Concept Note of EDA-SAHPRA Work Sharing Initiative (WSI) for Registration of Medical Products (Pilot Phase)

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1. Background

EDA-SAHPRA Work Sharing Initiative (**WSI**) for Registration comes as part of the longstanding cooperation between Egypt and South Africa. In alignment with the WHO (World Health Organization) Good Reliance Practices (**GRelP**) and the ongoing global efforts towards harmonization and promotion of regulatory reliance, the Egyptian Drug Authority (**EDA**) and the South African Health Products Regulatory Authority (**SAHPRA**) signed a Memorandum of Understanding (**MoU**) in July 2023 on mutual reliance for Pharmaceuticals, Biological Products, and Medical Devices. Within the framework for implementation of this MoU, EDA and SAHPRA decided to start a WSI in the function of registration. This concept note describes the pilot phase of the WSI for registration of large molecules in which the initiative is evaluated for improvements before enactment.

2. Objectives

2.1. The Objectives of EDA-SAHPRA Work Sharing Initiative (WSI)

2.1.1. Foster efficiency in regulation to enhance accessibility to quality-assured, safe, and effective medical products.

2.1.2. Decrease unnecessary regulatory burden and/or duplication.

2.1.3. Promote the harmonization of regulatory standards and requirements for the evaluation and authorization of medical products.

2.2. The Objectives of this ***Pilot Phase*** of EDA-SAHPRA Work Sharing Initiative (WSI) for Registration of Biologicals

2.2.1. Evaluate the effectiveness and impact of the WSI in the form of a pilot study.

2.2.2. Gather feedback from stakeholders and identify any areas for improvement before enacting the WSI.

2.2.3. Facilitate the development of framework for EDA-SAHPRA WSI

3. Definitions

3.1. Work Sharing: It is a form of mutual reliance and building trust between National Regulatory Authorities (NRAs). According to *WHO Technical Report Series, No. 1033, 2021*, it is "A process by which NRAs of two or more jurisdictions share activities to

accomplish a specific regulatory task. It also entails exchange of information consistent with the provisions of existing agreements and compliant with each agency's or institution's legislative framework for sharing such information with other NRAs".

3.2. **Biologicals:** are class of medicines which are grown and then purified from large-scale cell cultures of bacteria or yeast, or plant or animal cells. Biologicals are a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies, as well as products derived from human blood and plasma. They are distinct from small molecule drugs, which are chemically synthesized and have simpler structures.

3.3. **Pilot Phase:** This is a preliminary stage where a scaled-down version of the initiative is tested in the scope of biological products registration before wider-scale implementation. It aims to assess the feasibility, effectiveness, and potential challenges of the initiative (proof-of-concept).

3.4. **Parallel Assessment:** The same application is submitted to EDA and SAHPRA simultaneously where each authority conducts its complete evaluation in parallel and then both share their scientific assessments together.

3.5. **Alternate Assessment:** The same application is submitted to EDA and SAHPRA simultaneously then modules are distributed where each authority evaluates different module(s) for quality, nonclinical, and/or clinical data in parallel and both share their scientific assessments **alternately**.

4. Scope of Products/Applications

4.1. **Type of Products: Biologicals as a pilot phase**.

Note: Other medical products shall be considered for later stages of the initiative.

Post approval changes (PACs) could be considered for later stages of the initiative.

4.2. **Type of Application: New applications only**.

4.3. **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 **(See list on item No.9)**.

5. Modality of Assessment

For the purpose of joint- assessment of applications for registration of biologicals (pilot phase), there will be two stages:

5.1. The first application(s) accepted to be submitted will undergo **parallel assessment** by both EDA and SAHPRA.

5.2. Later application(s) will undergo **alternate assessment** by EDA and SAHPRA where both authorities will divide the assessment work of the one submitted application among them. There will be alternate review and peer review of each regulator's work.

6. Application Format

CTD application for EDA and **eCTD** for SAHPRA with a declaration of sameness included. **Fees** applied shall be according to the national laws and regulations in both countries. Please refer to Annexes I and II for more information.

7. Duration of the Pilot Phase

The estimated duration of the pilot phase for registration of biologicals is approximately **one year (240 working days)**. The pilot phase may be extended subject to a mutual decision by EDA and SAHPRA.

8. Benefits to Applicants

8.1. Streamlined review process.

8.2. Reduced review time.

8.3. Consolidated list of questions for multiple markets.

9. Common List of Reference Regulatory Authorities

9.1. European Medicines Agency (EMA)

9.2. Health Canada

9.3. Medicines and Health Products Regulatory Agency (MHRA), UK

9.4. Ministry of Health, Labour and Welfare (MHLW), Japan

9.5. Swiss Agency for Therapeutic Products (Swissmedic)

9.6. Therapeutic Goods Administration (TGA), Australia

9.7. US Food and Drug Administration (US FDA)

9.8. WHO Prequalification

9.9. WLA Listed Authorities in the approved functions:

9.9.1. Ministry of Food and Drug Safety (MFDS) Republic of Korea

9.9.2. Health Sciences Authority (HSA) Singapore

10. Annexes

Annex I: Application Form: This document calls for industrial stakeholders to express their interest in applying for EDA-SAHPRA WSI for registration of biologicals in its pilot phase.

Annex II: Operating Procedures: This document provides detailed information with regards to the submission process for the pilot project from the receipt of EOI, as well as the eligibility criteria, milestones, and anticipated timelines.