Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

July 18, 2000

ADMINISTRATIVE ORDER
No. 86 s.2000

SUBJECT: THE NEED AND ROLE of A MEDICAL DIRECTOR IN THE PHARMACEUTICAL INDUSTRY

To facilitate the objective evaluation of New and Registered Drugs, to provide adequate information to the consuming public and to ensure the safety and efficacy of drugs to protect the health of the people, this set of guidelines is prescribed

1. All Drug Establishments to include drug manufacturers drug traders and drug distributors/importers under AO 56 s. 1989, handling and dealing in new and registered drugs are required to have a Medical Director (or any equivalent title) as part of their staffing complement

2. The Medical Director may work for the drug establishment on a full time part time or en a consultancy basis.

3. The Medical Director must be registered With the Bureau of Food and Drugs (BFAD) by the management of the drug establishments provided that said Medical Director is a certified member of the Philippine College of Pharmaceutical Medicine.

4. The qualification of Medical Director are the following:

a. Must be a 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

5. Duties and responsibilities of the Medical Directors

Responsibilities of the Medical Director shall include but not limited to the following:

1. Clearance of all communications with the Bureau of Food and Drugs 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 establishment.

2. Approval of ail package inserts, labels, brochures and other labeling and promotion materials.

1 and 2 shall be undertaken with the assistance of the registered pharmacist of the establishment prior to submission to the Bureau of Food and Drugs.

3. Serve as liaison officer with the BFAD Pharmaceutical and HealthCare Association of the Philippines and other equivalent pharmaceutical industry associations, the Philippine Medical Associations and its specialty and
affiliate societies as well as other government agencies and related organizations;

4. Implementation of the following clinical trial actiVities

i. Prepare or adopt clinical trial protocols or pre- and post-marketing 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 the BFAD.

5. Assistance in the training program of medical representatives, supervisors, pharmacist and other personnel of the drug establishment.

This Order supersedes Administrative Order No. 34, series 1979 and all other orders inconsistent With this Order.

This Order shall take effect immediately upon publication in two (2) newspapers of general circulation.

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Secretary of Health