Quality Circle for GENERICS

What is the Quality Circle for Generics?

The Quality Circle for Generics is a campaign to provide patients and consumers with the best value in healthcare by ensuring the safety, efficacy and quality of given medicinal products. It is a practice and principle that should be embodied by different stakeholders involved in the regulation, manufacture, production, prescription, dispensing, sale and use of medicines.

Quality does not depend solely on strong regulations by the FDA but also adherence of all players to the standards of quality which include:

* Good Manufacturing Practices (GMP)
* Good Laboratory Practices (GLP)
* Good Clinical Practices (GCP)
* Good Distribution Practices (GDP)
* Good Storage Practices (GSP)
* Good Pharmacy Practices (GPP)

Everyone has a stake in ensuring that generic medicines fulfill their intended effects to provide cure to patients as clinically tested and expected.

What is a Generic medicine?

Generic medicines are 'copies' of originator branded products or "innovator" drugs. They contain the same active ingredients and therefore should work as well as the more expensive branded products provided that they have passed the safety and quality requirements of the Philippine Food and Drug Administration (FDA).

Why are Generic drugs actively promoted by the Department of Health?

Generic drugs offer substantial health and economic benefits to patients, their families and the national health system. The affordability of these medicines will better ensure that patients will complete their treatment regimen and get well.
Savings from quality generic products can be redirected toward other health priorities thus enabling the government to provide care for many and achieve universal health care (UHC).

The Philippine Generics Law (1988) contains important provisions that champion the welfare of the Filipino public through access to generics:

- Mandatory use of generic names in all product labels, advertisements, doctors' prescriptions and drug outlets

- Development and use of the *Philippine National Formulary* in government procurement and Philhealth reimbursement of medicines

- Emphasis on the role of the pharmacists as the source of information on available generically equivalent products and their comparative prices

- Empowerment of patients and consumers to make informed choices through ethical drug advertising and promotions

- Incentives for manufacturers to provide quality generic products affordable to the Filipino public and the government

Other Laws

a. Republic Act 9502, also known as "Universally Accessible Cheaper and Quality Medicines Act of 2008"
b. Republic Act 9711, also known as "Food and Drug Administration (FDA) Act of 2009"

Why is Quality important?

Quality is important as this will ensure that the product or the medicine will deliver the clinically-tested effects of medicines when used by the patients or consumers.

Who are part of the Quality Circle for Generics?

1. Legislators

a. Provide the legal and policy framework to assure the quality of generic medicines
b. Allocate adequate budget/resources to ensure that health regulators enforce the provisions of health laws

2. Regulators (DOH and FDA)

a. Enforce the provisions of the Generics Law (RA 6675) and other pertinent laws
b. Issue and update a sound national medicines policy anchored on the quality, safety, efficacy and cost-effectiveness of medicinal products

3. Pharmaceutical Industry

a. Produce and manufacture quality generic drugs for the Filipino public
b. Adhere to the regulatory standards on safety, efficacy and quality as well as ethical codes on the promotion, marketing and sale of medicinal products

4. Prescribers

a. Adhere to professional and ethical standards on the prescription and use of medicines
b. Educate patients on the benefits and rational use of generic medicines

5. Dispensers

a. Source quality generic medicines from reputable manufacturers, traders and distributors
b. Ensure a safe, clean, and secure dispensing environment for generic drugs
c. Counsel individual patients on generic drugs and give informed choice to consumers

6. Consumers/Patients

a. Buy medicines only from FDA-licensed outlets properly authorized to dispense medicines
b. Examine physically and visually the medicines they purchase to make sure that the right product strength was dispensed to them and that the product has a current expiry date
c. Read product labels and follow the advice of their physicians and pharmacists to guarantee that generic products work

The DOH and FDA are committed in giving Filipino patients only the highest standards of care through quality generic medicines, we are aggressively pursuing the following initiatives:

- Enforcement of cGMP requirements for all manufacturers
- Expansion of the list of medicines requiring proof of Bioavailability and Bioequivalence
- Regionalization of FDA Laboratory Services
- Strengthening of the National Pharmacovigilance Guidelines
- Formulation/ issuance of the National Policy on the Rational Use of Medicines (RUM)
- Launching of the Philippine Drug Price Reference Index (PDPRI)
- Creation of a National Procurement Strategy for Medicines (NPSM)

***Quality** is a collective right and responsibility of the government, the industry, patients and health providers!*

DOH