

AMENDMENT TO ADMINISTRATIVE ORDER NO. 2012-0023, ENTITLED: “REVISED IMPLEMENTING GUIDELINES FOR THE PHILIPPINE NATIONAL FORMULARY SYSTEM (PNFS)”

DOH ADMINISTRATIVE ORDER NO. 2012-0023-A, December 26, 2013

Read online (full-text search, related cases, audio case brief): <https://batas.org/library/bd8329629bdf/>

The implementation of Administrative Order No. 2012-0023 or the Revised Implementing Guidelines for the Philippine National Formulary System (PNFS) require a robust system for health technology assessment, economic evaluations and price negotiations.

In view thereof, AO 2012-0023 is hereby amended as follows.

Section V. General Guidelines

O.

The Medicines Price Board (MPB) shall be created to undertake price negotiation with the party proposing for the inclusion of a medicine in the PNF using the most cost-effective price to the government as the basis thereof.

Section VI. Specific Guidelines

B.

Evidence Review Groups

3. Accreditation

The DOH through the Undersecretary or Assistant Secretary responsible for the PNFS shall accredit academic institutions to undertake medicines evidence review based on the following criteria:

- with research capacity to conduct studies on clinical epidemiology, pharmacoeconomics, health economics, health technology assessment, evidence-based medicine (EBM) and other relevant fields;
- with identified evidence reviewers/experts for the abovementioned fields;
- can comply with the standards and methodologies including the timelines in conducting the review as prescribed by the DOH; and
- willingness to declare and manage conflicts of interests.

D.

Specific Guidelines for the Formulary Selection Algorithm

10. Exemptions

b. The application for exemption shall have the following as attached documents:

- Accomplished proposal form that includes justification, a report on disease burden and its ranking relative to the common diseases in the health facility or community;
- FDA Certificate of Product Registration or WHO certification;
- FDA-approved product information;
- Soft/electronic copies of all cited studies and published articles; and
- Other relevant documents (e.g. peer-reviewed local Philippine clinical practice guidelines which provides information on the indication or use of the product (preferred), excerpts from WHO documents or other formularies, etc., including photocopies of such).

c. The request for exemption shall only be granted if it fulfills ALL of the following criteria:

- The medicine has proven safety and efficacy.
- There is no other medicine listed in the formulary which is indicated for the same condition.
- The medicine will be used for a current or potential urgent health situation, where urgent is defined as requiring immediate action to prevent death, permanent disability or a major or irreversible organ dysfunction.”

E.

Facilitation of request for Inclusion or Deletion of medicines in the PNF

- The proponents shall submit Letters of Requests and accomplish the appropriate Proposal Forms prescribed by the FEC. These are the following forms: e. PNF Form No. 18 (Proposal Form for Health Professional/Health Professional Organization (PMA and PDA affiliated organizations))
- The proponents shall likewise submit two (2) hard and soft copies each of the following documents required by the FEC, to wit:
 - Executive Summary
 - Accomplished proposal form 1 and 9A, including all appropriate tables;
 - FDA Certificate of Product Registration with colored photograph or video of product;
 - FDA-approved product information;
 - FDA Certificate of Good Manufacturing Practice;

- Soft/Electronic copies of all cited studies and published articles;
- Signed Letter of undertaking to disclose all known published and unpublished studies;
- Systematic Review (preferably Cochrane) or Meta-analysis or at least Phase III Randomized Controlled Clinical Trials
- Executable file for cost-effectiveness study* if done by sponsor/drug company (*if available); and
- Other relevant documents (e.g. peer-reviewed local Philippine clinical practice guidelines which provides information on the indication or use of the product (preferred), excerpts from WHO documents or other formularies, etc., including photocopies of such).
- Proposal forms shall include the following: g. Copies of all the cited scientific journal articles, entries, other accepted legal documents and other supporting publications.

F.

PNF Formats and Publication

As thus amended, all other provisions of AO No. 2012-0023 not affected by the aforementioned amendments shall remain valid and in effect.

EFFECTIVITY

This Order shall take effect immediately.

(SGD) ENRIQUE T. ONA, MD
Secretary of Health

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