# Annex II - Operating Procedures of EDA-SAHPRA Work Sharing Initiative (WSI) in Registration of Medical products *(Pilot Phase)*

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## 1. Introduction

This document provides detailed information with regards to the submission process for the pilot project of EDA-SAHPRA Work Sharing Initiative (WSI) for Registration of Biologicals from the receipt of the Expression of Interest (EOI), as well as the eligibility criteria, milestones, and anticipated timelines. It is to be considered with the **concept note** document as well as **Annex I**: Call for Expression of Interest (EOI) and EOI Form.

## 2. Eligibility Criteria

**2.1.** **Type of Products:** Biologicals as a pilot phase. (Other medical products could be considered for later stages of the initiative).

**2.2.** **Type of Application:** New application only.
(Post Approval Changes (PACs) could be considered for later stages of the initiative)

**2.3.** **Type of Assessment**: Full assessment. Applications received should not be subject to reliance pathways by either of both authorities. The product should be approved & marketed in one of the Reference Regulatory Authorities as per the common list of reference authorities.

## 3. Submission Steps

**3.1.** The publication of an invitation to submit an **expression of interest** for pilot biological product evaluation project of EDA-SAHPRA Work Sharing Initiative.

**3.2.** Submission by the applicant to EDA-SAHPRA of an **EOI** to participate in this pilot procedure.

**3.3.** A **pre-submission meeting** with EDA-SAHPRA maybe requested after the submission by the applicant of an EOI.

**3.4.** A **screening procedure** to ensure that the dossier(s) submitted by the applicant as part of its EOI is complete.

**3.5.** **Assessment of product dossier**, which must include product data and information as specified in the applicable guidelines for submission.

**3.6.** The applicant submits the application for marketing authorization to both EDA & SAHPRA through each authority platform at the same time.

**3.7.** The application will be subjected to **validation** in 15 working days.

**3.8.** At the end of the validation step both authorities will discuss the findings.

3.3.1 When the validation requirements have been met/accepted the evaluation step **(Day 0)** will commence.

3.3.2 When the validation requirements have not been met, there will be requirements to be fulfilled by the applicant before the evaluation step **(Day 0)** can commence.

**3.9.** By **day 75** the applicant shall receive any queries raised during the evaluation step by both authorities

**3.10.** The applicant has **60 working days** to respond.

**3.11.** A single extension of **60 working days** is accepted upon applicant's request.

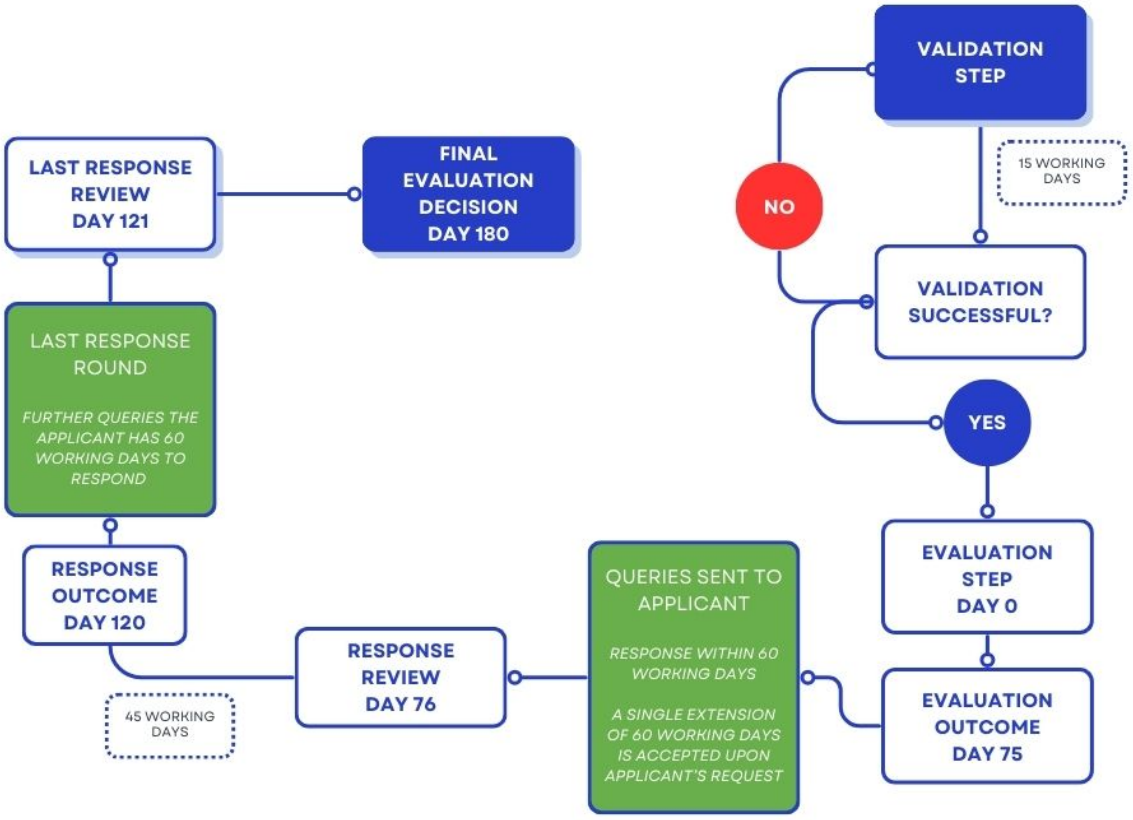
**3.12.** The response outcome will be shared with the applicant after **45 working days**.

**3.13.** If there are any further queries the applicant has **60 working days** to respond (last response round).

**3.14.** At **day 180** the final reports for the evaluation process should be completed by both authorities

**3.15.** The **validation criteria** for the submission can be accessed using the link provided for EDA and SAHPRA. **Visit link** [SAHPRA eCTD]

## 4. Flowchart with Milestones and Timelines




## 5. Focal Points for Technical Inquiries

**5.1.** EDA: Submission & Technical Requirements – EDA (Registration Administration – Central Administration of Biological, Innovative Products, & Clinical Trials) **Via email address: Bioreg.rec@edaegypt.gov.eg**

**5.2.** SAHPRA: Submission Requirements – SAHPRA Health Products Authorisation: **visit link [SAHPRA eCTD]**

**5.3.** Technical Inquiries – SAHPRA Portfolio Coordinator