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The Prevalence of Philippine Prescribing, Dispensing, and Use Behavior in Relation to Generic Drugs and their Risk Factors

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The Prevalence of Philippine Prescribing,
Dispensing, and Use Behavior in Relation
to Generic Drugs and their Risk Factors

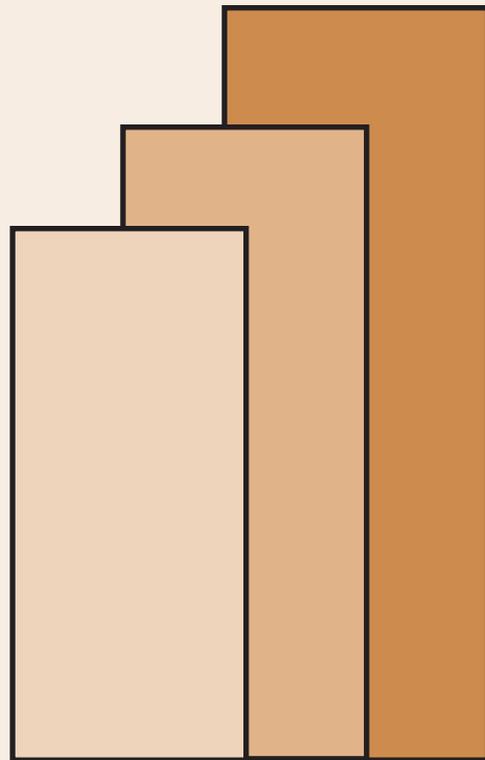
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**THE PREVALENCE OF PHILIPPINE PRESCRIBING, DISPENSING, AND USE
BEHAVIOR IN RELATION TO GENERIC DRUGS AND THEIR RISK FACTORS**

Final Report

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Executive Summary

This study was designed to address the issue of compliance of physicians and drug stores to the provisions of Generics Act of 1988. Furthermore it aims to explore the awareness of consumers on generic medicines to explain current trends and practices in drug prescribing, dispensing and use.

The study utilized a cross-sectional design. It is a descriptive study that assessed four variables: generic drug prescription, generic drug substitution/dispensing, price menu cards, and use of generic drugs. The country was divided into 6 zones, namely: North Luzon, South Luzon, NCR, Visayas, Mindanao and ARMM. Stratified cluster random sampling was used to identify which provinces and cities would be included in the study.

Data collection techniques used include the following: a survey of consumers coming out of a drugstore (a total of 1,160 respondents), key informant interview of 30 physicians, and focus group discussion with 6 to 11 patients/watchers per zone.

The survey revealed that five out of six drugs were written with generic names, with doctors in the public sector prescribing generics significantly more often than those in the private sector. Factors that positively affect generics prescribing behavior are patient's welfare, compliance, patient's financial situation, and fear of punishment. Quality concerns, lack of regulation by FDA, poor recall, patient's preference, and personal experience are factors that negatively affect generics prescribing behavior. Less than half of the consumers were offered with generic alternatives, and even less number of consumers actually asked for the alternative. There is preference for branded medicines over generics. The consumers more likely to purchase generic medicines consulted a public facility, knew the requirement to write generic name, and was influenced by friends and relatives. Because there is already high compliance from drug prescribers, government efforts should now focus to the drugstores and consumers. Drugstore compliance should be regularly monitored, and consumers empowered on their right to know alternatives. Bioequivalence tests should be done to finally put an end to concerns on the quality of generic medicines.

Keywords: generics, prescribing, dispensing, drug use, social marketing, cross sectional survey

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Table of Contents

I.	Introduction	6
	A. Background Information	
	B. Statement of the Problem	
	C. Literature Review	
	i. Rationale for the Generic Act	
	ii. Prevalence of Generic Prescribing, Dispensing, and Use	
	iii. Social Marketing Conceptual Framework	
	iv. Risk Factors Associated with Generic Prescribing Dispensing and Use	
II.	Objectives	19
	A. General	
	B. Specific	
III.	Methodology	19
	A. Study Type, Variables, Data Collection Techniques	
	B. Sampling	
	C. Data Collection	
	D. Data Processing and Analysis	
	E. Ethical Considerations	
	F. Pre-test	
IV.	Research Findings	21
	A. Survey	
	B. Key Informant Interview	
	C. Focus Group Discussion	
V.	Discussion.....	57
VI.	Recommendations and Conclusions	61
	A. Recommendations	
	i. Policy	
	ii. Research	
	B. Conclusions	
VII.	References	64
VIII.	Annex	65
	A. Informed Consent Form for Consumer Surveys (English)	
	B. Informed Consent Form for Consumer Surveys (Tagalog)	
	C. Informed Consent Form for Consumer Surveys (Bisaya)	
	D. Informed Consent Form for Consumer FGD (English)	
	E. Informed Consent Form for Consumer FGD (Tagalog)	
	F. Informed Consent Form for Consumer FGD (Bisaya)	
	G. Informed Consent Form for Physicians (English)	
	H. Consumer Survey Form	
	I. Focus Group Discussion Guide	
	J. Key Informant Interview Guide for Physicians (English)	

List of Tables

Table 1. Factors that affect consumers' choice of drug	25
Table 2. Percentage of generic prescribing, generic substitution, and use of generics	29
Table 3. Association of certain factors with offering of generics.....	36
Table 4. Association of factors with informing price of generics	38

List of Figures

Figure 1. Age distribution of the respondents	22
Figure 2. Age distribution of the respondents per zone.....	22
Figure 3. Distribution of respondents by place of consultation per zone.....	23
Figure 4. Distribution of respondents by type of facility per zone	24
Figure 5. Frequency distribution of drugstores included in the consumer survey by type of drugstore and zone	24
Figure 6. Proportion of medications correctly identified as generic or branded by zone	26
Figure 7. Persons that influence the perception of consumers regarding the efficacy of generic drugs.....	28
Figure 8. Distribution of drug stores by presence of generics menu card	29
Figure 9. Generic prescribing by type of prescriber	30
Figure 10. Generic prescribing by zone.....	31
Figure 11. Proportion of patients offered generic alternatives by the drugstore by zone	31
Figure 12. Generic substitution by type of drugstore	32
Figure 13. Generic substitution by zone	32
Figure 14. Distribution of respondents by request for generics per zone.....	33
Figure 15. Reason for asking for generic alternatives by zone	35
Figure 16. Reason for not asking for generic alternatives by zone.....	35
Figure 17. Reason for asking for the price of the generic alternative by zone.....	36
Figure 18. Reason for not asking for the price of the generic alternative by zone.....	36
Figure 19. Generic use by zone	37
Figure 20. Association of certain factors with offering of generics	37
Figure 21. Association of factors with informing price of generics.....	38
Figure 22. Factors associated with 'purchase generics' behavior.....	38

I. Introduction

A. Background Information

A debate on the premise that branded medicines are far better than their generic counterparts has been going for decades. According to the Republic Act 2382, or the Philippine Medical Act, physicians are the only ones authorized to prescribe medicines and, similarly, only registered pharmacists can dispense and sell medicines under the Republic Act 5921 or Pharmacy Law. Prior to the purchase of medicines, the patient has to present the prescription to the pharmacist before any drug can be dispensed. This is to safeguard the patient from taking unsafe medicines, or in some cases, wrong medicines. However, this setup limited consumer choice of the type of medicine, whether branded or generic, she could purchase. In most cases, the result was that the patient could only purchase expensive branded medicines. As a solution to the problem, the Republic Act 6675 or the Generics Act of 1988 was created. This law mandated generic labeling by drug manufacturers, generic prescribing by physicians, generic dispensing by pharmacists, and the choice of generics by consumers.

The Generics Act of 1988, also known as the Republic Act (RA) 6675, seeks “to promote, require, and ensure the production of an adequate supply, distribution, use, and acceptance of drugs and medicines identified by the generics names.” This law was written to ensure sufficient supply of medicines in the country at the lowest possible cost. In 2008, the Republic Act 9502 (Universally Accessible and Quality Medicines Act of 2008) amended the Generics Act by prescribing more severe penalties to those who do not follow Section 6 of the law. Inclusion of prominent labeling regarding equivalence of therapeutic efficacy of generics was also added to the duties of drug manufacturers.

Twenty-five years since its inception, follow-up studies on RA 6675 are notably lacking. In 2006, the Department of Health published a report on the status of compliance to the specific provisions of Republic Act 6675 (The Generics Act of 1988). In this report, it noted that some provision have not been strictly followed or implemented due to factors such as lack of budget, lack of human resources, and poor monitoring of prescribing and dispensing. This gap in implementation is worrisome and may have affected the access of the Filipinos to affordable quality medicines.

B. Statement of the Problem

1. What is the level of compliance of prescribers, dispensers, and consumers with the provisions of the Generics Act of 1988?
2. What are the factors associated with the expected behaviors in terms of prescribing, dispensing, and use of generic drugs?
3. How can we change the behavior of the prescribers, dispensers, and consumers?

C. Literature Review

i. Rationale for the Generic Act

1. Definition of Generic

The Center for Drug Evaluation and Research defined generic drugs as “*a drug product that is comparable to a brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics and intended use*”. Generics drugs can be marketed after patent and exclusivity protection ends, or patent owner waives its rights and FDA requirements are met. 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. The ultimate endpoint of the use of generic drugs results in reduction of drug costs, increased access to drug use and, the prevention of drug shortages. (U.S. Department of Health and Human Services, 2008)

2. Importance of generic prescribing, dispensing, and use

Batangan, et. al. (2005) from the Institute of Phil. Culture, Ateneo de Manila University performed a national survey on prices of medicines in the Philippines. They discussed that pharmaceuticals are expensive in the Philippines in comparison to prices in neighboring countries such as Thailand, Malaysia and Indonesia. The implementation of the Generic Drug Act of 1988 requiring the use of generic labeling, advertising, and prescriptions has led to a limited

penetration of generic drugs in the market, estimated currently at around 5%. This situation is mainly attributed to poor public perception of generic drugs by both consumers and providers reinforced by aggressive promotion of branded products by the industry. The study looked into the availability, price, affordability of medicines in the country. Availability of drugs was measured by defining the percentage of establishments where individual medications are found. This was done for both private and public facilities. The study found that lowest price generics had higher availability in the public sector while innovator brands were more available in the private pharmacies. In terms of price, the data show that consumers pay approximately three times more for innovator drugs compared to generic counterparts in both public and private pharmacies. The components of the price of medications were also identified which include finance/banking fees, quality control testing fee, import/tariff duty, national corporate tax, transport costs, wholesale mark-up and retail mark-up. Computing for the additional cost these factors added to the price, plus insurance and freight price, these could add as much as 273.24% to the costs of the drug. Hence, the authors of the study recommended efforts to increase awareness of the issues on drug prices and to encourage advocacy for lowering the price of the medications. They also brought up the need for policies on improving government procurement and in encouraging the use of generic medicines. The price components and mark-up data for this survey was gathered from various secondary sources. The study was limited in the difficulty in getting the necessary data from primary sources in government agencies and in the private sector. The government agencies approached informed the research team that they cannot release the data requested because of disclosure and confidentiality limitations. The private sector sources approached would not want to divulge 'trade secrets' but were willing to refer the research team to other data sources.

Another study investigating the price components of medicines through case studies of a small selection of essential medicines was done by Ball and Tisocki in 2009. The standardized methodology of the WHO/HAI

was used as a basis of the survey. Starting at the point of sale in a retail outlet, the price data is traced back through wholesalers/distributors, importers and government agencies using invoices and interviews to determine the components which go towards making the final price. They found out that there is a lack of transparency in the pricing of generic and originator brand medicines in the Philippines within the private sector that appears to be underpinned by suspicion of the acts of competitors and the government and a desire to preserve commercial secrets. The study also noted that the 12% VAT adds significantly to the cost of medicines and often has a larger effect than expected when mark-ups are based on the price including VAT from the supplier in the distribution chain. They also found out that public pharmacies tend to charge fixed retail mark-ups which may be as high as 30%. Moreover, the method of implementation of the senior citizen's discount (and now that for disabled persons) has the effect of raising medicine prices in such a way that the effect of the discount is largely negated where it is offered and any actual discount that may exist is "paid for" by patients, not by healthy members of society. Also, the market structure and market segmentation in the Philippines continues to support the observed pricing structures. If the Bureau of Food and Drugs were to rigorously ensure the quality of generic medicines on the market, this would help to increase the use and acceptability of low-priced generics. The authors recommended that interventions are needed to improve medicine pricing mechanisms and affordability. Specifically, the VAT on essential medicines and the use of regressive mark-ups at public pharmacies should be examined. They also suggested that mechanisms to increase utilization of low-priced generic medicines need to be explored and enhanced. Finally, the authors suggested that a reliable medicine price monitoring system should be established for essential medicines to monitor the effects of any policy or regulatory changes intended to affect medicine prices. Resistance from distributors and manufacturers/importers about divulging information on their prices and pricing structures limited the study.

ii. Prevalence of Generic Prescribing, Dispensing, and Use
1. Global

Worldwide, majority of the studies regarding the prescribing, dispensing and use of generic medication are qualitative. On review of the available literature, there exists an intellectually positive view towards generic medication from the physician and pharmacist standpoint, which is not reflective of actual generics prescribing and dispensing. This cognitive dissonance between belief and action must be resolved to increase the use of generics as a whole.

Generic Medicine Use

A qualitative study (Sewell et al, 2011) in the United States revealed that barriers to generic medication use included beliefs about generic medications having lower safety and efficacy as well as deep feelings of mistrust in the medical system. Participants observed how some doctors would prescribe branded medications in exchange for incentives they get from pharmaceutical companies, hence the feeling of mistrust in the medical system. The respondents believed that they are being told to use the generic over the branded medication because they are poor and therefore cannot afford the latter, which are perceived as highly effective. However the study demonstrated that health education may provide the consumers with accurate information regarding the efficacy and safety of generic medications.

That same year a qualitative study on consumer perception on generic medicines was done in Iraq (Sharrad et al, 2011). Their interviews revealed 5 themes regarding the consumers' knowledge on generics. The first was "*understanding of the term 'generic medicine'*" where they saw that this was not widely used and understood by the respondents and that they commonly use the term 'commercial medicine' instead. When they were asked about the difference between trade names and generic names, none of the participants could differentiate them well. The second theme was "*preference for generics*" which was highly influenced by the lower cost of these medicines. Its widespread availability,

recommendations from friends, and trust in the health care provider and manufacturers of generic drugs increased the likelihood that the participant will choose a generic drug. The third theme they uncovered was "*rejection of generic medicines*" which was based on the following factors: 1) physicians' inclination to prescribe innovative drugs, 2) confusion with other brands, and 3) comfort with the innovator drug. The fourth theme was "*generic substitution*" which revealed most patients depend on their physician's recommendation regarding generic substitution, compared to those offered by the pharmacist. Lastly, the fifth theme was "*education necessary to use generic medicine*" which revealed that the combined influence of both the physician and the pharmacist may result in a more favorable attitude regarding generic use.

This study lacks generalizability due to the small number of participants and the sampling method used; however, it reveals several key issues regarding generics acceptance and use in Iraq. The researchers concluded that consumer education on generic medicines is needed to correct misconceptions and provide them with the knowledge to make informed decisions regarding their medication choices

Generic Prescribing

A prospective study in France (Chu et al., 2011) regarding generic drug prescription following hospital discharge showed that at admission 413 drugs were prescribed, 272 (65.8%) of which were non-substitutable brand-name drugs, 118 (28.6%) were substitutable brand-name drugs and 23 (5.6%) were generics. Upon discharge, 488 drugs were prescribed, among these 308 (63%) were non-substitutable brand-name drugs, 175 were substitutable brand name drugs (36%), and five were generics (1%) in INN. It seems that there is still work to be done regarding changes in the prescribing practices of hospital physicians. The authors recommended "sensitizing physicians" to prescribe generics, using electronic software programs that support generic drug prescription and providing positive incentives to physicians who prescribe generics.

Physicians interviewed in Iraq (Sharrad et al, 2008) identified that the biggest barrier to generic prescribing is their belief that generics are not equivalent to branded counterparts. This can be remedied by educating them about the bioequivalence acceptability criteria for generic medicines (as set by the World Health Organization) and further reassurance about the quality, safety and efficacy of generic medicines .

Generic Dispensing

A cross-sectional national descriptive research was conducted with Australian community pharmacists in 2011 (Chong et al, 2011). Stratified random sampling was used to obtain representative numbers of urban, rural and remote pharmacies in Australia. Results showed that the generic substitution recommendation rate in remote areas (91.6%) was significantly lower than the urban (98.7%) and rural areas (98 %). The pharmacists demonstrated a significant higher tendency to offer generic substitution to concessional patients (low-income patients) compared to general patients (97.4% vs. 94.4%). Overall, 78.5% of the generic substitution recommendation cases were accepted by patients. Patients from remote areas were significantly more willing to accept generics (84.5%) compared to those in urban (73.2%) and rural area (78.6%). This can be explained by the variations in the social economic status of the patients across different areas. Patients from rural groups may have lower incomes and therefore being price sensitive and have higher acceptance level for generic substitution. Patients with acute conditions had a significantly higher acceptance rate (81.6%) than the chronic patients (72.4%). This result can be attributed to the stability of chronic patients on a brand product making them reluctant to switch their therapy.

Another study concerning the role of pharmacists in generic dispensing was conducted in Iraq (Sharrad et al, 2010). The result of the study showed that pharmacists interviewed were positively inclined towards generic substitution because it gives the pharmacist an expanded role in the education and health care of

patients. They agreed that the regulatory and professional bodies should educate pharmacists on bioequivalence requirements, which was a cause of confusion among them.

2. Philippines

There is a paucity of studies evaluating generic drug prescribing, dispensing, and use in the country. The following data is from SWS Surveys conducted from 1999 to 2008.

Generics prescribing

The 1999 survey revealed that sick respondents who consulted with a physician, 91% were given prescriptions, and in these prescriptions, 34% contained the generic name only, 41% brand name only, and 25% containing both generic and brand name. Comparing this to 2000, of the 78% respondents who said they were given a prescription by their doctor, the figures were 33%, 28%, and 39%, respectively. There was a decrease in 2008 when only 57% were given a prescription, and the data revealed 32%, 47%, and 21%, respectively.

This shows a disturbing trend from 1999 to 2008 where more physicians opt to write only the brand name of a medications (41% vs 47%) as well as a decrease in generics only prescription (34% vs 32%) and proper prescribing practice of generic plus brand (25% vs 21%). The conclusion can be made that instead of moving forward in the ten years from 1998 to 2008 proper prescribing practice has worsened.

Generics dispensing and use

From the SWS survey conducted in 2000, 48% of respondents who had generic names in their prescription (either alone or in combination with brand names), 51% were offered by the drugstore a generic drug, 24% with a branded drug, and 23% with both generic and branded drugs. What the respondents actually bought (either generic or brand name only, or

both) matched those that were offered to them (SWS, 2000).

More recent data (SWS, 2006-2008) showed not much difference in behavior of respondents. There are more respondents who bought generic medicines only (44% and 50%, respectively) compared to branded only (24% and 29%, respectively) or both (16% and 19%, respectively). And while there are more people buying generic medicines, 58% of the respondents still find the prices of medicines somewhat or very expensive.

Influences of customers

When asked about the opinion on the effectiveness of generic drugs (SWS, 2000), there is no significant difference between respondents believing that generic medicines are more effective (27%), branded medicines are more effective (24%), and those who believe both have the same efficacy (24%). Twenty-six percent are not aware at all of generic medicines.

In 2008, only 47% agreed that doctors should prescribe generic medicines exclusively. The remaining numbers of respondents were either undecided (20%) or disagreed (34%).

Awareness of generics

The 2000 survey (SWS, 2000) revealed that the main source of information regarding generic drugs are television (37%), doctor or nurse (22%), radio (15%), health centers (14%), drugstores (5%), magazines and newspapers (3%), and posters (2%). As mentioned previously, 26% of respondents have no awareness of generic medication.

In 2006, 18 years after the implementation of Generics Act of 1988, when respondents were asked if they have heard or read of programs of government regarding cheap prices of medicines, a whopping 72% answered no. From the 28% who said yes, 45% referred to various government programs such as *botika ng bayan*, *botika sa barangay*, and *botika ng masa*.

iii. Social Marketing Conceptual Framework

It is well known that strategic marketing is a proven method for solving problems in the commercial sector by focusing on two key questions: who are the consumers, and what do they need. Social marketing extrapolates from that concept by attempting to solve problems in the social sector. This brings us to the main purpose of social marketing: to develop constructive approaches to support desired behavior changes.

The driving principle behind social marketing is to increase the audience's perception that the benefits of the new behavior outweigh the costs of adopting it. Furthermore, the new behavior must be seen as having higher value than the current behavior.

A pioneer in social marketing, Stephen Smith points out that before the extreme poor can consume anything, they need social capital. This consists of health, reduced infant mortality, protection from diseases, education, and community connectivity. The importance of marketing as a means towards garnering social capital can not be emphasized more. This paves the way for the implementation of programs designed to meet fundamental and basic human needs.

The framework of Social Marketing is a systematic process consisting of 10 steps. It begins with (1) clarifying the plan's purpose and focus, moves on to (2) analyzing the current situation and environment, then (3) identifying target audiences, (4) establishing marketing objectives and goals, and (5) understanding your target population's position. It then (6) determines a desired positioning for the offer; (7) designs a strategic marketing mix (the Four Ps: Product, Price, Place, Promotion); (8) develops evaluation, (9) budget, and finally (10) implementation plans.

There are many theories and on-going debates over the causes of poverty and how to address the issue. In the book *"Up and Out of Poverty"*, the commonly cited factors are related to a few

major categories: health, the environment, the economy, infrastructures, education, social factors, and family planning. The focus is no longer limited to poverty of income but on poverty from a human development perspective, meaning poverty as a denial of choices and opportunities. Using the Human Poverty Index definition of the 1997 United Nations Human Development Report, there are four factors that come into play: the likelihood of a child not surviving to age 60, the functional illiteracy rate, long-term unemployment, and the population living on less than 50% of the median national income.

Expounding on the health situation, it was said that poor health may be caused by a lack of access to affordable health care, inadequate nutrition, low levels of physical activity, chronic diseases, clinical depression, substance abuse, lack of immunization, and the spread of diseases (AIDS, malaria, tuberculosis).

Generic medication plays a role in the improving the Human Poverty Index by providing affordable medication to a host of diseases, one of which is maintenance medication for chronic illness. Compliance with medications will be reflected in the increasing survival rate of the population.

From a recent local study (Banzon et al, 2010) Philippine households spend a significant percentage of medical care on drugs and the poorest households spend more than half (59 percent) of their medical care costs on drugs. Contrast this with the richest households who only spend 41 percent. Thus, relative to their income and medical care costs, it is the poor who bear a heavier burden on drug costs.

Using the Social Marketing framework, this study is at the second step in attempting to analyze the current situation and environment towards generic medication.

iv. Risk Factors Associated with Generic Prescribing Dispensing and Use

1. Global

In a study conducted in the United States (Shrank et al, 2009), it was revealed there have been widespread efforts by the insurance industry and the federal government to increase generic drug use, but actual use remains inconsistent. It was postulated that patient's perception on generic drugs may be the cause of this inconsistency. Thus, the authors conducted a national survey of commercially insured adults to evaluate their perceptions about generic drugs. The survey instrument, which was sent by mail, contained multiple-choice questions and 5-point Likert scale responses. It probed the respondent's perceptions of generics' efficacy, safety, cost, and value and their general preferences in using generics.

The researchers had a response rate of 48% with the average age of respondents at 51.6 years old, two thirds of who are female Caucasians. The majority of respondents (94%) believe that generic drugs are less expensive than brand-name drugs, 70% agree that 'generic drugs are a better value than branded drugs', and only 10% believe generics cause more side effects than brand-name drugs.

However, when the respondents were asked if they "would rather take generics than branded medications," only 37.6 % agreed. When asked about drugs that are older, 41% agreed that they are safer than newer drugs, but only 4.4% agreed that generics drugs are safer than brand-name drugs. This shows that the safety benefits attributed to older medications do extend to generics. About one-third of the respondents ask either their doctor or pharmacist to substitute generics for brand-name medications, and only 19.6% of doctors and 24.2% of pharmacists discuss generic drugs with the respondents. Of the respondents, 86.7% concurred that Americans spend too much on prescription drugs, 94.3% said that drug costs are too high, and 56% agreed that "Americans should use more generic drugs." It's interesting to note that a higher percentage agreed

to Americans using generic drugs than those who actually prefer to use generic drugs over brand-name medications (37.6%).

About two thirds of respondents are comfortable in asking their doctors to substitute generics for a branded drug and 61% are comfortable asking their pharmacists. Also, 60% say they don't mind when the pharmacist substitutes their medicines from branded to generic, but 30.5% somewhat or strongly disagreed.

When it comes to insurance agencies and the government creating rules to increase generics use, the perceptions were mixed. Wealthier respondents prefer generics more than those with lower incomes, healthier respondents question the efficacy of generic drugs more, and older and poorer respondents are less likely to believe that generics are safer than branded drugs, compared to younger and wealthier respondents.

The study revealed that, although views on generic drugs are favorable, there is still a problem faced by insurers and the government in promoting generic use. According to the authors, further education, the "rebranding" of generic medications, improved communication with prescribers, or the adoption of more-patient-friendly programs may help in this endeavor.

2. Philippines

As mentioned previously, there is a paucity of local data regarding risk factors (benefits, barriers, competitions, and influences) associated with generic prescribing, dispensing, and use. The local studies are mostly garnered for SWS telephone surveys where the focus is quantitative, regarding the compliance to the Generics Act of 1998, rather than on the subjective reasons why consumers opt for branded or generic medication.

II. Objectives

A. General

The goal of the project is to assess compliance with the provisions of Republic Act 6675 also known as the Generics Act of 1988.

B. Specific

1. To measure compliance of doctors in private and public hospitals in implementing the generics prescribing provision
2. To measure compliance of public and private drugstores in implementing generic substitution and price menu cards
3. To measure the awareness of patients and consumers on generic medicines, the Generics Act and their right to exercise choice when buying medicines from pharmacies
4. To explore factors that explains current trends and practices in the prescribing, dispensing and use of generic medicines.

III. Methodology

A. Study Type, Variables, Data Collection Techniques

The study utilized a cross-sectional design. It is a descriptive study that assessed four variables: generic drug prescription, generic drug substitution/dispensing, price menu cards, and use of generic drugs.

Data collection techniques used include the following: survey of consumers coming out of a drugstore, key informant interview of physicians, focus group discussion with patients/watchers. See Data Collection section below for specifics.

B. Sampling

Survey

The country was divided into 6 zones, namely: North Luzon, South Luzon, NCR, Visayas, Mindanao and ARMM. Stratified cluster random sampling was used to identify which provinces and cities would be included in the study. The number of provinces selected per zone was dependent on the population size of the zone. For chain drugstores, random sampling was then performed to identify which particular drugstores will be included. Two primary drugstores and a list of up

to 10 back-up drugstores were identified. A shift could be made from the primary drugstores to the other primary drugstore or to any of the the back-up drugstores if needed (ex. logistical problems, low foot traffic). In NCR, to maximize data collection in the area, if two of the same chain drugstores are present in the same intersection (one drugstore across another), both drugstores were used to recruit participants.

Free-standing drugstores were chosen purposively among free-standing drugstores located in front of prominent hospitals in each of the identified city/municipality.

Key informant interviews

A total of 30 physicians were interviewed for the key informant interviews. The distribution of the number of physicians interviewed per zone was based on the number of doctors in each zone, and the ratio of private to public physicians. Convenience sampling was done to select participants in each zone.

Focus group discussion

About 6 to 11 watchers were purposively chosen from one hospital from each of the zones to participate in the focus group discussion

C. Data Collection

Three data collection techniques were used in the study. The first is a survey of drug consumers coming out of a drugstore. The survey was administered by trained data collectors. The questionnaire was composed of 28 items, pertaining to the consumer's place of consult, experience inside the drugstore-- including generic drug substitution, perceptions, beliefs and preferences about generic drugs, and actual use/purchase of generic drugs.

The second is a key informant interview of physicians. Key informant interviews were conducted with 30 purposively selected physicians from the different zones. The interviews included questions on perceptions regarding generic drugs, obstacles and barriers to prescribing generic drugs and recommendations regarding the law and its implementation.

The third data collection technique used was a focus group discussion with patients/watchers in hospitals chosen from each of the zones. The discussion involved perceptions and beliefs regarding generic drugs and factors affecting use and purchasing of generic drugs.

D. Data Processing and Analysis

Analytical techniques include proportions with confidence intervals and cross-tabulations according to zones, types of drugstores, and private/government. Regression analysis was conducted to identify risk factors associated with the three behavioral outcomes: generic prescribing, generic dispensing, and generic use.

Qualitative data from the key informant interviews and focus group discussion are presented as themes.

E. Ethical Considerations

The study was approved by the DOH Research Ethics Committee (Approval No: DREC 2013-14) . Informed consent was taken from all the participants, including those from the survey, the key informant interview and the focus group discussion. Confidentiality was maintained.

F. Pre-test

The pre-test was done in a city in South Luzon, which was not part of the study sample. Chain and Free-standing drugstores were purposively chosen to test the recruitment strategy and the questionnaire. Thirty participants were recruited. Modifications to the questionnaire and the recruitment strategies were made based on the feedback of participants and the data collectors.

IV. Research Findings

A. Survey Results

The descriptive data will be discussed first. Included in the descriptive data are the characteristics of the sample, prevalence of exposure factors and outcome, and the benefits, barriers, competition and influences that affect them. After the descriptive data, the analytic data will be discussed, where the risk factors associated with generic prescribing, generic dispensing and generic use will be analyzed.

Descriptive

Sample characteristics

There were a total of 1,160 respondents for the survey. More than two-thirds (67.47%) of the respondents in the consumer survey are females. The mean age of the respondents is 41 years with a standard deviation of 16.24 years and a range from 13 to 90 years. Figure 1 shows the age distribution of the respondents and Figure 2 demonstrates the age distribution per zone.

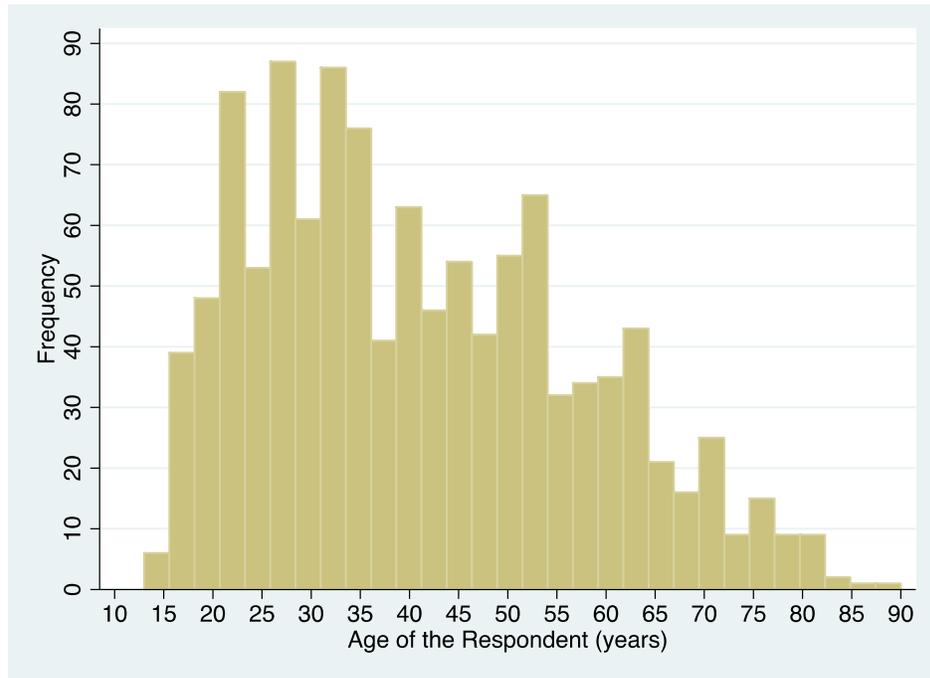


Figure 1. Age distribution of the respondents (N=1156)

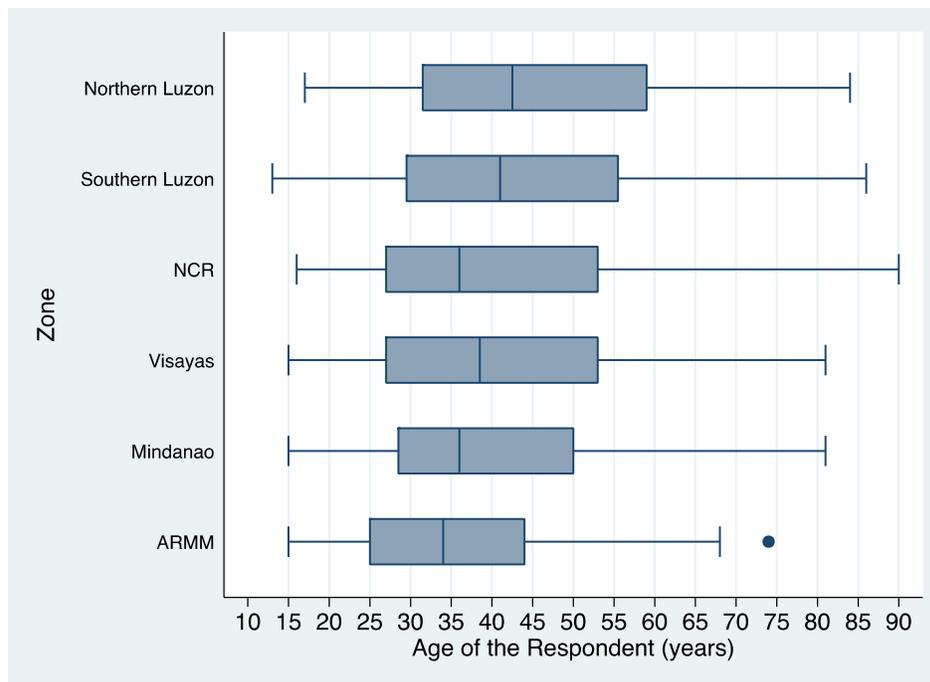


Figure 2. Age distribution of the respondents per zone

Of the 1,160 respondents, 65% were buying medicines for others, 33% were buying for themselves and 2% were buying for both themselves and others. Approximately 55% (635 out of 1,159) of the respondents said that they consulted a physician in the hospital, while the rest consulted in a clinic. The distribution of the place of consultation per zone is shown in Figure 3.

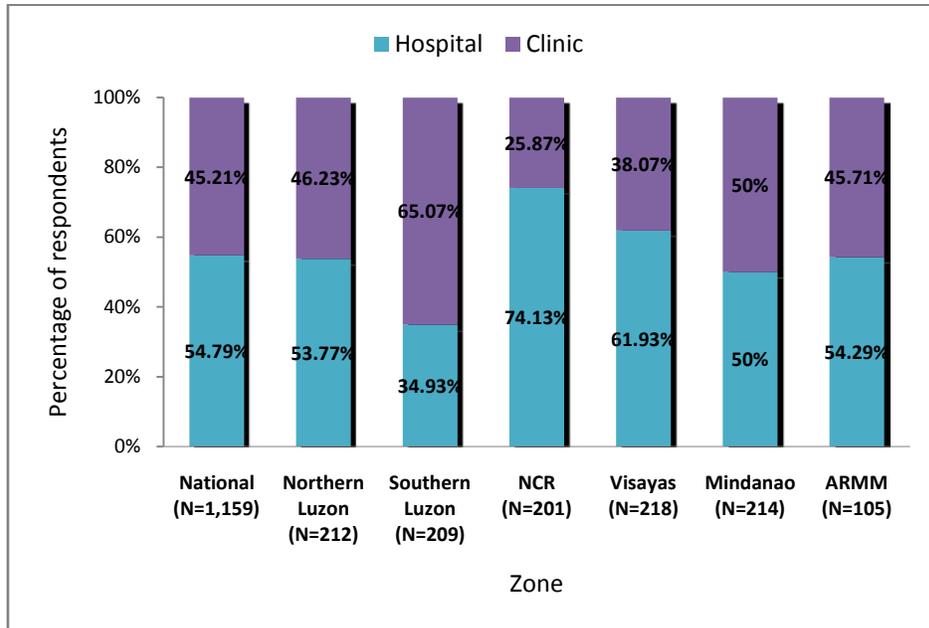


Figure 3. Distribution of respondents by place of consultation per zone

More than three-fifths (62.44% or 723 out of 1,158) of the respondents said that they consulted a private health facility, while the rest consulted in government health facility. The zone breakdown of the type of facility where the respondents consulted is shown in Figure 4.

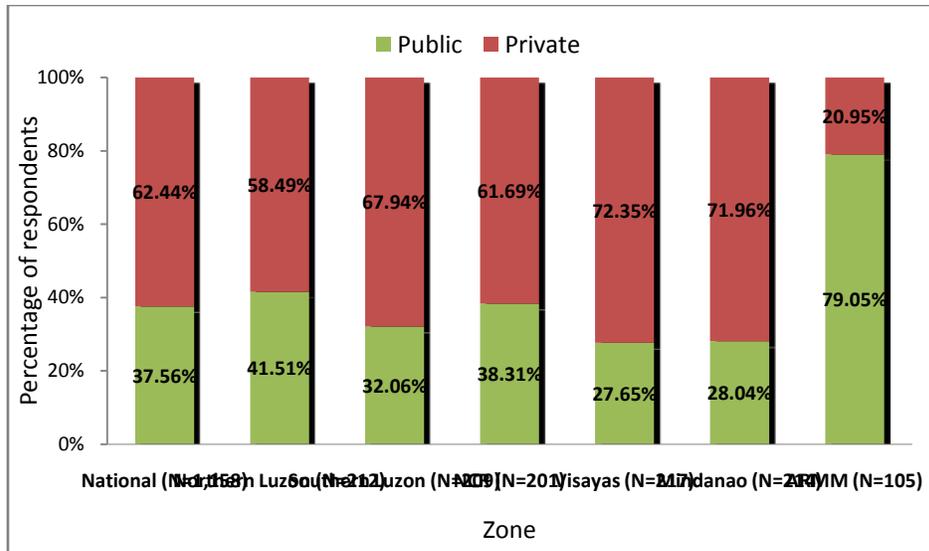


Figure 4. Distribution of respondents by type of facility per zone

The distribution of the respondents from the different zones is as follows: 18% from Northern Luzon, 18% from Southern Luzon, 17% from NCR, 19% from Visayas, 19% from Mindanao and 9% from ARMM. In the six zones, the researchers were able to cover 43 drugstores, 35% of which were free-standing drugstores and 65% were chain drugstores. Figure 5 shows the distribution of the drugstore type per zone.

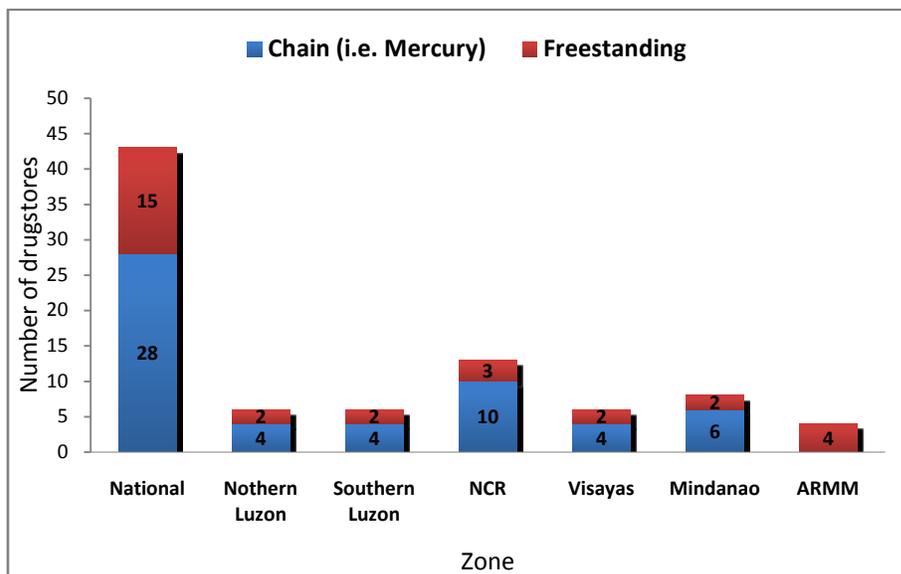


Figure 5. Frequency distribution of drugstores included in the consumer survey by type of drugstore and zone

Prevalence of Exposure

Benefits

To examine the decision-making process of the consumer, the researchers looked into how several factors affect their choice of medication. The factors that were included in the survey were price, effectiveness, following what the doctor wrote on the prescription, recommendation by the pharmacist, buying the drug that you are used to and recommendation of family, friends or neighbors. The consumers were then asked to rate the importance each factor on a scale of 1-6, with 1 being not important and 6 being very important. The responses are shown in Table 1.

Table 1. Factors that affect consumers' choice of drug

Factors	N	Median	Mean	S.D.	Range
Price	1,159	6	5.47	1.04	1-6
Effectiveness	1,159	6	5.77	0.68	1-6
Following what the doctor wrote on the prescription	1,159	6	5.62	0.85	1-6
Recommendation by the pharmacist	1,155	5	4.38	1.52	1-6
Buying the drug that you are used to	1,150	5	4.64	1.42	1-6
Recommendation of friends, family or neighbors	1,142	5	3.13	1.81	1-6

Barriers

The researchers looked into the knowledge and behaviors of the consumers to identify barriers to generic use.

They asked the respondents to define generic drugs. 1,157 out of the 1,160 respondents answered this item and only 7.17% (83 out of 1,157) of the respondents were fully knowledgeable of the correct definition of generic drugs. Meanwhile, 71.31% (825 out of 1,157) of the respondents were partially knowledgeable of its correct definition. Partially knowledgeable means that the respondent was able to mention either that the generic is of the same quality as branded medication or that the generic is cheaper than its branded counterpart. Among those who are partially knowledgeable, 10.06% (83 out of 825) mentioned quality only in their definition while

89.94% (742 out of 825) mentioned the price advantage of the generics only. Lastly, 21.52% (249 out of 1,157) of the respondents gave incorrect definitions of generic drugs. When asked to identify which drugs are generic or branded from a group of four drug samples, more than one-third of these respondents (33.71% or 388 out of 1,151) were able to correctly identify 2 out of the 4 medications shown to them as generic drugs. Meanwhile, only 18.85% (217 out of 388) of the respondents were able to correctly identify all the medications. Nevertheless, one-tenths (10.77% or 124 out of 1,151) of the respondents were unable to correctly identify any of the 4 medications shown to them. Figure 6 demonstrates the scores of the respondents per zone.

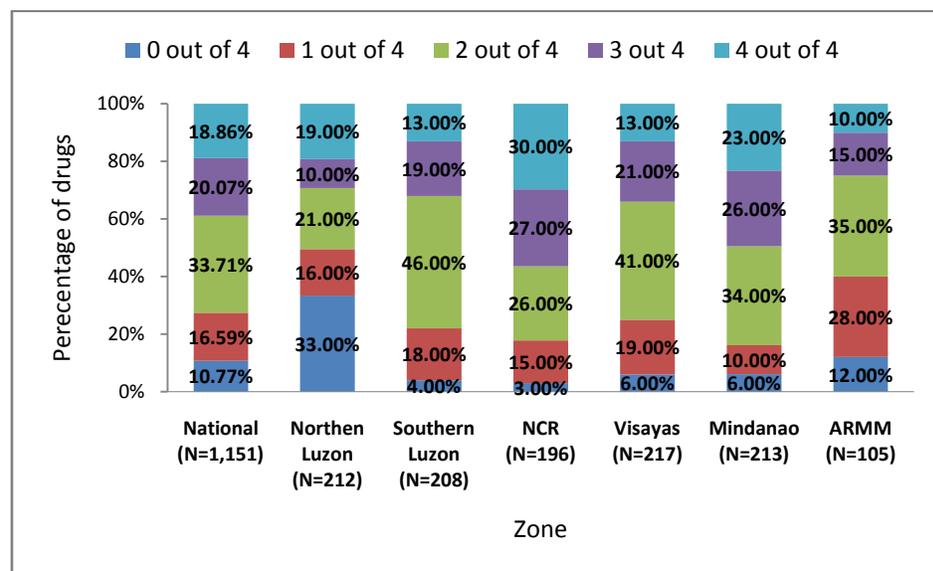


Figure 6. Proportion of medications correctly identified as generic or branded by zone

The researchers asked the respondents if they knew of a law that required physicians to write the generic names of the drugs in their prescription. For this question, 55% (634 out of 1,156) of the respondents said that they are aware of this law, while 45% (522 out of 1,156) of the respondents were either not aware or said that there is no such law requiring to write the generic name in the prescription. The respondents were then asked if they are aware of a law that requires the drugstores to offer generic alternatives to their customers. About 47% (537 out of 1,156) of the respondents said that they are aware of this law, while 53% (619 out of 1,156) of the respondents were either not aware or said that there is no such law requiring the drugstores to offer generic alternatives. The respondents were also asked if they knew of a law that required drugstores to tell them the prices of the generic alternatives for their

drugs. A little less than one-half (48.92% or 565 out of 1,155) of the respondents said that they are aware of this law, while 51.08% (590 out of 1,155) of the respondents were either not aware or said that there is no such law requiring drugstores to inform their customers of the prices of generics. Lastly, the respondents were asked if they knew that they have the right to choose to buy a generic or branded version of their medicines and most (83.88% or 968 out of 1,154) of the respondents said that they know that they have this right. Meanwhile, 16.12% said that they were not aware of this right.

Competition

In this study, the researchers considered the purchase of branded drugs as the main competitive behavior against the use of generic medications. First, they asked the respondents about their knowledge on generic drugs in comparison with what they know about branded drugs. When asked what they knew about generic drugs in terms of price, almost all (91.71% or 1,062 out of 1,158) of the respondents said that generics are cheaper compared to branded medicines, and only 2.68% (31 out of 1,158) of the respondents said that generics are more expensive compared to branded medications. In terms of efficacy, about one-half (48.44% or 560 out of 1,156) of the respondents said that generics are less effective compared to branded medicines, 32.87% (380 out of 1,156) said that generics have similar effectiveness to branded medications, and only 4.76% (55 out of 1,156) said that generics are more effective than branded medicines and 13.93% (161 out of 1,156) of the respondents couldn't tell which between generics and branded are more effective. The researchers then asked the consumers if they would prefer a generic drug or a branded drug if either price or effectiveness is equal. Only 15.19% (176 out of 1,159) of the respondents said that they would prefer the generic to the branded drug if prices were equal, while 70.32% (815 out of 1,159) said that they prefer the branded medicine. Lastly, 14.5% (168 out of 1,159) of the respondents said that they would not have any preference if the price of the generic and branded medicine were equal. More than two-fifths (41.23% or 477 out of 1,157) of the respondents said that they would prefer the generic to the branded drug if they were equally effective, while 39.76% (460 out of 1,157) said that they prefer the branded medicine. Lastly, 19.01% (220 out of 1,157) of the respondents said that they would not have any preference if the effectiveness of the generic and branded medicine were equal.

Influences

The researchers looked into the possible influences in generic use in consumers. They asked the respondents to choose one or more persons who can convince them that generic drugs are efficacious. The results are shown in Figure 7.

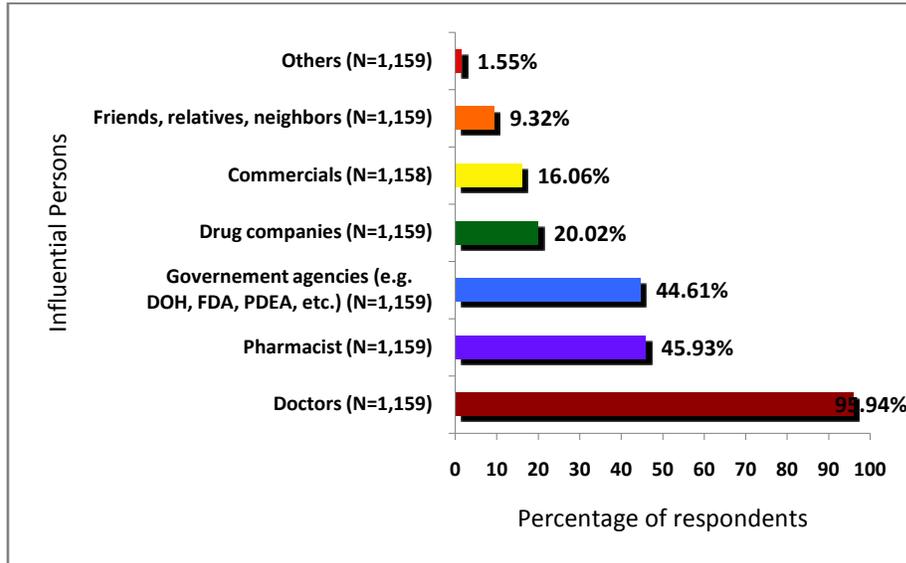


Figure 7. Persons that influence the perception of consumers regarding the efficacy of generic drugs

They surveyed the drugstores for the generic menu cards, as prescribed by the Generics Law. Of the 43 drugstores, 36 (83.7%) drugstores had price menu cards. The breakdown of the presence of generic menu cards per type of drugstore is shown in Figure 8. The difference between the two types of drugstores is statistically significant ($P=0.005$). The lone chain drugstore without a generic menu card was found in Northern Luzon.

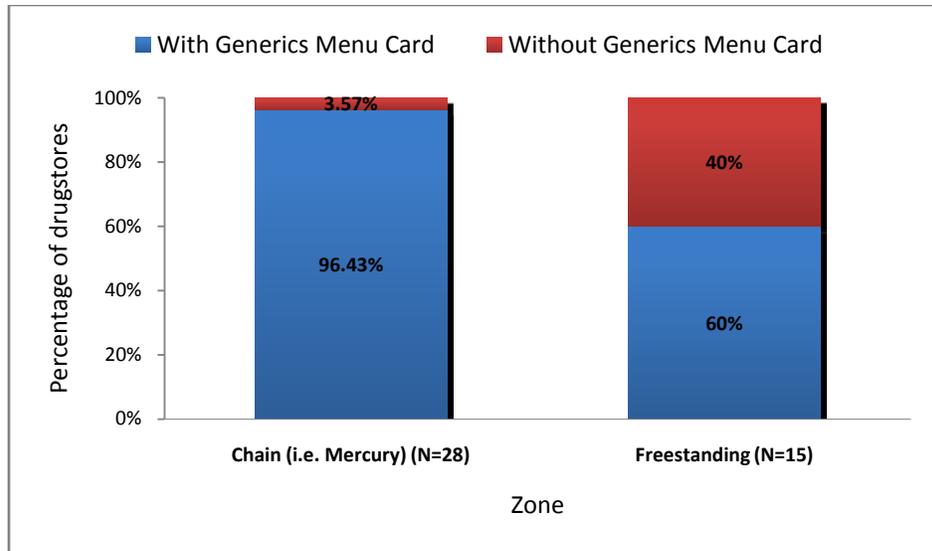


Figure 8. Distribution of drugstores by presence of generics menu card

When the respondents were asked if they saw the generic menu cards in the drugstore, only 44.33% (512 out of 1,155) noticed a generics menu card while others did not see it inside the drugstore.

Prevalence of Outcomes

The results showed that 83.92% of all the prescriptions by doctors included the generic names of the prescribed drugs. Drugstores only offered 40.61% of the respondents the generic alternative for their prescribed medications. Of all the drugs bought by the consumers, only 29.9% are generic and the rest are branded medications. The results are shown in Table 2.

Table 2. Percentage of Generic Prescribing, Generic Substitution and Use of Generics

Parameters	N	%	95% CI
Generic Prescribing (Proportion of drugs that were written with generic names)	1,069	83.92%	81.96% - 85.88%
Generic Substitution (Proportion of consumers offered with generic alternative by the drugstore)	1,150	40.61%	37.77% - 43.45%

Use of Generics (Proportion of generic drugs bought)	926	29.9%	27.23% - 32.57%
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Generic Prescribing

Figure 9 shows the generic prescribing behavior of physicians in the public and private sector. 89.47% of drugs prescribed by physicians in the public sector are generics compared to only 80.93% of drugs prescribed by physicians in private practice. The difference between the prescribing behavior between public and private sector physicians is statistically significant ($P = <0.001$).

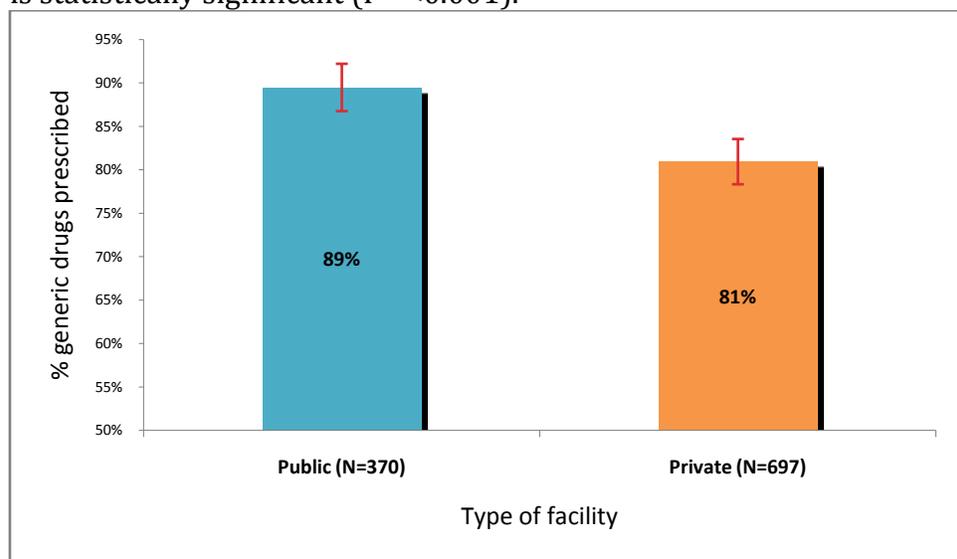


Figure 9. Generic prescribing by type of prescriber

The zone breakdown of the generic prescribing behavior of physicians is shown in Figure 10. Highest compliance with generic prescribing is in ARMM but the differences among zones are not significant.

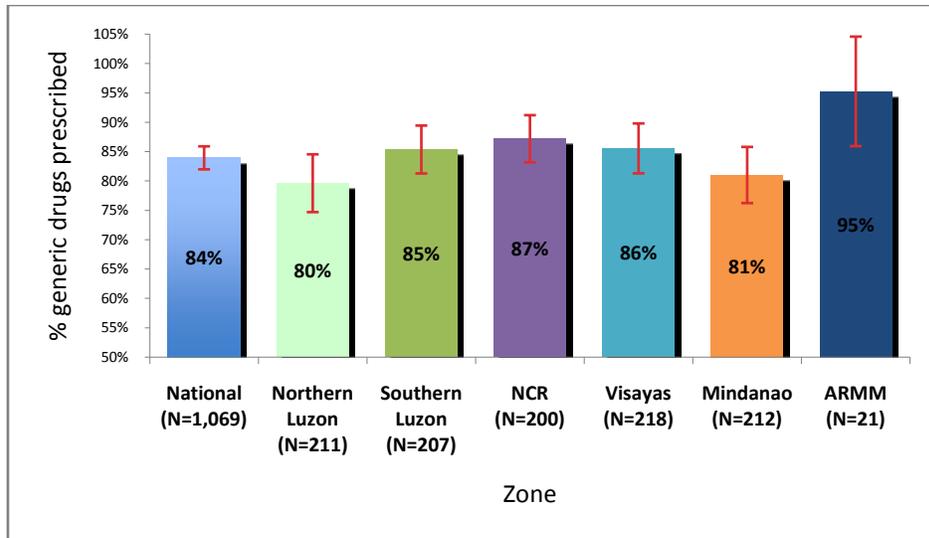


Figure 10. Generic prescribing by zone

Generic Substitution

They noted that when it comes to generics substitution, only two-fifths (40.61% or 467 out of 1,150) of the respondents said that they were offered the generic alternatives by the drugstore staff, while the said that they were not offered. The zone breakdown of the results is shown in Figure 11.

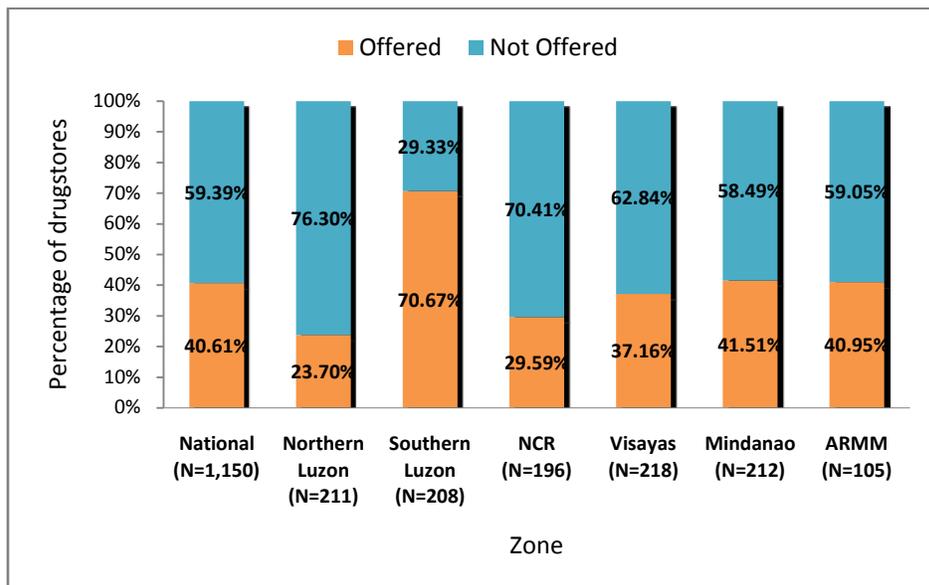


Figure 11. Proportion of patients offered with generic alternatives by the drugstore by zone

Figure 12 shows the prevalence of generic substitution based on the type of drugstore. Compliance is low for both chain and freestanding drugstores with them offering generic alternatives 39.97% of the time for the chain drugstores and 41.94% for the freestanding ones. The difference is not significant ($P=0.0515$).

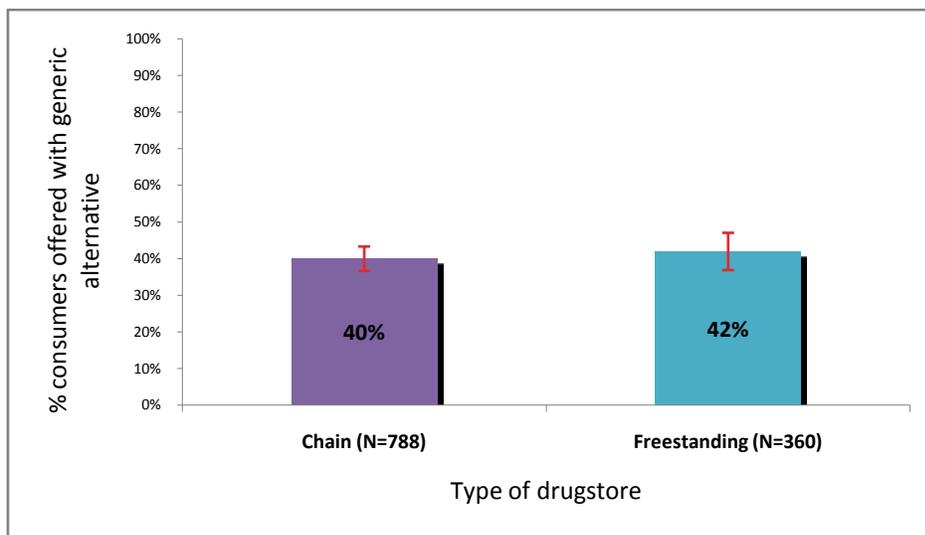


Figure 12. Generic substitution by type of drugstore

Based on location, generic substitution is not statistically significant except for Southern Luzon where it is significantly higher than all the other zones.

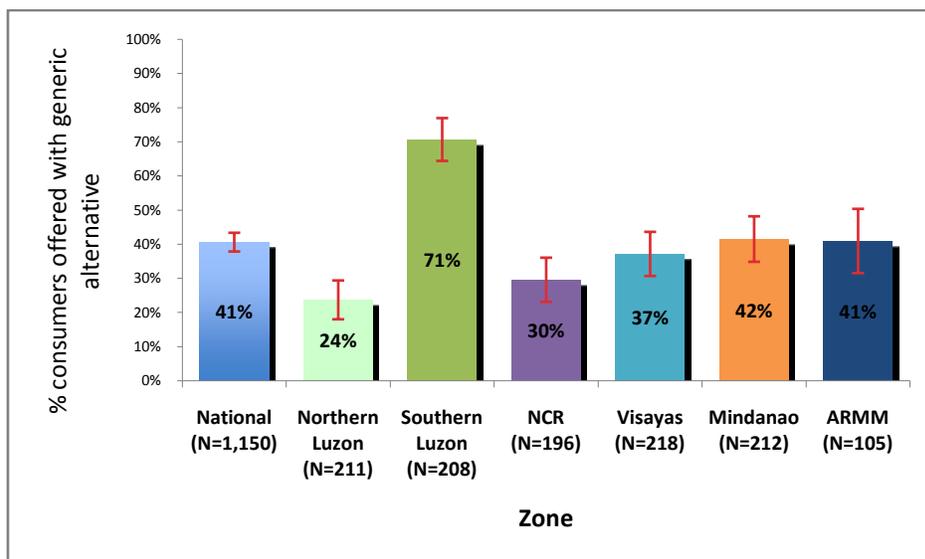


Figure 13. Generic substitution by zone

Meanwhile, of those who were not offered generics, only about 25% (183 out of 743) said that they requested for a generic alternative,

while three-fourths (75% or 560 out of 743) did not request for the generic alternative. The zone breakdown of this behavior is shown in Figure 14. NCR and ARMM has the highest prevalence of this behavior and they are significantly higher than the other zones

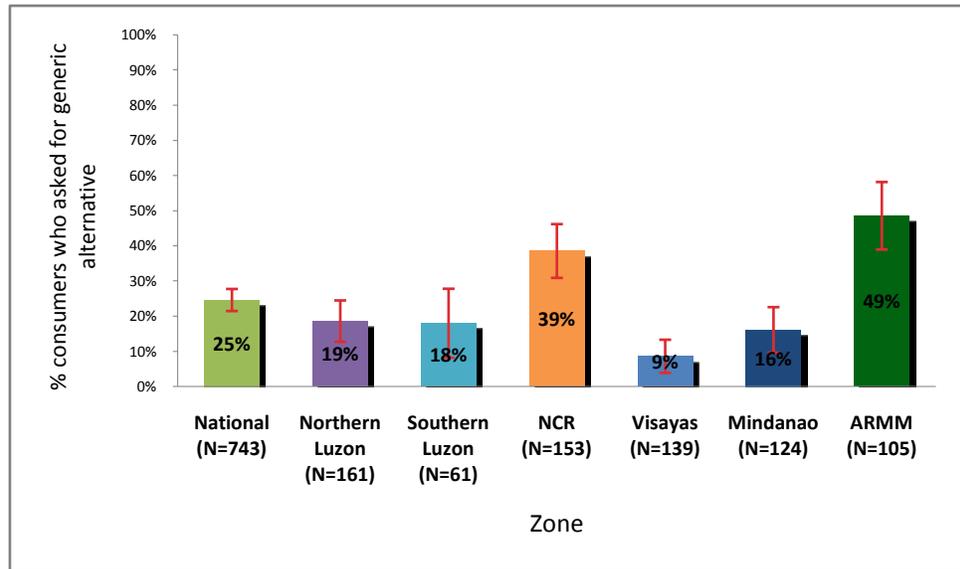


Figure 14. Distribution of respondents by request for generics per zone

The respondents were asked why they did or did not ask for generic alternatives of their drugs. The national and zonal breakdown of the answers of those who asked for generics and those who did not ask for generics are shown in Figure 15 and Figure 16, respectively. 78% of the respondents who requested for the generic alternative said they did so because generics are cheaper. For those who did not ask for the generic alternative, 77% said it is because they follow what was written in their prescription.

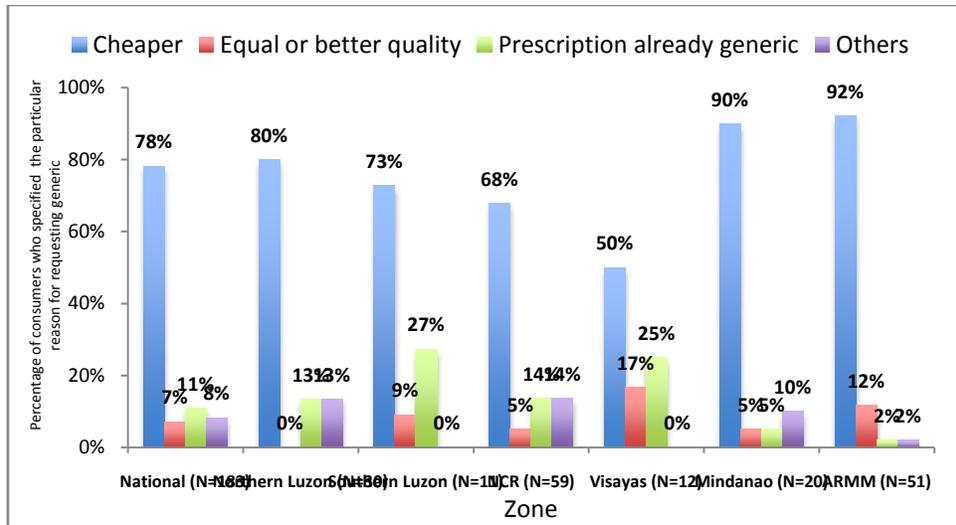


Figure 15. Reasons for asking for generic alternatives by zone

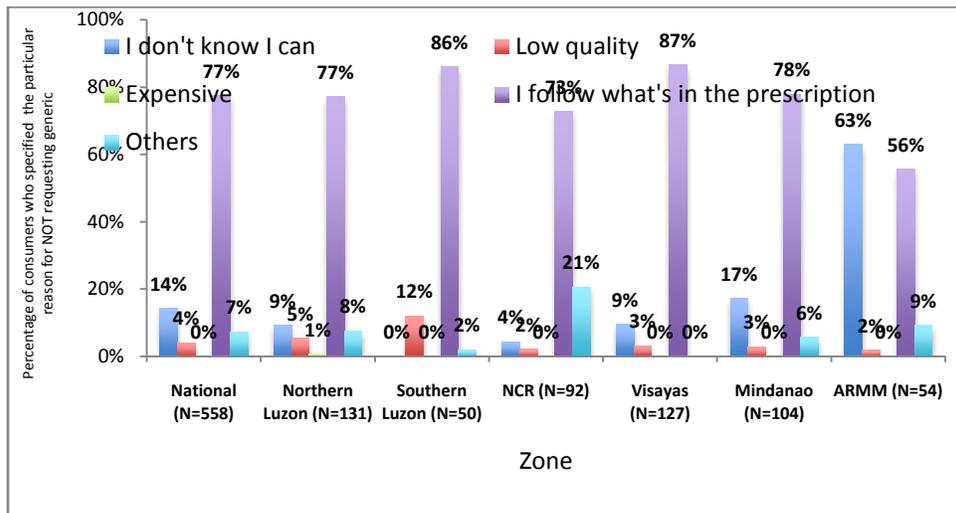


Figure 16. Reasons for not asking for generic alternative by zone

When it comes to informing the consumers of the price of the generic drugs, majority (86.78% or 525 out of 605) of the respondents who answered this item said that they were informed of the prices, while the remaining respondents were not told the price of the generic. Of those who were not informed of the prices of the generic alternative, only about 39% (30 out of 77) said that they did inquire about the price of the generic, while 61% (47 out of 77) did not ask about the price of the generic alternative. There were no significant differences between zones for this behavior.

The respondents were asked why they did or did not ask for the price generic alternatives of their drugs. The national and zonal breakdown of the answers of those who asked for the price of generics and those who did not ask for the price of generics are shown in Figure 17 and

Figure 18, respectively. 67% of those who asked for the price of the generic alternative did so because they want cheaper medicines and 10% asked so they may know what alternatives are available. For those who did not ask for the price of the generic alternative, 47% said they follow what is written in their prescription, 19% said they were not interested to know the price of the generics, 13% didn't know they could ask for the prices of the generic alternative and 23% had other reasons for not asking.

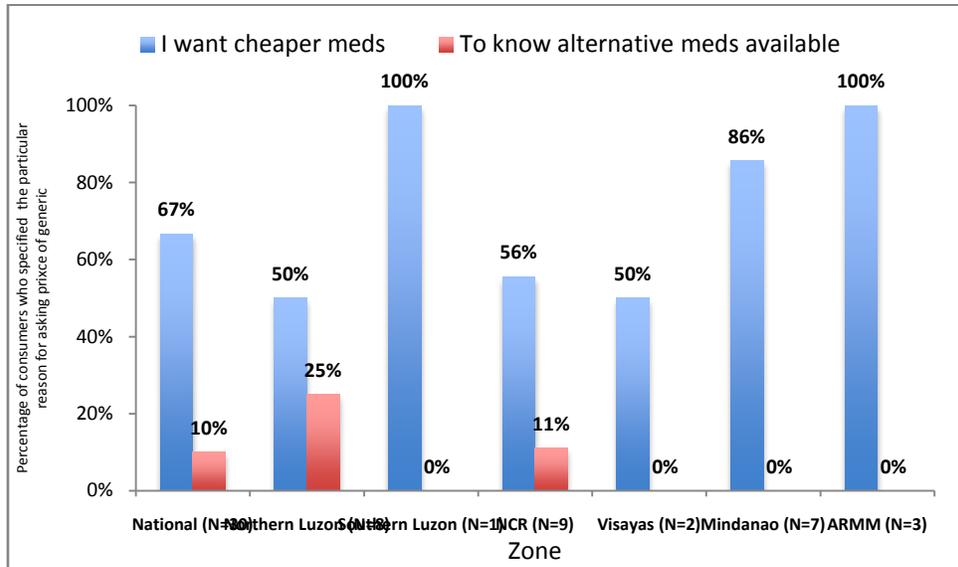


Figure 17. Reasons for asking for the price of the generic alternative by zone

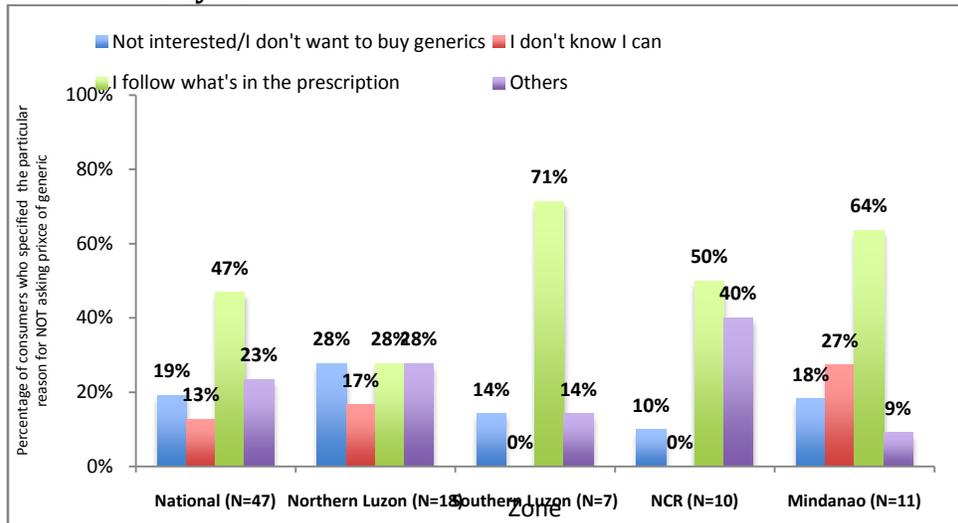


Figure 18. Reason for not asking for the price of the generic alternative by zone

Generics Use

The researchers looked into the actual purchased drugs of our consumer respondents. Total national prevalence of actual generic use or purchase is only at 29.9% of total drug items purchased, with the highest prevalence in ARMM and lowest in Mindanao. Significant differences in generic purchases exist between Southern Luzon and Visayas, Southern Luzon and Mindanao, NCR and Mindanao, Visayas and ARMM, and, lastly, Mindanao and ARMM.

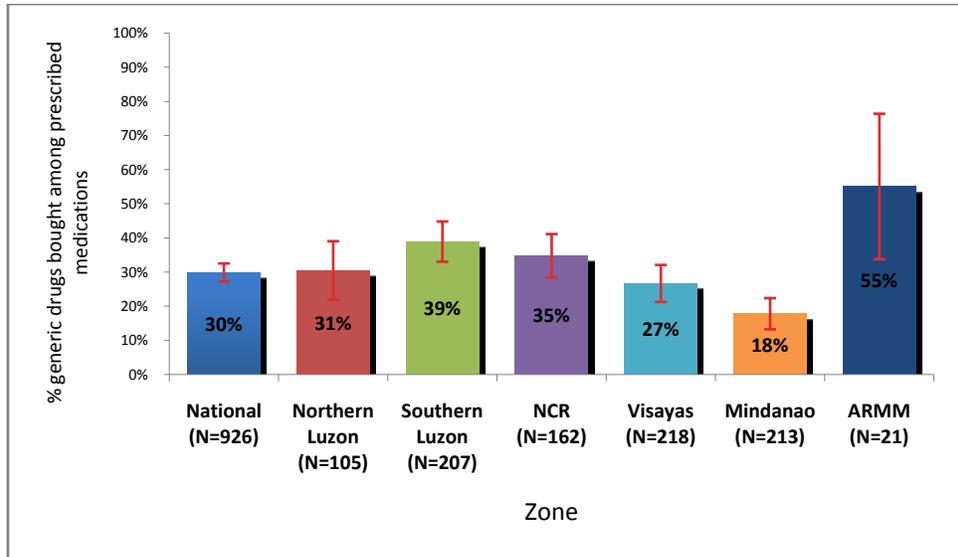


Figure 19. Generic use by zone

Table 3. Association of certain factors with offering of generics

Factors	OR	CI	p-value
Presence of menu cards			
Absent	1.00	--	--
Present	1.20	0.85, 1.7	0.291
Type of drugstore			
Mercury	1.00	--	--
Freestanding	1.09	0.84, 1.40	0.515
Zone			
Northern Luzon	1.00	--	--
Southern Luzon	7.76	5.02, 12.00	<0.001
NCR	1.37	0.89, 2.14	0.159
Visayas	1.90	1.25, 2.90	0.003
Mindanao	2.29	1.50, 3.47	<0.001
ARMM	2.23	1.35, 3.69	0.002

Analytics

Risk factors associated with generic prescribing

The factors associated with generic prescribing will be discussed in the results section of the key informant interviews with physicians.

Risk factors associated with generic dispensing

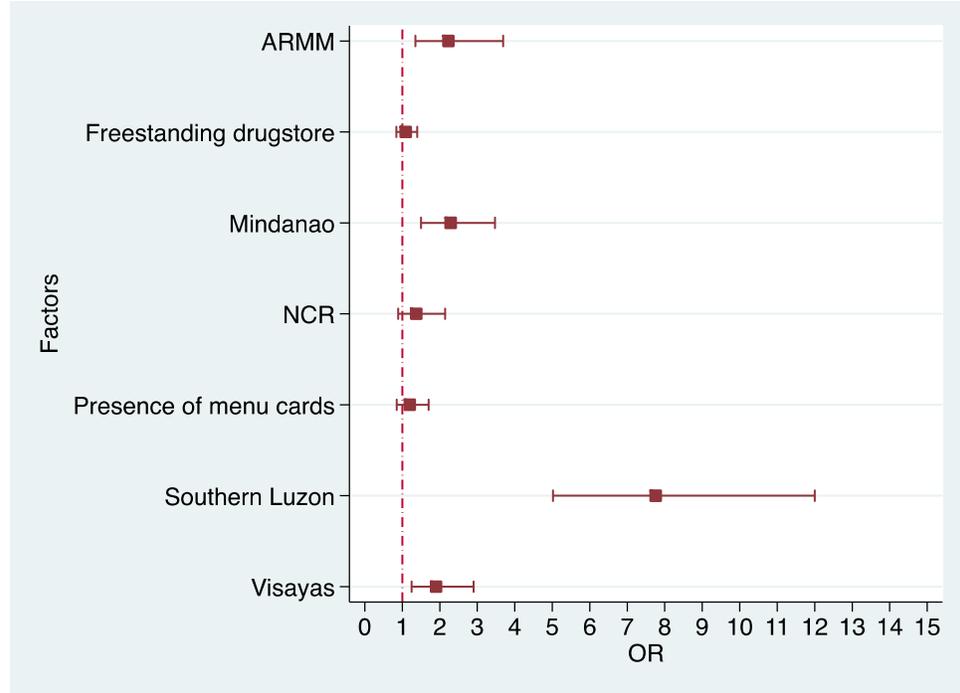


Figure 20. Association of certain factors with offering of generic

Table 4. Association of factors with informing price of generics

Factors	OR	CI	p-value
Presence of menu cards			
Absent	1.00	--	--
Present	0.93	0.44, 1.95	0.847
Type of drugstore			
Mercury	1.00	--	--
Freestanding	1.69	0.96, 2.98	0.070
Zone			
Northern Luzon	1.00	--	--
Southern Luzon	8.26	3.54, 19.29	<0.001
NCR	1.87	0.96, 3.66	0.067
Visayas	19.61	4.48, 85.75	<0.001

Mindanao	2.09	1.07, 4.08	0.030
ARMM	5.18	1.69, 15.87	0.004

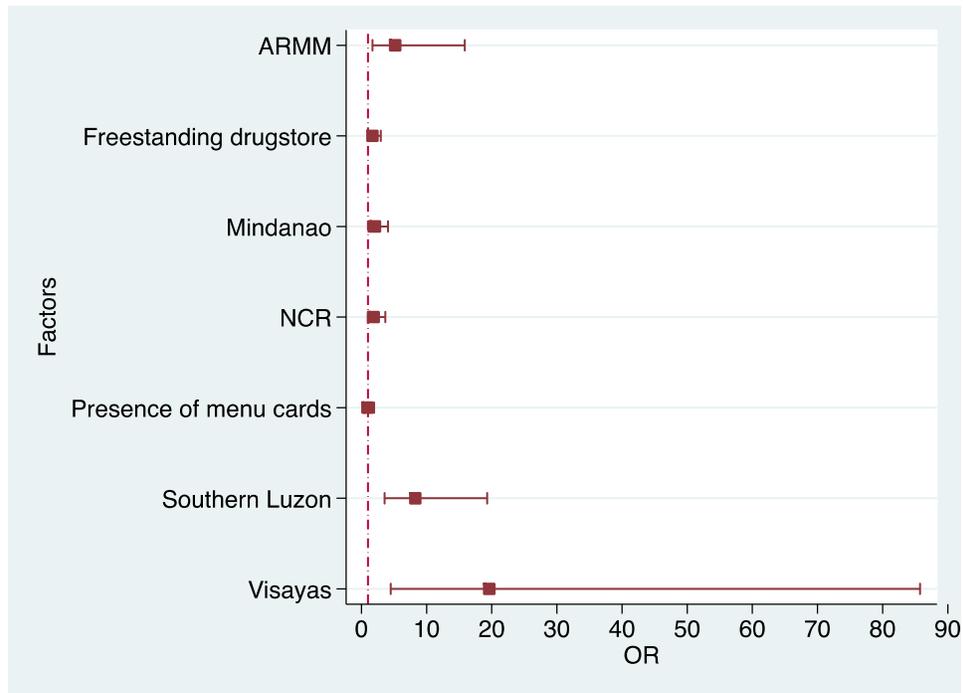


Figure 21. Association of certain factors with informing price of generics

Risk factors associated with generic use

For the analysis of which factors are associated with the desired behavior of purchasing generics drugs, the following were significantly associated:

Type of health facility

The odds of purchasing generic alternative among individuals who consulted in a public facility is 2.84x higher compared to those who consulted in a private facility.

Friends, relatives, neighbors

The odds of purchasing generic alternative among individuals who are influenced by friends and relatives in their medical decisions is 2.12x higher compared to those who are not influenced by friends and relatives.

Generic format

The odds of purchasing generic alternative among individuals whose prescription had at least one medication written in the generic format is 65% less compared to those who were given a prescription that did not follow the generic format.

Knowledge of requirement to write the generic name in the prescription

The odds of purchasing the generic alternative among individuals who knows that physicians are required to write the generic name in the prescription is 1.68x higher compared to those who do not about this law.

Knowledge of generic effectiveness

The odds of purchasing the generic alternative among individuals who perceive generic drugs to be more effective is 28% lower compared to those who perceive that generic drugs have similar effect as branded drugs. The odds of purchasing the generic alternative among individuals who perceive generic drugs to be less effective is 61% less compared to those who perceive that generic drugs have similar effect as branded drugs.

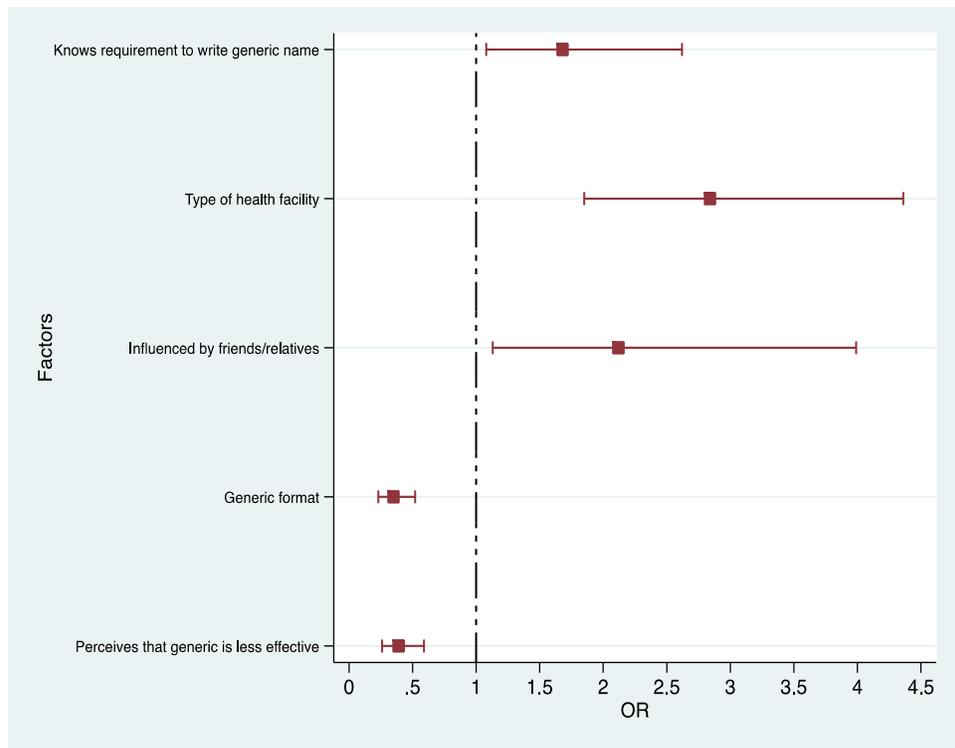


Figure 22. Factors associated with 'purchase generics' behavior

B. Key Informant Interview (Physicians)

Knowledge about the Generics Act of 1988

We asked the physicians what they knew about the Generics Act of 1988. Their answers covered what they believed the goals of the law are, what they understood their duty was as indicated by the law and their disillusionment with the law. There were two opinions on what the law requires of physicians, one is that it is illegal to write the brand name, and the other is that you can write the brand name provided that the generic name is also written.

Goals of the law

Lower the price of drugs: *"Ultimate goal is to lower the prices of the medicines."*

Empower the patient: *"Because of the generics law, the patient has a choice." "The idea is that you prescribe a drug with the generic name so the patient has an option if they want to buy branded or generic."*

Reduce doctors' bias toward branded drugs: *"So they won't be taken advantage of by drug companies."*

Doctor's duty

"It is illegal to write the brand name."

"That you're supposed to prescribe the generic name of the product without, if possible, endorsing any particular drug."

"When you prescribe medicines, you can specify brand names but in parenthesis. First, the generic name must be written then you can specify the brand name."

"From the directive before, the Generics Act of 1988 makes cheaper medicines accessible to patients, and, of course, it requires a physician to prescribe generic medicines whenever possible, and also to write the generic name of the medicines that they prescribe aside from the brand of choice."

Disillusionment

"The intention was good but the implementation was not followed. For example, when the law author's wife got sick, he did not want to use generics. I started doubting then."

Generics Act and physicians

When the physicians were asked what the law requires of them, it mirrored the answers of the first question. Two answers emerged, that is that doctors are required to prescribe generics only and that doctors can prescribe their preferred brand as long as they indicate the generic name, too. Some physicians also emphasized the need for

a complete prescription, with instructions to the patient and the doctor's license number.

Generics only

"We should dispense according to the Generic Act, not the branded."

"Prescribe the generic name and not the brand name."

"We should use the generic name rather than the brand name in ordering in the charts."

Branded allowed but with generic name

"The physicians should prescribe the medicine with generic name, open parenthesis close parenthesis brand name."

"Prescription should be complete with generics. If with brand name, should be smaller and in parentheses. The generics should be the star."

Complete prescription

"It should have the way how it should be taken. Of course, complete. There should be name of patient, age, doctor's name, signature and complete license number."

"The prescription should be understood by the patient. License number is included."

Opinion on the generic prescribing provision

The physicians were asked what they thought of the generic prescribing provision of the law and whether or not they favored it. Those who favored the provision said it was because it was better for the patient's welfare. None of the physicians directly said that they were not in favor of the provision, though some were not entirely supportive. Those who did not favor it entirely shared their concerns on the quality of generic drugs, personal experience with the use of generic drugs and reasoned out that it was only preferable in some cases. Two private physicians remarked on the dispensing side of the process, sharing their reservations. One physician shared his preference for "branded" generics. Other physicians shared their concerns about the implementation and regulation of the law, as a whole.

In favor

"I highly favour/ patronize it. That is how it should be. Patients should have the option of choosing what brand of drug to take."

"For me, it is okay especially since this is a government hospital and you can really see that the patients are poor."

"It's okay because the kind of government institution I am in is where patients are poorest of the poor. Sometimes, they are the ones that ask 'Doc, generics only.'"

Not entirely in favor

Poor quality:

"We cannot say that all generic products will work. There are certain generic products that do not work."

"Right now, we have these medicines coming from India, Pakistan and other countries. When they submit a medicine to the BFAD, the medicine will be bioequivalent to a multinational drug, but, sometimes, when you give those generic medicines to the patient, the effect is not as good as when you use a multinational brand."

Not for severe illnesses:

"Actually, if the patient is toxic, I don't (prescribe generics). Because the drug acts slow. Even simple analgesics or paracetamol, it's really slow. Especially in severe pneumonia, as a pulmonologist, I don't gamble."

"It depends. There are certain drugs, like in obstetrics, that we really need to specify the brand. Those are special cases. But, in general, I agree that it's okay to just prescribe generics, especially because it's a charity hospital so the patients need to avail of medications that are effective but are low cost... except for those special cases."

Physician's preference:

"I agree to it, but in my opinion, we also have the right to choose what brand we trust. And as I said, not all generics are the same, so it depends on what brand I trust. I know what works for my patients. Of course I'll give them the best, the one I know is best for them. "

Personal experience:

"I sometimes have reservations, not all generics are effective. Based on experience, when I get sick, i buy generic drugs... 4 days after I'm still not well."

Dispensing reservations

"There are a lot of loopholes, for example, the pharmacists - they change your prescription. Even if you put the brand, even if it's illegal, the power is still with the salesgirl."

"What we cannot control is what the patient get exposed to in the pharmacy. In the pharmacy what controls what will be given to the patient is not the price, but is what the pharmacist are advised to dispense with."

Implementation problems

"The idea is okay. The problem with the government is implementation and regulation. As far as Bacolod is concerned, generic is not usually used."

"It's okay. There should be (generic prescribing). The problem is that nobody regulates it. Number one, nobody regulates the physicians. If there is, it is sporadic. It was being followed before just because of Philhealth. Number two, who regulates generic drugs? For example, if we have a problem with a generic drug, who will we contact? There are some that don't have a company here in the Philippines."

"There is no agency that tests the drugs. There are a lot of generic drugs in the market, but we do not know which ones are really effective."

"We need budget for that. Like here, where is FDA? If you ask physicians, only 2 out of 100 knows where the FDA is. It is a small office with a handful of personnel to see to it that there is FDA in Negros. No budget, no personnel, no one regulates."

Practice of generic prescribing

The physicians were asked to rate themselves from 1-10 on how often they prescribe generics, 1 being never and 10 being always. They were then asked why they do or do not prescribe generics. For those who answered 10, they did so because it was required by the law and punishable if not followed, especially in government hospitals. One physician mentioned that if they need to specify the brand, they do so verbally without writing it down on the prescription to avoid penalties. For those who scored themselves less than 10 they did so because of concerns on generic drug quality and there is better recall of branded drug names.

Required by law and the hospital

"100%, because that is the policy of the government hospital. If you write the brand name, there is punishment."

"It's 10. We always put generics in our charts because we are required by the hospital."

"Always. It's the law. But I put my brand of choice for certain conditions."

Verbal advice

"10. Always. It's not allowed in the hospital. Brand names are not allowed. If ever we see that the patient's condition is severe, that it cannot be cured by generics, we tell them to buy a specific brand. We just give advice because it's for their own good."

Preference for brand names

"Just 20% or 2/10. Because i prefer that (specific) brand. If they (drugstore) change it, it is the patient that suffers."

"9/10. Because for the others, it's hard to recall the generic name like that for Daflon 500. It's easier (for patients) if it's branded."

Perception on generic drug prices

Similar to the FGD participants, the physicians were asked what their thought of generic drug prices, and why some generics are less expensive. The physicians responded that they believed generic drugs are cheaper because of the following: poorer quality, less marketing/advertising/research/manufacturing/taxation costs, and because it is off patent. One physician is of the view that generic drugs price is the same as branded in the long run.

Poor quality

"Too good to be true, you question the quality because it's too cheap. They probably added starch."

"They're cheaper because their quality is not at par with the branded drugs."

Less costs

Marketing:

"There is a big difference in the price, it's cheaper. It's because branded medicines have a lot of advertisements."

"It's cheaper. The medical representatives tell us that the reason why branded medications are more expensive is because they have to be promoted. They do commercials, costing about 1 M. They treat doctors."

"What I only know is, maybe because there is no need for medical representatives to push the products."

Research:

"Because they don't have research, they just copy. Once the patent is over, they just copy."

"Maybe the reason why it is cheaper is because it's an imitation of the chemical composition of the drug. And they didn't put much research into it. The innovator already did that."

Production/Manufacturing:

"Sometimes, the raw materials are from other countries, which are cheaper supplies."

"It is bought outside, India usually. Or manufactured locally"

Tax/Corruption:

"Because in the Philippines, they tax the heck out of every businessman. So when it is an international drug company, of course, sometimes they get taxed so much that their prices are so high. Bactroban, in Bangkok, it's just 180 pesos, but in the Philippines its 290. Why? Because of the corrupt official who just tax the heck of every company that comes in the Philippines."

Off patent

"Affordable because they are not bound by foreign drug companies' licensing. It's like the patent expired so others can use it. That's the only thing that makes it expensive, the patent."

Same expenses in the long run

"Actually, if you compute it, it's the same. Why? Because if you give branded, after 5 days the patient is well. If you use generics, it'll take 10 days... so the expenses become the same."

Perception of generic drug quality

The physicians were also asked about their perception on the quality of generic drugs. Physicians were divided, most said that generics are of poor quality, though there are some who said that generics are of equal quality as branded drugs and a few answered that only some generic drugs are of good quality but most are not. For those who believed that it is of poorer quality, they attributed it to impure additives, increased side effects, doubts about the manufacturer, slow action of the drug, and regulation problems. It is important to note that a recurrent theme through most of the questions is the preference for branded medications in severe illness and generic drugs for benign conditions.

Poor quality

Impure additives:

"If it's from India, there's hair. If it's from China, there is plastic. If it's from Bunuan, because cocaine is too expensive, they just put starch."

"Other drugs only reach the mouth, not even reaching the stomach."

Increased side effects:

"I have experiences, especially for drugs from India, the hypersensitivity reaction is high. So instead of just giving antibiotics, you have to give antihistamines, too."

Manufacturing doubts:

"I think it is important to see who the manufacturer is, because there are different manufacturers. That is my concern with generics, you are not as sure."

Slow action:

"Based on personal experience, using mefenamic acid, it wasn't as effective. It was slow, there seemed to be no effect."

Regulation problems:

"Sometimes they have to bribe the BFAD just to get approval. If you don't do that, they will not approve your drug. That is why some generics, sub-quality generic brands get approved because they paid off the BFAD officials."

"We had an experience where we had to write to the pharmacy/donors because our patients weren't improving with the use of this certain drug. We thought that the drug might be fake. We wrote to the pharmacy, told them what we noticed. Sad to say, the drug apparently passed bioequivalence and bioavailability tests."

Same quality

"Some generics are relatively good in quality, specially they have gone through bioequivalent studies. Not all generics are bad. Some of them are good. We are using them. We look into the bioequivalent studies before using them."

"Theoretically, since it has the same chemical components, supposedly, it should be as effective as the branded. However, [quality] depending on the additives and the quality of materials, the origin of manufacturer. But in general, theoretically, it is just as effective as branded."

Quality is not consistent

"Depends. If for vitamins, it's okay. But for antibiotics, you should give branded."

"Judgment call, for example in toxic cases, antibiotics or rare cases, we prefer to use branded. Not because we get anything but because we know it's some brand we can trust. But, for example, OPD, hypertension, diabetes, less toxic cases, less life on the line, then we can use generic more."

"Some medicines are good-like maintenance meds. But for infectious, we still use branded. It is better. Generics are too cheap. Based on my experience of 19 years, patients on generics come back unresolved."

"Quality wise, there are some that are okay. But there are incidences when I tried prescribing generics that the patient comes back and asks if the drug can be changed to a branded one. They come back with no changes, no improvement, especially with antibiotics."

"Not all generic drugs are of good quality, I think. Not all are able to copy the chemical composition of the innovator brand, so quality wise, they can have more side effects."

Benefits of prescribing generics

The researchers asked the physicians what they viewed as benefits for prescribing generic drugs to their patients. The benefits they saw was better patient compliance because drugs are affordable and more widely available, able to support local economy, and better communication between patients and doctors, and doctors and other doctors, especially when endorsing patients from institution to institution. A few doctors said that the benefit of prescribing generics is that, for patients who are less financially capable, "it is better than

nothing.” The doctors also mentioned that one benefit from prescribing generic drugs is that they follow the law and will not be penalized.

Better patient compliance

“They can spend less, so they have more choice.”

“They now have options of buying cheaper meds. They will now be cured since they can buy cheaper meds rather than not buying meds at all because of high prices.”

“They are able to buy immediately because it’s inexpensive. And since there is no specific name (brand), they can easily find the drug. Sometimes, if it’s out of stock, they have to look for it elsewhere. If it’s just generic, then they can buy from any pharmacy.”

“The patients have better compliance and the outcome is not really that different.”

Better communication

“You’ll be closer to your poor patients because you are pro-poor. You feel their sentiments that they should use generics because they don’t have the money to buy (branded).”

“Also, it helps the patient in recall. If we say the generic name, when they consult other physicians they are aware of the drug that was given to the patient because it is the generic name they know, instead of just giving a brand.”

Barriers to generic prescribing

The doctors were asked what they thought were barriers to generic prescribing. Again, quality and regulation issues were brought up as possible barriers to generic prescribing. They also shared reservation on the dispensing behavior of the pharmacies. They also mentioned that the marketing of branded drugs, patient’s choice and doctor’s previous experience with certain drugs are possible barriers to generic prescribing. There were a select few who did not see any barriers in generic prescribing. According to them, there are no barriers since it is the patient’s choice (*“Usually when I prescribe generic, I ask the patient. There are those who are okay to choose the cheapest while there are those who are not.”*), and they are trained to use generics from the start (*“Maybe, we, the younger generation, are already used to prescribing using generic names. When I was in internship and clerkship, I was in a government hospital, I only moved to a private hospital during residency. I think it’s in the training.”*).

Quality and regulation

“Efficacy is the main problem, patients come back to you with no improvement.”

"You know that generic might not be as effective. So at the back of your mind, you are thinking that the patient might not get well right away, you will lose your reputation. That's basically it- quality control."

"Not all generics can be trusted, I haven't tested them. If I give them the generic name, I don't know what brand they will buy, So I am not assured that they will have no side effects or if the drug will actually work for the patients."

"Because it's probably starch. I question BFAD. They approve drugs with money under the table. I don't believe in BFAD."

"The severity of the illness, the desire to see immediate results, to see improvement in your patient (are barriers)."

Marketing of branded drugs

"Of course, the machinery of med reps and pharmacies. We cannot avoid it. You know, we are sponsored by certain companies, we are fed, we are given free things by certain companies."

"There are some doctors who prefer drugs with brand name. The generics don't have med reps:"

Patient's choice

"There are patients who can afford, who will really ask you about the brand name. If you tell them that generic drugs are okay, they don't want it. So I think the status of the patient matters."

Doctor's previous experience

"Barriers, probably personal preference. Sometimes, in certain fields, based on clinical experience, although not proven by studies, certain drugs are more effective than others. Or if it is the only known brand, physicians tend to prescribe that brand, especially if it is popular and supported/prescribed by other physicians."

The doctors were then asked what they do when they encounter such barriers. There were three themes that emerged, helplessness, patient empowerment/education and giving verbal advice. These three pertain mostly to the fact that some generics they encountered were of poor quality.

Helplessness

"Nothing, because this is where we work, we have to use generics. We know that it is of lesser quality but there is nothing we can do. Our hydrocortisone is not effective."

Patient empowerment/education

"I just tell them if it's not in the budget, they can try another one that is cheaper."

“So, for example, a certain brand is effective, you prescribe that brand to the patient, but you explain that that drug’s generic name is this.”

Verbal advice

“I try to use a different medication, instruct the patient to get a better alternative. Sometimes, 3 weeks after, patients on generic come back, even with just simple UTI, still with the infection. If I use branded, they get well in just 1 week. I tell them to buy from Mercury, even if they get generic, there is still a brand.”

“Like I said before, i will just advise them verbally: this is what you should buy, it’s more expensive but, in my experience, it’s more effective.”

“What we do, we observe the patient. I tell them, I will still use the same drug, but let’s try branded. The branded works. But that is the last resort already, as much as possible. It’s expensive, and most of our patients are indigent.”

Influences on generic prescribing

The physicians were then asked what or who they think can influence them to prescribe generic drugs more. They enumerated the following sources of influence: government through the BFAD/FDA, patient status, their seniors/training instructors/consultants, their conscience and medical representatives. There were a few who answered that nothing can influence them to prescribe generics.

Government

“They should improve BFAD. Put more integrity in BFAD. Do bioequivalence studies.”

“Studies (on bioequivalence) should be done properly. I will believe what they say rather than what drug companies would say.”

Patient status

“The patients. If they don’t have money, they can use generics and we will extend the duration from 7 days to 10 to 14 days. They’ll still get well and save.”

Seniors

“Mostly since we are in training, the recommendation of the consultants. Not so much the medical representatives. We listen more to the recommendations of our older consultants.”

“Those who train us, our consultants and seniors. They are the ones who teach us. Even the preference for certain medications, we learn from them.”

Conscience

Conscience. There are more factors to convince you to prescribe brand names. Maybe in med school, generics, but in the real world, brands.

Medical representatives

"Maybe if the drugstores offer good quality generic drugs. Or those branded generics – if they can send medical representatives and supply me with enough proof that their drugs are of good quality."

Nothing

"Nothing. When I leave (the government hospital), I will use branded because it's my private practice. If you give low-class generics, the patients will not trust you. The companies present studies proving that they are more effective compared to generics."

Recommendations for improvement of the Generics Act of 1988

For the last question in the interview, the physicians were asked for their recommendations on the improvement of the Generics Act of 1988. Almost all physicians mentioned that improved quality testing and regulation will help doctors trust the generics that are available in the market, and thus, increase generic prescribing behaviors. One doctor mentioned that, *"you have to make doctors see the benefits of prescribing generics, or else, they'll continue prescribing branded because they are getting something from it."*

Quality testing and regulation

"Make more bioequivalence centers/facilities/scientists available in provinces and other cities so that we can immediately test the drugs. If there is a problem (with a generic drug), we can do spot checks quickly. Make the bioequivalence tests more affordable, devolved."

"My recommendation is primarily the regulation of the generics being released. They should have bioequivalent studies to support their efficacy."

"They should improve the quality, even if it's just generics. It seems like we are fooling the consumers."

"If we physicians are required to give the generic name of the drug, I think they should control the kinds of generic drugs that are coming into the country. Especially those from India or from other countries, they should all pass our quality control standards."

C. Focus Group Discussion

Knowledge about the Generics Act

When asked what they knew about the Generics Act of 1988, most participants responded with what they knew about generic drugs, in general, and not about the law.

The responses ranged from commenting on the inexpensive nature of generic drugs, comparing the efficacy of generic drugs with branded drugs and sharing their belief that generic drugs were made specifically for the poor. One respondent mentioned that it meant “good service”.

The following are representative responses, translated into English.

Inexpensive

“Inexpensive medicine.”

Comparing to branded drugs: same efficacy

“Even if it is an inexpensive drug, even if it is a generic drug, it is the same with the expensive drugs.”

“There really is no difference, just the names.”

“Same medicine but less expensive.”

Comparing to branded drugs: less effective

“My cousin said that generics are weaker. It is okay, but branded works faster.”

“Generic drugs are also effective but slower; if branded drugs can cure in two days, generics can do it in five days.”

Made for the poor

“Generic drugs are made cheap in order for poor people to afford (the drug).”

“Medicines purposely made for the poor.”

“Help for the poor.”

When the moderators probed more into what they knew of the law itself, a number of respondents from the different zones mentioned that they did not know that such law existed.

Perceptions on the price of generic drugs

When asked about what they thought about the price of the generic drugs, there were varied responses. The expected and most common response was that they are less expensive compared to branded. They answered: *“In terms of price, the difference is almost half. What differs is that branded drugs are expensive,” “You get one if branded, five if generic,”* and *“Less cost for the poor.”* There were some who said that there were generic drugs which had the same price as branded drugs.

"... but there are other generic drugs that have the same price as the branded ones. Although it is generics, it is still expensive." There were also a few respondents that mentioned that generic drugs turn out to be more expensive. "More expensive in the long run because you have to buy more medicines because of delayed onset of action."

The participants were asked why they thought that generic drugs were less expensive. Prevailing themes were that it was made for the poor, subsidized by the government, made locally, less popular manufacturer, quality and patent issues. Their answers and some representative responses are listed below.

For the poor

*"For people with low income, so they can buy inexpensive medicines."
"It is for the masses."*

Subsidized by the government

"Maybe it is funded by the government. Or maybe they have a counterpart on that."

Popularity

"Because of the name. If the manufacturer is popular (it is more expensive)."

Quality

"If you compare a Php 1.50 Metformin to a Php16 Metformin, the Php 1.50 dissolves immediately, even if it is just in the mouth."

Patent issue

"Generic copied the branded so that people can afford them (drugs)."

Perceptions about the quality of generic drugs

Several themes emerged when the participants were asked about their perception on the quality of generics. These are: generic drugs are of the same quality as branded drugs, they are of lower quality compared to branded drugs, use of generic drugs only in minor ailments and inconsistent results when generic drugs are used.

Same quality

*"Other people say it is less effective, but for us in Alaminos, we use generics and it is effective."
"They're ok, similar, the difference is really the price."*

Lower quality

"It takes a long time to work/recover (compared to branded)."

“Some want to get well in 2 days, 3 days, they choose branded. With generic, you’ve taken a number already, but the effect is still mild.”

For minor ailments only

“If the illness is severe, you need branded. If it’s just fever, you can use generics. For antibiotics, it must be branded.”

Inconsistent results

“Depending on the body type of every individual. Generic drugs may be effective for me but not for another person.”

Benefits of generic drug use

The participants enumerated the benefits of using generic drugs and they are: generic drugs are inexpensive, effective, more accessible, and recommended by doctors.

Inexpensive

“I can save.”

“It is light on the budget, ma’am.”

“You can buy more because it is less expensive. Instead of just buying one piece of branded medicine, you can buy three pieces of generic.”

Effective

“The healing is faster.”

More accessible

“Generic drugs are more accessible and easier to find. Wherever drugstore we go to, generic drugs are always present unlike branded ones.”

“Easy to find (generic drugs), just go to the (health) center and ask.”

“Easy to find (generic drugs) at the barangay, it’s free, as long as you’re not very sick.”

Recommended by doctors

“When I asked the doctor what medicine is good (for the patient), (the doctor said) the generic is generally okay. Same as branded. So if it is recommended by the doctor, then it means it can cure the patient.”

Barriers to generic drug use

The participants mentioned some barriers to the use of generic drugs. They are that some drugs/drug combinations are not available in generics, pharmacy personnel preference for offering branded, doctors recommending branded and preference for branded drugs in severe illnesses.

Unavailable in generics

"Sometimes we want to buy in the generics pharmacy, but if it is not available, we now try to look for it in Mercury (drugstore)."

Pharmacies offering branded drugs

"There are other drugstores ma'am that, when you're looking for generics, let's say like mefenamic acid, the price is thirty pesos. When I went to another drugstore there was a two-peso or three-peso mefenamic acid. So I went back and ask that drugstore why their mefenamic acid is expensive. It was already the branded one. Just because I was looking for mefenamic acid they gave me the expensive one because they were out of stock of the cheaper drug."

"Sometimes they would say they are out of stock but they have other brands of the same generic."

Doctor preference

"Well for me, what I can say is sometimes doctors would prescribe a specific brand because of side effects. They would say that you must take this branded drug because you have an allergy of the generic drug."

"I bought a generic drug and when I gave it to the doctor, the doctor used another drug. They used their drug instead of what I bought. And upon discharge, they returned the drug to me."

"I wanted to buy generic drugs but if the doctor prescribes a specific drug then I would be forced to buy it."

"Before, i bought generic azithromycin and the doctor got angry! She said, that's not the medicine I prescribed for you! But i reasoned out and said, Ma'am, they're the same otherwise they won't make them if they are not the same. Sometimes, I wonder why doctors prefer the branded... but there is no choice because we are budgeting our money."

Severe illness

"Status of the patient, if the patient is in a critical condition, choose branded."

The participants were then asked about what they do when they encounter such barriers. They answered that they can either consult the doctor, the health center personnel or the pharmacist for an alternative or find ways to purchase branded medicines.

Ask for an alternative

"We can always ask the doctor if we can buy the generic drug."

"...but I have tried a prescription from a doctor in the private clinic, it did not produce an effect. So I went to the center and ask if it can be replaced. They replaced it and I was feeling well."

"The pharmacist said that the only difference between them is the manufacturer."

Purchase branded medicines

"If branded is needed, borrow money so that there will be enough budget to cover the need."

Competition

Without mentioning branded medicines in the FGD guide, the participants used them as a point of comparison for most of the questions. Opinions on the branded medicine touched on quality (branded being better than generics for severe illnesses, having faster onset of action) and price comparisons (branded being either more expensive, as expensive or less expensive in the long run).

Influences

The participants were asked who or what can influence them to buy generics. The three most common answers were advertisements, doctors and past experience.

Advertisements

"Because we also believed in Fernando's wife (Susan Roces). Because she is the endorser." (referring to the RiteMed commercials)

"We get familiarized with those we frequently see or hear on TV, so when we buy meds, those brands are what we usually remember."

"The one with Ate Vi (Santos), that is effective." (referring to The Generics Pharmacy commercials)

Doctors

"For my kid, I would really follow the doctor's prescription because we wanted our child to be better. That's why I would buy what is on the prescription. It would be better if the doctor himself would tell us it's okay to buy generic drugs. The doctor himself would be the one to assure us that the generic drug has no side effects. Or it will not cause allergies. It would be even better if they would write it in the prescription."

Past experiences

"For me, ma'am, it is because I used it before. If it still the same illness as I felt before then I would buy that drug automatically."

"My husband used to spend 11 thousand a month every month for his diabetes. When I switched to generics, we spend only 3 thousand a month. His blood sugar is still okay."

*"My father always buys generics because his body got used to it. Whenever he uses other brand, he feels uneasy and uncomfortable."
"It seems that I don't get well with other brands. So I buy what I'm used to."*

Recommendations

The moderators then asked the participants if they have any recommendations for the improvement of the Generics Act. They participants actively responded to this question and there were many suggestions. They suggested better implementation of the following provisions of the law: price menu cards, generic dispensing and substitution and penalties for noncompliance. They also mentioned that a wider information campaign may be beneficial. There was also a recommendation to improve the quality and types of the generic drugs.

Price menu cards

"For the drugstores outside, I didn't see any price list of their generic drugs. They did not post it."

"They have posted it but we just cannot see it because it is far from us. It is found inside. It should be posted outside for the buyers."

Generic substitution

"But in the chain drugstore, they offer you branded (instead of generics). Maybe they don't know that it's against the law."

Penalties

"Since there is a law already, and we are only hearing about it now, the government should be stricter in imposing punishment to those who don't follow the law."

Information dissemination

"I hope they spread the information so that people will know their rights."

"It should be shown on TV or announced on the radio that there are existing law on generic drugs."

"I'd suggest something more practical – perhaps the DOH can partner with the barangays and conduct intensive orientations or workshops at each barangay that would give out proper information/education to the masses."

Generic drugs

"Improve quality of generic drugs."

"Some branded drugs do not have generic counterparts. I hope they remedy that."

V. Discussion

A. Generic prescribing

This study reveals good compliance to generic prescribing in the country, showing that five out of six drugs are written with generic names. This is significantly higher compared to past data gathered by the SWS. Based on data generated in 1998, only 59% of the prescriptions were written with a generic name, decreasing to 30% in 2008. The reason for decrease in generic prescribing was not discussed in the SWS survey.

Doctors in the public sector prescribe generics slightly more often than those in the private sector and the difference is statistically significant. This difference could be attributed to the fact that compliance to generic prescribing is strictly implemented in public hospitals and clinics rather than in private ones.

As seen by the results of the KIIs done with the physicians, generics prescribing is mostly driven by patient-oriented concerns. The patient's welfare as well as their compliance reinforces this behavior. Because these drugs are generally inexpensive compared to branded medications, it will allow them to buy and finish the drug regimen despite the patient's financial situation. It will enable them to complete the course of treatment and hopefully, lead to recovery, rather than not be able to use any medication at all. Aside from these, another factor that was elicited was the physician's fear of punishment when the law is violated moreso now that penalties have been up scaled in the recent amendment of the law. However, despite the high compliance to generics prescribing, there still lie the concerns of the doctors regarding the quality of generic medicines and lack of regular monitoring by the FDA. Past experiences of ineffectivity of the said drug prohibit physicians from prescribing it. This is no different in the study in Slovenia in 2006, which revealed that general practitioners are aware of prescribing costs and recognize that generic drugs are usually used in place of branded ones but they need reassurance on the legal and quality-assurance aspects of generics. This general view is the same all over the world as seen in the studies of Sharrad et al. in 2008 in Iraq and Sewell in 2011 in the United States. However, an issue though that was barely touched on by this study was the provision of incentives by multinational drug companies in prescribing branded ones. Although this was tackled by Shrank et al. (2009), the consumers were the ones wary of the incentives rather than an issue raised by physicians.

B. Drug dispensing

Drug price menu cards, although present in majority of the drugstores, do little to influence both the behavior of the pharmacist and the consumer. About 96% of chain drugstores have price menu cards, while only 60% of freestanding drugstores have it, a statistically significant finding. However, despite high compliance to the price menu cards, it must also be noted that it is not strategically placed in conspicuous areas convenient for the viewing of consumers. Moreover, only two out of five consumers were offered with generic alternatives by the drugstore. This is similar to the results from the 2008 SWS survey where 45% of consumers were offered a generic alternative. For those who were not offered an alternative, only 25% of the consumers requested information on generics, the reason mainly because they want a cheaper alternative. There is no significant difference in generic dispensing between chain and freestanding drugstores. This relatively low compliance to generic dispensing calls for a stricter implementation and regulation in this aspect of the law. It is possible that drugstores have been complacent in following the Generics Act over the years due to the lack of regular monitoring by the FDA. The pharmacists and/or the pharmacy assistants have resorted to simply following what is written in the prescription.

Globally, generic dispensing is encouraged albeit done in different approaches. The Australian government encouraged the utilization of generic medicines through a policy allowing community pharmacists to voluntarily substitute specified PBS-listed brand name medicines with equivalent generics, provided consent was obtained from both the prescriber and the patient. In Malaysia, however, there exists dispensing doctors, who takes the place of pharmacists and dispense the drugs themselves. They charge higher for the generic medicine for a larger profit. On the contrary, there is no current law in Iraq which regulates generic substitution. Due to a lack of existing health insurance system in Iraq, prescribing drugs by generic name and encouraging pharmacists to dispense prescriptions with generic medicines is one frequently suggested means for lowering the costs of healthcare.

C. Generic drug use

Knowledge of the existence of generic medications is the first step towards its use. To better understand use of generic drugs, awareness of consumers to generic medicines as well as the different factors that influence its use were taken into consideration. There is still low awareness of the Generics Act 25 years after its implementation. Only fifty-five percent of respondents[1] are aware that there is a law that

requires physicians to include the generic name in the prescription. Even less are informed that the law requires pharmacists to offer them generic alternatives (47%) and to notify them the prices of generic alternatives for their drugs (48.92%). When asked to define what a generic drug is, only 7.17% correctly identified the definition while 64% of the respondents defined generic drug in terms of its price advantage. When compared to branded medicines, almost all (91.71%) said generic medicines are cheaper, and half (48.44%) perceives it to be less efficacious. It was seen that effectiveness is of utmost importance for the consumers. Other factors influential to the use of generic medicine seen in this study is following what the doctor wrote in the prescription, its price, and buying the drug that they are used to. Recommendations by the pharmacist and suggestions by family, friends, and neighbors also affect, although minimally, their decision in using generic medicines.

With the consumer's awareness and the factors mentioned above, we now look into actual use of consumers. Despite being offered an option, only 30% of our respondents actually bought generics. Several factors were identified our study. Those who were more likely to purchase generics knew the requirement to write generic name, consulted a public facility, and was influenced by friends and relatives. For those who perceived that the generic drug is less effective, this did not affect their decision in buying the alternative. This can be due to a number of reasons. One, the consumer follows only what is written in the prescription and what was advised by the doctor. Two, public doctors are more compliant in writing the generic drug. They are, in fact, prohibited to write any brand name in the prescription. Hence, those who consulted a public doctor were more likely to purchase generics. Third, past experiences of friends and relatives still play a major role in affecting use of generics. Positive encounters further promoted use of the alternative and negative ones prevented buying of generics.

Although not mentioned by the patients, other potential factors that could have affected the choice of generic are: (1) the consumer's previous with a particular medicine product and (2) the duration of the drug regimen.

Globally, consumers in Malaysia generally follow the doctor's advice. On the other hand, a study in Alabama (Sewell, 2011) revealed that use of generic drugs are affected by several factors such as perceived differences in efficacy, side-effects, and severity of illnesses. Generic medications were believed to have lower safety and efficacy.

D. Limitations

This study did not measure two variables that may affect the responses of respondents. First is the socioeconomic status of the respondent. The generic drug is seen as a cheaper alternative, and respondents with lower socioeconomic class may prefer this drug over branded ones. A study by Chong (2011) also observed that pharmacists are more likely to offer generic alternatives on people with low income.

The educational attainment of the respondent could also affect his preference for generic/branded drugs. Individuals who studied health-related courses may be more aware of generic alternatives compared to those who studied other courses and those who were unable to reach college-level. In this study, a dismal 7% correctly stated the definition of generic drugs, while majority equated it to a cheaper alternative.

E. Biases

This study employed a cross-sectional design. Associations can be inferred but causality cannot be determined.

This study excluded drugstores that exclusively sell generic medicines because there are no branded alternatives that the consumer can choose from. However, this exclusion may lead to the following: 1) Lower percentage of consumers who bought or asked for generics since individuals who are intent to buy generics are likely to proceed to a generic drugstore located in his area, and 2) Lower percentage of consumers who are knowledgeable about generics.

Sampled non-chain drugstores in all zones were replaced with another non-chain drugstore in front of a hospital for better foot traffic. This replacement did not cause any bias since the reason for replacement was not associated with any variables for generic drug prescribing, dispensing, and use.

Surveys for this study were done in different parts of the country, with different dialects. Translated questionnaires are validated, however, to questions that are open-ended, the proficiency of the data collector to speak and understand the local dialect affects his correct interpretation of the respondent's answers.

The small number of respondents who answered the question regarding asking for the price of the generic alternative lead to a decrease in the power of the test. A statistical test with low power has poor ability to identify significant predictors of an outcome. Consequently, only sex was found to be a significant predictor of asking for the price of generic alternative in this study

VI. Recommendations and Conclusions

A. Recommendations

i. Policy

Because the study results show higher compliance among prescribers compared to dispensers and consumers, there should be a refocusing of the government's regulatory and social marketing efforts from physicians to drugstores and consumers. Identifying drugstores and consumers as the primary targets in need of behavior change allows greater effectively and efficiency in the use of limited government resources. The past focus on physicians have already produced positive outcomes and the time is opportune to move on to new behavior change targets.

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. In the long run, the benefits can outweigh the costs and justify the costs from both a public health and a business perspective. A cost-benefit analysis may be done to establish this.

Generic drugs need to be rebranded to emphasize more their equivalence in quality to branded drugs rather than their lower cost. A lower-cost market positioning of generic drugs, unfortunately, also associates them with lower quality. There should be a shift in the narrative from one in which their lower cost is the major selling point to one in which the accessibility of generic drugs are mapped to positive health outcomes.

Given the limits of drugstore compliance monitoring by the FDA, monitoring can be expanded through collaboration with civil society using a 'mystery shopper' approach. This approach potentially provides compliance information to FDA that it can then act on through its own network of regulation officers. The indicators that need to be monitored, generic substitution and

menu card visibility, are simple enough that even minimally-trained observers will be able to measure them. Information from these observers can be sent in through SMS and provide actionable information to the FDA.

Together with the push to reposition generic drugs, consumers need to be influenced to ask for generic substitutes in the context of their rights as both consumers and as patients. Asking for a generic substitute in the drugstore should be portrayed as the default behavior and as an act that consumers should do as a matter of course when they purchase medicines. This behavior can be equated with the usual consumer behavior when purchasing non-drug commodities. Choice should be both expected and accepted.

Because of the influence of a person's social network, both physical and virtual, on their purchase behavior, the use of this communication channel can potentially be more effective than the usual avenues. 'Generic believers' can be encouraged to convince friends, family, and neighbors to ask for and to buy generics.

ii. Research

An agenda for continuing research on generic drug behavior includes:

1. A health technology assessment of the cost-effectiveness of requiring bioequivalence tests for generic drugs.
2. The effectiveness of using the tools of both 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 towards positive outcomes.
3. A community trial can be carried out of the effectiveness of the 'mystery shopper' technique in improving drugstore compliance with the generic dispensing provisions of the Generic Law.

B. Conclusions

This survey revealed that five out of six drugs were written with generic names, with doctors in the public sector prescribing generics significantly more often than those in the private sector. Factors that

positively affect generics prescribing behavior are patient's welfare, compliance, patient's financial situation, and fear of punishment. Quality concerns, lack of regulation by FDA, poor recall, patient's preference, and personal experience are factors that negatively affect generics prescribing behavior. Less than half of the consumers were offered with generic alternatives, and even less number of consumers actually asked for the alternative. There is preference for branded medicines over generics. The consumers more likely to purchase generic medicines consulted a public facility, knew the requirement to write generic name, and was influenced by friends and relatives. Because there is already high compliance from drug prescribers, government efforts should now focus to the drugstores and consumers. Drugstore compliance should be regularly monitored, and consumers empowered on their right to know alternatives. Bioequivalence tests should be done to finally put an end to concerns on the quality of generic medicines.

VII. References

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VIII. Annex

A. Informed Consent Form for Consumer Surveys (English)

Investigator's Name: Wong, J. et al. /DREC12-2013/ July 4, 2013/ page1 of 2 pages

Appendix B. Informed Consent Form for Consumer Surveys (English)

Information Sheet and Informed Consent Form for Survey of Drug Consumers regarding Compliance to Generics Act of 1988

This is an informed consent form for participants of the nationwide study "**Analysis of the prescribing and dispensing of generic drugs as provided by Generics Act of 1988**". A total of 42 participants will be interviewed per drugstore, encompassing 33 drugstores nationwide. This is a study funded by the Philippine Institute for Development Studies mainly for the National Center for Pharmaceutical Access and Management of the Department of Health.

Introduction

We are a group of researchers doing a study to assess the compliance of physicians and pharmacies to the provisions of the Generics Act of 1988. We would also like to explore the opinion of consumers regarding generic medications. We would like to ask you to participate in a short survey. You may think about whether or not you want to participate. Participation is completely voluntary. If you have any questions, we will be happy to answer them.

Purpose of the research

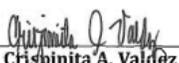
The Generic name is a drug name that all medications have, whether branded or non-branded. The Generics Act of 1988 requires doctors to write prescriptions using generic names. It also requires drugstores to inform consumers about the different drug products (including brands) under the same generic name and the costs of these different products to help consumers decide which product to buy. The aim of this research is to find out whether doctors and pharmacies conform to the said law. We also want to find out how consumers, such as yourself, view generic non-branded medications and what factors you consider when buying medications.

Participant selection

As a consumer, you were chosen to participate in this research because you were able to interact with both a doctor and a pharmacist in order to buy your medication. We would like to find out how the provisions of the Generics Act of 1988 was practiced in your case. Also, we would like to find out what your views are regarding generic non-branded medications, and what factors you consider when choosing the medications you buy.

Voluntary participation

Participation is voluntary. You are free to choose whether or not to participate in this study. If you choose to participate, a member of the research team will ask you a few questions. We would also like to ask you to allow us to take a picture of your prescription in order to see whether the drug prescribed was written using its generic name. The survey will take approximately 20 minutes. If you do not wish to answer any question,

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please tell the interviewer and he will proceed to the next question. You are also free to end the interview at any point, for any reason, if you wish to.

Risks, Benefits, Reimbursements

We do not anticipate any risks to you if you participate in this study. There may also be no direct benefits to you. However, the results of this study may inform policy makers as to how the law is being implemented. Improvements in the implementation of this law will benefit public health and all medicine consumers in the long run. A small token will be given to participants.

Confidentiality

Everything you say will be held in confidence. Your name will not appear in any of the reports that will be made.

Results

The results of this study will be reported at the NCPAM 25th Generics Summit. A report will also be given to the Philippine Institute for Development Studies and National Center for Pharmaceutical Access and Management of the Department of Health. The results of this study may also be published.

Who to contact

If you have any questions, please feel free to contact any member of the research team:

- Dr. John Q. Wong
- Dr. Grace Kathleen T. Serrano – 024750105 (National Capital Region)
- Dr. Jenina Olivia A. Tumlos– 09178466264 (Northern Luzon)
- Dr. J. Richelcyn M. Baclay– 09478999387 (Southern Luzon)
- Dr. Richelle G. Duque – 09178838783 (Visayas)
- Dr. Patricia Margarita S. Roque– 09175076572 (Mindanao)
- Dr. Aisha-Aziza A. Ronsing - 0927-401-1341 (ARMM)

If you choose to participate in this study, please sign the consent form below:

I have been asked to participate in a study assessing the compliance to the Generics Act of 1998. My questions about the study have been answered adequately. I choose to voluntarily participate in the study. I am also allowing the members of the research team to take a picture of my prescription.

Signature: _____
 Name: _____
 Date: _____

Investigator's Signature: _____
 Name: _____
 Date: _____

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B. Informed Consent Form for Consumer Surveys (Tagalog)

Investigator's Name: Wong, J. et al. /DREC12-2013/ July 4, 2013/ page1 of 2 pages

Appendix C. Informed Consent Form for Consumer Surveys (Tagalog)

IMPORMASYON TUNGKOL SA PAGAARAL AT PAHINTULOT NA MAKASAMA SA ISANG PAG-AARAL PARA SA MGA BUMIBILI NG GAMOT

Gumagawa kami ngayon ng pag-aaral na pinamagatang "**Analysis of the prescribing and dispensing of generic drugs as provided by Generics Act of 1988**". Apatnapung mamimili ng gamot ang pipiliin sa bawat botika, 33 botika mula sa iba't ibang panig ng pilipinas ang kasama. Isa itong pag-aaral na pinondohan ng *Philippine Institute for Development Studies* para sa *National Center for Pharmaceutical Access and Management* ng *Department of Health*.

Introduksyon

Isa kaming grupo ng mga mananaliksik na gumagawa ng isang pag-aaral upang malaman kung nasusunod ba ang mga probisyon sa *Generics Act of 1988*. Nais din naming malaman ang opinion ng mga mamimili tungkol sa mga gamot na walang *brand name* (generics). Nais sana naming hingin ang inyong pahintulot na kayo ay mainterview. Ang pagsali sa pag-aaral na ito ay boluntaryo. Maaari kayong magtanong kung may nais kayong malaman o maliwanagan tungkol sa pagaaral na ito.

Layunin ng pag-aaral

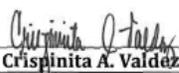
Ang *generic name* ay pangalan na mayroon ang lahat ng gamot (branded man o hindi). Ang *Generics Act of 1988* ay isang batas na nag-oobliga sa mga doctor na gamitin ang *generic name* kapag gumagawa ng reseta. Ayon sa batas na ito, ang mga *drugstores* ay obligado din na ipaalam sa mga mamimili ang pangalan at presyo ng iba't ibang produkto na may parehong *generic name*. Ito ay upang matulungan ang mga mamimili na pumili ng nararapat na produkto para sa kanila. Layunin ng pag-aaral na ito na malaman kung totoo bang nasusunod ang mga probisyon na ito ng *Generics Act of 1988*. Nais din naming malaman kung ano ang inyong opinion bilang isang mamimili tungkol sa mga gamot na walang brand (generics na gamot).

Bakit kayo napiling sumali?

Bilang isang mamimili ng gamot, pumunta kayo sa isang doktor at isang botika upang makabili ng inyong gamot. Nais naming malaman kung paano naipatupad ang mga probisyon ng *Generics Act of 1988* base sa inyong karanasan. Bilang isang mamimili, nais din naming malaman ang inyong opinion tungkol sa mga gamot na generics, at kung ano ang inyong mga kinokonsidera kapag pumipili ng gamot.

Ang pagsalisa pag-aaral na ito ay boluntaryo.

Boluntaryo ang pagsali sa pag-aaral na ito. Nasa inyong desisyon kung nais ninyong maging parte nito o hindi. Kung papayag kayo na masali sa pag-aaral na ito, may ilang mga tanong na itatanong sa inyo ang isang myembro ng aming grupo. Nais din naming kuhanan ng litrato ang inyong reseta upang makita kung *generic name* ang sinulat doon ng inyong doktor. Ang buong *interview* ay di lalampas sa 20 minuto. Kung may mga

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tanong na ayaw ninyong sagutin, sabihin niyo lamang sa *interviewer* at pupunta siya sa susunod na tanong. Maaari ninyo ring itigil ang *interview* sa kahit na anong panahon, o para sa anumang dahilan, kung inyong nanaisin.

Mga ilang pang paalala

Ang pangalan ninyo ay hindi makikita sa kahit na alin mang *report* na gagawin para sa pag-aaral na ito. Wala kaming naiisip na kapahamakan na maidudulot sa inyo sa pagsali sa pag-aaral na ito. Wala ring direktang benepisyo. Ngunit, ang resulta ng pag-aaral na ito ay makakatulong sa mga mambabatas upang mas mapabuti ang pagpapatupad ng *Generics Act*

of 1988. Ang mas mabuting pagpapatupad ng batas na ito ay makakabuti sa inyo at sa lahat ng mamimili ng gamut pagdating ng araw. May munting regalo na ibibigay sa mga sumali sa pag-aaral. Ang resulta ng pag-aaral na ito ay ipapakita sa *NCPAM 25th Generics Summit*, sa *National Center for Pharmaceutical Access and Management ng Department of Health* at sa *Philippine Institute for Development Studies*.Maari ring ilathala ang resulta ng pag-aaral na ito.

Kung mayroon kayong mga katanungan, wag mag-atubiling tawagan ang mga miyembro ng *research team*:

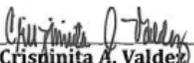
- Dr. John Wong
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- Dr. Patricia Margarita S. Roque– 09175076572 (Mindanao)
- Dr. Aisha-Aziza A. Ronsing - 0927-401-1341 (ARMM)

Kung pumapayag kayong makasali sa pag-aaral na ito, maari po lamang na pirmahan ang *form* sa baba:

Ako ay naimbitahang maging parte ng isang pag-aaral na nagsasaliksik kung nasusunod ba ang mga probisyon sa *Generics Act of 1988*. Ang aking mga tanong ay nasagot nang lubusan. Pumapayag akong maging parte ng pag-aaral na ito. Pumapayag din ako na kuhanan ng litrato ng mga mananaliksik ang aking reseta.

Pirma: _____
 Pangalan: _____
 Petsa: _____

Pirma ng mananaliksik: _____
 Pangalan: _____
 Petsa: _____

DOH Research Ethics Committee (DREC)	DREC Ref. No.	DREC12-2013
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	To	09 November 2013
Date :	DREC Approval No.	DREC 2013 - 14

C. Informed Consent Form for Consumer Surveys (Bisaya)

Investigator's Name: Wong, J. et al. /DREC12-2013/ July 4, 2013/ page1 of 2 pages

Appendix D. Informed Consent Form for Consumer Surveys (Bisaya)

Impormasyong naay Pagtugot sa mga tigpalit

Mao kini ang impormasyong naay pagtugot mga porma para sa mo-apil /mosalmot sa pagsusi "Analysis of the Prescribing and Dispensing of Generic Drugs as provided by the Generics Act of 1988." Sa 33 ka botika sa tibuok nasuod, kwarenta dos ka-konsumidor ang pagpillion matag botika. Mao kini ang pagsukod nga giponduhan sa Philippine Institute for Development Studies para ra gayud sa National Center for Pharmaceutical Access and Management of the Department of Health.

Pasiuna

Kami grupo nga nagtuki-tuki nagbuhat ug pagtoon, pagtasal pagtuman sa mga doktor ug pharmasyotiko sa kahimanan tubay sa Generics Act of 1988. Gusto pod namo nga usisahon ang huna-huna sa mga tigpalit bahin sa generic nga mga tambal. Gihangyo ko kamo nga mo -apil sa mobo nga pagsusi. Siguro kamo naghuna-huna kung mo-apil o dili. Pahibalo lang ang inyohang pagsalmot boluntaryo. Kung naay mga pangutana, malipay mi nga motubag ni ini.

Tumong ug tuyo sa pagtuki-tuki

Ang Generic nga ngalan kay usa ka ngalan sa tambal nga ang tanang medicina naa bisan branded o dili branded. Ang Generics Act sa 1988 gikinahanglan ang mga doktor magsulat ug reseta gamit ang generic nga ngalan. Gikinahanglan pod ang mga botika magpahibalo sa mga tigpalit bahin sa lain-laing tambal nga producto (lakip ang brand)ubos sa parehong generic nga ngalan ug ang presyo ni ining laing-laing producto para tabangan ang mga mamalitay ug desisyon kung unsang producto paliton. Ang tumog ug tuyo ni ini nga pagtuki-tuki kay para mahibaw-an kung ang doktor o pharmasyotiko nagsubay sa maong balaod. Gusto pod nato mahibaw-an kung unsaon sa mga tigpalit sama sa inyohang kaugalingon kung unsay paglantaw sa generic walay brand nga mga tambal ug kung unsa ang mga detalye/rason ang huna-hunaon kung mopalit ug mga tambal.

Pagpili sa Mosalmot

Kay ikaw ang mamalitay, ikaw gipili pagsalmot/pag-apil nining pagtuki kay ikaw ang may gahum nga mo diskusyon/mo atobang sa doktor ug pharmasyotiko para mopalit ug imohang tambal. Gusto pod namo mahibaw-an kung unsaon ang kahimanan sa Generics Act of 1988 gamiton sa mga tigpalit. Usab kung unsa pod ang inyohang opinyon/huna-huna bahin sa Generic nga walay brand nga tambal ug unsa ang himoahan/alindasay nga inyohang paghatag ug pagtugot agi ug pagsugot kung magpili ug paliton nga tambal.

Boluntaryong Pagsalmot

Ang pag-apil boluntaryo. Ikaw libre mopili kung moapil ka or dili ni ining pagtoon. Kung gusto nimo mo-apil ang usa sa membro sa pagtuki mangutana sa imoha ug pipila ka mga pangutana. Gusto unta namo mangutana sa imoha kung imo ming tugotan nga magkuha ug hulagway sa imong reseta, para mahibaw-an namo kung ang tambal nga gi-reseta gi-sulat ang Generic nga pangalan. Ang pagsusi mahitabo sa kapin o kulang, bana-bana sa biente minutos. Kung dili nimo buot/gusto motubag sa bisan unsang pangutana, palihug sultii ang

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nangutana para diretso siya sa sunod nga pangutana. Libre pod ka motapos sa mga pangutana sa bisan asa nga punto or rason o kung gusto lang nimo.

Kakuyaw, Benepisyo Paguli/Pagtapal

Wala namo gidahom nga naay kakuyaw o peligro nga mahitabo kung moapil ka di ining pagtoon. Ug wala sab ni diretso benepisyo para sa inyoha. Apan, ang resulta sa pagtoon ni ini makahibalo ang nga naghimo/nagmugna sa policea kung gi unsa pagpatuman sa balaod, kausbawan/asenso sa pagtuman sa niining balaod makabenepisyo sa kahimsog sa publiko ug ang tanang mopalitay ug tambal sa taas nga panahon.

Confidensyal (Ato-Ato)

Ang tanang imong gitabi ato-ato lang. Ang imong ngalan dili ibutang sa bisang unsang mga papeles or listahan nga himoon.

Resulta

Ang resulta aning pagtuon ihatag sa NCPAM 25th Generics Summit. Isa pud kasulatan ang ihatag sa the Philippine Institute for Development Studies and National Center for Pharmaceutical Access and Management of the Department of Health.

Kung naa moy mga pangutana, palihog lang pagdapat sa mga miyembro sa tigdumla sa kalihokan:

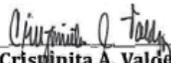
- Dr. John Wong
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- Dr. Aisha-Aziza A. Ronsing - 0927-401-1341 (ARMM)

Kung gusto mo mu-apil, palihog lang ug pirma sa gihatag na katugotan na gipakita sa ubos:

Ako mu-apil sa tigdumala sa kalihokan mahitungod sa tambal na generic. Kung naa man koy pangutana maayo unta ug matubag ug saktos. Mosogot ko nga moapil sa pag-aaral. Mosogot sad ko nga kuhaan og litrato sa mga miyembro ang akong reseta.

Pirma: _____
 Pangalan: _____
 Petsa: _____

Pirma ng mananaliksik: _____
 Pangalan: _____
 Petsa: _____

DOH Research Ethics Committee (DREC)	DREC Ref. No.	DREC12-2013
Approved :	Document	Information & Informed Consent Form
 Crispinita A. Valdez Chairperson	Permitted for use (Inclusive Dates)	
	From	08 July 2013
	To	09 November 2013
Date :	DREC Approval No.	DREC 2013-14

D. Informed Consent Form for Consumer FGD (English)

Appendix F. Informed Consent for Consumer FGD (English)

**Information Sheet and Informed Consent Form for Focus Group Discussion
On Perceptions of consumers on Generic Medications**

This is an informed consent form for participants of the study "**Analysis of the prescribing and dispensing of generic drugs as provided by Generics Act of 1988**". This is a study funded by the Philippine Institute for Development Studies mainly for the National Center for Pharmaceutical Access and Management of the Department of Health.

Introduction

We are a group of researchers doing a study to explore the opinion of consumers about generic medications. We would like to ask you to participate in a focus group discussion (FGD), along with 7-11 other persons. You may think about whether or not you want to participate. Participation is completely voluntary. If you have any questions, we will be happy to answer them.

Purpose of the research

We would like to assess the acceptability of generic medications by exploring the views of consumers, such as yourself, on generic medications and how such views influence what drugs you buy.

Participant selection

You were chosen to participate in this study because you are a consumer of medications.

Voluntary participation

Participation is voluntary. You are free to choose whether or not to participate in this study. If you choose to participate, you will be asked to participate in a focus group discussion. This is a discussion with a group of 8-12 participants, all of which are drug consumers, such as yourself. A moderator will ask the group questions about your views on generic medications. Another member of the research team will be videotaping the discussion and taking notes. The FGD will take approx.45-60 minutes. You do not have to answer questions you do not wish to answer. You can terminate your participation in the FGD at any point, and for any reason.

Risks, Benefits, Reimbursements

We do not anticipate any risks to you if you participate in this study. There may also be no direct benefits to you. However, the results of this study may inform policy makers as to how generic medications are viewed, which can then help them address issues of acceptability. You will also receive a small token of gratitude for your participation in this FGD.

Confidentiality

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Approved :  Crispinita A. Valdez Chairperson	Document	Information & Informed Consent Form
	Permitted for use (Inclusive Dates)	
	From	08 July 2013
	To	09 November 2013
Date :	DREC Approval No.	DREC2013-14

The views that you share during the discussion will be heard by the other participants in the FGD and the researchers. The discussion will also be videotaped. However, your name will not appear in any of the tapes, transcripts or reports.

Results

The results of this study will be reported at the NCPAM 25th Generics Summit. A report will also be given to the Philippine Institute for Development Studies and National Center for Pharmaceutical Access and Management of the Department of Health. The results of this study may also be published.

Who to contact

If you have any questions, please feel free to contact any member of the research team:

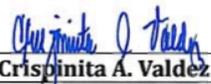
- Dr. John Wong
- Dr. Grace Kathleen T. Serrano – 024750105 (National Capital Region)
- Dr. Jenina Olivia A. Tumlos– 09178466264 (Northern Luzon)
- Dr. J. Richelcyn M. Baclay– 09478999387 (Southern Luzon)
- Dr. Richelle G. Duque – 09178838783 (Visayas)
- Dr. Patricia Margarita S. Roque– 09175076572 (Mindanao)
- Dr. Aisha-Aziza A. Ronsing- 0927-401-1341 (ARMM)

If you choose to participate in this study, please sign the consent form below:

I have been asked to participate in a study assessing the views of consumers regarding generic medications. My questions about the study have been answered adequately. I choose to voluntarily participate in the focus group discussion. I am also allowing the members of the research team to videotape the discussion.

Signature: _____
 Name: _____
 Date: _____

Investigator's signature: _____
 Name: _____
 Date: _____

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	To	09 November 2013
	DREC Approval No.	DREC 2013 - 14

E. Informed Consent Form for Consumer FGD (Tagalog)

Investigator's Name: Wong, J. et al. /DREC12-2013/ July 4, 2013/ page1 of 2 pages

Appendix G. Informed Consent for Consumer FGD (Tagalog)

IMPROMASYON TUNGKOL SA PAG-AARAL ATPAHINTULOT NA MAKASAMA SA ISANG FOCUS GROUP DISCUSSION PARA SA MGA BUMIBILI NG GAMOT

Gumagawa kami ngayon ng pag-aaral na pinamagatang "**Analysis of the prescribing and dispensing of generic drugs as provided by Generics Act of 1988**". Isa itong pag-aaral na pinondohan ng ng *Philippine Institute for Development Studies* para sa *National Center for Pharmaceutical Access and Management ng Department of Health*.

Introduksyon

Isa kaming grupo ng mga mananaliksik na gumagawa ng isang pag-aaral upang malaman ang opinyon ng mga mamimili tungkol sa mga gamot na walang *brand name* (generics). Nais sana naming hingin ang inyong pahintulot na kayo ay maisali sa isang *focus group discussion (FGD)*, kasama ang 7-11 na iba pang katao. Ang pagsali sa pag-aaral na ito ay boluntaryo. Maaari kayong magtanong kung may nais kayong malaman o maliwanagan tungkol sa pagaaral na ito.

Layunin ng pag-aaral

Nais naming malaman kung gaano katanggap-tanggap sa mga mamimili ang mga gamot na generic. Nais naming alamin kung ano ang pananaw ng mga mamimiling katulad ninyo, tungkol sa mga gamot na generic, at kung paano nakakaapekto ang mga paniniwalang ito sa pagpili ninyo ng gamot na bibilhin.

Bakit kayo napiling sumali?

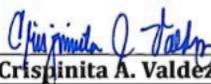
Napili kayong sumali sa pag-aaral na ito dahil isa kayong mamimili ng gamot.

Ang pagsali sa pag-aaral na ito ay boluntaryo.

Boluntaryo ang pagsali sa pag-aaral na ito. Nasa inyong desisyon kung nais ninyong maging parte nito o hindi. Kung papayag kayo na masali sa pag-aaral na ito, aanyayahan naming kayong makasama sa isang *focus group discussion*, kasama ang 8-12 na mga mamimili ng gamot na katulad ninyo. Isang myembro ng *research team* ang magtatanong tungkol sa inyong mga pananaw tungkol sa mga gamot na generic. Isa pang myembro ng *team* ang magvi- *videotape* at magsusulat ng mga pinag-uusapan ng grupo. Tatagal ng 45-60 minuto ang *FGD*. Hindi ninyo kailangan sagutin ang mga tanong na ayaw ninyong sagutin. Maari rin kayong tumigil sa pagsagot sa mga katanungan sa kahit na anong panahon, o para sa anumang dahilan, kung inyon nanaisin.

Mga ilan pang paalala:

Ang mga opinyon/pananaw na inyong ilalahad sa *FGD* ay maririnig ng iba pang mga kasali sa *FGD*, pati na rin ng mga myembro ng *research team*. Ang *FGD* ay itatala din gamit ang *video recorder*. Ngunit, hindi isusulat ang inyong pangalan sa mga *video tape*, *transcripts*, at sa *report* na isusulat.

DOH Research Ethics Committee (DREC)	DREC Ref. No.	DREC12-2013
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	Permitted for use (Inclusive Dates)	
	From	08 July 2013
	To	09 November 2013
Date :	DREC Approval No.	DREC2013-14

Wala kaming naiisip na kapahamakan na maaring madulot ng pagsali sa pag-aaral na ito, sa inyo. Maaring wala ring direktang benepisyo kaung makuha mula sa pagsali dito. Gayunman, ang resulta ng pag-aaral na ito ay makakatulong sa mga mambabatas na malaman ang mga pananaw ng mga mamimili tungkol sa gamot na generic. Ang impormasyon na ito ay makakatulong sa kanila upang magawan ng paraan na maging maskatanggap-tanggap ang

mga gamot na generic. Makakatanggap din kayo ng maliit na simbolo ng aming pasasalamat sa pagsali ninyo sa *FGD*.

Ang mga resulta ng pag-aaral na ito ay ipapakita sa *NCPAM 25th Generics Summit*, sa *National Center for Pharmaceutical Access and Management ng Department of Health* at sa *Philippine Institute for Development Studies*. Maari ring ilathala ang mga resulta ng pag-aaral na ito.

Kung mayroon kayong mga katanungan, wag mag-atubiling tawagan ang mga miyembro ng *research team*:

- Dr. John Wong
- Dr. Grace Kathleen T. Serrano – 024750105 (National Capital Region)
- Dr. Jenina Olivia A. Tumlos– 09178466264 (Northern Luzon)
- Dr. J. Richelcyn M. Baclay– 09478999387 (Southern Luzon)
- Dr. Richelle G. Duque – 09178838783 (Visayas)
- Dr. Patricia Margarita S. Roque– 09175076572 (Mindanao)
- Dr. Aisha-Aziza A. Ronsing- 0927-401-1341 (ARMM)

Kung pumapayag kayong makasali sa pag-aaral na ito, maari po lamang na pirmahan ang *form* sa baba:

Ako ay naimbitahang maging parte ng isang pag-aaral tungkol sa mga pananaw ng mga mamimili tungkol sa mga gamot na generic . Ang aking mga tanong ay nasagot ng lubusan. Pumapayag akong maging parte ng pag-aaral na ito. Pumapayag din ako na *i-video tape* ang diskusyon.

Pirma: _____
 Pangalan: _____
 Petsa: _____

Pirma ng mananaliksik: _____
 Pangalan: _____
 Petsa: _____

DOH Research Ethics Committee (DREC)	DREC Ref. No.	DREC12-2013
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Date :	From	08 July 2013
	To	09 November 2013
	DREC Approval No.	DREC 2013 - 14

F. Informed Consent Form for Consumer FGD (Bisaya)

Investigator's Name: Wong, J. et al. /DREC12-2013/ July 4, 2013/ page1 of 2 pages

Appendix H. Informed Consent for Consumer FGD (Bisaya)

Impormasyong naay Pagtugot sa mga tigpalit

Kini isa ka katugotan na naga pahibalo para sa mga partisipante sa pagtuon "**Analysis of the prescribing and dispensing of generic drugs as provided by Generics Act of 1988**". Kining pagtuona na ni gipundohan sa Development Studies mainly for the National Center for Pharmaceutical Access and Management of the Department of Health.

Pasiuna

Isa kami ka grupo nga tagapangita og kasayoran o opinyon sa mga paghibalag para sa mga mangungonsumo sa generik na tambal. Gusto namo mo imibitahon na mu-apil sa focus group discussion (FGD), kauban sa 7-11 ka mga tao. Kung alanganin mo mu-apil sa kani na partisipasyon, ipahibalo namo sa inyo na kani kay boluntaryo lang. kung naa kay pangutana kami na grupo pursigido mutubag sa imong mga pangutana.

Tumong ug tuyo sa pagtuki-tuki

Sa kani na pagtuon, gusto namo mahibal-an labi na ikaw kung ang generik na tambal dawt ba sa mga mamamalit ug unsa ilang opinyon tungod ani og kung unsa pud ang naka impluwensya sa ilang pagpalit.

Pagpili sa Mosalmot

Ikaw ang among napilian na mo apil sa aning pagtuon kay ikaw nagapalit ug tambal.

Boluntaryong Pagsalmot

Ang pag apil aning panaglitan na diskusyon kay boluntaro. Kani na diskusyon nay dapat 8-12 partisipante, tanan mga naga gamit ug tambal pareho nimo. Isa ka tigdumala sa kalihokan ang mangutana alang sa inyong opinyon ug pagtanaw sa tambal na generik. Isa pud ka miyembro sa tagapangita or kasayoran ang mu akta sa diskusyon. Ang FGD muabot mga 45-60 minutos. Dili na kinihanglan tubagon ang tanang panguta kung dili mo ka uyon. Pwede mo muhawa sa diskusyon maski unsang orasa nimo gusto)

Kakuyaw, Benepisyong Paguli/Pagtapal

Ang grupo dili mu tubag sa inyong kaayohan og wala pud moy madawat na benepisyong. Bisan na wala moy madawat, ang resulta sa aning pagtuon ang mutabang og pagpahibalo sa mga tao kung unsa ang opinyon ug pagsabot sa generik na tambal na makatabang sa pagdawat ani na ideya para sa katawhan. Sa among pagpasalamat, makadawat mo ug gamay na kaayuhan sa inyong pag apil gikan sa FGD.

Confidensyal (Ato-Ato)

Ang inyong gihatag na mga tubag sa ani nga diskusyon madungog sa uban partisipante sa FGD ug sa mga tigdumala sa kalihokan. Ang inyong mga pangalan dili mugawas sa mga kasulatan.

DOH Research Ethics Committee (DREC)	DREC Ref. No.	DREC12-2013
Approved :  Crispinita A. Valdez Chairperson	Document	Information & Informed Consent Form
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	From	08 July 2013
	To	09 November 2013
Date :	DREC Approval No.	DREC2013-14

Resulta

Ang resulta aning pagtuon ihatag sa NCPAM 25thGenerics Summit. Isa pud ka sulatan ang ihatag sa the Philippine Institute for Development Studies and National Center for Pharmaceutical Access and Management of the Department of Health. Ang resulta sa pagtoon napagawas.

Kung naa moy mga pangutana, palihog lang pagdapat sa mga miyembro sa tigdumla sa kalihokan:

- Dr. John Wong
- Dr. Grace Kathleen T. Serrano – 024750105 (National Capital Region)
- Dr. Jenina Olivia A. Tumlos– 09178466264 (Northern Luzon)
- Dr. J. Richelcyn M. Baclay– 09176298493 (Southern Luzon)
- Dr. Richelle G. Duque – 09178838783 (Visayas)
- Dr. Patricia Margarita S. Roque– 09175076572 (Mindanao)
- Dr. Aisha-Aziza A. Ronsing- 0927-401-1341 (ARMM)

Kung gusto mo mu-apil, palihog lang ug pirma sa gihatag na katugotan na gipakita sa ubos:

Ako mu-apil sa tigdumala sa kalihokan mahitungod sa tambal na generic. Kung naa man koy pangutana maayo unta ug matubag ug sakto. Ako, nagboluntaryo na mu-apil ani na diskusyon. Ako pud gina tugtan ang mga miyembro na mag akta sa among gi hisgutan.

Signature: _____
 Name: _____
 Date: _____

Signature of investigator: _____
 Name: _____
 Date: _____

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	From	08 July 2013
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Date :	DREC Approval No.	DREC12013-14

G. Informed Consent Form for Physicians (English)

Investigator's Name: Wong, J. et al. /DREC12-2013/ July 4, 2013/ page1 of 2 pages

Appendix J. Informed Consent Form for Physicians (English)

Information Sheet and Informed Consent Form for Physicians participating in a study assessing the implementation of the Generics Act of 1988

This is an informed consent form for participants of the study "**Analysis of the prescribing and dispensing of generic drugs as provided by Generics Act of 1988**". This is a study funded by the Philippine Institute for Development Studies mainly for the National Center for Pharmaceutical Access and Management of the Department of Health.

Introduction

We are a group of researchers doing a study to assess how the Generics Act of 1988 is being implemented. We would like to ask you to participate in a short interview. You may think about whether or not you want to participate. Participation is completely voluntary. If you have any questions, we will be happy to answer them.

Purpose of the research

The Generics Act of 1988 has been in effect for 25 years. However, many of its provisions are not being fully implemented. We would like to find out how the law is being implemented and to identify factors that explain current trends and practices in the prescribing, dispensing and use of generic medicines

Voluntary participation

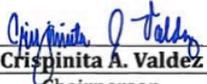
Participation is voluntary. You are free to choose whether or not to participate in this study. If you choose to participate, a member of the research team will ask you a few questions. The interview will take approximately 30 minutes. If you do not wish to answer any question, please tell the interviewer and he will proceed to the next question. We hope to video tape the interview to facilitate documentation, however, if you would rather not be recorded, please inform the interviewer and he will just take notes instead.

Risks, Benefits, Reimbursements

We do not anticipate any risks to you if you participate in this study. Please be assured that we will ensure confidentiality. Your name will not appear in any of the tapes/transcriptions/ datasets/questionnaire forms. In terms of benefits, the results of this study may not benefit you directly, however, the results of this study may inform policy makers as to how the law is being implemented. Improvements in the implementation of this law will benefit public health in the long run.

Confidentiality

Everything you say will be held in confidence. Your name will not appear in any of the reports that will be made. Your name will not be written in the tapes or corresponding transcriptions.

DOH Research Ethics Committee (DREC)	DREC Ref. No.	DREC12-2013
Approved :	Document	Information & Informed Consent Form
 Crispinita A. Valdez Chairperson	Permitted for use (Inclusive Dates)	
	From	08 July 2013
	To	09 November 2013
Date :	DREC Approval No.	DREC2013-14

Results

The results of this study will be reported at the NCPAM 25th Generics Summit. A report will also be given to the Philippine Institute for Development Studies and National Center for Pharmaceutical Access and Management of the Department of Health. The results of this study may also be published.

Wong, J. et al, protocol #: ___
Version: May 13, 2013
Page 2 of 2

Who to contact

If you have any questions, please feel free to contact any member of the research team:

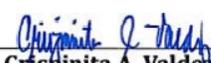
- Dr. John Q. Wong
- Dr. Grace Kathleen T. Serrano – 024750105 (National Capital Region)
- Dr. Jenina Olivia A. Tumlos– 09178466264 (Northern Luzon)
- Dr. J. Richeicyn M. Baclay– 09478999387 (Southern Luzon)
- Dr. Richelle G. Duque – 09178838783 (Visayas)
- Dr. Patricia Margarita S. Roque– 09175076572 (Mindanao)
- Dr. Aisha-Aziza A. Ronsing- 0927-401-1341 (ARMM)

If you choose to participate in this study, please sign the consent form below:

I have been asked to participate in a study assessing the implementation of the Generics Act of 1998. My questions about the study have been answered adequately. I choose to voluntarily participate in the study. I am also allowing the investigators to video tape the interview.

Signature: _____
Name: _____
Date: _____

Signature of investigator: _____
Name: _____
Date: _____

DOH Research Ethics Committee (DREC)	DREC Ref. No.	DREC12-2013
Approved :	Document	Information & Informed Consent Form
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	From	08 July 2013
	To	09 November 2013
Date :	DREC Approval No.	DREC2013 - 14

H. Consumer Survey Form

Zone: _____

Data collector: _____

Province: _____

Date: _____

Name of drugstore:

Time: _____

- Mercury
- Generic
- Stand alone

Step 1: Introduce self, purpose of interview

Step 2: Ask respondent to sign informed consent form

Step 3: Survey proper

A. Prescription

Question	Response	Precode
1. Do you have a prescription?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. <i>If the patient has a prescription:</i> Is your doctor from a hospital or a clinic?	<input type="checkbox"/> Hospital <input type="checkbox"/> Clinic	
3. public or private?	<input type="checkbox"/> Public <input type="checkbox"/> Private	

B. Drug preferences

Question	Response	Precode		
1. Did you choose a generic or branded drug?	<input type="checkbox"/> Generic <input type="checkbox"/> Branded			
2. Why did you choose the drug/brand that you chose? <i>May check more than one</i>	<input type="checkbox"/> Cheap <input type="checkbox"/> What was prescribed <input type="checkbox"/> Promoted by the pharmacist <input type="checkbox"/> Good quality <input type="checkbox"/> Others: _____			
3. Personally, what do you prefer, generic or branded drug?	<input type="checkbox"/> Generic <input type="checkbox"/> Branded			
4. Why?	<table border="1" style="width: 100%;"> <tr> <td style="width: 50%; vertical-align: top;"> If answer to #3 is generic: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already generic <input type="checkbox"/> Others: _____ </td> <td style="width: 50%; vertical-align: top;"> If answer to #3 is branded: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already branded <input type="checkbox"/> Others: _____ </td> </tr> </table>	If answer to #3 is generic: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already generic <input type="checkbox"/> Others: _____	If answer to #3 is branded: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already branded <input type="checkbox"/> Others: _____	
If answer to #3 is generic: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already generic <input type="checkbox"/> Others: _____	If answer to #3 is branded: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already branded <input type="checkbox"/> Others: _____			
4. Compared to branded medications, do you think generic medications have the same price, higher price or lower price?	<input type="checkbox"/> Same price <input type="checkbox"/> Higher price <input type="checkbox"/> Lower price <input type="checkbox"/> Others: _____			
4. Compared to branded medications, do	<input type="checkbox"/> Similar			

you think generic medications are more effective, less effective, or similar?	<input type="checkbox"/> More effective <input type="checkbox"/> Less effective <input type="checkbox"/> Cannot tell	
5. With prices being equal, would you prefer generics over branded?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
6. Which of the following individuals or groups are you most likely to believe if they say that generics have similar efficacy with branded drugs?	<input type="checkbox"/> Drug companies <input type="checkbox"/> DOH <input type="checkbox"/> Doctors <input type="checkbox"/> Pharmacist <input type="checkbox"/> Commercials <input type="checkbox"/> Friends, relatives, neighbors <input type="checkbox"/> Others: _____	

C. Awareness vs. Practice

Question	Response	Precode		
1. Do you know what generic medicine is?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
2. If yes, what is it? <i>"A drug product that is comparable to a brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use."</i> http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/ucm127615.pdf	Key words used: _____ _____ <input type="checkbox"/> Correct <input type="checkbox"/> Partially correct <input type="checkbox"/> Incorrect			
3. Are doctors required to write the drug's generic name in the prescription?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
4. Are drugstores required to offer you an alternative generic drug?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
5. Are drugstores required to inform you of the prices of generic alternatives?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
6. Did you ask the drugstore for a generic version of this drug?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
7. Why or why not?	<table border="1"> <tr> <td> If answer to #6 is Yes: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already generic <input type="checkbox"/> Others: _____ </td> <td> If answer to #6 is No: <input type="checkbox"/> I didn't know I can <input type="checkbox"/> Low quality <input type="checkbox"/> Expensive <input type="checkbox"/> Others: _____ Proceed to Q#10 </td> </tr> </table>	If answer to #6 is Yes: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already generic <input type="checkbox"/> Others: _____	If answer to #6 is No: <input type="checkbox"/> I didn't know I can <input type="checkbox"/> Low quality <input type="checkbox"/> Expensive <input type="checkbox"/> Others: _____ Proceed to Q#10	
If answer to #6 is Yes: <input type="checkbox"/> Cheaper <input type="checkbox"/> Better quality <input type="checkbox"/> Prescription already generic <input type="checkbox"/> Others: _____	If answer to #6 is No: <input type="checkbox"/> I didn't know I can <input type="checkbox"/> Low quality <input type="checkbox"/> Expensive <input type="checkbox"/> Others: _____ Proceed to Q#10			
8. <i>If yes to no. 6</i> Did you ask the drugstore for the price of the generic version?	<input type="checkbox"/> Yes <input type="checkbox"/> No			
9. Why or why not?	If answer to #8 If answer to #8 is No:			

	is Yes: <input type="checkbox"/> I want cheaper meds <input type="checkbox"/> Others: _____	<input type="checkbox"/> Not interested, I don't want to buy generics <input type="checkbox"/> Didn't know I can <input type="checkbox"/> Others: _____	
10. Did you ask the drugstore for a cheaper version of the drug you needed?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
11. Why or why not?	If answer to #10 is Yes: <input type="checkbox"/> I want cheaper meds <input type="checkbox"/> Others: _____	If answer to #10 is No: <input type="checkbox"/> I only follow what is in the prescription <input type="checkbox"/> Cheaper meds means low quality <input type="checkbox"/> Didn't know I can <input type="checkbox"/> Others: _____	

D. Pharmacy and Prescription

Question	Response	Precode
1. Did the drugstore offer you a generic alternative?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
2. Did the drugstore inform you of the prices of the different generic alternatives?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
3. Did you see a list of generic drugs and their prices in the drugstore that you visited? <i>Check if there is a list of generic drugs inside the drugstore.</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No	
4. <i>If patient has a prescription:</i> Can I get a picture of the prescription?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
5. <i>If patient refuses to have a picture taken, check the prescription for the ff:</i>		
5.a Generic name of drug <i>Please write the name of drug in space provided</i>	<input type="checkbox"/> Yes : _____ <input type="checkbox"/> No	
5.b Brand name of drug <i>Please write the name of drug in space provided</i>	<input type="checkbox"/> Yes: _____ <input type="checkbox"/> No	

Thank you!

I. Focus Group Discussion Guide

Zone: _____

Date and Time of Interview: _____

Facilitator: _____

Recorder: _____

I. Introduction by Moderator

Good morning/afternoon! We are researchers conducting a study on the compliance to the provisions of the Generics Act of 1988. This is a study commissioned by the Philippine Institute for Development Studies. We hope that through this study, we would be able to gain information that would help policy makers improve access of consumers to medications. We would like to ask for your participation in our Focus Focus Group Discussion. In this discussion, we would be asking you questions on your views on generic medications. Participation is completely voluntary. You can leave anytime if during the discussion. We will be recording your responses using a voice recorder and our colleague will be writing down your responses during the discussion on this manila paper. To maintain confidentiality, your name will not appear in any of our documents.

Here are some ground rules for those who wish to participate:

1. There are no right and wrong answers.
2. Speak clearly.
3. Give everyone a chance to answer each question.

II. Guide questions

1. What do you know about the Generics Act of 1988?
2. What is your perception of generic drugs in terms of price? Why do you think generic medicines are cheaper?
3. What is your perception of generic drugs in terms of quality?
4. What do you think are the benefits of buying generic drugs?
5. What are the barriers that consumers like you may encounter when buying generic drugs?
6. What do you do if you encounter such barriers? Why do you choose to do such?
7. Who and/or what do you think can influence you and other consumers to buy generics?
8. Do you have any other recommendations for improvement of the Generics Act?

III. Closing by Moderator

(Give short summary of the discussion following what was written on the manila paper.)

Thank you for your participation! Before we end our discussion, are there any more questions or suggestions that you might want to add? If there are no more additions, please accept these simple tokens as a sign of our appreciation. Have a good day!

J. Key Informant Interview Guide for Physicians (English)

Zone: _____

Date and Time of Interview: _____

Type of practice: _____ Public _____ Private

Location: _____ Hospital _____ Clinic

1. What do you know of the Generics Act of 1988?
2. To your understanding, what does the Generics Act of 1988 require of physicians?
3. What is your opinion on the generic prescribing provision? Why do you/do you not favor it?
4. On a scale of 1-10 with one as Never and 10 as Always, how often do you put the generic name of a drug in your prescriptions? Why do you/do you not prescribe generics that often?
5. What is your perception of generic drugs in terms of price? Why do you think generic medicines are cheaper?
6. What is your perception of generic drugs in terms of quality?
7. What do you think are the benefits of prescribing generics?
8. What are the barriers that physicians like you may encounter when prescribing generic drugs?
9. What do you do if you encounter such barriers? Why do you choose to do such?
10. Who and/or what do you think can influence you and other physicians to prescribe generics?
11. Do you have any other recommendations for improvement of the Generics Act?