

Status of Compliance of Specific Provisions of Republic Act No. 6675 (The Generics Act of 1988)

PROVISION	STATUS OF COMPLIANCE	RESPONSIBLE OFFICE
<p>Section 4 The Use of Generic Terminology for Essential Drugs and Promotional Incentives</p> <p>(a) In the promotion of the generic names for pharmaceutical products, special consideration shall be given to drugs and medicines which are included in the Essential Drugs List to be prepared within one hundred eighty (180) days from approval of this Act and updated quarterly by the Department of Health on the basis of health conditions obtaining in the Philippines as well as on internationally accepted criteria.</p>	<p>Revision and updating of the Essential Drugs List or Philippine National Drug Formulary (PNDF) is strictly followed but not within the time frame indicated</p> <p>Printing of PNDF Volume 1, sixth edition is currently underway.</p>	<p>National Drug Policy Program, Department of Health – National Formulary Committee (<i>only ad hoc</i>)</p>
<p>(b) The exclusive use of generic technology in the manufacture, marketing and sales of drugs and medicines, particularly those in the Essential Drugs List, shall be promoted through such a system of Incentive as the Board of Investment jointly with the Department of Health and other government agencies as may be authorized by laws, within one hundred eighty (180) days after approval of this Act.</p>	<p>Not implemented due to lack of budget for incentives</p>	<p>Department of Health and other government agencies</p>
<p>Section 5 Posting and Publication</p> <p>The Department of Health shall publish annually in at least two newspapers of general circulation in the Philippines the generic names, and the corresponding brand names under which they are marketed, of all drugs and medicines available in the Philippines.</p>	<p>No revision made due to lack of human resource from the Bureau of Food and Drugs to handle the updating of the Cross Reference Index (a compilation of BFAD-registered drug products in generic names and their corresponding brand names marketed in the Philippines)</p>	<p>Department of Health and Bureau of Food and Drugs</p>

<p>Section 6 Who shall Use Generic Terminology</p> <p>(a) All government agencies and their personnel as well as other government agencies shall use generic terminology or generic names in all transaction related to purchasing, prescribing, dispensing and administering of all drugs and medicines.</p>	<p>Not strictly followed since there is poor monitoring for prescribing and dispensing</p> <p>Procurement strictly followed by virtue of E0 49 (1993), which directs the mandatory use of the Philippine National Drug Formulary as basis for government's drug procurement</p>	<p>All government health agencies</p>
<p>(b) All medical, dental and veterinary practitioners, including private practitioners, shall write prescriptions using generic name. The brand name may be included, if so desired.</p>	<p>Not strictly followed since some practitioners prescribe exclusive brands</p> <p>Poor monitoring</p>	<p>All medical, dental, veterinary practitioners, including private practitioners</p>
<p>(c) Any organization or company involved in the manufacture, importation, repacking, marketing and/or distribution of drugs and medicines shall indicate prominently the generic name of the product. In any case of brand name products, the generic name shall appear prominently and immediately above the brand name in all product labels as well as in advertising and other promotional materials.</p>	<p>Strictly followed by Product Services Division of BFAD prior to registration of drugs</p>	<p>BFAD and Philippine Board of Advertising</p>
<p>(d) Drug outlets, including drugstores, hospital and non-hospital pharmacies and non-traditional outlets such as supermarkets and stores shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise his option.</p> <p>Within one (1) year after approval of this Act, the drug outlets referred to herein shall post in conspicuous places in their establishments, a list of drug products with the same generic name and their corresponding prices.</p>	<p>Not strictly followed since some outlets are biased with some brands</p> <p>Poor monitoring especially in depressed regions</p> <p>Most drugstores not complying with the use of price menu cards</p>	<p>BFAD</p>

<p>Section 7 Provision on Quality, Manufacturer's Identity and Responsibility</p> <p>In order to assure responsibility of drug quality in all instances, the label of drugs and medicines shall have the following: name and country of manufacture, dates of manufacture and expiration. The quality of such generically labeled drugs and medicines shall be duly certified by the Department of Health.</p>	<p>Strictly followed</p>	<p>DOH and BFAD</p>
<p>Section 8 Required Production</p> <p>Subject to the rules and regulations promulgated by the Secretary of Health, every drug manufacturing company operating in the Philippines shall be required to produce, distribute and make available to the general public the medicine it produces, in the form of generic drugs.</p>	<p>Not followed as there are no implementing rules and regulations</p> <p>No budget allocation</p>	<p>DOH, National Drug Policy program, Department of Trade and Industry, Board of Investments, pharmaceutical industry</p>
<p>Section 9 Rules and Regulations</p> <p>The implementation of the provision of this Act shall be in accordance with the rules and regulations to be promulgated by the Department of Health. Rules and regulations with penal sanctions shall be promulgated within one hundred eighty (180) days after approval of this Act.</p>	<p>Followed</p>	<p>DOH</p>
<p>Section 10 Authority to Import</p> <p>Within three (3) days from the effectivity of this Act, extendible by the president for another two (2) years and during periods of critical shortage and absolute necessity, the Department of Health is hereby authorized to import raw materials of which there is</p>	<p>Such provision was implemented in the following cases:</p> <p>Due to high mortality rate of tuberculosis in 1996 in order to address the health concerns of Filipinos, then Sec. Hilarion Ramiro Jr. initiated the importation of raw materials for the manufacture of</p>	<p>Office of the President, Congress, DOH, DTI</p>

<p>shortage for the use of Filipino-owned or controlled drug establishments to be marketed and sold exclusively under generic nomenclature. The Secretary of Health shall ensure that the imported raw materials are allocated fairly and efficiently among Filipino-owned or controlled drug establishments. He shall submit to the Office of the President and to Congress a quarterly report of the quantity, kind and value of the raw materials imported.</p>	<p>rifampicin.</p> <p>As a counter measure against pandemic influenza, DOH signed a MOA with Unilab in November 2005 for Unilab to import raw materials of the avian flu drug Oseltamivir (Tamiflu from Roche) for donation to the government.</p>	
<p>Section 11 Education Drive</p> <p>The Department of Health jointly with the Department of Education, Culture and Sports, Philippine Information Agency and the department of Local Government shall conduct a continuous information campaign for the public and a continuing education and training for the medical and allied medical professions on drugs with generic names as an alternative of equal efficacy to the more expensive brand name drugs. Such educational campaign shall include information on the illnesses or symptoms which ease generically named drug is suppose to cure or alleviate, as well as its contraindications. The Department of Health with the assistance of the Department of Local Government and the Philippine Information Agency shall monitor the progress of the education drive, and shall submit regular reports to Congress.</p>	<p>Training on National Drug Policy ad Rational Drug Use to medical and allied medical professionals conducted by DOH Central Office through National Drug Policy Program and Centers for Health Development from 1996 to1999</p> <p>Therapeutics Committee revitalized</p> <p>Information and education campaign materials disseminated to prescribers, dispensers and consumers</p> <p>In coordination with U.P. College of Public Administration, training and dissemination of information to local executives and auditors of the Commission on Audit on EO 49 and RA 6675 conducted</p> <p>RA 6675 included in the present curriculum of pharmacy and medical professions</p>	<p>DOH, Department of Education, Commission on Higher Education, Department of Interior and Local Government, Philippine Information Agency, National Drug Policy Program, U.P. College of Public Administration</p>

Source: DOH, 2006