Workflow For Marketing Authorization Process

Year 2024

Code: EDREX.NP.BioInn.013
Version No: 1
Issue Date: 21/11/2024
Effective date: 21/11/2024

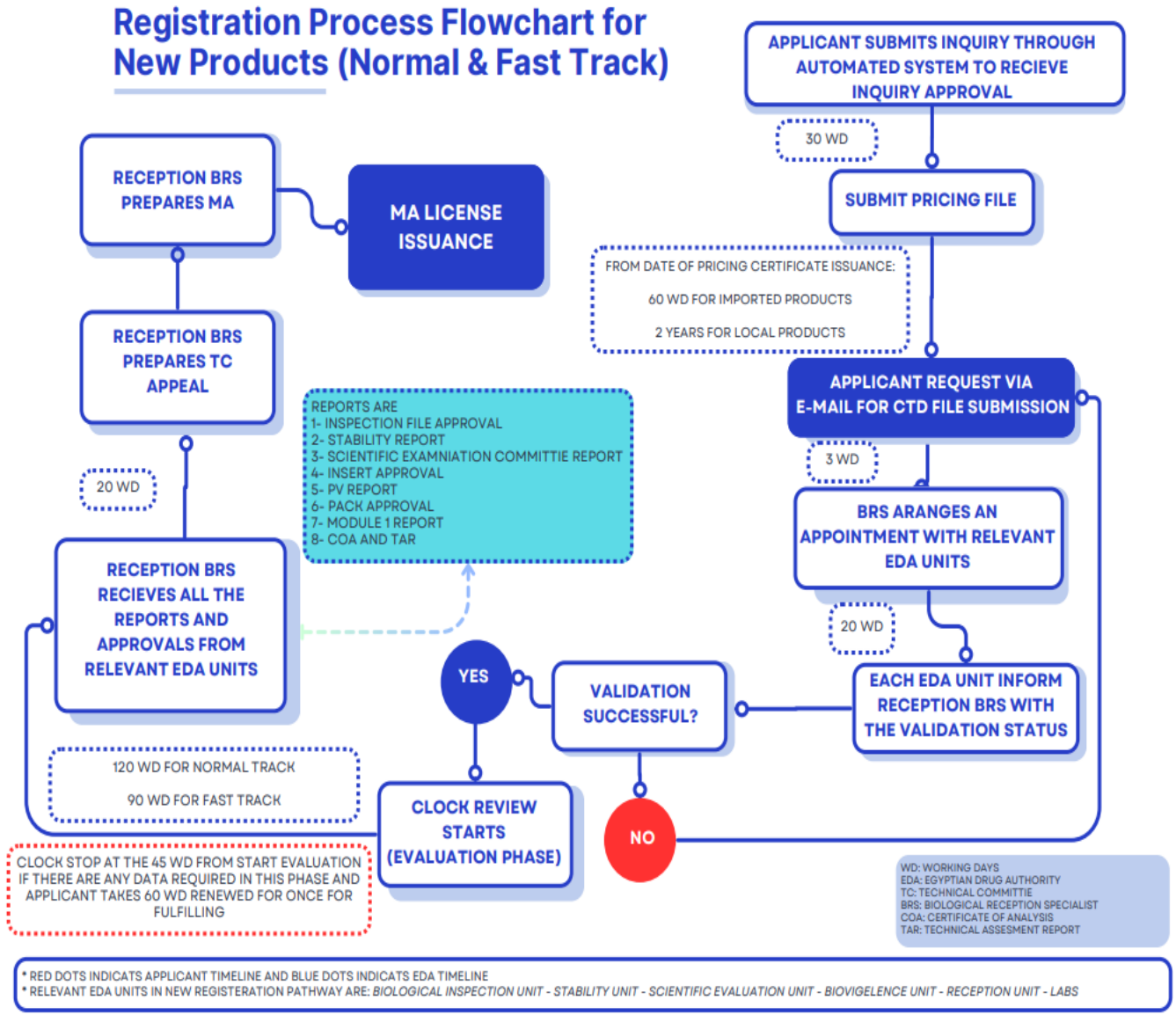
Objective:

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.

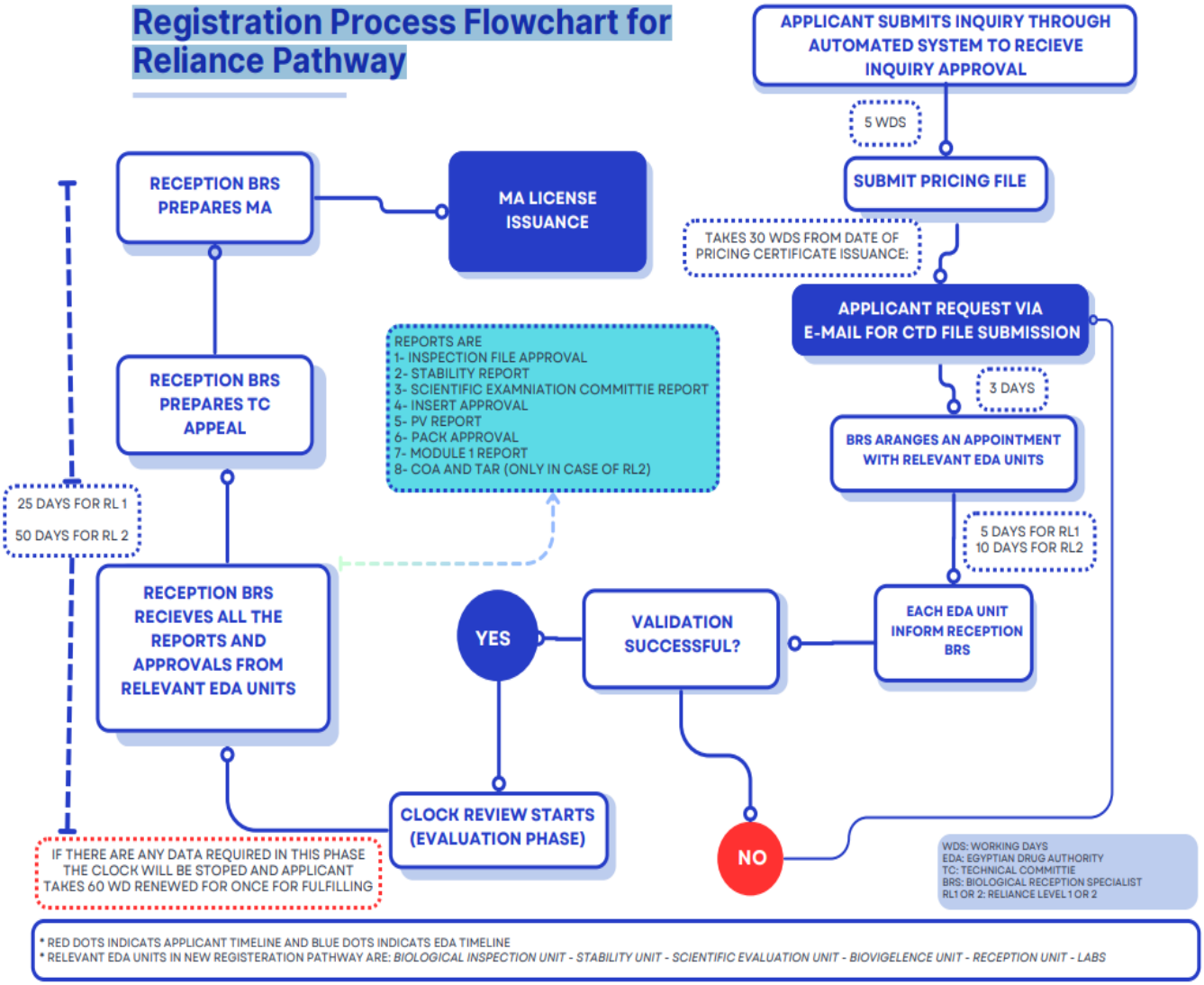
This notice to applicant has been prepared in accordance with the following EDA guidelines & notice to applicants:

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 for registration of biosimilar products in Egypt, Code: EDREX.GL.Bioinn.005
4. Guideline on the regulation of post-approval changes to a registered biotherapeutic product in Egypt Code: EDREX.GL.Bioinn.008
5. Notice to applicant describing the regulation of registration of biological products through fast track pathway code: EDREX.NP.Bioinn.007
6. Notice to applicant describing the regulation of registration of second brand products code: EDREX.NP.Bioinn.008

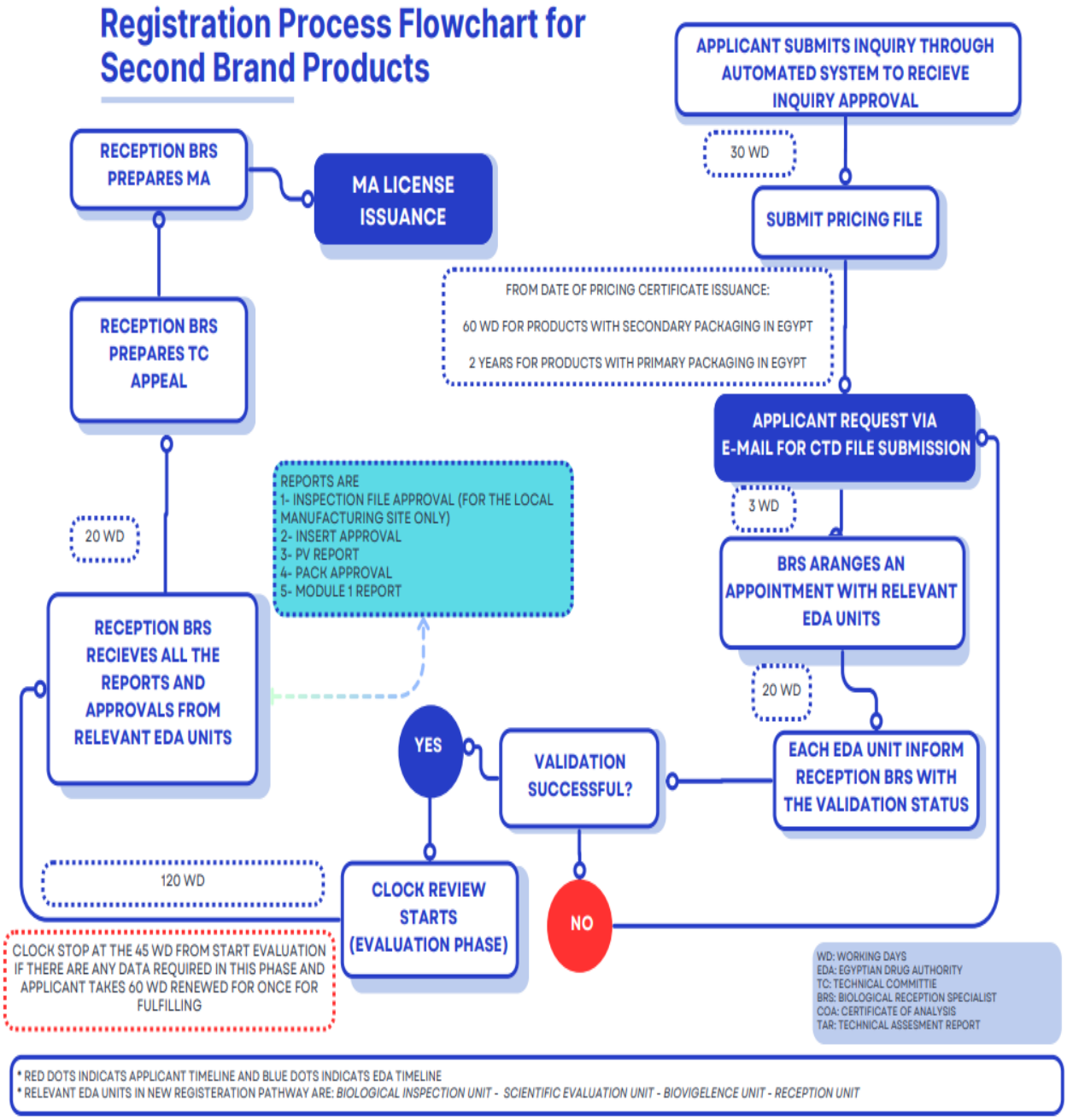
Registration process flowchart for new products (normal & fast track pathway):



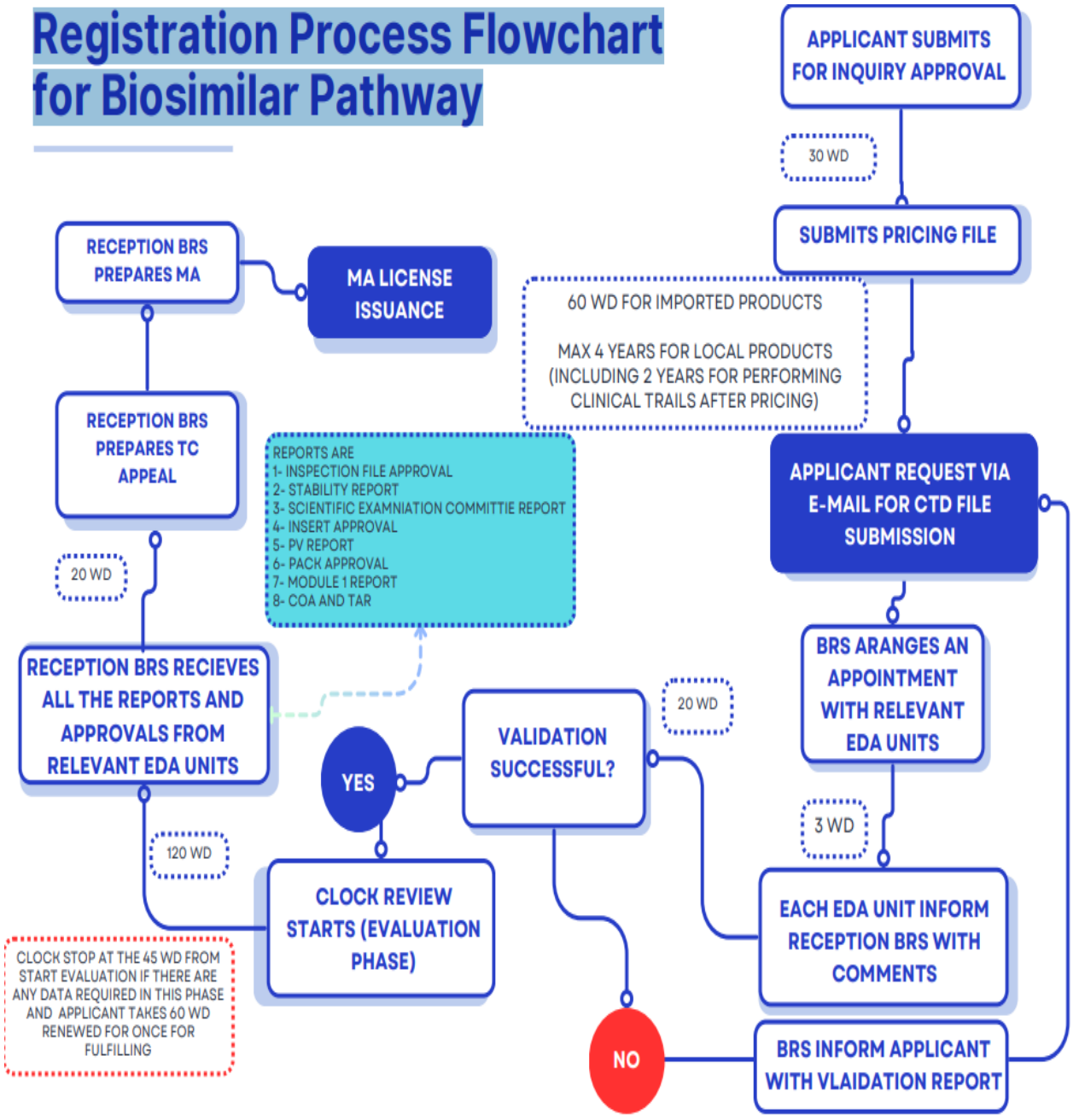
Registration process flowchart for new products (reliance pathway):



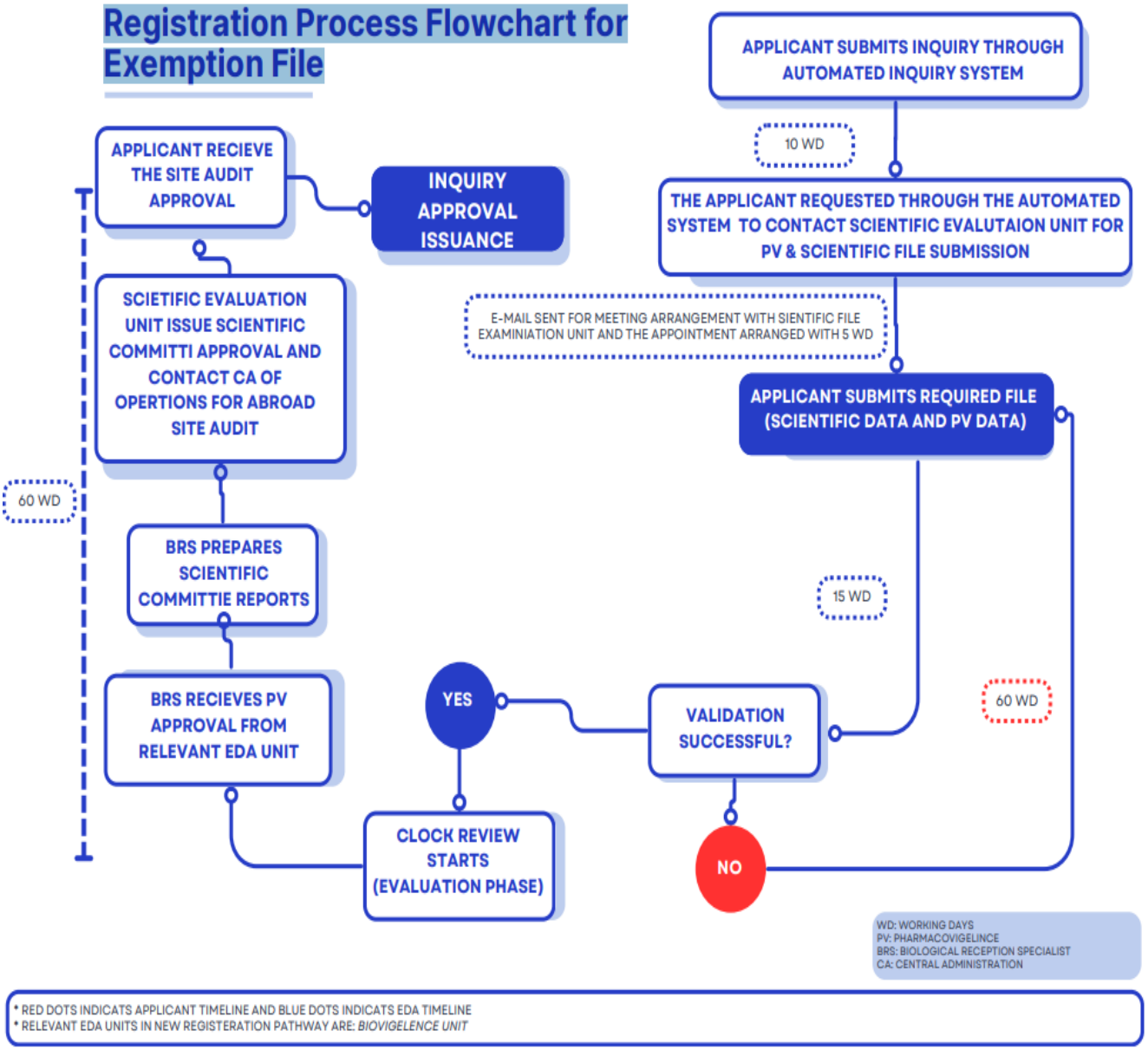
Registration process flowchart for second brand products:



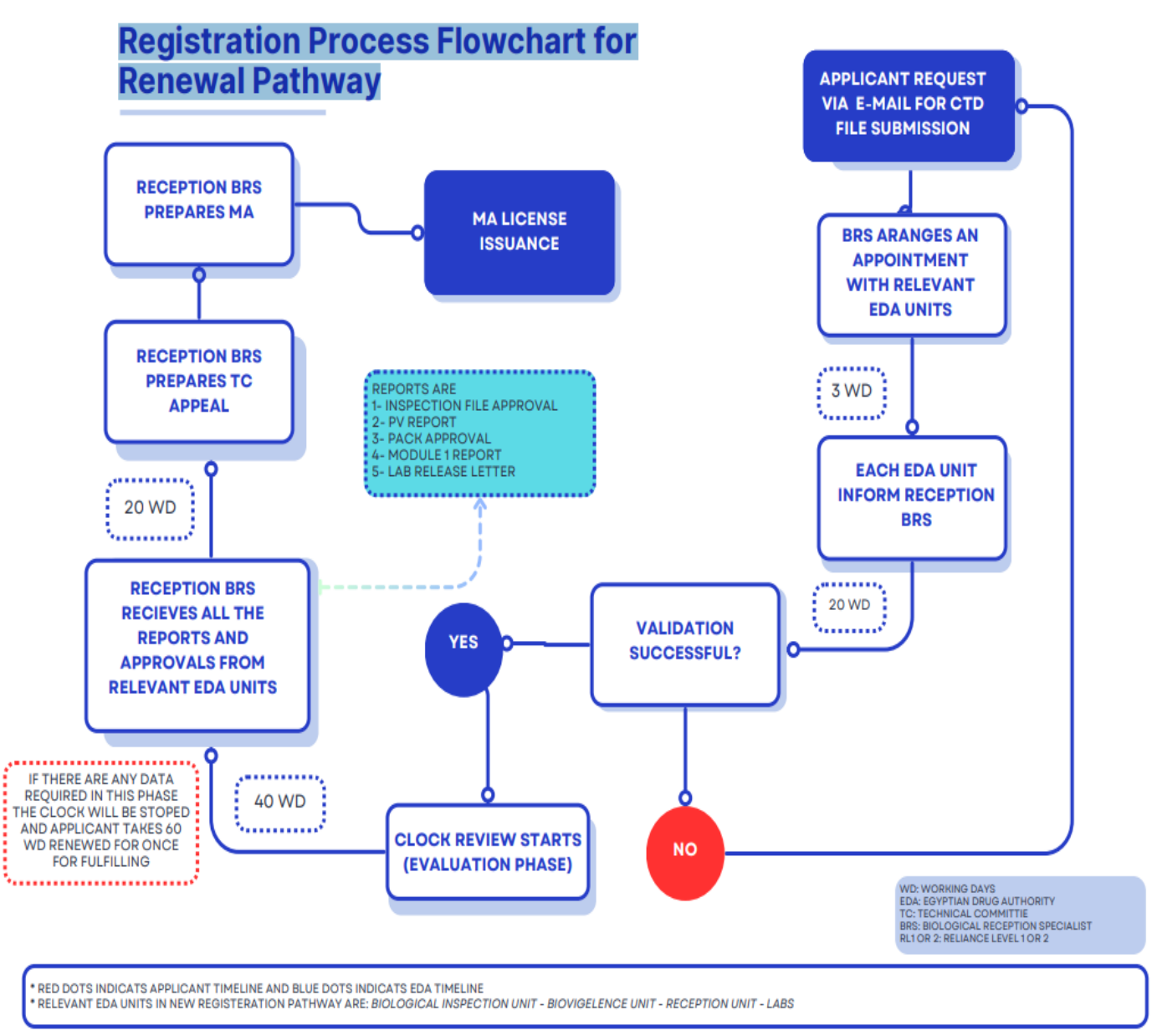
Registration process flowchart for biosimilar pathway:



Registration process flowchart for exemption file:



Registration process flowchart for renewal pathway:



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

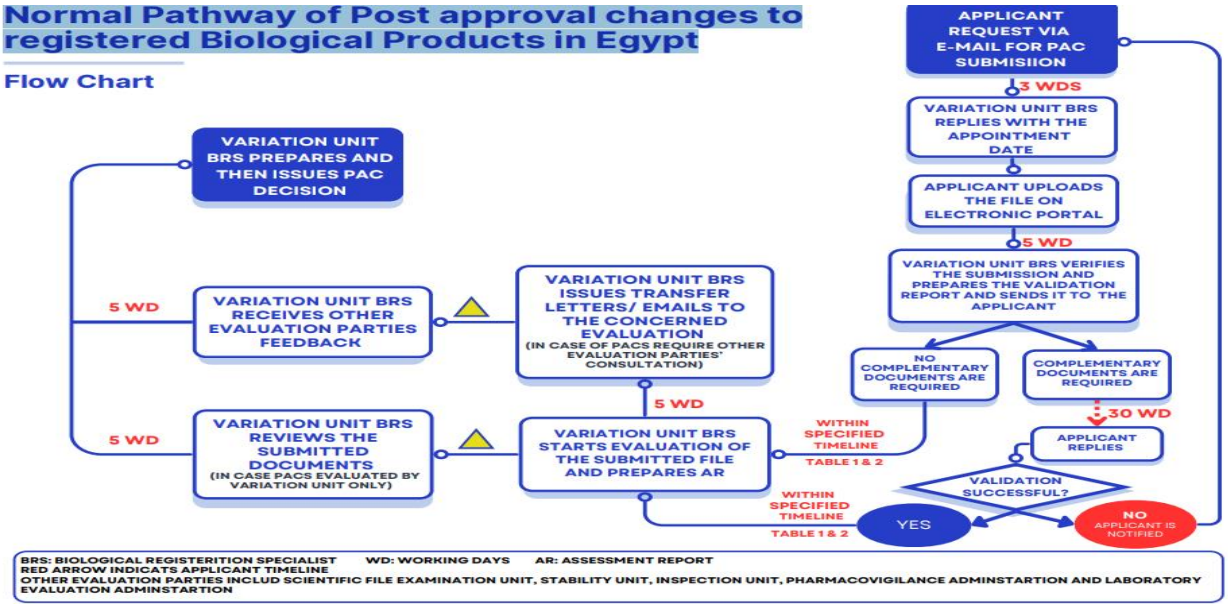


TABLE 1

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

TABLE 2

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 VARIATION FILE TILL THE ISSUANCE OF PAC DECISION EXCLUDING THE TIME GRANTED FOR THE MAH TO FULFIL ANY COMPLEMENTARY DOCUMENT

△ 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:

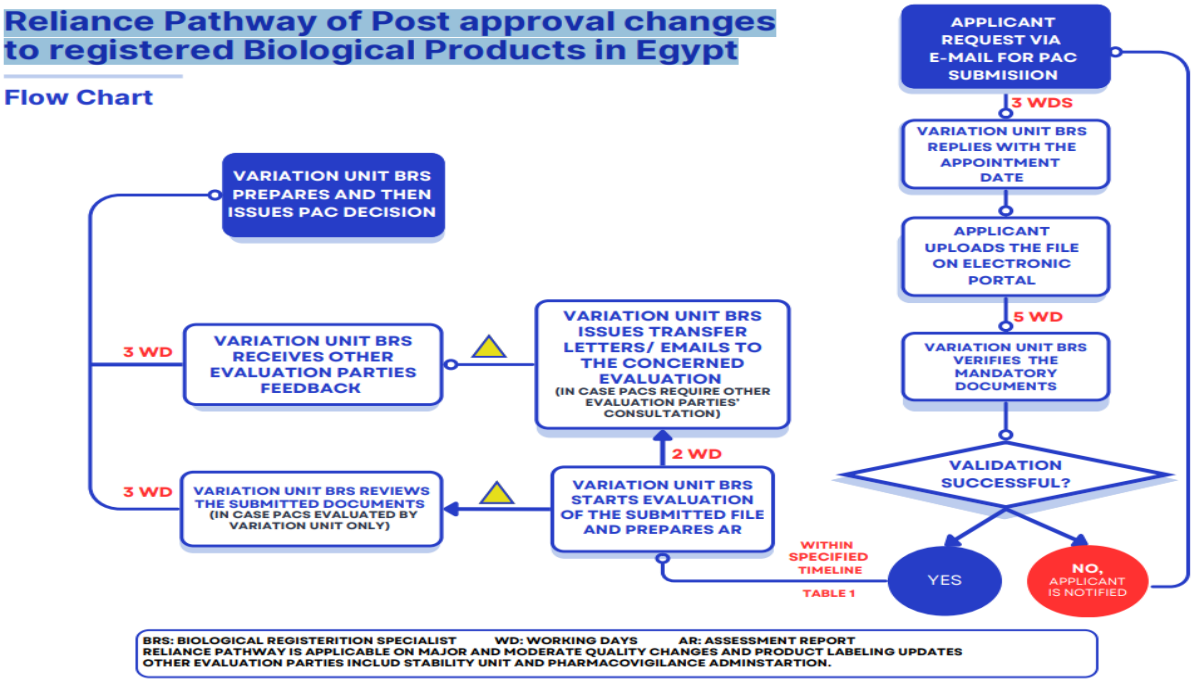


TABLE 1

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 VARIATION TILL THE ISSUANCE OF PAC DECISION FILE EXCLUDING THE TIME GRANTED FOR THE MAH TO FULFIL ANY COMPLEMENTARY DOCUMENT

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

Pathway of minor post approval changes to registered biological products in Egypt flowchart: