



**FDA CIRCULAR**  
No. **2020-036**

14 DEC 2020

**SUBJECT : Guidelines on the Issuance of Emergency Use Authorization for Drugs and Vaccines for COVID-19**

## **I. BACKGROUND/ RATIONALE**

Article II, Section 15 of the 1987 Constitution of the Republic of the Philippines mandates the State to protect and promote the health of the people and instill health consciousness among them. The State is further mandated under Article XIII, Section 11 of the Constitution to adopt an integrated and comprehensive approach to health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost.

Under Republic Act No. 3720, or the "Food, Drug and Cosmetic Act," as amended by Executive Order No. 175, s. 1987, and Republic Act No. 9711, or the "Food and Drug Administration Act of 2009," the Food and Drug Administration (FDA) was created to establish and maintain a drug regulatory system to ensure the purity, safety, efficacy and quality of drugs and vaccines in the country. Section 21 of Republic Act No. 3720, as amended, provides that any new drug should have an authorization from the FDA based on an application containing full reports of investigations to show whether or not such drug is safe, efficacious and of good quality for use based on clinical studies, prior to manufacture, sale, importation, exportation, distribution or transfer thereof.

Pursuant to Proclamation Nos. 922 (s. 2020) and 1021 (s.2020), the Philippines was declared under a State of Public Health Emergency, and a State of Calamity due to the COVID-19 pandemic.

Subsequently, Republic Act No. 11494 or the "Bayanihan to Recover as One Act" was enacted authorizing the President to suppress the COVID-19 pandemic through the procurement of drugs and vaccines.

Considering that no registered drug and vaccine exist for COVID-19 in the Philippines, the President of the Republic of the Philippines issued Executive Order (EO) No. 121 entitled "Granting Authority to the Director General of the Food and Drug Administration to Issue Emergency Use Authorization (EUA) for COVID-19 Drugs and Vaccines, Prescribing Conditions therefore and for other Purposes." Said issuance gave authority to the Director General to issue an EUA, and established the conditions under which said authorization may be issued.

The FDA is hereby introducing the process for the issuance of EUA to sustain and strengthen the national preparedness for the COVID-19 public health emergency. The principles of regulatory reliance and recognition are adopted to accelerate the evaluation





and approval process for EUA to ensure immediate access to drug products and vaccines for COVID-19.

## **II. OBJECTIVES**

This Circular aims to provide guidelines on the regulation of EUA for drugs and vaccines for COVID-19.

## **III. SCOPE AND APPLICATION**

This Circular shall apply to the pharmaceutical industry and government entities such as the national procurer or health program implementors intending to apply for an EUA for drugs and vaccines for COVID-19, and shall pertain only to unregistered (anywhere in the world) drugs and vaccines for prevention, diagnosis and treatment of COVID-19 and granted an EUA by the National Regulatory Authority (NRA) of the country of origin or any other mature and established NRA as identified by FDA.

## **IV. DEFINITION OF TERMS**

- A. Emergency Use Authorization (EUA) – is an authorization issued for unregistered drugs and vaccines in a public health emergency. The EUA is not a Certificate of Product Registration (CPR) or a marketing authorization. The evaluation process of the product may be facilitated by reliance and recognition principles, but stricter conditions on the use and monitoring following authorization shall be imposed.
- B. Drugs – as used in this issuance, refer to pharmaceutical products that pertain to chemical compounds or biological substances, other than food, intended for use in the treatment, prevention, or diagnosis of disease in humans or animals, including the following:
  - 1. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man,
  - 2. Articles (other than food) intended to affect the structure or any function of the body of humans, and
  - 3. Articles intended for use as a component of any articles specified in the foregoing clauses but do not include devices or their components, parts or accessories.
- C. Recognition – shall refer to the acceptance of the regulatory decision of another trusted institution. It shall be based on evidence of conformity that the regulatory requirements of the reference regulatory authority are sufficient to meet the regulatory requirements of the relying authority.
- D. Reliance – shall refer to the act whereby the NRA in one jurisdiction may take into account and give significant weight to assessments performed by another NRA or trusted institution, or to any other authoritative information in reaching its own decision.



## **V. GENERAL GUIDELINES**

- A. The EUA shall only be issued and remain valid under all of the following conditions provided herein.
- B. The applicant shall submit requirements to support the application for EUA.
- C. The Center for Drug Regulation and Research (CDRR) and an Expert Panel shall review the application and provide recommendations on the COVID-19 drug or vaccine being applied for an EUA.
- D. The Director General shall act on the application by either issuing the EUA or a Letter of Disapproval (LOD).
- E. A COVID-19 drug or vaccine with issued EUA shall be subject to post authorization surveillance. Pharmacovigilance obligations and post-authorization commitments shall be imposed on the holder of the EUA. The pharmacovigilance obligations and post-authorization commitments by the holder of the EUA shall also be shared with the national procurer and health program implementors.

A flowchart of the process for the issuance of the EUA for drugs and vaccines is provided in Annex "A" of this Circular.

## **VI. SPECIFIC GUIDELINES**

### **A. Conditions for Issuance of the EUA**

The EUA shall only be issued and remain valid only when all of the following circumstances are present:

- 1. Based on the totality of evidence available, including data from adequate and well- known controlled trials, it is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose, or treat COVID-19;
- 2. The known and potential benefits of the drug or vaccine, when used to diagnose, prevent, treat COVID-19, outweigh the known and potential risks of the drug or vaccine, if any; and
- 3. There is no adequate, approved and available alternative to the product for diagnosing, preventing or treating COVID-19.

The last condition is deemed present when there exists no registered drug or vaccine in the country for diagnosing, preventing or treating COVID-19.

### **B. Filing of Application**

All applications shall be filed with the FDA Action Center (FDAC).



### C. Requirements

Applications for EUA for drugs and vaccines shall comply with the following documentary requirements which shall be in the English language.

1. Cover letter requesting to issue an EUA with comprehensive discussions on the public health need for the product,
2. Valid License to Operate (LTO) as Drug Importer, with copy of the exclusive distributorship agreement with the manufacturer of the drug or vaccine,
3. Good Manufacturing Practice (GMP) Certificate or equivalent document issued by the national regulatory authority or other competent regulatory authority. For drugs or vaccines coming from non-PIC/S countries or non-WHO-Prequalified, the application must be supported by a Foreign current Good Manufacturing Practice (FcGMP) Certificate following Administrative Order No. 2013-0022 (see Annex "B" for list PIC/S Member Countries),
4. List of Countries where the EUA is approved, with proof of approval for emergency use (or equivalent document) from the corresponding approving counterpart NRAs,
5. Reports on actual use from the issuance of EUA of approving counterpart NRA to the application for EUA in the Philippine FDA;
6. Complete assessment report including question and answer documents from the approving counterpart NRA,
7. Clinical trial data and results with the inclusion of racial distribution showing Filipino/Asians/ Pacific Islanders,
8. Currently available stability studies and list of ongoing studies,
9. Risk Management Plan,
10. Summary of Product Characteristics,
11. Summary Lot Protocol,
12. Product labeling with minimum information including name of vaccine, type of vaccine, method of administration, dose per vial, storage, batch or lot number, manufacturing and expiration dates (compliance with Administrative Order No. 2016-0008 or the Revised Rules and Regulations Governing the Generic Labelling Requirements of Drug Products for Human Use shall not be required), and instruction for usage--- smart labelling is encouraged; and
13. Proof of Payment (Official Receipt or Landbank Oncoll Payment Slip).

Should the above stated requirements be unavailable, a sufficient justification should be provided with an undertaking to submit the requirement when available.

The above stated requirements may be updated or supplemented by the FDA through circulars on the matter. Further, the FDA may require additional documents should it deem necessary for proper review of the drug or vaccine applied for EUA.

In all applications for EUA, a sworn assurance of sameness that the product including but not limited to the composition/ formulation, strength, manufacturing of finished product and active pharmaceutical ingredients, specifications, packaging, product information and others, at the time of the submission and after EUA, are the same in all respects as the product given the



EUA by the approving counterpart NRA. Also, the application should be accompanied by an undertaking by the manufacturer to complete the development of the drug and vaccine applied for an EUA.

**D. Pre-assessment**

The Office of the Director General (ODG) shall determine the completeness of the submission for application. Thereafter, the application shall be referred to the Expert Panel and CDRR for a simultaneous review of the application.

**E. Review and Recommendation**

CDRR shall review the quality of the drug or vaccine applied for an EUA based from the requirements submitted.

In addition to the review of the CDRR, the Director General shall also consult an Expert Panel which shall review the safety and efficacy of the product applied for EUA. The Expert Panel shall come up with its recommendations to the Director General on the action on the application for EUA.

The Expert Panel shall be composed of at least three (3) experts on drug and vaccine development or related fields such as immunology, infectious disease, pharmacology, public health, toxicology and others.

The review of the expert panel shall identify whether (a) based on the totality of evidence available, including data from adequate and well-known controlled trials, it is reasonable to believe that the drug or vaccine may be effective to prevent, diagnose, or treat COVID-19, and (b) the known and potential benefits of the drug or vaccine, when used to diagnose, prevent, treat COVID-19, outweigh the known and potential risks of the drug or vaccine, if any.

The identity and recommendations of the Expert Panel shall be strictly confidential.

The recommendations of CDRR and the Expert Panel are for the consideration of the Director General.

**F. Decision**

**1. Approval of the application for EUA**

The FDA may rely on and/or recognize EUAs of mature and established NRAs as enumerated in Annex "C" of this Circular. The FDA may also issue circulars at any point to include other regulatory agencies that it deems mature and established.

Only the Director General shall approve the application for EUA. The Director General shall issue the EUA after having been satisfied that all of the conditions as provided in this issuance exist.



The approval may include one or more special conditions for use. These can include post-authorization safety and effectiveness reporting requirements, limitations, restrictions on advertising and promotion, and other special conditions.

## 2. Disapproval

The following shall be considered as basis for disapproval of the application:

- a. Failure to satisfy all of the conditions for the issuance of the EUA;
- b. Failure to demonstrate the safety, effectiveness, and quality profile to prevent, diagnose, and treat COVID-19;
- c. Failure to settle unresolved problems regarding quality, safety, and effectiveness;
- d. Failure to disclose other relevant quality, safety, and effectiveness issues; and
- e. The label of the product (including package insert) is false and misleading.

The decision to disapprove an application is final and irrevocable. An applicant may re-apply in case of a disapproval of its application for EUA provided that the deficiencies initially noted have been complied.

## 3. Revocation / Suspension or Cancellation of EUA

- a. Violation of pharmacovigilance obligations and post authorization commitments; and
- b. Violation of any provision of the Circular and applicable laws, rules and regulations as identified by FDA.

In case of revocation, cancellation or suspension of EUA, the Uniform Rules of Procedure under R.A. No. 9711 shall apply.

## G. Validity

The EUA shall be valid only within the duration of the declared public health emergency due to COVID-19, or upon issuance of full market authorization/Certificate of Product Registration.

In the event that the declared public health emergency is lifted, or when a COVID-19 drug or vaccine is registered with the FDA, any issued EUA shall have a provisional validity for a period of one (1) year from date of lifting of the declaration or registration of the drug or vaccine for the sole purpose of exhausting remaining products.

The foregoing is without prejudice to the discretion of the Director General to revisit or revoke any issued EUA, as may be appropriate, to protect the general public health and safety.

## H. Post Authorization



1. Lot Release

The holder of the EUA of COVID-19 Vaccines shall ensure that a complete Summary Lot Protocol which contains the manufacturer's production data and quality control test results, and recognition/acceptance of Lot Release Certificate from the country of origin (responsible NRA/NCL) or its equivalent is submitted to FDA.

2. Monitoring

The holder of the EUA has the ultimate responsibility for monitoring the safety of their products. These responsibilities include inventory control and maintenance of appropriate storage until delivery, among others.

The FDA together with concerned offices of the DOH shall conduct post-authorization monitoring to track product deployment, additional relevant information, and the status from the manufacturer concerning full-product life-cycle. Post-authorization monitoring shall include adverse events following immunization (AEFI) or adverse drug reactions (ADR).

3. Commitments of the Holder of the EUA

- a. Complete specific pharmacovigilance obligations (ongoing or new studies, or additional activities) with a view to providing comprehensive data confirming a positive benefit-risk balance. Pharmacovigilance obligations shall adhere to the guidelines and subsequent circulars as issued by the FDA;
- b. Complete pending studies and trials. The holder of the EUA shall subsequently proceed to a marketing authorization following FDA guidelines on the condition that it has proven to be safe and effective for the proposed indication;
- c. Complete unavailable documents or submit additional necessary documents as may be required by FDA, including provision of further data and response to inquiries; and
- d. Secure Lot/Batch Release Certification for all biologicals from the FDA prior to distribution.

4. Pharmacovigilance

The holder of the EUA shall have a comprehensive pharmacovigilance system for their product following the system or protocol for of a registered drug and biological product.

The holder of the EUA shall ensure compliance with the Risk Management Plan (RMP) including additional pharmacovigilance activities. A summary of RMP shall be provided containing information on product safety profile and explain the measures to characterize the risk including ongoing, new studies or additional activities. The summary of RMP shall be published in the FDA website.

5. Post Authorization Changes

Any deviation from or changes to the manufacture and changes in label of the product must be notified with the FDA.

6. Responsibility of the national procurer and health program implementors

The pharmacovigilance obligations and post-authorization commitments of the holder of the EUA shall be shared by the national procurer and health program implementors to the fullest extent possible and applicable.

**I. Fees**

The fee for application for EUA is P50,000.00 + LRF\*

*\*LRF is equivalent to one percent (1%) of the filing fee imposed, but in no case lower than ten pesos.*

**VII. SEPARABILITY CLAUSE**

If any provision in this Circular, or application of such provision to any circumstances, is held invalid, the remainder of the provisions in this Circular shall not be affected.

**VIII. REPEALING CLAUSE**

All rules and regulations contrary to or inconsistent with the provisions of this Circular are hereby repealed, modified or amended accordingly.

**IX. EFFECTIVITY**

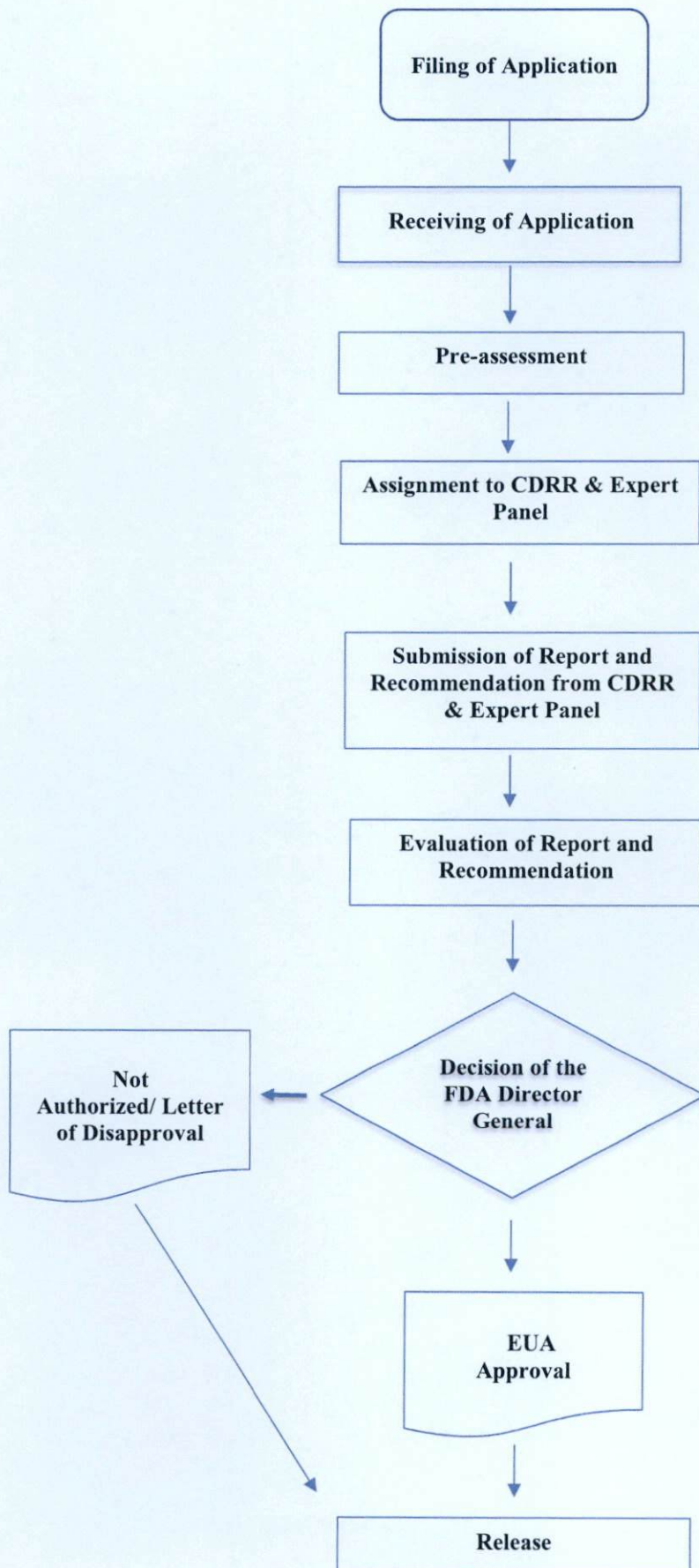
This Circular shall take effect immediately following its publication in at least one (1) newspaper of general circulation, and upon submission to the University of the Philippines Office of National Administrative Register (UP-ONAR).

  
**ROLANDO ENRIQUE D. DOMINGO, MD**  
Director General



## Annex "A"

### COVID-19 EUA Registration Process Flow Chart





## Annex "B"

### List of Pharmaceutical Inspection Co-operation Scheme (PIC/S) Member Countries

<b>Argentina</b>	National Institute of Drugs <i>Instituto Nacional de Medicamentos (INAME)</i>
<b>Australia</b>	Therapeutic Goods Administration (TGA)
<b>Austria</b>	Austrian Agency for Health and Food Safety (AGES) <i>Österreichische Agentur für Gesundheit und Ernährungssicherheit (AGES)</i>
<b>Belgium</b>	Federal Agency for Medicines and Health Products <i>Agence Fédérale des Médicaments et des Produits de Santé (AFMPS)</i> <i>Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten (FAGG)</i>
<b>Brazil</b>	National Health Surveillance Agency (ANVISA) <i>Agência Nacional de Vigilância Sanitária (ANVISA)</i>
<b>Canada</b>	Health Canada <i>Santé Canada</i>
<b>Chinese Taipei</b>	Taiwan Food and Drug Administration (TFDA)
<b>Croatia</b>	Agency for Medicinal Products and Medical Devices of Croatia/ <i>Agencija za lijekove i medicinske proizvode (HALMED)</i>
<b>Cyprus</b>	Pharmaceutical Services (CyPHS)
<b>Czech Republic</b>	State Institute for Drug Control <i>Státní Ústav pro Kontrolu Léčiv (SÚKL)</i>  Institute for State Control of Veterinary Biologicals and Medicines (ISCVBM)
<b>Denmark</b>	Danish Medicines Agency (DKMA)
<b>Estonia</b>	State Agency of Medicines (SAM)
<b>Finland</b>	Finnish Medicines Agency (FIMEA)



<b>France</b>	<p>French National Agency for Medicines and Health Products Safety  <i>Agence nationale de sécurité du médicament et des produits de santé (ANSM)</i></p> <p>Agency for Food, Environmental &amp; Occupational Health Safety/  <i>Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES)</i></p>
<b>Germany</b>	<p>Federal Ministry of Health  <i>Bundesministerium für Gesundheit (BMG)</i></p> <p>Central Authority of the Laender for Health Protection regarding Medicinal Products and Medical Devices *  <i>Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG)</i></p> <p><small>*the German Ministry of Health (BMG) and the German Central Authority of the Laender (ZLG) count as one PIC/S Participating Authority. All German Medicinal Authorities, which are listed on the ZLG web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by ZLG.</small></p>
<b>Greece</b>	<p>Greek National Organisation for Medicines/  <i>Εθνικός Οργανισμός Φαρμάκων (EOF)</i></p>
<b>Hong Kong SAR, China</b>	<p>Pharmacy and Poisons Board of Hong Kong (PPBHK)</p>
<b>Hungary</b>	<p>National Institute of Pharmacy and Nutrition (NIPN)</p>
<b>Iceland</b>	<p>Icelandic Medicines Agency (IMA)</p>
<b>Indonesia</b>	<p>National Agency for Drug and Food Control (NADFC)  <i>Badan Pengawas Obat dan Makanan Republik Indonesia</i></p>
<b>Ireland</b>	<p>Health Products Regulatory Authority (HPRA)</p>
<b>Israel</b>	<p>Institute for Standardization and Control of Pharmaceuticals (ISCP)</p>
<b>Italy</b>	<p>Italian Medicines Agency  <i>Agenzia Italiana del Farmaco (AIFA)</i></p> <p>Directorate General for Animal Health and Veterinary Medicinal Products  <i>Direzione generale della sanità animale e dei farmaci veterinari (DGSAF)</i></p>



<b>Japan</b>	Ministry of Health, Labour and Welfare (MHLW) *  Pharmaceuticals and Medical Devices Agency (PMDA) *  <small>* Japan's Ministry of Health, Labour and Welfare (MHLW) and Japan's Pharmaceuticals and Medical Devices Agency (PMDA) count as one PIC/S Participating Authority. The Japanese Prefectures are represented by MHLW.</small>
<b>Korea</b>	Ministry of Food and Drug Safety (MFDS)
<b>Latvia</b>	State Agency of Medicines <i>Zāļu valsts aģentūra (ZVA)</i>
<b>Liechtenstein</b>	Office of Healthcare <i>Amt für Gesundheit (AG)</i>
<b>Lithuania</b>	State Medicines Control Agency (SMCA)
<b>Malaysia</b>	National Pharmaceutical Regulatory Agency (NPRA)
<b>Malta</b>	Malta Medicines Authority (MMA)
<b>Mexico</b>	Federal Commission for the Protection Against Sanitary Risks (COFEPRIS) <i>Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS)</i>
<b>Netherlands</b>	Health and Youth Care Inspectorate* <i>Inspectie Gezondheidszorg en Jeugd (IGJ)</i>  <small>* The competence for GMP/GDP inspections in the Netherlands is allocated to the central authority, Dutch Health and Youth Care Inspectorate (IGJ). IGJ is the PIC/S Participating Authority representing GMP/GDP for human as well as veterinary medicinal products. IGJ performs national and international GMP/GDP inspections representing the Health and Youth Care Inspectorate - Pharmaceutical Affairs as well as the Medicines Evaluation Board - Veterinary Medicinal Products Unit, which is mandated to issue GMP certificates on behalf of the Ministry of Economic Affairs.</small>
<b>New Zealand</b>	Medicines and Medical Devices Safety Authority (Medsafe)
<b>Norway</b>	Norwegian Medicines Agency (NOMA)
<b>Poland</b>	Chief Pharmaceutical Inspectorate (CPI)
<b>Portugal</b>	National Authority of Medicines and Health Products, IP <i>Autoridade Nacional do Medicamento e Produtos de Saúde IP (INFARMED IP)</i>
<b>Romania</b>	National Agency for Medicines and Medical Devices of Romania (NAMMDR)



<b>Singapore</b>	Health Sciences Authority (HSA)
<b>Slovak Republic</b>	State Institute for Drug Control (SIDC)
<b>Slovenia</b>	Agency for Medicinal Products and Medical Devices/ <i>Javna agencija Republike Slovenije za zdravila in medicinske pripomočke (JAZMP)</i>
<b>South Africa</b>	South African Health Products Regulatory Authority (SAHPRA)
<b>Spain</b>	Spanish Agency of Medicines and Medical Devices* <i>Agencia Española de Medicamentos y Productos Sanitarios (AEMPS)</i>
	<small>* The competence for GMP/GDP inspections in Spain is shared between the central authority, Spanish Agency for Medicines and Medical Devices (AEMPS), and the Spanish regional authorities, which count as one PIC/S Participating Authority. All Spanish Medicinal Authorities, which are listed on the AEMPS web site, are considered as PIC/S Participating Authorities and are represented in PIC/S by the AEMPS.</small>
<b>Sweden</b>	Swedish Medical Products Agency (MPA)
<b>Switzerland</b>	Swiss Agency for Therapeutic Products (Swissmedic)
<b>Thailand</b>	Food and Drug Administration (Thai FDA)
<b>Turkey</b>	Turkish Medicines and Medical Devices Agency (TMMDA)
<b>Ukraine</b>	State Service of Ukraine on Medicines and Drugs Control (SMDC)
<b>United Kingdom</b>	Medicines & Healthcare Products Regulatory Agency (MHRA)  Veterinary Medicines Directorate (VMD)
<b>U.S.A</b>	U.S. Food and Drug Administration (US FDA)



## **Annex “C”**

### **National Regulatory Authorities and International Health Organization**

#### **International Health Organization eligible as reference for recognition:**

1. World Health Organization (WHO)

#### **NRAs eligible as reference for reliance:**

1. US Food and Drug Administration- United States of America (US FDA)
2. Therapeutic Goods Administration- Australia (TGA)
3. European Medicines Agency (EMA)
4. Health Sciences Authority- Singapore (HSA)
5. Pharmaceuticals and Medical Device Agency- Japan (PMDA)
6. Ministry of Food and Drug Safety- South Korea (MFDS)
7. Medicines and Healthcare Products Regulatory Agency- United Kingdom (MHRA)
8. Swiss Agency for Therapeutic Products- Switzerland (Swissmedic)
9. Health Canada- Canada

*\*The Philippine FDA may update this list at any point to include other regulatory agencies*