ADOPTION AND IMPLEMENTATION OF THE WORLD HEALTH ORGANIZATION ANNEX 5 GUIDE TO GOOD DISTRIBUTION PRACTICES (GDP) FOR PHARMACEUTICAL PRODUCTS, AND ANNEX 9 GUIDE TO GOOD STORAGE PR...

Read online (full-text search, related cases, audio case brief): https://batas.org/library/2530053a5d6e/

I. RATIONALE

In order to maintain the original quality of the product, every activity in the distribution of pharmaceutical products should be carried out in the principles of Good Manufacturing Practice (GMP), Good Storage Practice (GSP) and Good Distribution Practice (GDP).

The Mutual Recognition Agreement (MRA) created by the ASEAN member States adopted the Pharmaceutical Inspectorate Cooperation Scheme - Good Manufacturing Practice (PIC/s-GMP) as a standard for inspection. Originally, the PIC/s-GMP Guide was derived from the WHO-GMP Guide and was further developed in order to comply with stringent manufacturing and health requirements in PIC/S countries, to cover new areas (e.g. biologicals, radiopharmaceuticals, etc.) and to adapt to the changing scientific and industrial technology (e.g. biotech, parametric release etc.). The aim of such improvements was to ensure that high quality medicines were produced in line with the PlC Convention and then the PIC Scheme.

In order to align with the international level of standard for GMP, Administrative Order No. 2012-0008, “Adoption and Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guides for the Good Manufacturing Practice for Medicinal Products” was issued by FDA.

The World Health Organization (WHO) Annex 5 Guide to Good Distribution Practice (GDP) and Annex 9 Guide to Good Storage Practices (GSP) for Pharmaceutical Products serve as the standards for the different aspects of the distribution and storage processes for pharmaceutical products.

The FDA, consistent with the 1987 Philippine Constitution Sec. 12 Article XIII, which states that “the state shall establish and maintain an effective food and drug regulatory system”, and pursuant to the provisions of Republic Act No. 9711, otherwise known as Food and Drug Administration (FDA) Act of 2009, Sec. 3, which declares a policy of the State “to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms, measures and initiatives that are aimed, directed and designed to: (a) protect and promote the right to health of the Filipino people; and (b) help establish and maintain an effective health products regulatory system responsive to the country's health needs and problems”, has crafted and implemented several issuances in order to enhance its regulatory policy and strengthen its capability with regards to the proper storage and distribution of pharmaceutical products. However, these issuances are not equivalent to standards set by the WHO in the international level. This Order is hereby issued for the effective adoption and implementation of the aforementioned WHO guidances.

II. OBJECTIVES

GENERAL OBJECTIVE

To officially adopt and implement the World Health Organization “Annex 5 Guide to Good Distribution Practices (GDP) for Pharmaceutical Products” and “Annex 9 Guide to Good Storage Practices for Pharmaceuticals”, attached as Annex A and Annex B, respectively.

SPECIFIC OBJECTIVES

- To use the WHO Annex 5 Guide to Good Distribution Practices (GDP) for Pharmaceutical Products and Annex 9 Guide to Good Storage Practices for Pharmaceuticals as the standard in assessing GDP and GSP compliance of drug establishments and retailers.

- To have a coordinated transition period for the FDA and the Drug Establishment from the previous guidelines to the WHO GDP and GSP Guide

III. SCOPE

This Order shall apply to FDA and Drug Establishments and Retailers.

IV. DEFINITION OF TERMS

- “Authorization” means a permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the manufacture, importation, exportation, sale, offer for sale, distribution, transfer, and/or, where appropriate, the use, testing, promotion, advertising, or sponsorship of health products. The authorization can take the form of a permit, a license, a certificate of registration, of accreditation, of compliance, or of exemption, or any similar document.

- “Distributor/importer/exporter” means any establishment that imports or exports raw materials, active ingredients and/or finished products for its own use or for wholesale distribution to other establishments or outlets. If the distributor/importer/exporter sells to the general public, it shall be considered a retailer.

- “Distributor/wholesaler” means any establishment that procures raw materials, active ingredients and/or finished products from local establishments for local distribution on wholesale basis.

- “Drug” means

(a)

Articles recognized in the official pharmacopoeias and formularies, including official homeopathic pharmacopoeias or any documentary supplement to any of them, which are recognized and adopted by the FDA

(b)

Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

(c)

Articles (other than food) intended to affect the structure of any function of the body of humans or animals; or

(d)

Bar review courses, mock exams and a study planner that keeps you on pace - batas.org

Articles intended for use as a component of any articles specified in clauses (1), (2), or (3) but do not include devices or their components, parts or accessories

- “Drug Establishment” refers to drug manufacturers/repackers, drug importers, drug distributors, drug wholesaler or drug exporter and entities belonging to definition of establishment, as per RA 9711 and its implementing rules and regulations “Establishment” means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacture, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products including the facilities and installations needed for its activities.

- “Good Distribution Practices” or “GDP” means that part of quality assurance which ensures that the quality of a pharmaceutical product is maintained through adequate control throughout the numerous activities which occur during the distribution process.

- “Good Manufacturing Practice” or “GMP” means that part of quality assurance which ensures that medicinal products are consistently produced and controlled in accordance with quality standards appropriate for their intended use and as required by the applicable marketing authorization or product specifications.

- “Good Storage Practices” or “GSP” means that part of quality assurance which ensures that the quality of a pharmaceutical product is maintained through adequate control throughout the storage.

- “Retailer” means any establishment which sells or offers to sell any health product directly to the general public.”

V. GENERAL GUIDELINES

The Department of Health (DOH) - FDA hereby adopts the current version of WHO Annex 5 Guide to Good Distribution Practices (GDP) for Pharmaceutical Products and Annex 9 Guide to Good Storage Practices for Pharmaceuticals to supplement A.O. 56 s. 1989 and other related RAs.

VI. SPECIFIC GUIDELINES

- Supplements and Revisions. All supplements and revisions related to the WHO Annex 5 Guide to Good Distribution Practices (GDP) for Pharmaceutical Products and Annex 9 Guide to Good Storage Practices for Pharmaceuticals shall be adopted automatically.

- Accessibility. The adopted guides shall be made accessible at the FDA Website.

- Inspection of Drug Establishments and Retailers. Drug establishments and retailers will be inspected using the WHO GDP and GSP guides as the standard for Good Distribution and Good Storage Practices.

- Revision of Forms and Templates. The forms and templates of the Food and Drug Administration shall be revised to reflect the adopted WHO GDP and GSP guides.

- Capacity Building. The FDA and the industry shall provide trainings and workshops and may create technical working group/s for the effective implementation of the WHO GDP and GSP guides.

VII. TRANSITORY PROVISIONS

The establishments shall be given a 1-year transition period to comply with the WHO Annex 5 Guide to Good Distribution Practices (GDP) for Pharmaceutical Products and Annex 9 Guide to Good Storage Practices for Pharmaceuticals starting from the effectivity date of this Order.

Study hands-free: podcast-style lessons with read-along highlighting - batas.org

VIII. PENALTY

The existing administrative and legal sanctions shall be imposed to any person, judicial or natural, who have violated any provisions of this Order, or other regulations referring/related to the licensing of drug establishments including retail outlets.

Unless subsequently amended or superseded, the existing penalties in relation to violation of Good Distribution and Storage Practice shall remain in full force and effect.

IX. SEPARABILITY CLAUSE

If any of the provisions of this administrative order is found by a court of competent jurisdiction to be void or unenforceable, in whole or in part, such provision shall be deemed deleted from this Order but the remaining provisions thereof shall remain in full force and effect.

X. REPEALING CLAUSE

All provisions of existing administrative orders, circulars, regulations and other issuances inconsistent with this Order are hereby repealed or amended accordingly.

XI. EFFECTIVITY DATE

This Order shall take effect after fifteen (15) days following its publication in a newspaper of national circulation and upon submission to the University of the Philippines Law Center.

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

ABOUT BATAS.ORG

Study smarter at BATAS.org

The Philippine bar review and law-school companion built around how your brain actually remembers.

The complete Philippine law library - free for everyone.

More than 100,000 Supreme Court decisions, Republic Acts, and executive issuances - full-text searchable, browsable by category and year, and always free. No paywall, no login. This PDF came from it.

Audio case-brief lectures.

Any decision becomes a podcast-style lecture - facts, issues, ruling, and doctrine - with read-along highlighting and a hands-free presentation mode. Study while commuting, working out, or resting your eyes.

Bar review built on the science of memory.

Complete, sequenced courses for all eight bar subjects, narrated like podcasts and reinforced with retrieval practice and spaced review - the study techniques with the strongest evidence behind them.

The full law-school curriculum.

One subscription unlocks the entire J.D. curriculum - every subject, every lesson, with your progress tracked down to the paragraph so you can pick up exactly where you left off, on any device.

Mock exams that tell you where you stand.

Timed multiple-choice exams graded instantly, with per-subject score breakdowns and focus suggestions that point you at your weakest topics first.

A study planner that keeps you on pace.

Set your schedule and BATAS tells you every day whether you are on track for bar day - and exactly which lesson to take next.

Start free at https://batas.org

The law library is free forever - and your first lesson is one click away.

The text of this document is an official public record and remains in the public domain. Formatting, presentation, and compilation © 2026 batas.org.

Downloaded free from the batas.org Law Library. Share it freely - the library is free for every law student, bar reviewee, and practitioner.