Notice to Applicant

Workflow For Marketing Authorization Process

Year 2026

Code:EDREX.NP.BioInn13
Version No: 2.0
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Effective date: 16/7/2026

Table of contents

List of abbreviations:

CTD	Common Technical Document
EDA	Egyptian Drug Authority
EDREX	Egyptian Drug Regulatory Index
EPVC	Egyptian Pharmacovigilance Center
EUA	Emergency Use Approval
GL	Guideline
GMP	Good Manufacturing Practices
LOQ	List of Questions
MA	Marketing Authorization
NP	Notice to Applicant
PAC	Post Approval Change
PV	Pharmacovigilance
RL	Reliance Level
TC	Technical Committee
WDs	Working Days

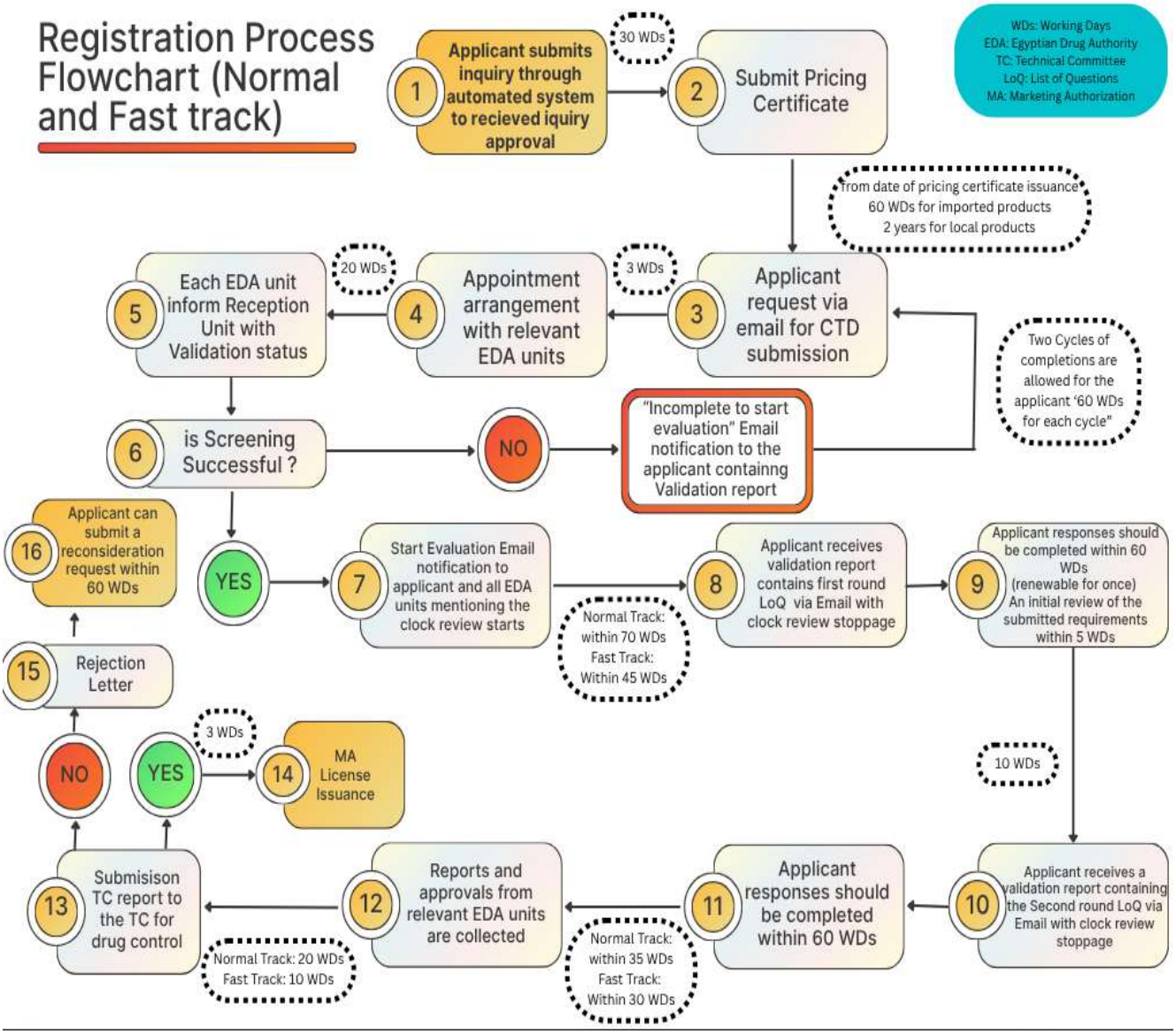
Objective:

This notice to applicant is intended to give a roadmap for the marketing authorization holders of biological products during the registration, re-registration and post approval process through an illustrative workflow of file submission of each process pathway.

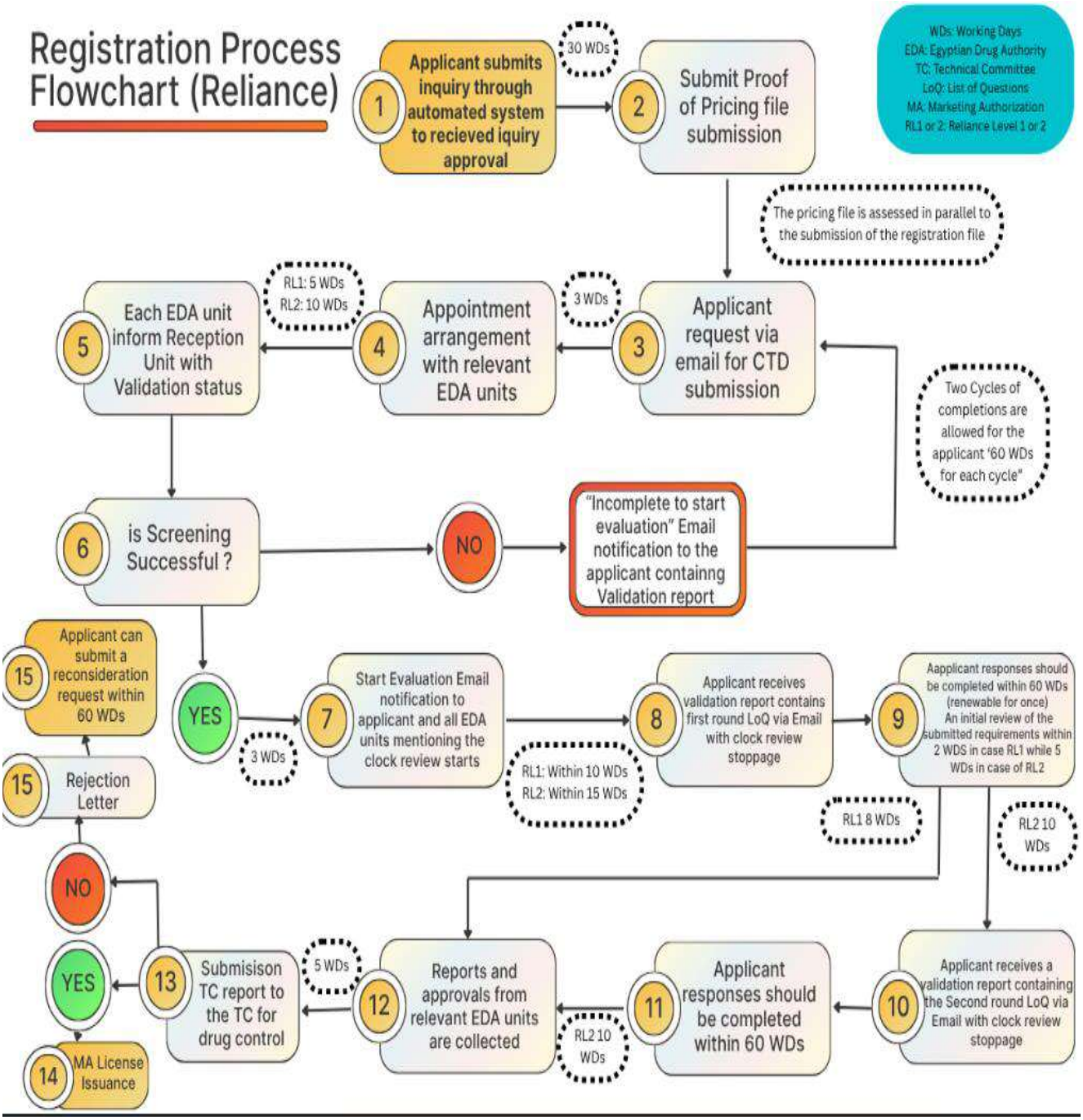
This notice to applicant has been prepared in accordance with the following EDA guidelines & notice to applicants:

1. Regulatory guideline of mechanisms and rules of implementing the decree of Egyptian Drug Authority's Chairman No. (343) of 2021 (Code: EDREX.GL. BioInn.001)
2. Procedures for registration of biological products through reliance pathways (Code: EDREX.GL.Bioinn.002)
3. Guideline on the regulation of post-approval changes to a registered biotherapeutic product in Egypt (Code: EDREX.GL.Bioinn.008)
4. Guideline on emergency use approval (Code: EDREX: GL.BIOINN/CAPP.001)
5. Rules for registering biological products under the fast-track registration pathway (Code: EDREX.NP.Bioinn.007)
6. Mechanisms for registering the second brand products in Egypt (Code: EDREX: NP. Bioinn.008)

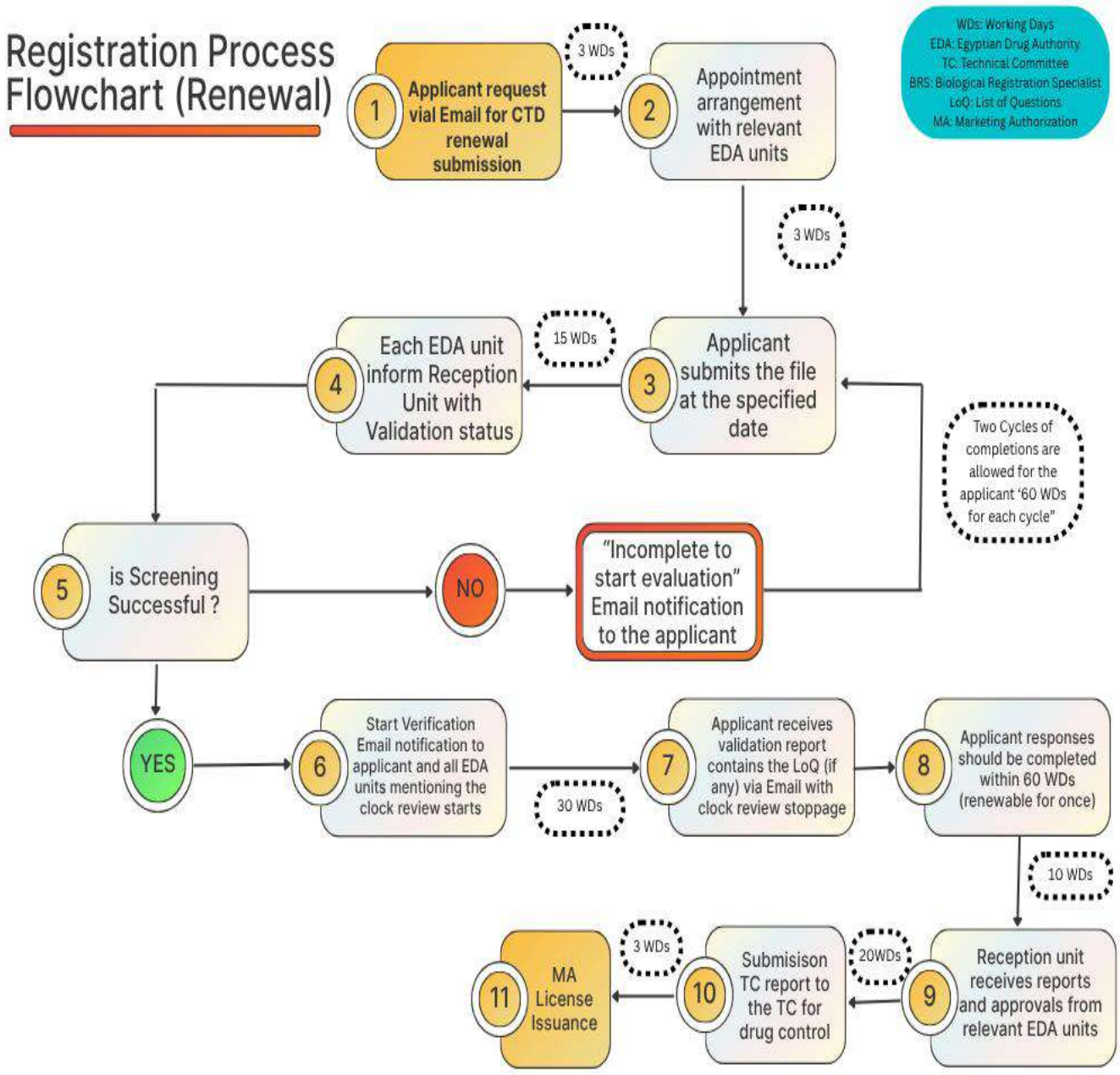
Registration process flowchart for new products (normal & fast track pathway):



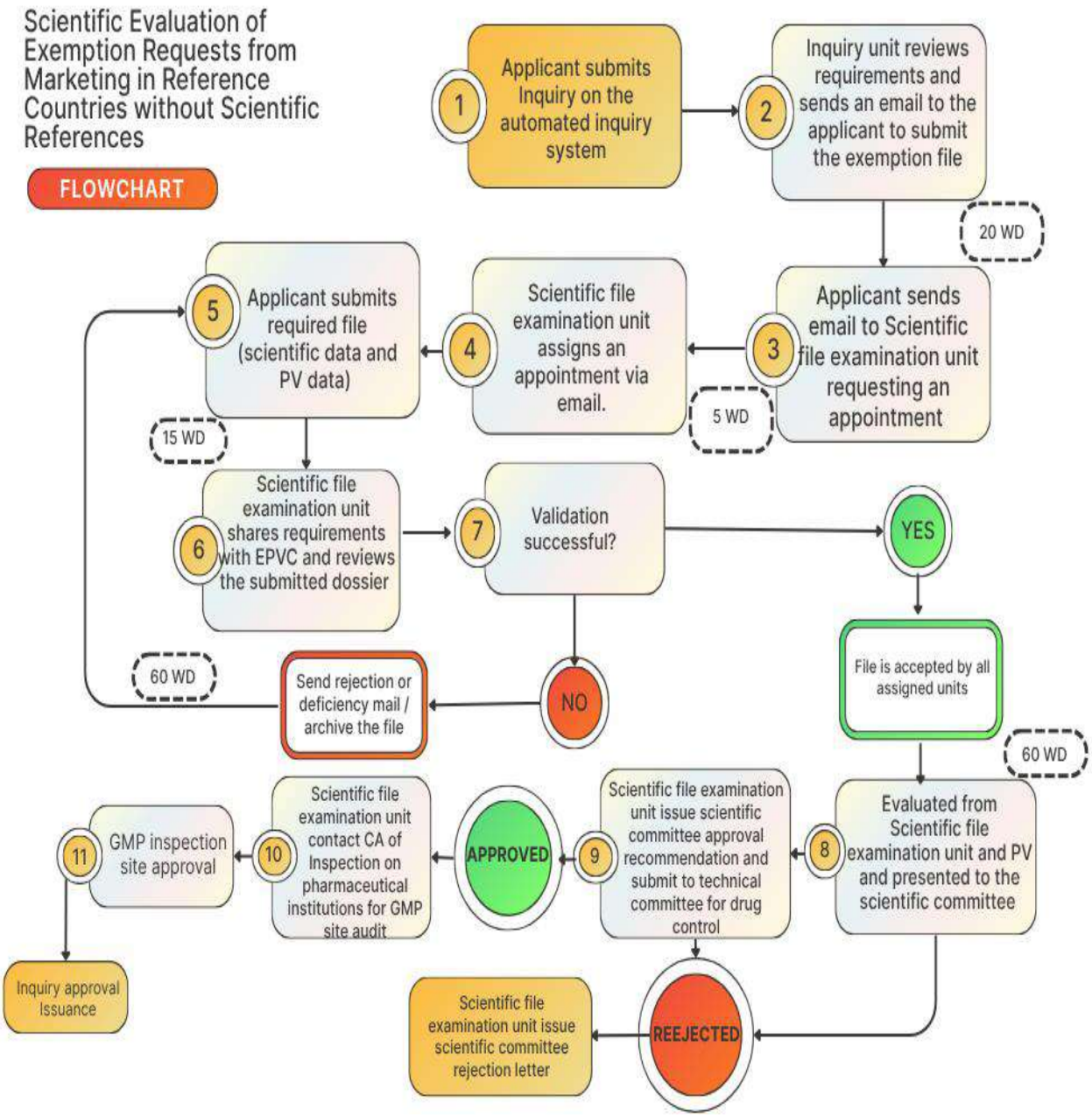
Registration process flowchart for new products (reliance pathway):

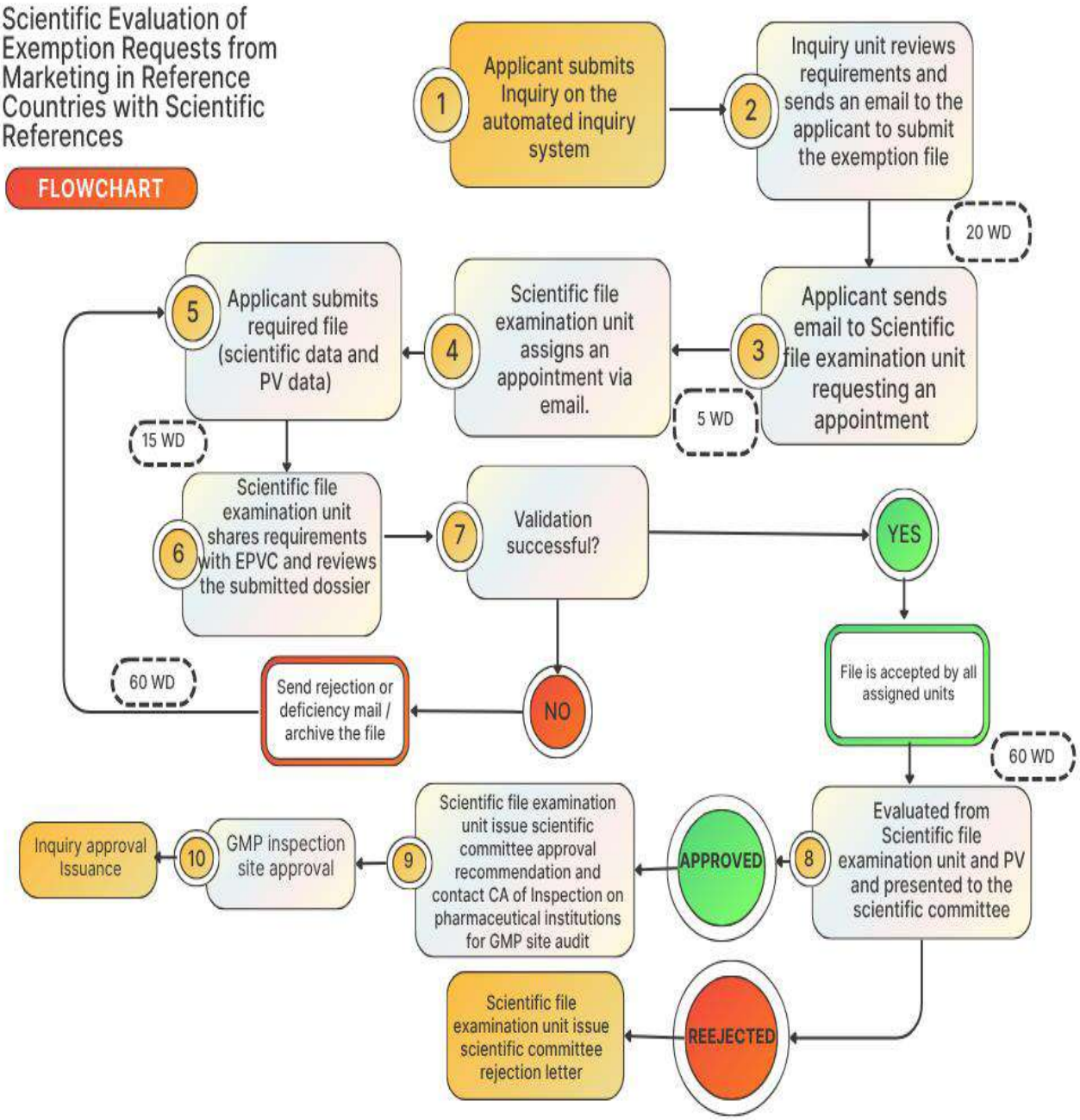


Registration process flowchart (Renewal pathway):

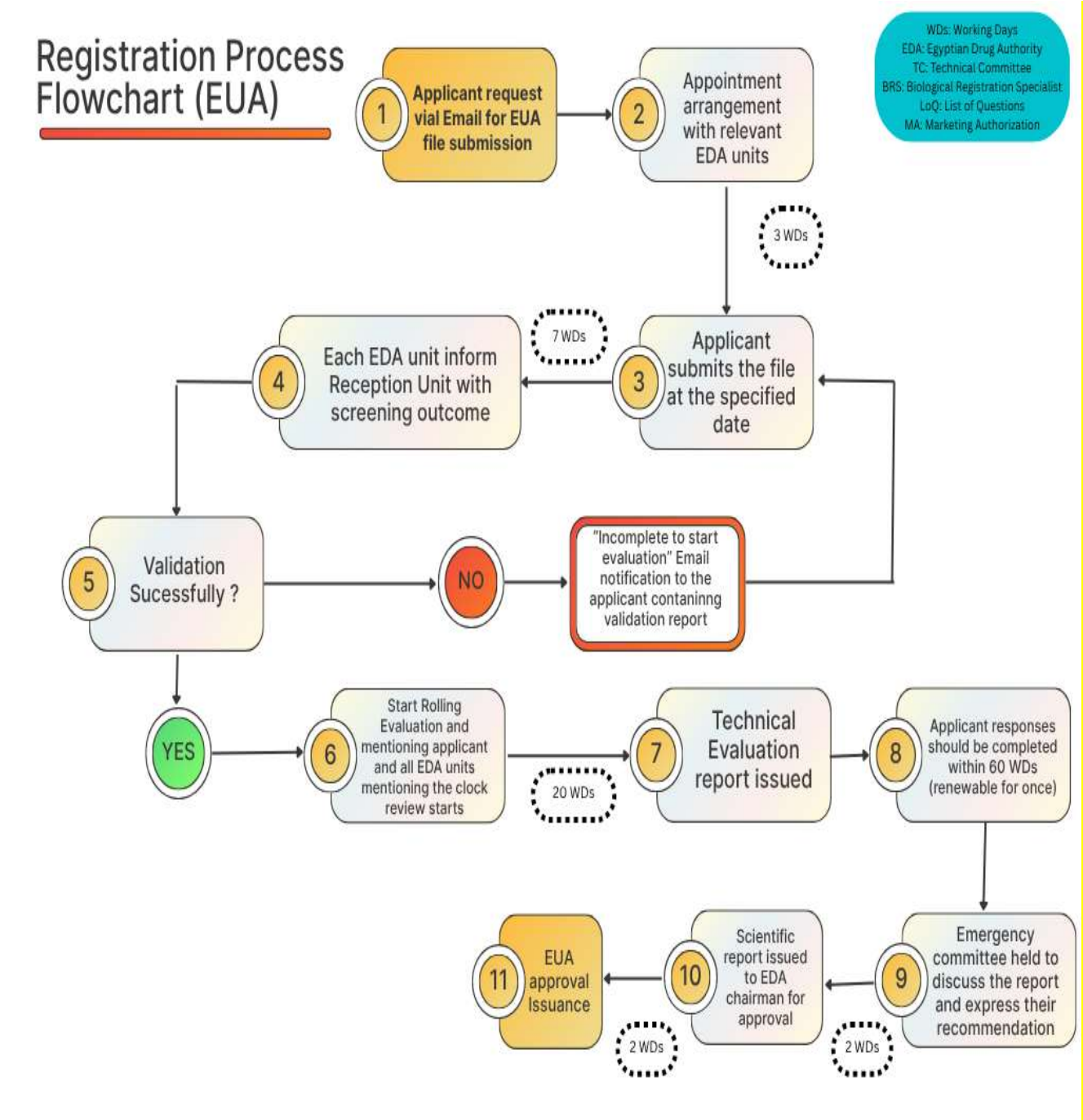


Registration process flowchart (exemption request):

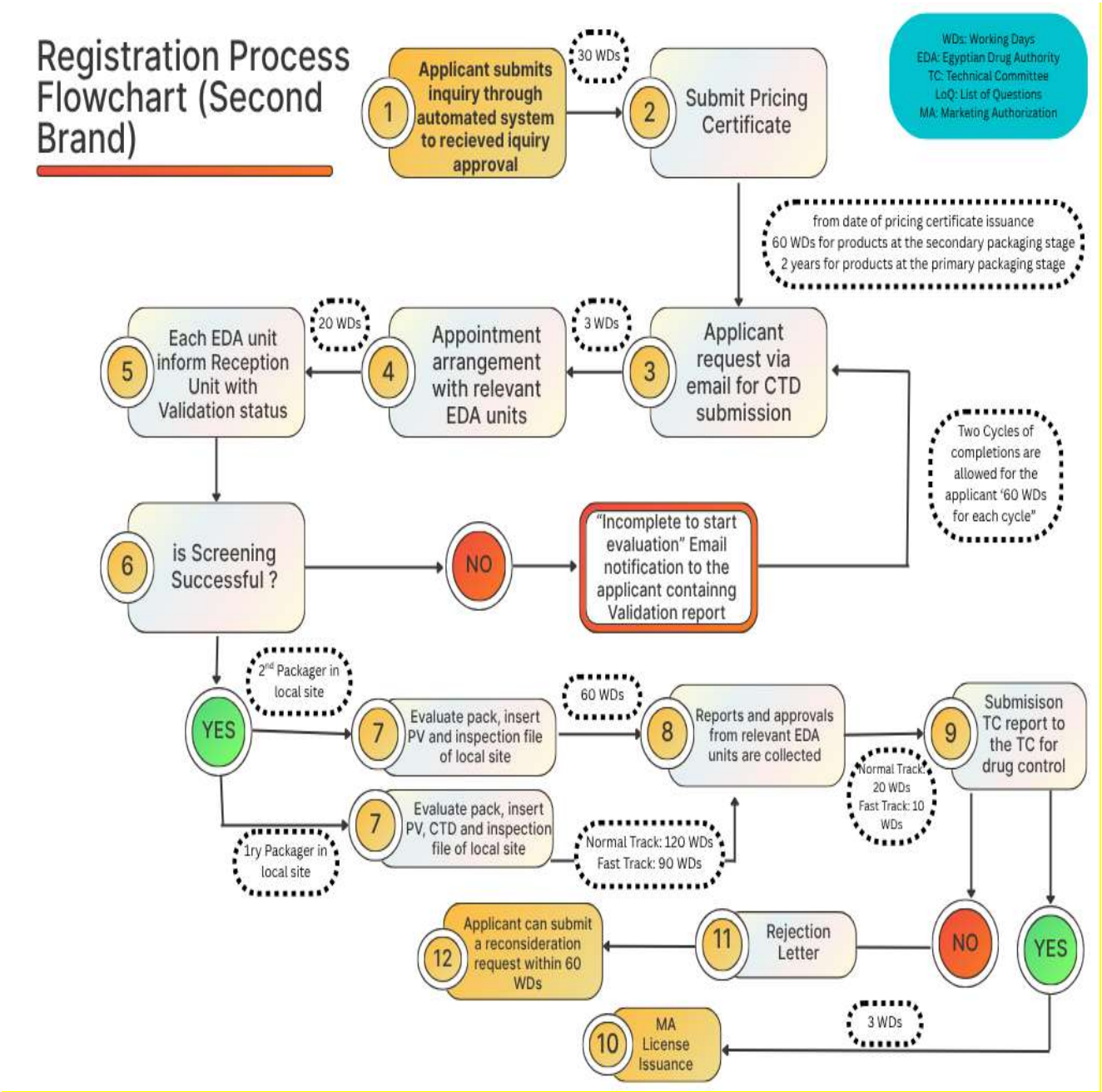



Scientific Evaluation of Exemption Requests from Marketing in Reference Countries with Scientific References
FLOWCHART
1
Applicant submits Inquiry on the automated inquiry system
2
Inquiry unit reviews requirements and sends an email to the applicant to submit the exemption file
20 WD
3
Applicant sends email to Scientific file examination unit requesting an appointment
5 WD
4
Scientific file examination unit assigns an appointment via email.
5
Applicant submits required file (scientific data and PV data)
15 WD
6
Scientific file examination unit shares requirements with EPVC and reviews the submitted dossier
7
Validation successful?
YES
File is accepted by all assigned units
60 WD
8
Evaluated from Scientific file examination unit and PV and presented to the scientific committee
APPROVED
REEJECTED
9
Scientific file examination unit issue scientific committee approval recommendation and contact CA of Inspection on pharmaceutical institutions for GMP site audit
10
GMP inspection site approval
Inquiry approval Issuance
Scientific file examination unit issue scientific committee rejection letter
NO
Send rejection or deficiency mail / archive the file
60 WD

Registration process flowchart (EUA):



Registration process flowchart (second brand):



Normal pathway of post approval changes to registered biological products in Egypt flowchart:

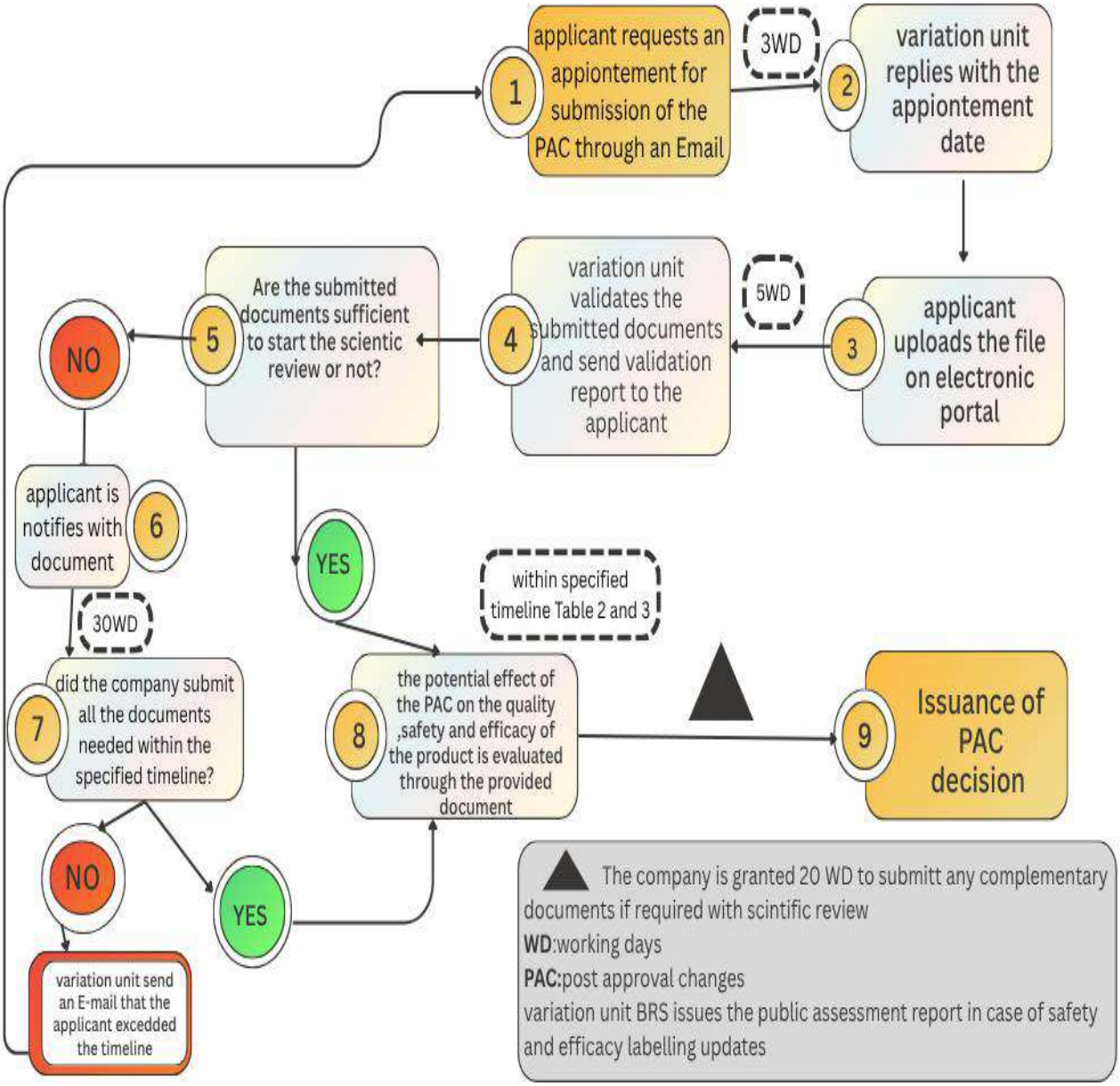


TABLE 2

Reporting category	Review timeline
Moderate quality changes	40 WD
Administrative change	10 WD
Administrative product labeling update	10 WD
Pack updates	10 WD

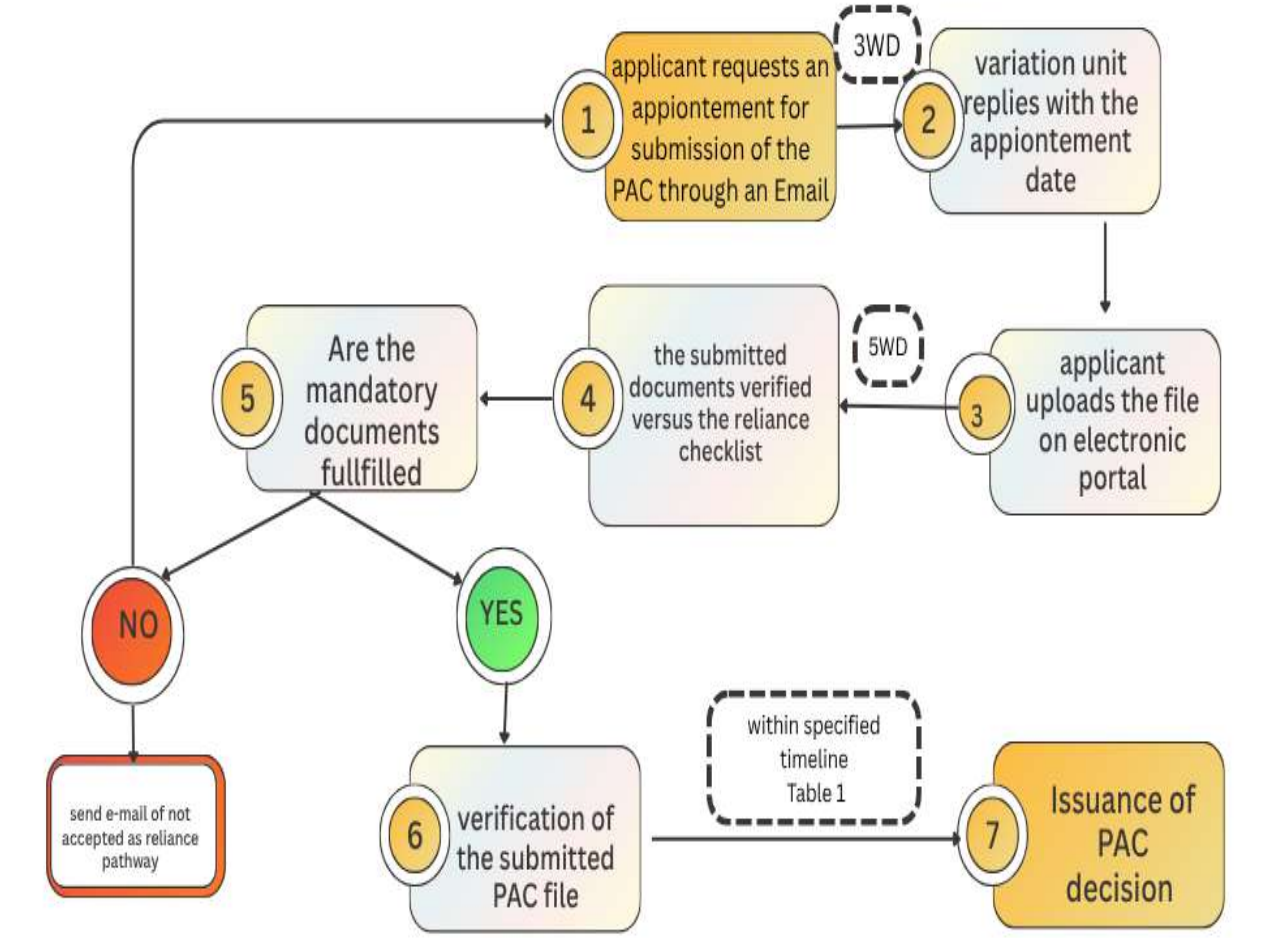
TABLE 3

Reporting category	Review timeline
Quality Changes	
Major quality changes	60 WD
Moderate quality changes	40 WD
Labelling update Change	
Safety and efficacy changes	40 WD
Product labelling information changes	30 WD

THESE TIMELINES ARE CALCULATED FROM THE DATE OF RECEIVING THE PAC FILE EXCLUDING THE TIME GRANTED FOR THE MAH TO FULFILL ANY COMPLEMENTARY DOCUMENTS

⚠ WHENEVER A COMPLEMANTORY DOCUMENT IS REQUIRED DURING THE FILE REVIEW THE APPLICANT IS GRANTED 20 WD TO FULFILL IT

Reliance pathway of post approval changes to registered biological products in Egypt flowchart:



WD:working days
PAC:post approval changes
Reliance pathway: is applicaple on Major and moderate quality changes and product information labelling updates

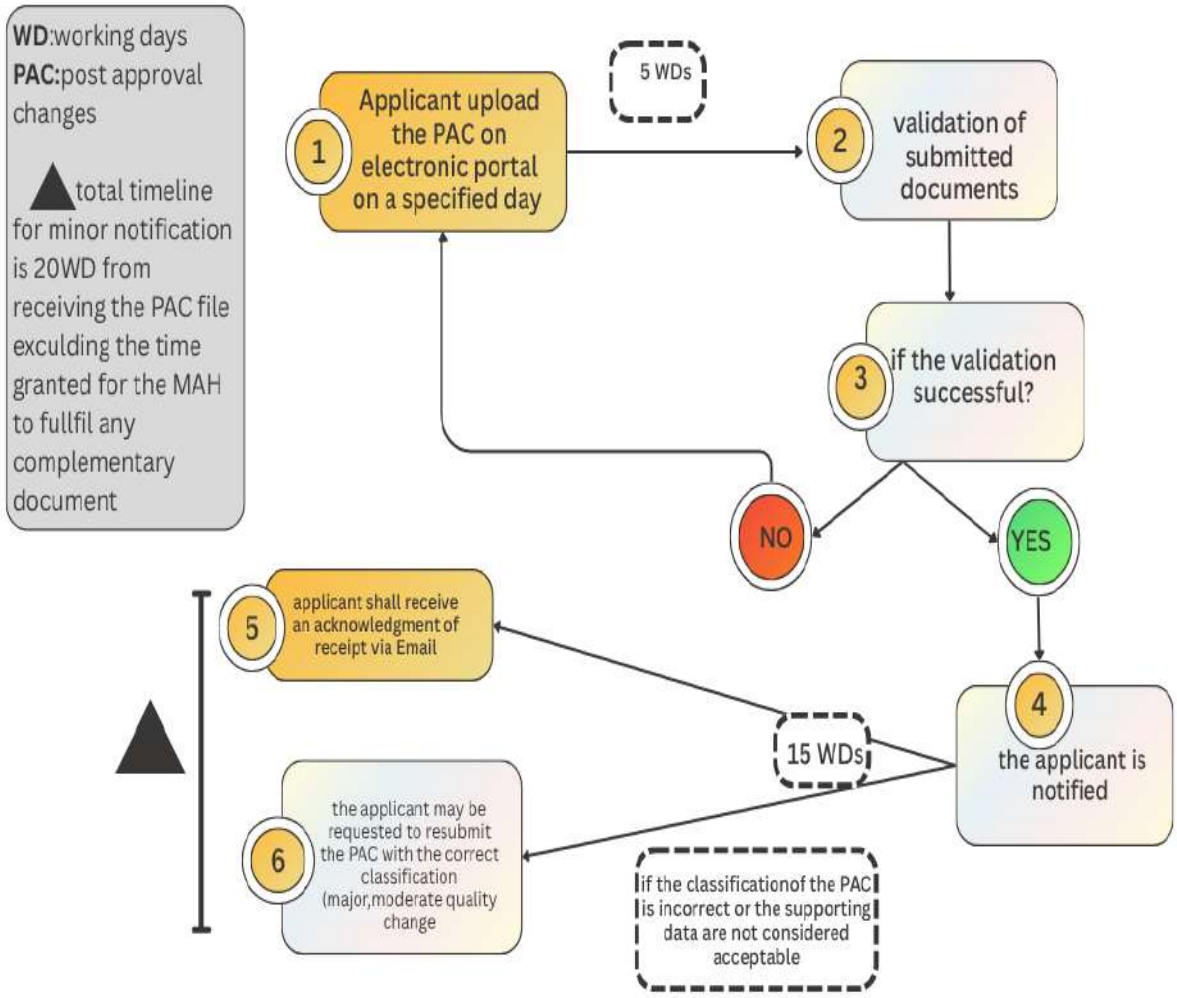
TABLE 1

Reporting category	Review timeline
Quality Changes	
Major quality changes	15 WD
Moderate quality changes	10 WD
Labelling update Change	
Product labelling information changes	10 WD

THESE TIMELINES ARE CALCULATED FROM THE DATE OF RECEIVING THE PAC FILE EXCLUDING THE TIME GRANTED FOR THE MAH TO FULFILL ANY COMPLEMENTARY DOCUMENTS

⚠ WHENEVER A COMPLEMANTORY DOCUMENT IS REQUIRED DURING THE FILE REVIEW THE APPLICANT IS GRANTED 20 WD TO FULFILL IT

Minor pathway of post approval changes to registered biological products in Egypt flowchart:



History table

Version No	Issue date	Summary of changes
1	21/11/2024	Initial issue
2	15/7/2026	Addressing certain gaps that were identified following implementation