

**[ ADMINISTRATIVE ORDER NO. 86, S. 2000, July 18, 2000 ]**

**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 AO56 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 on 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 qualifications of Medical Director are the following:
  - 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.
5. Duties and responsibilities of the Medical Director:

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.