Annex I: Application Form for EDA-SAHPRA Work Sharing Initiative (WSI) for Registration of Medical Products *(Pilot Phase)*

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1. Introduction

This document encompasses the call for industry stakeholders to express their interest in applying for EDA-SAHPRA WSI for registration of biologicals in its pilot phase as well as the relevant form to use.

2. Call for Expression of Interest

Egypt, as represented by the Egyptian Drug Authority (EDA), and South Africa, as represented by the South African Health Products Regulatory Authority (SAHPRA), are extending an invitation to industry partners to participate in the **pilot phase** of the Work Sharing Initiative (WSI) aimed at streamlining the registration process for biological products in both countries through joint assessment. As stakeholders in the pharmaceutical and biotechnology sectors, your collaboration is paramount to the success of this initiative.

By participating in this joint assessment initiative, **industry partners will have the opportunity** to:

- Collaborate with the leading African regulatory authorities to shape the future of regulatory policies and practices.
- Contribute to the development of regulatory frameworks that support mutual reliance and access to medicines and vaccines.

We invite you to express your interest in participating in this transformative initiative by submitting a formal application in the enclosed form after reviewing the *concept paper* of the initiative and its *operating procedures*. Deadline to receive your application is *[28th February 2025] via email:*

- ***EDA: Bioreg.rec@edaegypt.gov.eg***
- ***SAHPRA: eoi@sahpra.org.za***

3. Application Form

Product Information		
Product Name (should be same as on product label):		
ATC Code:		
Additional Comments:		
Pharmaceutical Form	Strength(s) with units	Route of Administration

Active Pharmaceutical Ingredient (API) Information
API (including salt and solvated form, if applicable):

National Reference Product Information	
Product Name	Authorisation Holder/Sponsor

Applicant Information	
Company Name (Full legal name):	
Address:	
Contact Person:	
Tel:	Email:

Application/submission filing information
Please note that the agencies will negotiate an evaluation plan with the applicant.

Consent to share regulatory information (to be signed by the applicant)
The undersigned hereby acknowledges and gives consent to the sharing of assessment reports and information with EDA and SAHPRA. **Subsequently, I declare sameness of the submitted files to both authorities.** Name of Authorized Signing Official: Title, Company: Signature**: Date: **Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted.

Consent to share regulatory information on the Restricted Part of the ASMF/DSMF (to be signed by the ASMF/DSMF holder). If needed.
The undersigned hereby acknowledges and gives consent to the sharing of assessment reports and information on the restricted part of the ASMF/DSMF with EDA and SAHPRA. Name of Authorized Signing Official: Title, Company: Signature**: Date: **Signatures (including digital/electronic versions, where permitted) must comply with the legal requirements of the jurisdiction(s) in which the EOI is being submitted.