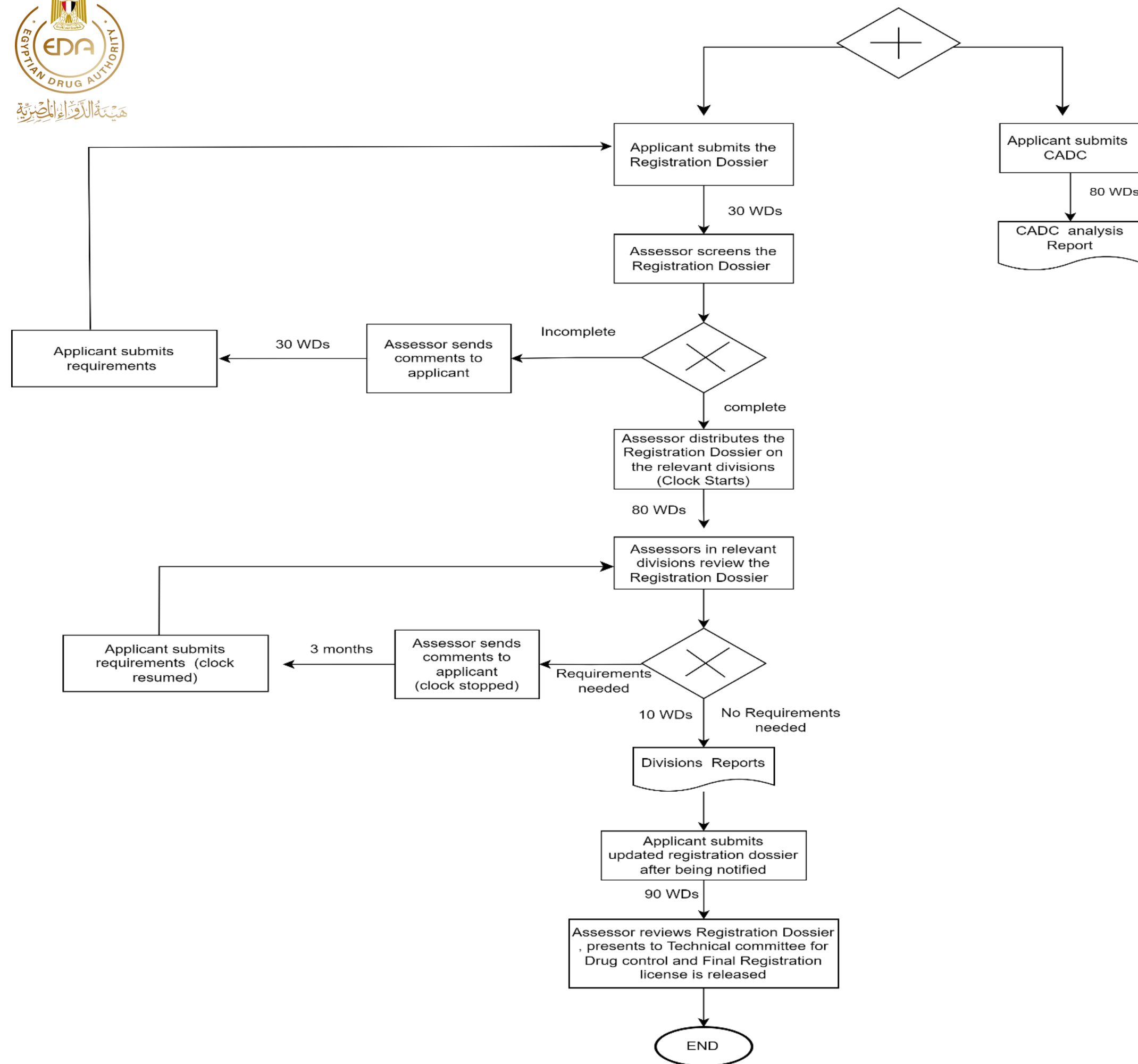
EDA Chairman Decree (450/2023) Case I Flowchart for Imported Products from Reference Countries with assessment timelines





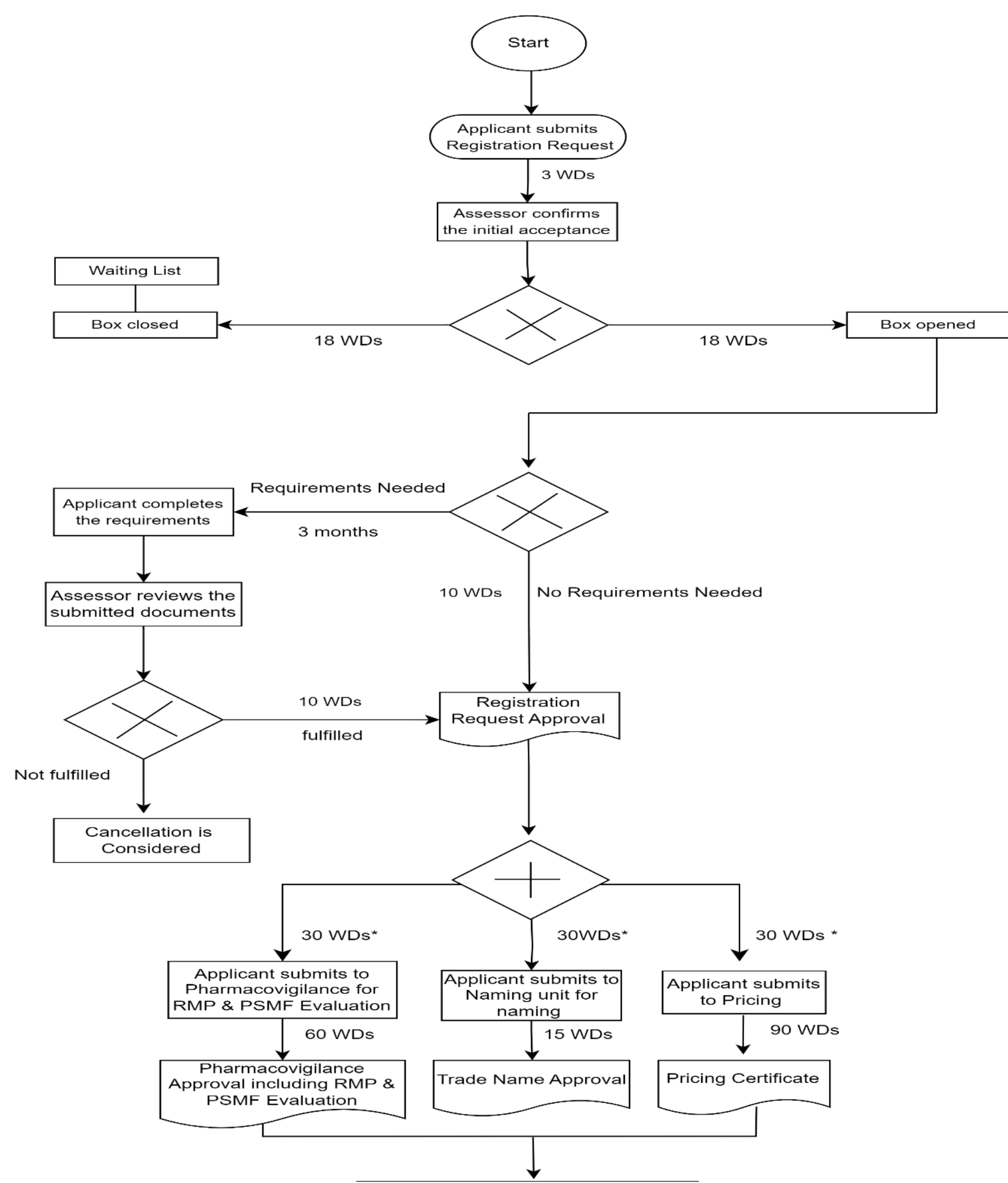
**EDA Chairman Decree
(450/2023) Case I**

**Flowchart for
Imported Products
from non-reference
countries and not
marketed in one of
reference countries
with assessment
timelines**



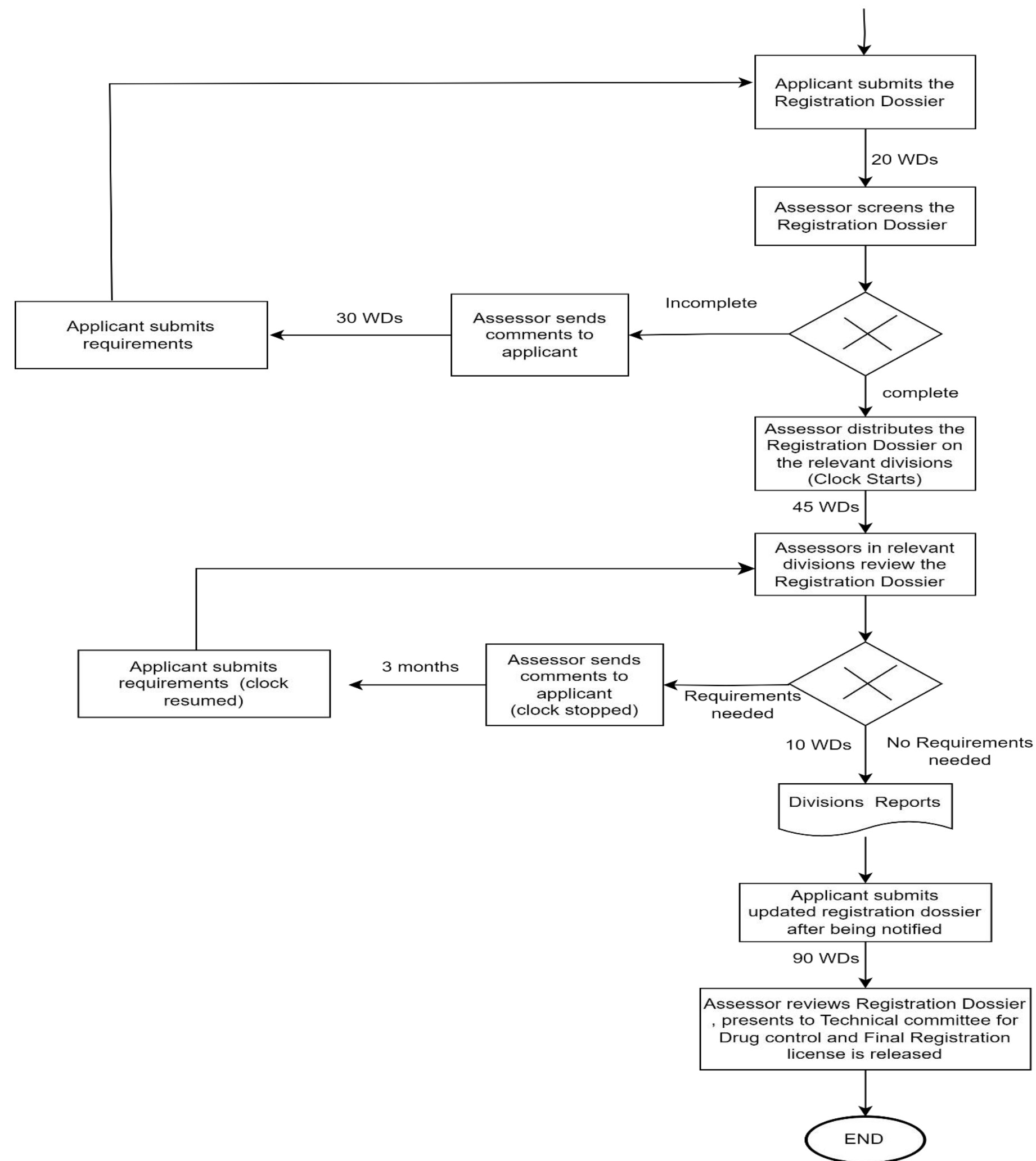
EDA Chairman Decree (450/2023) Case I

Flowchart for Imported Products from non-reference countries and not marketed in one of reference countries with assessment timelines



EDA Chairman Decree (450/2023)

Case III Flowchart for Imported Products with assessment timelines



EDA Chairman Decree (450/2023)

Case III Flowchart for Imported Products with assessment timelines

EDA Timeframes



	Procedures	Timeline Related to	Imported from Reference country	Imported from non- Reference country and not marketed in Reference country
1	Screening	EDA	20 WDs	30 WDs
2	Distribution and Technical evaluation from related departments	EDA	45WDs	80 WDs
3	Release of approval from related departments	EDA	10 WDs	10 WDs
4	Final Revision of Registration Dossier	EDA	45WDs	45WDs
5	Review of Supplementary documents	EDA	15WDs	15WDs
6	Present to Technical committee & license release after complete Registration Dossier	EDA	30WDs	30WDs

Form Name	Link
Submission for Full Registration Dossier for Imported products according to EDA Chairman Decree 450/2023 Case 1 & Case 3 Track A Imported	https://forms.gle/DJ3g9HtahsVgN4zS6
Final File Submission for Imported Products (Submission for Updated Module (I) after getting Approvals)	https://docs.google.com/forms/d/1aZovRpArFvgWraBdlYCGdZFh3SGbAf5YTb1JziA57-8/edit?usp=sharing
Supplementary Document for Imported Products	https://forms.gle/6EjfeZ2UoxwYTfCq5

Thank You

