



1 February 2023

(23-0712)

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Committee on Technical Barriers to Trade

Original: English

### NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

<b>1. Notifying Member:</b> <u>PHILIPPINES</u> <b>If applicable, name of local government involved (Article 3.2 and 7.2):</b>
<b>2. Agency responsible:</b> DR. SAMUEL A. ZACATE Director General Food and Drug Administration DEPARTMENT OF HEALTH  <b>Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:</b>  JESUSA JOYCE N. CIRUNAY, RPh Director IV Center for Drug Regulation and Research Food and Drug Administration DEPARTMENT OF HEALTH Email: <a href="mailto:cdrr.od@fda.gov.ph">cdrr.od@fda.gov.ph</a> ; <a href="mailto:cdrr.sds@fda.gov.ph">cdrr.sds@fda.gov.ph</a> ; <a href="mailto:bps@dti.gov.ph">bps@dti.gov.ph</a> <a href="http://www.fda.gov.ph">www.fda.gov.ph</a>
<b>3. Notified under Article 2.9.2 [ ], 2.10.1 [X], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:</b>
<b>4. Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):</b> Medical equipment (ICS code(s): 11.040); Pharmaceuticals (ICS code(s): 11.120)
<b>5. Title, number of pages and language(s) of the notified document:</b> Updated Guidelines for Availing Compassionate Special Permit for the Restricted Use of Unregistered or Unauthorized Drug Products including Vaccines and Medical Devices; (11 page(s), in English)
<b>6. Description of content:</b> The proposed policy aims to repeal the current policy on the national guidelines for availing a Compassionate Special Permit (CSP) for the restricted use of unregistered or unauthorized drug products including vaccines and medical devices, and provide the updated guidelines which allows additional covered products and medical condition, and streamlines the submission of applications and post-approval commitment reports to ensure compliance of CSP applicants and holders to the requirements.
<b>7. Objective and rationale, including the nature of urgent problems where applicable:</b> Currently, the policy on CSP does not include vaccines in the list of health products which may be given CSP. There is a need to consider the inclusion of compassionate use of unregistered vaccines, 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 our healthcare providers who are at the frontlines, during public health emergencies and public health threats brought about by emerging infectious diseases.

Likewise, patients suffering from rare diseases and other diseases that could lead to permanent medical impairment are not covered by the current policy and should thus be considered for inclusion in line with the original intent of the policy.; Protection of human health or safety

**8. Relevant documents:**

- Administrative Order No. 4 s. 1992: Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/ Preparation
- AO No. 2020-0028: Amendment to Administrative Order No. 4 s. 1992: Policy Requirements for Availing Compassionate Special Permit (CSP) for Restricted Use of Unregistered Drug and Device Product/ Preparation

**9. Proposed date of adoption:** 2nd Quarter of 2023

**Proposed date of entry into force:** 2nd Quarter of 2023

**10. Final date for comments:** 9 February 2023

**11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:**

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 Website: <http://www.bps.dti.gov.ph>

<https://www.fda.gov.ph/draft-for-comments-updated-guidelines-for-availing-compassionate-special-permit-for-the-restricted-use-of-unregistered-or-unauthorized-drug-products-including-vaccines-and-medical-devices/>

[https://members.wto.org/crnattachments/2023/TBT/PHL/23\\_0794\\_00\\_e.pdf](https://members.wto.org/crnattachments/2023/TBT/PHL/23_0794_00_e.pdf)