

القرارات العامة للجنة الفنية لمراقبة الأدوية الخاصة بالموقع الإلكتروني لهيئة الدواء المصرية

قرارات اللجنة الفنية لمراقبة الأدوية بجلستها في ٢٠٢٦/٠٥/٠٥

* - الموافقة على تحديث معايير اختيار الدول المرجعية للمستحضرات الحيوية وللمستحضرات البشرية بحيث تكون الدول المرجعية: هي الدول ذات السلطات التنظيمية الوطنية المختصة بالإجراءات الرقابية والتنفيذية والتنظيمية للمستحضرات الحيوية والدوائية والتي تتوفر فيها إحدى معايير الاعتماد المرجعي الآتية :

- 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

NRA/Country	Criteria	Regulatory Functions	Scope
EMA (Europe) Products with EMA CPP	ICH Founding Regulatory Authority	<ol style="list-style-type: none"> 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 	<p>Medicine Vaccine biotherapeutics</p>
Japan (PMDA/MHLW)	ICH Founding Regulatory Authority	<ol style="list-style-type: none"> 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 	<p>Medicine Vaccine biotherapeutics</p>
England (MHRA)	WLA	<ol style="list-style-type: none"> 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 	<p>Medicine Vaccine biotherapeutics</p>

NRA/Country	Criteria	Regulatory Functions	Scope
Canada (Health Canada)	ICH Standing Regulatory Members	<ol style="list-style-type: none"> 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 	<p>Medicine Vaccine biotherapeutics</p>
Switzerland (Swissmedic)	ICH Standing Regulatory Members	<ol style="list-style-type: none"> 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) 	<p>Medicine Vaccine biotherapeutics</p>
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	<ol style="list-style-type: none"> 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 	<p>Medicine Vaccine biotherapeutics</p>

NRA/Country	Criteria	Regulatory Functions	Scope
Republic of Korea (MFDS)	WLA	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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
<p>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).</p>	<p>WLA</p>	<p>Approved Function</p>	<p>Approved Scope</p>

New Countries			
NRA/Country	Criteria	Regulatory Functions	Scope
<p>*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).</p>	WLA	Approved Function	Approved Scope
Indonesia (BPOM)	WLA	<ol style="list-style-type: none"> 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.

- بالنسبة للمستحضرات البشرية المقدمة طبقاً لمرجعيتها من الدول المضافة حديثاً، يتم خلال الستة أشهر الأولى من بدء تطبيق القرار العرض على لجان التقييم العلمي للمستحضرات الطبية للنظر في مدى الحاجة إلى المستحضر قبل الموافقة على السير في إجراءات التسجيل. وبعد انتهاء هذه المدة، يُعاد تقييم الموقف بعد العرض على اللجنة الفنية لمراقبة الأدوية.
- يتم العمل بالقائمة المحدثة بداية من ٢٠٢٧/٠١/٠١، مع مراعاة تحديث قائمة السلطات التنظيمية المرجعية طبقاً للمستجدات العالمية وبعد العرض على اللجنة الفنية لمراقبة الأدوية.