



# PHILIPPINES LIVING HiT UPDATE

## 2.7.7 Regulation and governance of pharmaceutical care

Pharmaceuticals are regulated by the Food and Drug Administration (FDA), together with processed food, cosmetics and health devices. There are 4 speciality areas: (1) Centre for Drug Regulation and Research (to include veterinary medicine and vaccines); (2) Centre for Food Regulation and Research; (3) Centre for Cosmetics Regulation and Research (to include household hazardous/urban substances); (4) Centre for Device Regulation, Radiation Health, and Research. In addition, the FDA also covers enforcement of law to deal with illegal companies and their unregistered products that may harm the public.



The FDA has taken several steps to ensure the quality of the available drugs on the market. In 2013, it has adopted the ASEAN common technical document for drug registration (FDA, 2013a) and was allowed by the Department of Health (DOH) administrative order to undertake foreign cGMP inspection of medicine suppliers (FDA, 2013b). It also signed two APEC declarations on ethics, in order to increase ethical standards and provide greater transparency; one for the biopharmaceutical sector<sup>1</sup> and the other for medical devices<sup>2</sup> (FDA, 2013c). It is also mandating bioavailability and bioequivalence (BA/BE) analyses for generic drugs (FDA, 2013d). Additionally, the FDA has also established an e-reporting system for adverse drug reactions (ADR), providing an avenue for consumers to give feedback and form an on-the-ground surveillance network to monitor the safety, quality and efficacy of the medicines (FDA, 2012; FDA, 2013e; FDA, 2013f).

To ensure the enforcement and the sustainability of such efforts however, investment into the FDA has to be made. Currently, growth of the FDA has stagnated,

1 The Mexico City Principles For Voluntary Codes Of Business Ethics In The Biopharmaceutical Sector

2 The Kuala Lumpur Principles For Medical Devices Sector Code Of Ethics

despite its increasing responsibilities from a growing nation. The FDA lacks facilities, equipment and trained personnel to guarantee the quality, safety and efficacy of drugs on the market. Financial constraints should not hinder the regulators from fulfilling its duties.

The regulation process can be strengthened along the 6 building blocks of health systems strengthening (World Health Organization, 2010): (1) Health Service Delivery – Implementation of Information and Communications Technology (ICT) to improve transparency and efficiency. E.g. The FDA is using mobile technologies to improve the effectiveness of its inspection and surveillance system (Chua, 2013). (2) Health Workforce - The FDA has created its own academy; training current staff and starting up an internship programme, to build up its human resource capacity (FDA, 2013d). This is due to the lack of formal training for professional regulators in the country. (3) Health Information Systems – The FDA hopes to implement a health systems research team in coordination with DOH and Department of Science and Technology (DOST). (4) Access to Essential Medicines – Currently, there is information asymmetry regarding the efficacy, safety and quality of existing health products in the market. The FDA is unable to cope with the responsibilities of the country without sufficient financial support from the government. Hence, access to essential medicines, vaccines and technology of assured quality, safety and efficacy cannot be guaranteed. (5) Financing – Due to the constraints of the FDA, the government might be financing poor quality health products, which results in poor health service delivery due to low credibility. Hence, it is imperative that the FDA is able to regulate health products in the market properly. (6) Governance – Despite the passing of laws (Republic Act No. 9711 of 2009 and Republic Act No. 9502 of 2008) to strengthen the FDA and improve access to medicines, full implementation is yet to be done. Additionally, the Philippines is in Phase III of the Good Governance for Medicines programme (GGM) of the World Health Organization (WHO) (Martin & Ollier, 2013). Hence the government should work together with the partners of the GGM programme, enforce its laws and push for greater cooperation between the various departments, in order to contribute to health system strengthening; thereby improving universal access to affordable, quality-assured medicines (Martin & Ollier, 2013) in the Philippines.

In sum, it is essential that government departments collaborate, to ensure the FDA has sufficient resources to protect consumers. Without proper regulation, ineffective and unsafe health products might circulate within the market, causing mistrust in the population and ultimately, distrust of the entire public health system.

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