Philippine Center for Diabetes Education Foundation, Inc.
(DIABETES CENTER PHILIPPINES)

The Philippine Center for Diabetes Education Foundation's Position Statement on Generics Only Prescribing

The Philippine Center for Diabetes Education Foundation supports legislation that will help make healthcare affordable and accessible to a majority of Filipinos.

However, in the interest of patient safety and quality of care, we propose that Section 23 - F of "The Universal Health Care for All Filipinos Act" be deleted. It states that "Medical and dental practitioners, including private practitioners, shall write prescriptions using the International Nonproprietary Name (INN) or generic name only. No brand names shall be allowed in any part of the prescription."

For many medicines, the generic drug has been shown to be as safe and effective as the innovator brand. However, there are many instances wherein the brand name of the medication needs to be specified.

1. Adverse reaction to the generic preparation

The generic name refers only to the active ingredient of the drug. The inactive ingredients such as the tablet coating, color, binder, etc. usually vary among different drug preparations whether generic or branded.

Some patients when switched from a particular brand to a generic form develop an adverse reaction.

Adverse reactions to the inactive ingredient can range from a mildly irritating rash or stomach upset to a severe allergic reaction leading to suffocation, organ shutdown and death.

Specifying the preparation known to be safe and effective for the patient is imperative in these cases as not doing so could be fatal.

2. Non-interchangeability of some drug preparations

Some drug preparations simply cannot be substituted for another. Bioavailability (how much or how quickly a drug is absorbed by the body) between drugs may differ significantly such that the amount of drug in the bloodstream can become too high or too low.

Bioequivalence is also questionable for many drug preparations. Bioequivalence refers to the property wherein two drugs with identical active ingredients have the same bioavailability and produce the same effect on the human body.

Non-interchangeability is especially true for drugs with a narrow therapeutic index. Narrow therapeutic index drugs have a very slim dose range wherein the drug is beneficial. A fine line separates the drug's effective and toxic dose level. Very small differences in dosage can lead to: 1) treatment failure as drug levels in the blood fall below the range, or 2) toxicity as the dose goes above the range.

Examples of drugs with a narrow therapeutic window are antiepileptics[1], anticoagulants (drugs used to prevent blood clots) and levothyroxine[2].

When antiepileptic blood levels are inadequate, the patient can develop seizures that when left uncontrolled, could lead to lack of oxygen in the brain, disability, coma, even death.

Levothyroxine or thyroid hormone preparations likewise are not bioequivalent to each other. Switching brands or generic preparations of levothyroxine frequently results in changes in blood levels of the hormone necessitating repeat blood testing to ensure adequacy of dose. Excessive or inadequate levels of thyroid hormone can have deleterious effects on the heart, bone and pregnancy status.

3. Substandard generics

While some generic drug preparations meet regulatory standards, there have been several instances when stocks of vital generic medicines like insulin[3] and antihypertensives[4] were issued warning letters[5] by regulatory agencies, recalled or pulled from the market due to absent, insufficient or excess content of the active ingredient, presence of impurities and/or microbe contamination.

A recent study in Canada also showed a significant increase in adverse events in the generic users of three blood pressure lowering drugs after these became commercially available[5]. Huge differences in bioavailability were found in the generic formulations compared with their branded counterparts.

Our own FDA has proclaimed recently that the market is flooded with fake medicines reportedly imported from China/India.[6] Many generic preparations can easily be counterfeit or substandard as their makers may be pushed to cut corners to keep them as cheap as possible.

Specifying the drug brand whether it is manufactured by a generic or the innovator company could help ensure that the medication is from a reputable source.

4. Risk of confusion

Indicating the brand also saves the patient from confusion about whether or not he or she is taking the right medication.

If the generic name alone is written on the prescription, the patient may be dispensed an innovator brand medication one time, a generic medication next time and a branded generic medication on another visit to the drugstore.

The patient may get confused since the pill may be of a different size, color or and/or shape each time he fills his prescription. The elderly would particularly be vulnerable to this confusion and end up taking the wrong medication or taking the medication the wrong way because of pill mix-up. Specifying the preparation could help assure consistency in drug dispensing.

With solely generic prescriptions, dispensing would be at the whim of the pharmacist, who may be tempted to just dispense a drug with the highest profit margin or nearest expiration date.

5. Patient's preference

There are patients who insist that the brand be indicated on their prescription.

These patients may have tried other brands or preparations of a particular drug and just prefer one to another for whatever reason. For example, some may tolerate one tablet better than another; be able to swallow one better than the other due to a smaller pill size or slimmer shape; or just like the packaging of one brand over another because it comes in individually wrapped foil while another comes in small glass bottles.

Patients should be able to exercise their right to choose and their right to pay for quality.

What's in a name?

Generics only prescriptions do not assure affordability. In the United States a few years ago, prices of established generic drugs like digoxin and captopril rose 894% and 129% respectively.[7]

Current legislation is already adequate and appropriate. Both the Generics Drug Act of 1988 and Cheaper Medicines Act of 2008 mandate that the generic name be indicated on the prescription with the brand name as an **option**. This is more responsive to the needs and rights of both the patient and prescribing practitioner.

Barring healthcare practitioners from indicating the brand name on the drug prescription is overregulation of their profession and a disservice to the masses.

As physicians, we have taken an oath to "first, do no harm". Prohibiting prescribers from indicating a brand name when the patient's condition and circumstance dictate it could cause irreparable harm to the patient.

The prices of illness, hospitalization, and death are too high to pay when simply writing the brand name could very well prevent them.

Yes, generic drugs are cheap, but generics ONLY prescriptions are **not**.

References:

1. P. Crawford, et al. *Are there potential problems with generic substitution of antiepileptic drugs? A review of issues*. Seizure (2006) 15, 165—176.

2. AACE, TES, and ATA. Joint Position Statement on the Use and Interchangeability of

Thyroxine Products.

3. https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/state-fda-pulls-plug-on-wockhardt-insulin-drug/articleshow/609704.cms

4. J. LeClerc, et al. *Impact of the Commercialization of Three Generic Angiotensin II Receptor Blockers on Adverse Events in Quebec, Canada: A Population-Based Time Series Analysis.* Circ Cardiovasc Qual Outcomes (2017) 10:e003891. DOI: 10.1161/CIRCOUTCOMES.117.003891.

5. https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/2016/ucm534983.htm

6. PH market 'flooded' with fake meds, beauty products: FDA. http://www.pna.gov.ph/articles/1023649

7. EM Antman, et al. *American Heart Association Principles on the Accessibility and Affordability of Drugs and Biologics: A Presidential Advisory From the American Heart Association*. Circulation (2017) 136:e441–e447.

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