Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 25 2012

ADMINISTRATIVE ORDER
No. 2012-0008

SUBJECT: **Adoption and Implementation of the Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guides for the Good Manufacturing Practice (GMP) for Medicinal Products**

I. RATIONALE

Consistent with the 1987 Philippine Constitution Sec. 12 Article XIII " The state shall establish and maintain an effective food and drug regulatory system" and Republic Act 9711 Sec. 3 "It is hereby declared a policy of the State to adopt, support, establish, institutionalize, improve and maintain structures, processes, mechanisms 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 xxx xxx xxx responsive to the countries health needs and problems. Pursuant to this policy, the State must enhance its regulatory capacity and strengthen its capability with regard to the inspection, licensing and monitoring of establishments and the registration and monitoring of health products".

On 29 November 2004, the ASEAN Sectoral Integration Protocol for healthcare reached an agreement to aspire for a free flowing exchange / trade of products in the ASEAN market having the same quality and manufactured following the ASEAN GMP standards. ASEAN member states created a Mutual Recognition Agreement (MRA) and agreed to use the Pharmaceutical Inspectorate Cooperation Scheme (PIC/S) Good Manufacturing Practice (GMP) as a basis for the MRA or an equivalent GMP as determined by the ASEAN Panel of Experts.

The FDA has been implementing the Administrative Order 43 s. 1999 "Current Good Manufacturing Practice Guidelines for Drugs" in the conduct of GMP inspection of drug establishments. However, this guideline is not equivalent to the PIC/S GMP Guides.

Therefore, this Order is being issued for the effective adoption/ implementation of the PIC/S GMP Guides and to align with the international GMP standards.

CERTIFIED TRUE COPY
JUN 26 2012
MAYLEEN V. AGUIRRE
Chief, Records Section - IMS
Department of Health

II. OBJECTIVES

GENERAL OBJECTIVE

To officially adopt and implement the PIC/S Guides for the GMP for Medicinal Products.

SPECIFIC OBJECTIVES

1. To use the PIC/S guide as the standard in assessing GMP compliance of drug establishments.

2. To have a coordinated transition period for the FDA and the Drug Establishment from the previous GMP Regulation (A.O. 43 s. 1999 and related issuances) to the PIC/S GMP Guides.

III. SCOPE

This Order shall apply to FDA and Drug Establishments.

IV. DEFINITION OF TERMS

1. *"Drug"* means

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

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

   (3) Articles (other than food) intended to affect the structure of any function of the body of human beings or animals

   (4) 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.

2. *"Medicinal Products"* means any medicine or similar products intended for human or animal use which is subject to control under health legislation in the manufacturing or importing country.

3. *"PIC/S GMP Guide"* refers to the current Pharmaceutical Inspection Cooperation Scheme (PIC/S) Guides for the Good Manufacturing Practice (GMP) for Medicinal Products Parts I and II and its Annexes

4. *"Establishment"* means a sole proprietorship, a partnership, a corporation, an institution, an association, or an organization engaged in the manufacturer, importation, exportation, sale, offer for sale, distribution, donation, transfer, use, testing, promotion, advertising, or sponsorship of health products, including the facilities and installation needed for its activities.

5. *"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.

6. *"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 authorizations or product specifications.

V. GENERAL GUIDELINES

The Food and Drugs Administration, Department of Health hereby adopts the current version of PIC/S GMP Guide to supersede A.O. 43 s. 1999 and other related issuances.

The drug establishments shall adopt the current version of PIC/S GMP Guide as the standard for Good Manufacturing Practice.

VI. SPECIFIC GUIDELINES

1. Supplements and Revisions

All supplements and revisions related to the PIC/S GMP Guides shall be adopted automatically.

2. Accessibility

The adopted PIC/S GMP Guides shall be made accessible at the FDA Website.

3. Inspection of Establishments

The drug establishments will be inspected using the PIC/S GMP Guides as the standard for Good Manufacturing Practice.

4. Revision of Forms and Templates

The forms and templates of the Food and Drug Administration bearing Administrative Order 43 s. 1999 shall be revised to reflect the adopted PIC/S GMP Guides.

5. Capability Building

The FDA and the industry shall provide trainings and workshops and may create technical working group/s for the effective implementation of the PIC/S GMP Guides.

CERTIFIED TRUE COPY
JUN 26 2012
Chief, Records Section - IMS
Department of Health

VII. TRANSITORY PROVISION

The establishments shall be given a One (1) year transition period to comply with the PIC/S GMP Guide starting from the effectivity date of this Order.

VIII. PENALTY

The existing administrative and legal sanctions shall be imposed to any person, juridical or natural, who have violated any provisions of this Order.

Unless subsequently amended or superseded, the existing penalties for violation of the provisions of GMP in the Implementing Rules and Regulations of Republic Act 9711 shall also apply for violation of any provisions of the PIC/S GMP Guides starting from the effectivity of this Order.

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.

ENRIQUE T. ONA, MD, FPCS, FACS
Secretary of Health

CERTIFIED TRUE COPY

JUN 26 2012

MAYLEEN V. AGUIRRE
Chief, Records Section - IMS
Department of Health