Technical Committee for Drug Control Decision at its session on 05/05/2026

Approval of the update to the criteria for selecting reference countries for biological products and human pharmaceutical products, such that the reference countries shall be those with national regulatory authorities responsible for the oversight, enforcement, and regulatory control of biological and pharmaceutical products, and that meet at least one of the following reference accreditation criteria:

1- ICH Founding Regulatory Authority.

2- ICH Standing Regulatory Members.

3- Regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement.

4- Regulatory authority that is WLA as listed by WHO (for the approved function & scope).

5- 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**

NRA/Country	Criteria	Regulatory Functions	Scope
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**
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**
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**

New Countries			
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.