



Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

OCT 27 2014

ADMINISTRATIVE ORDER

No. 2014-0040

SUBJECT: REVISED GUIDELINES ON THE NEED /ROLE OF A MEDICAL DIRECTOR IN THE PHARMACEUTICAL INDUSTRY

I. RATIONALE

Administrative Order 34 s 1979 was issued by the Bureau of Food and Drugs (BFAD), now the Food and Drug Administration (FDA), to require pharmaceutical laboratories and drug departments handling and dealing with new drugs to have a Medical Director. The primary responsibility of the Medical Director is to review clinical protocols and supervise the conduct of clinical trial and to review product labels. This issuance was superseded by Administrative Order 86 s 200 to clearly set the FDA requirement for drug establishments to have a Medical Director, his/her qualifications, roles and responsibilities among others.

The Food and Drug Administration has undergone a series of reforms to improve the efficiency of its operations and improved compliance of the industry to policies, guidelines, rules and regulation for the protection of public health and welfare, with the passage of several Republic Acts, notably RA 9502, otherwise known as the Universally Accessible Cheaper and Quality Medicines Act of 2008; RA 9711 or the FDA Act of 2009, Administrative Order 009 s 2011 on the National Policy and Program on Pharmacovigilance, and other pertinent FDA Circulars on Post Market Surveillance, Clinical Trials, Adoption of the Mexico City and Kuala Lumpur Principles, among others.

With the undergoing reforms and major changes in the regulatory landscape, both here and abroad, the pharmaceutical industry has also made major changes. As market pressures have intensified and commercial practices have come under closer scrutiny, there has been a marked increase in scientific rigor in drug evaluation and regulation. One consequence of this shift has been to put more importance on the role and function of Medical Directors.

In the light of the current developments, it is now being proposed to issue supplemental guidelines to Administrative Order 86 s 2000.

II. LEGAL BASES

The following are the legal bases for this issuance:

1. RA 9711 otherwise known as "The FDA Strengthening Act of 2009
2. RA 9502 otherwise known as the "Universally Accessible Cheaper and Quality Medicines Act of 2008
3. RA 7394 otherwise known as the "Consumer Act of the Philippines"
4. AO 009 s 2011, otherwise known as the "National Policy and Program on Pharmacovigilance"
5. AO 86 S 2000, "The Need and Role of A Medical Director in the Pharmaceutical Industry"

III. OBJECTIVES

The following are the objectives in issuing this Administrative Order:

1. To provide supplemental guidelines that would strengthen and reinforce FDA's requirement for a Medical Director.
2. To provide guidance to drug establishments in selecting Medical Directors;
3. To ensure that Medical Directors play an active role in complying with FDA rules and regulations, particularly, in advocating and implementing the strictest ethical standards and the highest scientific standards to protect the patients and the consumer;
4. To ensure that drug establishments submit product dossiers and other documents, package labels and inserts, protocols, clinical trial results, and promotional materials, among others, are based on relevant, up to date and strong scientific or clinical data; and
5. To require drug establishments to have Medical Directors in their companies as part of the requirements for licensing establishments and registration of products.

IV. SCOPE

This Administrative Order shall apply to 1) all drug establishments, including drug manufacturers, drug traders and drug distributors/importers, handling and dealing in new and registered drugs, and 2) to all Medical Directors (or any equivalent title) employed as such.

V. DEFINITION OF TERMS

1. **Medical Director** refers to a duly registered physician who provides guidance, leadership and oversight and quality assurance for the medical affairs department in a pharmaceutical company

2. **Drug establishment** refers to any organization or company involved in the manufacture, importation, repacking and/or distribution of drugs or medicines.
3. **Pharmacovigilance** refers to the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems.
4. **Good Clinical Practice** refers to the standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

VI. POLICIES AND PROCEDURES

A. General Guidelines

1. Qualifications of the Medical Director

- a. Must be a Doctor of Medicine duly registered with the Professional Regulation Commission.
- b. Finished a residency training program in a reputable medical facility or is a faculty member in a recognized medical school, preferably in Pharmacology for at least three (3) years or any equivalent training in the field of Pharmacology or Clinical Pharmacology.
- c. Must have satisfactorily earned the Diploma in Pharmaceutical Medicine or passed the examinations given by the Specialty board of Pharmaceutical Medicines within three (3) years of being employed by any pharmaceutical company in the Philippines.
- d. Has a broad understanding of the regulatory environment, healthcare system and market dynamics in the Philippines.
- e. Has excellent communication skills, good people management and cross functional collaboration skills.
- f. Has indisputable personal and work ethics.

2. Roles and Functions/Responsibilities

2.1 Medical Director

- a. Lead the company in implementing product stewardship
- b. Ensure the following activities are complied or effectively and efficiently carried out by the company:
 1. clinical trials are in compliance to GCP and FDA regulations
 2. quality assurance of products through vigilant monitoring of adverse events
 3. reporting of adverse events

4. product information is science based and product claims are well substantiated, factual and balanced and rational
 5. marketing and promotions are strictly based on ethical practices
 6. formulate policies, solutions, strategies and plans to address/minimize product risks.
- c. Submits a "No Conflict of Interest" declaration to the FDA.
 - d. Clearance of all communications with the FDA regarding New Drugs and Investigational New Drugs, including follow-up of application for registration of New Drugs, Investigational New Drugs and matters arising from clinical investigation must be coursed through the Medical Director with the assistance of the registered pharmacist of the drug establishment.
 - e. Approval of all package inserts, labels, brochures and other labeling and promotion materials.
 - f. Serve as liaison officer with the FDA, Pharmaceutical and Healthcare Association of the Philippines and other equivalent pharmaceutical industry associations, the Philippine Medical Association and its specialty and affiliate societies as other government agencies and related organizations.
 - g. Implementation of the following clinical trial activities:
 - i. Prepare or adopt clinical trial protocols for pre and post-market phases of drug development;
 - ii. Coordinates the conduct of clinical trials with the clinical investigator(s) and clinical research associates;
 - iii. Submits a complete report on the outcome of a clinical trial to FDA.
 - h. Assistance in the training program of professional sales representatives, supervisors, pharmacists and other personnel of the drug establishment.

2.2 Head of The Company Responsible for the Medical Director:

- a. Ensures that Medical Directors have the necessary support and authority to perform their functions effectively without any encumbrance/s.
- b. Provides training to Medical Directors to update their Good Clinical Practice, Pharmacovigilance and Risk Management skills, etc.
- c. Ensure that their Medical Director attend any scientific meetings or trainings conducted/organized by the FDA.
- d. Ensures that the Medical Director submits a "No Conflict of Interest" Declaration to FDA.
- e. In case of sudden separation of the Medical Director from the drug establishment, the FDA shall be informed in writing within 10 working

days. The company shall appoint a new Medical Director within 2-3 months.

B. Specific Guidelines

1. The requirement for Medical Directors shall be part o the application for License to Operate (LTO).
2. All drug establishment shall submit to FDA Ethical Market Communications Unit (EMCU) the name of their respective Medical Directors (CV attached) , tenure of contract as such and the corresponding job description.
3. The FDA, through the EMCU, shall be notified in writing, within a month's period, of any change/s in the appointment of the Medical Director. A copy shall be provided to the CDRR.
4. The Ethical Market Communications Unit shall develop a database of all submitted names of Medical Directors.
5. The Medical Director and all other responsible officers shall be accountable for the integrity of their products, labels and promotional materials, company dossiers and other submissions to the FDA.

C. SANCTION


Any violation/s of this Order and other pertinent issuances shall be a ground for the suspension, cancellation or revocation of any authorizations granted by the FDA to the concerned drug establishment and other applicable sanctions, as provided for in the FDA Act of 2009.

VII. REPEALING CLAUSE

Administrative Order No. 86 s 2000 and all other issuances whose provisions are inconsistent with this Order shall be repealed/rescinded.

VIII. EFFECTIVITY

This Order shall take effect fifteen (15) days after its publication in two newspapers of general circulation.


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