ADMINISTRATIVE ORDER
No. 2022-_____

SUBJECT : Updated Guidelines for Availing Compassionate Special Permit for the Restricted Use of Unregistered or Unauthorized Drug Products including Vaccines and Medical Devices

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I. BACKGROUND

Under Administrative Order (AO) No. 4 s. 1992, otherwise known as *Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/ Preparation*, access to products for terminally or seriously ill patients suffering from Acquired Immune Deficiency Syndrome, Cancer, or Life-threatening conditions is allowed through the grant of a CSP to a Specialized Institution (SI) or Specialized Society (SS), when there is no existing superior or alternative therapy that can likely or adequately control their conditions, provided that the conditions and requirements specified under the issuance exist and are complied with.

FDA Memorandum Circular No. 2015-008, titled *Policy and Requirements for availing of Compassionate Special Permit for Registrable Medical Devices*, was issued to provide clarity in the issuance of CSP for the restricted use of medical devices which are not yet registered or are in the process of registration in the Philippines by patients in need of immediate medical attention.

AO No. 4 s. 1992 was then amended by AO No. 2020-0028, to address identified implementation gaps such as inclusion of emerging or re-emerging infectious diseases considered as public health emergencies or public health threats under Republic Act (RA) No. 11332 or the *Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act*, and to allow access to investigational products.

Past experiences show that outbreaks of emerging or re-emerging infectious diseases could not only potentially cause large numbers of human deaths as they spread, but also have huge social and economic impact in today's interconnected world. Unfortunately, many of these diseases do not yet have any cure, and healthcare providers are also often victims of such diseases. Immunization reduces the risks of getting a disease and are critical to the prevention and control of infectious disease outbreaks.

In order to protect the well-being of all Filipinos, the Food and Drug Administration (FDA) determined a need to consider the inclusion of unregistered or unauthorized vaccines with no registered counterparts in the list of health products which may be given CSP in cases where there are no existing treatment alternatives and where benefits of using such vaccines outweigh the risks. This would allow the immunization of certain vulnerable populations, including healthcare providers who are at the frontlines, during public health emergencies and public health threats brought about by emerging infectious diseases.

It has also been found necessary to include diseases which may lead to permanent disability in the conditions covered by CSP, in line with the original intent of the policy.

In view of the foregoing, the updated policy and requirements for availing CSP for the restricted use of unregistered or unauthorized drug products including vaccines and medical devices are hereby provided.

II. OBJECTIVES

This Order aims to:

1. Provide updated guidelines for availing CSP; and
2. Streamline the submission of applications and post-approval commitment reports to ensure compliance of CSP applicants and holders to the requirements.

III. SCOPE

This Order applies to qualified institutions and licensed physicians who shall be responsible for complying with the technical requirements of FDA for CSP, and covers the applicable conditions, and the submission of application requirements and post-approval commitment reports.

IV. DEFINITION OF TERMS

Compassionate Special Permit (CSP) refers to a special permit signed by the FDA Director General granting a qualified institution such as the Department of Health (DOH), a Specialized Institution (SI), and a DOH-licensed hospital, or a qualified licensed physician the privilege to avail an unregistered or unauthorized drug product, vaccine, or medical device through an FDA-licensed establishment for its restricted use.

Emerging infectious disease refers to a communicable or transmissible disease that either has appeared and affected a population for the first time, or has existed previously but is rapidly spreading (**re-emerging**), either in terms of the number of people getting infected, or to new geographical areas.

Institutional use refers to a CSP granted to a qualified institution for the compassionate use of a subject product on patients or patient groups under the care of the said institution.

Investigational drug product refers to a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorization when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use. For clarity, this does not include medical devices undergoing clinical investigation.

Life-threatening conditions refers to any disease or condition from which the likelihood of death is probable unless the course of the disease or condition is interrupted.

Named patient use refers to a CSP granted to a qualified licensed physician for the compassionate use of a subject product on an identified patient.

Orphan drug refers to any drug or medicine used to treat or alleviate the symptoms of persons afflicted with a rare disease and declared as such by the DOH upon recommendation of the National Institutes of Health (NIH). **Orphan product** refers to any healthcare or nutritional product, other than a drug or medicine, including, but not limited to, diagnostic kits, medical devices and biological products, used to prevent, diagnose, or treat rare diseases and declared as such by the DOH upon recommendation of the NIH.

Permanent medical impairment refers to the permanent loss, loss of use, damage, or malfunction of a part of the body, or a part of a bodily system or function caused by a disease or medical condition. The loss or abnormality of a body function may be anatomical, physiological or psychological, e.g. a missing limb or a diagnosed mental disorder.

Rare disease refers to disorders such as inherited metabolic disorders and other diseases with similar rare occurrence as recognized by the DOH upon recommendation of the NIH but excluding catastrophic (i.e., life threatening, seriously debilitating, or serious and chronic) forms of more frequently occurring diseases.

Qualified institution refers to an institution that has the medical expertise and technical competence to provide the necessary treatment and interventions for the medical condition/s intended to be addressed by virtue of the professions, trainings, or experiences of the attending physicians belonging to the institution. The FDA shall determine through evaluation the qualification of the applying institution who shall be responsible for complying with the technical requirements of FDA.

Qualified licensed physician refers to a physician licensed by the Professional Regulation Commission (PRC) and who possesses the medical expertise and technical competence which matches the medical condition/s intended to be addressed by virtue of training or experience. The FDA shall determine through evaluation the qualification of the applying licensed physician who shall be responsible for complying with the technical requirements of FDA.

V. GENERAL GUIDELINES

A. The following are the acceptable conditions wherein a CSP may be issued by FDA for a drug or vaccine:
    1. Patient medical conditions:
        a. Acquired Immune Deficiency Syndrome (AIDS)
        b. Cancer
        c. Life-Threatening Conditions
        d. Emerging or re-emerging infectious diseases declared as Public Health Emergencies (PHE) or Public Health Threats (PHT)
        e. Diseases which may lead to permanent medical impairment
        f. Rare diseases

        For emerging or re-emerging infectious diseases declared as PHE/PHT, CSP for vaccines for the immunization of those belonging to a population who are most

vulnerable to, or at high risk of extracting such diseases may be allowed where there are no recommended and available alternatives for treatment other than to prevent infection.

2. Product registration status:
   a. A CSP may be issued for a product which does not have a valid FDA registration or authorization.
   b. Alternatively, a CSP may also be issued for an investigational drug product (for the same disease it is sought to be used) for the following conditions:
      i. the requested investigational drug product must be the same product that has an ongoing Phase III clinical trial in the country of origin or in other countries;
      ii. is in a global or national registry;
      iii. there is an ongoing clinical trial in the Philippines but the enrollment of the patient in the clinical trial is not possible; or
      iv. the investigational drug product has entered the process of marketing authorization application in the country of origin or in the Philippines.
   c. For imported products, CSP may only be issued for a product that is currently registered/authorized in the national regulatory authority (NRA) of the country of origin or other NRAs.

B. The following are the acceptable conditions wherein a CSP may be issued by FDA for a medical device:
   1. The medical device shall only be used for patients suffering from life-threatening conditions;
   2. Product registration status:
      a. There is no other registered/authorized medical device of the same kind/technology available in the Philippine market;
      b. The device is brand new.

C. Conditions on the issuance of CSP
   1. The subject product shall only be used in the treatment and/or prevention of the conditions specified in the CSP.
   2. The volume or quantity to be imported shall not exceed the allowed maximum number as stated in the CSP.
   3. The FDA shall not be held responsible for any damage or injury arising from the use of the drug product or medical device product, and that the CSP Holder shall have the full responsibility.
   4. In coordination with the importer, the clinical report/s after the use of the product, reconciliation report, and other product details shall be submitted.
   5. At any time deemed necessary by the FDA, the validity of the CSP may be revoked.
   6. The one-time permit is valid for only one (1) year from the date of issue except for orphan drugs/products which shall be effective for a period of three (3) years, renewable for a period of three (3) years thereafter.

D. General requirements
   1. The application shall include the estimated volume or number of units needed and the licensed drug or medical device establishment through which the unregistered or unauthorized drug or medical device may be procured.

2. The identities and addresses of the medical officers or specialists qualified and authorized to administer or use the product shall be provided.
3. Product to be applied for CSP shall be currently registered in the national regulatory authority (NRA) of country of origin or other NRAs.
4. Submission of applications and post-approval commitments shall be through the official FDA Website following FDA Advisory No. 2021-0842, or the guidelines on the latest official application platform based on the latest issuance as may be applicable.

VI. SPECIFIC GUIDELINES

A. Requirements for CSP application
   1. Named Patient Use:
      a. Accomplished e-Application Form as prescribed by FDA regulations
      b. Curriculum vitae of the qualified physician applying for CSP
      c. Medical abstract of the patient
      d. Proof of payment
      e. Letter of information regarding the importer (for products to be imported by a private individual)
      f. Additional requirements:
         i. For drugs including vaccines:
            - Medical prescription
         ii. For vaccines:
            - A report of the risk-benefit assessment conducted by the applicant on the risks and benefits surrounding the use of the vaccine on the target recipient
         iii. For medical devices:
            - Technical description of the medical device from the manufacturer; not downloaded from the company's website
            - Justification letter from the attending physician regarding the urgency of the use of the medical device

   2. Institutional Use:
      a. Accomplished e-Application Form as prescribed by FDA regulations.
      b. Rationale for volume/quantity requested
      c. Distribution agreement
      d. Proof of payment
      e. For imported products:
         i. For products to be imported by a private individual, a letter of information regarding the importer shall be submitted.
         ii. For products which has prior approval or registration from another NRA, a proof or certification of such shall be submitted.
      f. For investigational drug products, the rationale with supporting documents establishing the conditions stated above under V.C.4
      g. Additional requirements:
         i. For drugs including vaccines:
            - Medical prescription
         ii. For vaccines:

- The immunization scheme issued by the DOH with justification for the identified target recipients/groups under the scheme
- A report of the risk-benefit assessment conducted by the applicant on the risks and benefits surrounding the use of the vaccine on the target recipients/groups

iii. For medical devices:

- Technical description of the medical device from the manufacturer; not downloaded from the company's website; and
- Justification letter from the attending physician regarding the urgency of the use of the medical device.

B. Documentary requirements to be submitted as post-approval commitments:

1. The CSP holder shall submit the reports of the clinical study conducted, adverse drug reactions (ADR) (for drugs), adverse events following immunization (AEFI) (for vaccines), adverse events involving the medical device, and the manufacturing and reconciliation data through the drug /medical device establishment at the end of the treatment or the immunization monitoring, or upon the request for additional quantity whichever comes first. The report shall follow the format in Annex A for the Clinical Study and ADR/AEFI reports. For the manufacturing and reconciliation data, submission of these records must be provided in a .xlxs or .xlsm file format (Microsoft Excel) with the following format for consistency:

Batch No.	Lot No.	Mfg. Date	Expiry Date	Quantity Approved	Quantity Delivered	Balance	Date of Delivery

Post-approval commitment report for medical devices shall follow the format in Annex B.

2. The drug/medical device establishment shall be responsible for the submission of the report of the total volume/quantity of the drug/vaccine /medical device imported along with the importation documents.
3. Submission of data and reports as part of the post-approval commitment shall be from the start of treatment, administration, or use and updated quarterly, and shall be through the official applications platform as implemented through the latest FDA issuance.
4. Failure on the part of the CSP Holder to submit the required reports will be grounds to deny the applications for CSP through or using its establishment and/or future applications for import clearances of the unregistered or unauthorized drug/vaccine/medical device under a valid CSP.

C. Review and Evaluation

1. The review shall be based on the assessment for compliance of the submitted application documents to the requirements. The FDA shall consider the benefits and risks as they apply to the Philippine context based on the available data provided by the CSP applicant and may consider seeking opinions from clinical experts as necessary.
2. Compliant applications shall be approved for CSP.

3. For non-compliant applications, the disapproval shall be communicated to the applicant as well as the deficiencies and/or clarifications.

VII. SEPARABILITY CLAUSE

The provisions of this Order are hereby declared separable and in the event of any such provision/s is/are declared invalid or unenforceable, the validity of enforceability of the remaining portions or provisions which are not affected, shall remain in full force and in effect.

VIII. REPEALING CLAUSE

All issuances or parts thereof, pertaining to CSP applications covered by this Administrative Order are hereby repealed, including AO No. 4 s. 1992: Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/ Preparation and AO No. 2020-0028: Amendment to Administrative Order No. 4 s. 1992 entitled "Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/ Preparation."

IX. EFFECTIVITY

This Order shall take effect fifteen (15) days following the publication in the Official Gazette or in a newspaper of general circulation and filing with the University of the Philippines Office of the National Administrative Register.

Compassionate Special Permit
Post-Approval Commitment Compliance

Compassionate Special Permit

Post-Approval Commitment Compliance

CSP Number:

1. **Hospital:**

2. **Physician's Information and Physician's Qualification Statement** *(Including medical school attended, year of graduation, medical specialty, PRC license number, current employment, and job title. Attaching the CV electronically is preferred, please use normal PDF functions for file attachment.)*

3. **Name of Patient:**

4. **Clinical Information**
   a. **Target Indication**

   b. **Brief Clinical History** *(Patient's age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy, reason for request, including an explanation of why the patient lacks other therapeutic options)*

5. Treatment Information:
    a. **Drug Product Name** (Generic name/ Brand name) **/ Investigational Drug Name**
    b. **Name of the entity responsible for supplying the product for compassionate use (as reflected in its License to Operate)**

    c. **Treatment Result** *(Including the dose, route and schedule of administration, duration, monitoring procedures, therapeutic outcome, and reporting of any adverse drug reactions / adverse events following immunization. Also include modifications to the treatment plan in the event of toxicity.)*

I, (name of the responsible Directors or health program implementors for the DOH, medical directors for hospitals and SIs, or licensed physicians for named patient use), (legal age), (citizenship), resident of (address), after being sworn according to law, hereby depose and state:

1. I am the responsible (Director / health program implementor / medical director / licensed physician) given Compassionate Special Permit for the above product.

2. I understand that the Food and Drug Administration may verify through both government and private entities the authenticity of all the information and documents submitted. I fully consent and authorize the Food and Drug Administration to conduct such verification for purposes of evaluation of my application.

IN WITNESS WHEREOF, I have hereunto set my hand this (date) in (city).

(Name of Head of Regulatory Office)
Affiant

SUBSCRIBED AND SWORN to before me this _____ at _____, Philippines.

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Book No.
Series of

Compassionate Special Permit
Post-Approval Commitment Compliance for Medical Device

Compassionate Special Permit

Post-Approval Commitment Compliance

CSP Number:

1. **Hospital:**

2. **Physician's Information and Physician's Qualification Statement** *(Including medical school attended, year of graduation, medical specialty, PRC license number, current employment, and job title. Attaching the CV electronically is preferred, please use normal PDF functions for file attachment.)*

3. **Name of Patient:**

4. **Clinical Information**
   a. **Target Indication**

   b. **Brief Clinical History** *(Patient's age, gender, weight, allergies, diagnosis, prior therapy, response to prior therapy, reason for request, including an explanation of why the patient lacks other therapeutic options)*

5. Treatment Information:
    a. **Medical Device Name** (Brand & Generic Medical Device Name) / **Investigational Medical Device Name**
    b. **Name of the entity responsible for supplying the product for compassionate use (as reflected in its License to Operate)**

    c. **Treatment Result** *(Including the dose/quantity, route and schedule of administration, duration, monitoring procedures, therapeutic outcome, and reporting of any adverse events following treatment. Also include modifications to the treatment plan in the event of toxicity.)*

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