

How effective has the Generics Act been?

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Introduction

The demand for affordable and effective medicines has grown significantly as the international community works to improve global health care and combat diseases. People are also more concerned than ever about their health.

There have been notable changes in the existence and acceptance of generic drugs and medicines since the enactment of Republic Act (RA) No. 6675, also known as the Generics Act of 1988. This act aims to promote generic medicines as quality alternatives for expensive branded drugs by mandating physicians to include both branded and generic alternatives in their prescriptions.

Meanwhile, RA 2382, or the Philippine Medical Act, specifies that only physicians are authorized to prescribe medicines. Similarly, under RA 5921 or the Pharmacy Law,

only registered pharmacists are allowed to dispense and sell medicines.

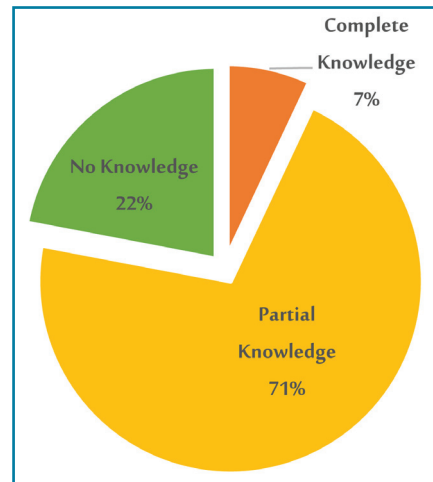
Due to some lapses in implementation, monitoring, and regulation, RA 6675 was amended in 2008 by RA 9502 to mete out heavier penalties for noncompliance with Section 6 of the law (“Who shall use generic terminology: personnel of government health agencies and other agencies; all medical, dental, veterinary, and private practitioners; any organization or company involved in the production process up to the distribution process of drugs and medicines; drug outlets; hospital and nonhospital pharmacies”). RA 9502 also

PIDS Policy Notes are observations/analyses written by PIDS researchers on certain policy issues. The treatise is holistic in approach and aims to provide useful inputs for decisionmaking.

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The views expressed are those of the authors and do not necessarily reflect those of the PIDS or the DOH.

Figure 1. Generic drugs definition



Source: Authors' compilation based on the survey responses

provides more regulating power to specific government bodies to monitor and regulate the prices of common medicines in order to provide affordable and effective medicines.

However, the effect of the law is barely noticeable as the number of prescription offenders continues to proliferate and as some consumers continue to believe that branded medicines are far better than their generic counterparts. Doctors themselves may also not believe that generic drugs are bioequivalent¹ and bioavailable in the same degree as originator brands. Twenty-five years

¹ A generic drug is considered to be bioequivalent to a brand name drug if: (a) the rate and extent of absorption do not show a significant difference from the listed drug or (b) the extent of absorption does not show a significant difference, and any difference in rate is intentional or not medically significant.

² The total number of respondents mentioned varies across each research objective because of missing responses on some questions.

after RA 6675 was enacted, there has not been a large-scale study of its effectiveness.

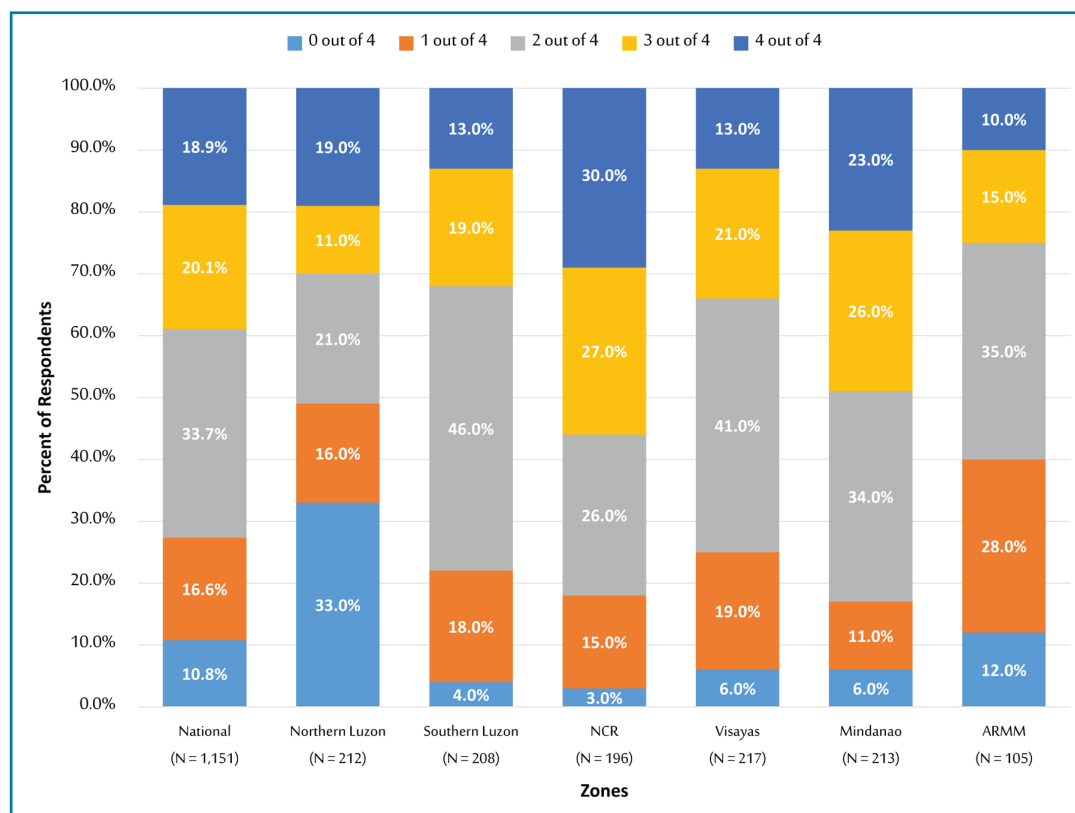
This *Policy Note* discusses the results of a study done by Wong et al. on the issue of compliance of physicians and drug stores with the provisions of the Generics Act of 1988. It aims to explore the awareness of consumers on generic medicines and to explain current trends and practices in drug prescribing, dispensing, and use. The study assessed four variables: generic drug prescription, generic drug substitution/dispensing, price menu cards, and use of generic drugs within the country. In conducting the study, the authors divided the country into six zones: North Luzon, South Luzon, National Capital Region (NCR), Visayas, Mindanao, and Autonomous Region in Muslim Mindanao (ARMM).

Indistinct knowledge about generic drugs and the Generics Act

Out of the 1,157² survey respondents who were asked to define generic drugs, only 7.2 percent knew the correct definition of generic drugs. Seventy-one percent were partially knowledgeable or able to mention that either (1) generic drugs were of the same quality as that of branded drugs or (2) generic drugs were cheaper than branded drugs. About 21.52 percent were not knowledgeable at all and gave incorrect definitions of generic drugs (Figure 1).

Furthermore, respondents were shown four drugs and were asked to identify whether the drugs were branded or generic. It was notable that across six geographic zones, NCR had

Figure 2. Proportion of medications correctly identified as generic or branded, by zone



Source: Authors' compilation based on the survey responses

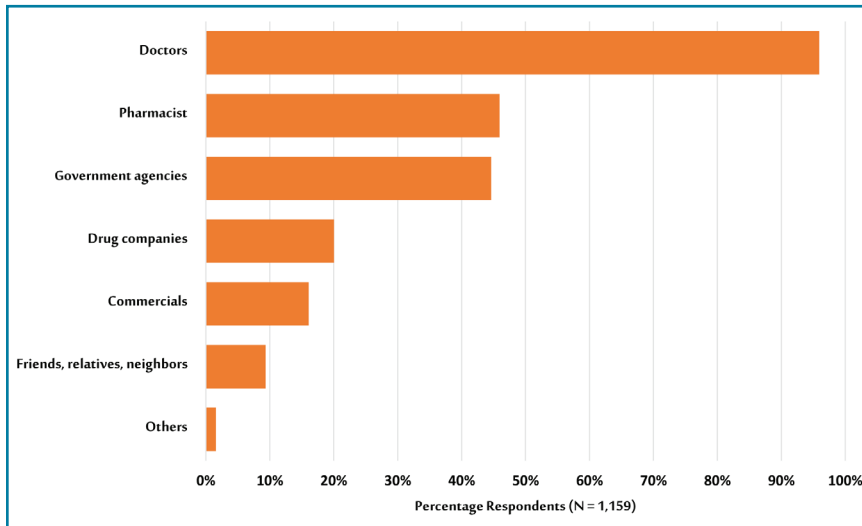
the highest percentage of respondents who correctly identified three or four drugs. ARMM, on the other hand, had the lowest proportion of those who could correctly identify three or four drugs (Figure 2). This reflects the higher level of awareness of generic drugs among respondents in the NCR that may be attributed to the stronger promotional campaigns through generic medicine pharmacies, TV commercial, price menu cards, and posters. Such promotional activities are difficult to implement in ARMM where media reach is limited.

Moreover, the percentage of respondents that identified at least three medicines correctly

is fairly low compared to the percentage of respondents who were partially knowledgeable about the definition of generic drugs. This reflects the fact that even if consumers know that generic drugs are generally cheaper and just as effective as branded ones, they still cannot distinguish these two from one another leading to confusion and purchase of whichever drug is available.

Section 11 of RA 6675 as amended by RA 9502 requires the Department of Health (DOH), together with the Philippine Information Agency and the Department of the Interior and Local Government, to conduct

Figure 3. Persons that influence the perception of consumers regarding the efficacy of generic drugs



Source: Authors' compilation based on the survey responses

an information campaign on the Generics Act. Only 55 percent of the respondents were aware that the law requires generic names to be written in prescriptions. Only 47 percent were aware that drugstores were required to offer generic alternatives to consumers. However, when asked if they knew that they had the right to choose between generic and branded medicines, 84 percent of consumers knew that they had this right.

These results imply that although most consumers were aware of their rights, half of them were unaware that there was a law promoting the prescription of generic medicines. Preference for generic drugs was also low as indicated by the large percentage of consumer respondents who were unaware that cheaper generic drugs are just as effective as expensive branded drugs.

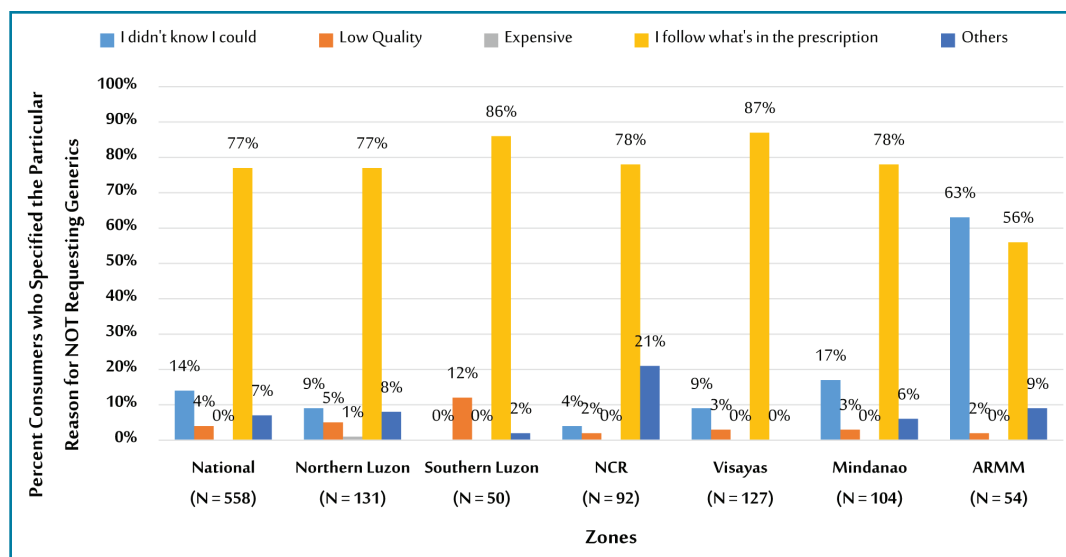
DOH was tasked to spearhead an education drive about the law. Section 11 of the law states that "...such educational campaign shall include information on the illnesses or symptoms which each generically named drug is supposed to cure or alleviate..." If the public is properly informed that generic drugs are as effective as branded medicines at less cost, it might help guide their choices the next time they purchase medicines.

Doctors' prescription in accordance with the law and how it influences consumers' preference

Ninety-six percent of the respondents said that doctors would be influential in convincing them about the effectiveness of generic drugs (Figure 3).

Based on the survey, the percentage of physicians who included the drugs' generic names in their prescriptions increased substantially between 1999 and 2008. The results showed that 83.92 percent of the respondents' prescriptions (89.47% for public pharmacist and 80.93% for private) had the generic names of the prescribed drugs. The stronger penalty for not complying with RA 9502 might have been the reason for this compliance. However, it was disturbing that there were still physicians that did not adhere to the law.

Figure 4. Reasons for not asking for the generic alternative, by zone



Source: Authors' compilation based on the survey responses

A follow-up question was made to further clarify the effect of the prescriptions on consumer preferences. The respondents were asked why they did not ask for the generic equivalent of their prescribed medicine (Figure 4).

Seventy-seven percent of the respondents confirmed that they did not ask for the generic equivalent at the pharmacy because they typically follow what is written in the doctor's prescription. Intriguingly, a considerable percentage disclosed that they were not aware that they could ask for generic alternatives. This may be attributed to the lack of consumer education and the consumer's tendency to just follow doctor's prescription. In addition, some of the interviewed physicians still have the tendency to prefer branded medicines.

Drugstores' compliance with the law

Section 6 of RA 6675 as amended by RA 9502 states that:

"Drug outlets, including drugstores, hospital and nonhospital pharmacies and nontraditional 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...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..."

Even though informing buyers of the generic alternatives and their corresponding prices is mandated by law, the survey showed that out of 1,150 respondents, only 40.61

percent said that they were offered the generic alternatives. Of those who were not offered generics, 25 percent requested for a generic alternative particularly because it was cheaper. But the other 75 percent did not make such a request because they mostly followed what was written in their prescriptions.

Additionally, when the respondents were asked if they saw generic menu cards in the drugstore, only 44.33 percent of the 1,155 respondents responded positively. Of the 43 drugstores observed, 36 (83.7%) had price menu cards. But even if price menu cards were present, some respondents complained that these were not placed in visible places.

Because of these problems and poor monitoring of compliance with the law, the total national prevalence of actual generic use is only 29.9 percent of the total drug items purchased by the respondents.

Inconsistency of generic medicines

“Physicians interviewed in Iraq identified that the biggest barrier to generic prescribing is their belief that generics are not equivalent to branded counterparts” (Sharrad et al. 2008, p. 61).

The same reason was stated during the focus group discussion with public and private physicians. Even though they prescribe generic equivalents, they prefer to recommend branded medicines to their patients. The interviewed physicians cited the following reasons in prescribing generic drugs to patients:

- Generic drugs are inconsistent. Sometimes they work, sometimes they do not.
- Patients come back unrelieved from sickness after being given generic drugs.
- Generic drugs typically take longer to cure sickness on average than branded ones.
- Monitoring by the Food and Drug Administration (FDA) is not reliable. Some generic drugs are approved by the FDA even though these drugs are not of good quality and not effective.
- Generic drugs from countries like China and India are of bad quality and are suspected to contain starch.
- When generic drugs fail to cure patients, it is the physicians’ reputation that is damaged.
- When the patient is financially incapable, generics are better than nothing at all.
- There are certain drugs that are not yet available in their generic form.

A qualitative study done in the United States revealed that barriers to the widespread use of generic medication included beliefs about generic medications having lower safety and efficacy as well as deep mistrust in the medical system.

The reasons cited by the physicians interviewed in the study show that the same is true in the Philippines. Physicians are doubtful of the effectiveness of generic drugs. They say that there is an obvious lack of regulation with these drugs, allowing even the bad-quality drugs to enter the market. Physicians’ opinions affect the perspective of the consumers on generic drugs.

Bioequivalence and bioavailability studies are needed to prove the effectiveness of generic drugs. These processes may be extensive and expensive but are necessary to resolve the conflict and to eliminate the ineffective drugs that are circulating in the market.

Weak regulation

The weak implementation of RA 6675 led to its further strengthening through RA 9502. However, it is evident that some of the parties involved still do not abide by the law.

While the law appears to be a strong way to make drugs accessible to the poor, challenges to attain its objectives exist due to weak regulation. Very few offenders are given sanctions or penalized under the law. The government should be stricter in imposing penalties on those who do not follow the law.

Monitoring can be expanded through collaboration with civil society using a 'mystery shopper' approach. It can provide compliance information to the FDA about the indicators that should be monitored like generic substitution and menu card visibility.

How the Generics Act uplifted health care especially for the poor

In the Philippines, the poorest households spend 59 percent of their medical care on drugs. This is in contrast to the 41 percent spent by the richest households, implying that it is the poor who bear the burden of drug expenses. Thus, relative to their income and

medical-care costs, it is the poor who bear a heavier burden on drug costs.

Physicians, especially in public hospitals, prescribe generics to their patients to avoid being penalized. Drug distributors post price menu cards and are required to inform buyers of the generic counterparts of the medicines in the prescriptions and their prices. Because of these, consumers know that they have alternatives, which may reduce their medical-care expenditure.

Because generic drugs are generally less expensive compared to branded ones, financially challenged individuals will have greater access to medicines they need and better chances to finish the course of treatment.

Recommendations

The study results show higher compliance with the Generics Act among physicians than among drugstores and consumers. Identifying drugstores and consumers as primary target groups in need of behavioral change allows for greater efficiency and effectiveness in the use of limited government resources for promotional campaigns.

A mix of social marketing efforts and consumer education is needed to change the mindset of consumers. Continuous education drives that will reach the most important cluster of the population must be done strategically to educate the people about the law and make them aware of their rights. A relevant strategy would be to tap 'generic believers' to

encourage others. The study showed that the odds of purchasing generic alternatives among individuals who are influenced by friends and relatives in their medical decisions are higher compared to those who are not influenced. Asking for a generic substitute in the drugstore should be portrayed as the default behavior of consumers whenever they purchase medicines.

Comprehensive regulation on drugstores and proper implementation of penalties may change the norm of disobedience to the law. The mystery shopper approach will make the distributors aware that there is always someone monitoring their compliance. Although the deficiency in offering generic counterparts and corresponding prices is not always by intent, pharmacists should be reminded constantly that it is their responsibility, not only legally but also humanely, to inform buyers of their choices.

The government should seriously consider subjecting generic drugs to bioequivalence tests. Even though they are expensive, bioequivalence tests can put to rest the persistent questions related to the quality of generic drugs. Decades of repetitive

information and communication have had little impact on physician and consumer perceptions.

Eliminate substandard and ineffective generics in the market. This is to improve consumers' negative perceptions of generic drugs in general. If all generic drugs on the market are proven and tested by consumers to be effective, the effect on consumer preference will be enormous. This is also one way of restoring the integrity of the FDA.

Finally, this *Policy Note* recommends an agenda for continuing research on generic drug behavior. This agenda includes:

- A health technology assessment of the cost effectiveness of requiring bioequivalence tests for generic drugs.
- The effectiveness of using the tools of social marketing and behavioral economics (BE) to influence prescribing, dispensing, and use behavior. BE is a new science that applies the principles of cognitive psychology, social psychology, and economics to understand human behavior and to influence them toward positive outcomes.
- A community trial that can be carried out based on the effectiveness of the mystery shopper technique to improve drugstore compliance with the generic-dispensing provisions of the Generic Law. 📄

References

- Sharrad, A., M. Hassali, and A. Shafie. 2008. Generic medicines: Perceptions of physicians in Basrah, Iraq. *Australasian Medical Journal* 1(8):58–64.

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