

21 April 2013

**FDA Advisory**  
**No. 2013- 011**

**SUBJECT: ENSURING ACCESS OF FILIPINO PEOPLE TO SAFE,  
EFFECTIVE AND AFFORDABLE ESSENTIAL MEDICINES  
AND THE PHARMACY LAW OF THE PHILIPPINES**

The FDA is concerned over the statement made by the Philippine Pharmacists Association (PPhA) and the Drugstores Association of the Philippines (DSAP) last 13 April 2013 that warned the public over drugstores that employ “ghost pharmacists”, referring to absentee registered pharmacists employed by unscrupulous drugstore owners. The statement made by PPhA EVP, Dr. Yolanda Robles, that around 70% of the owners in the CAMANAVA area have no pharmacists is alarming. The FDA would like to assure the public that the FDA shall continue to make sure that safe and effective medicines are available to consumers in the CAMANAVA area and the rest of the country. The FDA further informs the public that it has initiated series of activities to address “ghost pharmacies” and acute shortage of dedicated community pharmacists that have severely affected the DOH delivery of public health goods and services and health outcomes.

Section 27 of RA 5921 (1969; as amended), or The Pharmacy Law, requires all drug outlets to be under the personal and immediate supervision of a registered pharmacist. This requirement is provided by DOH AO No. 56, s. 1989 re: Revised Regulations for the Licensing of Drug Establishments and Outlets. All licensed pharmacists are required to undergo FDA training on AO No. 56. All drugstore owners are required to display the PRC license certificates of all employed pharmacists in a conspicuous place of the drugstores. These requirements are subject to FDA verification, inspection and monitoring. Section 43 of RA No. 9502, or the Universally Accessible Cheaper and Quality Medicines Act of 2008, amended, in part, RA No. 5921, “Pharmaceutical, drug or biological manufacturing establishments, importers and wholesalers of drugs .... shall not sell their products for re-sale except only to retail drug outlets, hospital pharmacies, or other drug wholesalers under the supervision of a registered pharmacist, ...”.

As of October 2012, there are 32,443 retail drug outlets all over the country, 5,132 more than in 2010. The figure does not include 625 retail outlets for non-prescription drugs and 332 Chinese drugstores, 302 drug manufacturers, 45 medical device manufacturers, 412 drug traders, and 6,044 drug distributors, which also require the presence of pharmacists when open for business. Chain of drugstores and drug manufacturers or distributors requires more than one pharmacist. The figures do not include veterinary drug establishments all over the country. According to Dr. Y. Robles, there are only around 20,000 registered pharmacists.



The lack of licensed pharmacists in community service became evident when the DOH launched the *Botika ng Barangay* (BnB) Project in early 2000. BnBs serve as the retail outlets of government-procured medicines in order to increase accessibility of Filipino people, especially the underprivileged sector, to safe, effective and affordable essential medicines. The FDA plays a key role in the DOH's effort to overcome inequities in the health system and delivery of better health outcomes.

On the other hand, the FDA faces the challenge, if not the dilemma, of ensuring all Filipinos have access to essential medicines down to the farthest *barangay* of the country with Section 27 of the Pharmacy Law and other rules and regulations, still in effect. In addition, the same provision of the Pharmacy Law may be a contributory factor that limits, if not hampers, the growth and expansion of the drug retail industry given the shortage in community pharmacists.

Thus, the FDA has to find the balance. In fact, the FDA has taken steps to review the Pharmacy Law and its rules and regulations implemented by the FDA. Last October, the FDA reported to the Secretary of Health, Dr. Enrique T. Ona, that there are existing legislations that may prevent full access to essential medicines and health products in the regions. In a meeting last January between the FDA and the PRC, Hon. Chairman of the Board of Pharmacy, Ms. Marilyn Y. Tiu, reported that there are disparities in the number of licensed pharmacists who are in community practice and the number of drug establishments licensed by the FDA. The FDA also met with the National Center for Pharmaceutical Access and Management (NCPAM) Program Manager, Dr. Virginia G. Ala, last February to align the current FDA objectives with the plans of the NCPAM. Consistent with State policy to protect the interest and welfare of the public, and to establish standards of conduct for business and industry as guaranteed by RA 7394, or the Consumer Act of the Philippines, the FDA will undertake several consultations with stakeholders, including the legislators and the civil society, to help find the balance and the solution that would best serve the interest of the public.

The FDA advises all consumers to buy their medicines from legitimate drug outlets. All drugstore owners are warned to observe the provision of AO No. 56, s, 1989, which will be strictly enforced by the FDA drug inspectors. The FDA appeals to all pharmacists to adhere to the Code of Ethics for Pharmacist and to comply with the professional conduct of pharmacists as provided by the Pharmacy Law.

  
**KENNETH Y. HARTIGAN-GO, MD**  
Acting Director IV