Central Administration of Pharmaceutical Products (CAPP)
General Administration ----

EDA Reference Countries

Year 2026

Code: EDREX: NP. CAPP. 089

Version No: 2

Issue Date: 06/2026

Effective date: 01/01/2027

Table of Contents

EDA Reference Countries

- ## List of Abbreviations

EDA: Egyptian Drug Authority

EUDRA: European Union Drug Regulatory Authorities.

CPP: Certificate of Pharmaceutical Product

GMP: Good Manufacturing Practice

ICH: International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

NRA: National Regulatory Authority

TCDC: Technical Committee for Drug Control

WHO: World Health Organization

WLA: WHO Listed Authority

- ## Definition

Reference Countries: are countries with National Regulatory Authorities (NRA) competent for the regulatory, executive, and supervisory procedures for biological and pharmaceutical products.

- **EDA Reference Countries Selection Criteria**

  - The criteria for selecting the Egyptian Drug Authority (EDA) list of Reference Countries have been updated in accordance with the decision of the Technical Committee for Drug Control (TCDC) at its session held on 05/05/2026 and **shall enter into force on 01/01/2027**.

  - The selection criteria for Reference Countries applicable to both biological products and human pharmaceutical products have been approved. The selected Reference Countries must meet at least one of the following reference accreditation criteria:

    - ✓ ICH Founding Regulatory Authority.
    - ✓ ICH Standing Regulatory Members.
    - ✓ Regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement.
    - ✓ Regulatory authority that is WLA as listed by WHO (for the approved function & scope).
    - ✓ WHO prequalification process.

- **List of Countries NRA & their classifications according to previously mentioned criteria:**

NRA/Country	Criteria	Regulatory Functions	Scope
United States of America (USFDA)	ICH Founding Regulatory Authority	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**
EMA (Europe) Products with EMA CPP	ICH Founding Regulatory Authority	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversight 8.Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**
Japan (PMDA/MHLW)	ICH Founding Regulatory Authority	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversight 8.Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**
England (MHRA)	WLA	1.Registration and marketing authorization 2.Vigilance 3. Licensing establishments 4.Regulatory inspection 5.Laboratory testing 6.Clinical trials oversights 7.Regulatory Authority (RA) lot release	**Medicine Vaccine biotherapeutics**

NRA/Country	Criteria	Regulatory Functions	Scope
Canada (Health Canada)	ICH Standing Regulatory Members	1.Registration and marketing authorization 2.Vigilance 3.Market surveillance and control 4.Licensing establishments 5.Regulatory inspection 6.Laboratory testing 7.Clinical trials oversight 8.Regulatory Authority (RA) lot release	**Medicine** **Vaccine** **biotherapeutics**
Switzerland (Swissmedic)	ICH Standing Regulatory Members	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversight 8. Regulatory Authority (RA)	**Medicine** **Vaccine** **biotherapeutics**
Australia (TGA) & New Zealand	Regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement with EU member states, England and Canada	1.Registration and marketing authorization 2.Vigilance 3.Market surveillance and control 4.Licensing establishments 5.Regulatory inspection 6.Laboratory testing 7.Clinical trials oversights 8.Regulatory Authority (RA) lot release	**Medicine** **Vaccine** **biotherapeutics**

NRA/Country	Criteria	Regulatory Functions	Scope
Republic of Korea (MFDS)	**WLA**	1.Registration and marketing authorization 2.Vigilance 3.Market surveillance and control 4.Licensing establishments 5.Regulatory inspection 6.Laboratory testing 7.Clinical trials oversights 8.Regulatory Authority (RA) lot release	**Medicine** **Vaccine** **biotherapeutics**
Singapore (HAS)	**WLA**	1. Registration and marketing authorization 2. Vigilance 3. Market surveillance and control 4. Licensing establishments 5. Regulatory inspection 6. Laboratory testing 7. Clinical trials oversights	**Medicine & biotherapeutics**

NRA/Country	Criteria	Regulatory Functions	Scope
Austria (BASG), France (ANSM), Germany (BfARM/ PEI), Iceland (IMA), Ireland (HPRA), Italy (AIFA), Luxembourg (MoH), Belgium (FAMHP), Norway (NOMA), Denmark (DKMA), Finland (FIMEA), Portugal (INFARMED), Sweden (SMPA), Spain (AEMPS), the Netherlands (CBG MEB).	**WLA**	**Approved Function**	**Approved Scope**

- **List of newly added Countries NRA:**

NRA/Country	Criteria	Regulatory Functions	Scope
***EU countries:** Bulgaria (BDA), Croatia (HALMED), Cyprus (PHS MoH), Czechia (SUKL), Estonia (SAM), Greece (EOF), Hungary (NNGYK), Latvia (ZVA), Liechtenstein (LLV), Lithuania (VVKT), Malta (MMA), Poland (URPL), Romania (NAMMDR), Slovakia (SUKL), Slovenia (JAZMP).	**WLA**	**Approved Function**	**Approved Scope**
Indonesia (BPOM)	**WLA**	1. Registration and marketing authorization 2. Licensing establishments 3. Regulatory inspection 4. Laboratory testing 5. Regulatory Authority (RA) lot release	**Vaccines**

- **For newly added EU countries, Eudra GMP and CPP from two reference authorities are mandatory to be submitted.**
- For human pharmaceutical products submitted based on their reference from the newly added countries, during the first six months from the decision effective date, the applications shall be referred to the **Scientific Evaluation Committees for Medical Products** to assess the need for the product prior to approving the registration procedures.
- After the expiry of this period, the matter shall be referred to the TCDC for re-evaluation.
- The updated list shall enter into force on **01/01/2027**, considering that the list of **Reference NRA** may be updated in line with global developments and upon submission to the **TCDC**.

History Table

Version No.	Issue date	Summary of Changes
1	8/2024	New Issue
2	6/2026	• Updating EDA Reference Countries Selection Criteria • New List of EDA Reference Countries • Requirements for newly added Countries