Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUL 0 6 2020

ADMINISTRATIVE ORDER
No. ~~4 s. 1992-A~~ 2020-0028

SUBJECT: **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"**

Section 15, Article II of the 1987 Constitution declares that it is the policy of the State to protect and promote the right to health of the people and instill health consciousness among them. Section 11 of Article XIII further mandates the State 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 costs.

The Food and Drug Administration (FDA) (formerly the Bureau of Food and Drugs (BFAD), is mandated under R.A. No. 3720, otherwise known as the "Foods, Drugs and Devices, and Cosmetics Act", as amended, and R.A. No. 9711 otherwise known as the "Food and Drug Administration (FDA) Act of 2009", and its implementing rules and regulations to protect and promote the right to health of the Filipino people by establishing an effective health product regulatory system that is responsive to the country's health needs and problems.

Though the law requires registration prior to use, there is a need for patients who are terminally or seriously ill to have access to drugs and devices which are not yet registered or are in the process of registration in the Philippines. Hence, Administrative Order No. 4 s. 1992, entitled "*Policy and Requirements for Availing of Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/Preparation,"* was issued.

Under Administrative Order No. 4 s. 1992, access to products for patients which are terminally or seriously ill is allowed through the grant of a CSP, 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.

Under the Administrative Order No. 4 s. 1992, the CSP, signed by the FDA Director General (formerly the BFAD Director), grants a Specialized institution (SI) or a Specialty Society (SS) the privilege to avail of an unregistered drug and device product/ preparation through a certain licensed establishment for certain kind/type of patients, specific volume and period.

However, gaps have been identified in the course of the implementation of the said policy.

Specifically, Administrative Order No. 4 s. 1992 does not contemplate conditions of emerging or re-emerging infectious diseases considered as public health emergencies or public health threats as provided under R.A. No. 11332 otherwise known as the "Mandatory Reporting of Notifiable Diseases and Health Events of Public Health Concern Act."

Moreover, said issuance does not contemplate granting access to investigational products. Investigational Products are pharmaceutical forms 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.

Hence, this amendment is being issued to include emerging and re-emerging infectious diseases considered as public health emergencies or public health threats as one of the conditions for the grant of a CSP, and allow access to investigational products through a CSP. However, it is understood that unregistered and investigational drugs are not yet approved by the FDA or have gone through the process of pre-marketing assessment. Such drugs have not been found to be safe and effective for their intended use, and these may also cause unexpected serious adverse reactions to the patient. In this premise, a CSP is not an assurance of the safety, efficacy and quality of the unregistered or investigational product. The CSP is therefore not a Certificate of Product Registration (CPR). Therefore, it is imperative for the physician to carefully assess based on sound clinical judgement prior to availing the CSP whether the benefit of the use of the unregistered or investigational product outweighs the potential risks it may pose to the patient.

In view of the foregoing, the following provisions of DOH Administrative Order No. 4 s. 1992 are hereby amended as follows:

I. A Specialized Institution/ Specialty Society shall file a request for CSP only for patients suffering from the following conditions:

1. Acquired Immune Deficiency Syndrome,
2. Cancer,
3. Life- Threatening Conditions, and
4. **Emerging or re-emerging infectious diseases considered as Public Health Emergencies or Public Health Threats.**

The application shall include the estimated volume needed and the licensed drug/device establishment through which the unregistered drug may be procured.

It shall also identify the names and addresses of the specialists qualified and authorized to use the product.

II. Requirements

1. A written commitment on the part of all authorized specialists to submit a Clinical Study Report for every patient given the product describing the quantity administered/use, therapeutic/desired effect and any adverse reaction, to the Institution or Specialty for **FDA**, at the end of each year.
2. An estimate of the total requirement of the product for one year.
3. A waiver of **FDA** responsibility from any damage or injury arising from the use of the unregistered drug or device to be signed by the responsible official of the Institution or Specialty Society.
4. **In addition to the foregoing requirements, a CSP may also be issued to a Specialized Institution/ Specialty Society or the Department of Health (DOH) even for an investigational product, provided that the rationale with supporting documents is submitted establishing the following conditions:**

   a. **The requested investigational product must have an ongoing Phase III clinical trial in the country of origin or in other countries or there is an ongoing clinical trial in the Philippines but the enrollment of the patient in the trial is not possible; or**
   b. **The investigational product has entered the process of marketing authorization application in the country of origin or in the Philippines.**

III. The specified drug/ **medical device** establishment shall secure clearance to import from the **FDA** and its applications shall be accompanied by:

a. A certificate that the product is currently registered in the country of origin **for an unregistered drug/device, or the clinical trial registry for an investigational product for the same disease it is sought to be used for patients suffering from any of the conditions identified in Item I above.**
b. A true copy of the CSP issued to the Specialized Institution (SI)/ Specialty Society (SS).

IV. A. The SI/SS shall submit the Clinical Study Reports through the drug/device establishment at the end of the year.

B. The drug/device establishment shall be responsible for the submission of the Clinical Study Reports from the SI/SS and the report of the total volume of the drug/device imported for the year.

Failure on its part to submit these reports will be a ground to deny the applications of CSP through or using its establishment and/or future applications for import clearances of the unregistered drug/device under a valid CSP.

This Order shall take effect fifteen (15) days after its publication in a newspaper of general circulation, **and upon filing with the U.P. Law Center three (3) certified true copies of this Order.**

FRANCISCO T. DUQUE III, MD, MSc
Secretary of Health