



Republic of the Philippines  
Department of Health  
**OFFICE OF THE SECRETARY**

07 November 2022

**DEPARTMENT CIRCULAR**

No. 2022 - 0524

**FOR: ALL CENTERS FOR HEALTH DEVELOPMENT, NATIONAL DRUG POLICY COMPLIANCE OFFICES, LEAGUES OF CITIES, PROVINCES AND MUNICIPALITIES, PROFESSIONAL HEALTH SOCIETIES, DIRECTORS OF BUREAUS AND REGIONAL OFFICES, BARMM MINISTER OF HEALTH, CHIEFS OF MEDICAL CENTERS AND SANITARIA, AND OTHER CONCERNED**

**SUBJECT: Amendment to the Department Circular 2022-0254 dated 05 April 2022 titled, "Updates on the HTAC Processing of Minor Inclusion"**

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This serves as an amendment to the Department Circular 2022-0254 dated 05 April 2022 entitled, "Updates on the HTAC Processing of Minor Inclusion" to reflect the following changes:

Depending on the policy questions and urgency to respond to public health concerns, there are different types of HTA tracks being followed:

- **Major Applications**
  - General HTA Process - for the assessment of health technologies that require evidence gathering which will have a major impact on the policy and research questions; for new and existing health technologies
  - Expedited HTA Process - for health technologies that are used in public health emergencies
- **Minor Applications**
  - Minor Inclusion Track - for health technologies that are listed in the Philippine National Formulary (PNF), but are being applied for additional strength, net content, and additional or change in packaging and additional pack size/volume of the drug for the same indication

To make the HTA process more responsive and facilitative for the other PNF applications, applications which may be considered as minor changes only, the HTAC would like to amend the above-mentioned issuance to add **"any other change that will not result in a significant difference in terms of bioavailability and meaningful clinical outcomes with the PNF-listed drugs"** as another case that may be classified as minor application for inclusion in the PNF. *Meaningful clinical outcomes* refer to final outcomes or epidemiologically validated surrogate outcomes.

We would like to reiterate that submissions for minor inclusions shall be accepted following the appropriate topic nomination forms and complete documentary requirements as disseminated by the Health Technology Assessment Division (HTAD).


Application for minor inclusion shall be accepted at any time of the year given that they are already listed in the PNF. Proponents shall submit completed requirements (e.g., topic nomination form, minor inclusion form, proof/evidence to support that they do not result in significant differences in terms of bioavailability and meaningful clinical outcomes) to HTAD **within 14 working days** after the acknowledgment and validation of the HTAD on the requirements submitted. Please be advised that **incomplete submissions within the compliance period will not be processed.**

The topic nomination forms with guidance on the documentary requirements are accessible via this link: <https://hta.doh.gov.ph/topic-nomination/>.

All other provisions of Department Circular No. 2022-0254 not affected by this amendment still stand in effect.

Dissemination of the information to all concerned is requested. Should you have further questions or concerns, you may coordinate with HTAD through email at [hta@doh.gov.ph](mailto:hta@doh.gov.ph). Thank you very much.

By Authority of the Secretary of Health:

  
ATTY. CHARADE MERCADO-GRANDE  
OIC Undersecretary  
Health Regulation Team