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KNOWLEDGE AND PERCEPTIONS OF GENERIC MEDICATIONS AMONG FINAL YEAR DIPLOMA IN PHARMACY STUDENTS IN MALAYSIA: A CROSS-SECTIONAL SURVEY

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Abstract:

Introduction: The Diploma in Pharmacy programme in Malaysia equips students with the essential skills and knowledge to become proficient pharmacy assistants. Exploring their understanding of the knowledge and perceptions of generic medications is crucial for ensuring their readiness to contribute efficiently to healthcare settings. Methods: A cross-sectional survey was conducted using convenient sampling. This survey is designed to assess students' knowledge and perceptions of generic medications. Data was collected via Google Forms from final-year students undergoing hospital training in 13 hospitals across Malaysia. Results: The majority of participants demonstrated adequate knowledge about generic medications, scoring a mean of 3.62 (± 0.537) on a 5-point Likert scale. Seventy percent of the students acknowledged the efficacy of generic medications as comparable to brand-name drugs. Moreover, students expressed confidence in distinguishing between brand-name and generic medicines, with 65.5% indicating perceived knowledge. Overall, students held positive perceptions regarding generic medications, scoring an average of 3.56 (± 0.516) on the Likert scale. Conclusion: Final year Diploma in Pharmacy students in Malaysia exhibit satisfactory knowledge and positive perceptions of generic medications. This

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suggests that the curriculum effectively prepares students to understand and appreciate the existence of generic medication in healthcare settings. However, continuous education and reinforcement of the importance of generic medications could further help in enhancing students' understanding and utilization of generic medications in the future.

Keywords:

Diploma, Generic, Knowledge, Medicine, Perception, Pharmacy

Introduction

Generic medicine refers to a pharmaceutical product closely resembling its branded counterpart in various aspects, including dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use (Rana & Roy, 2015; Seeley & Kanavos, 2008). These medications achieve the same bioequivalence as their brand-name counterparts, thus offering equivalent clinical benefits interchangeable with the originator (Garattini & van de Vooren, 2015). Despite potential differences in names, generic drugs carry similar risks and benefits as their branded counterparts. Differences in absorption rate or extent, if any, are typically insignificant or intentionally designed. In Malaysia, the term "generic" does not encompass Biologics. Instead, according to National Pharmaceutical Regulatory Agency (NPRA), generics are categorized into two groups: Scheduled and Non-scheduled Poison. Scheduled Poison, also referred to as Controlled Medicine/Controlled Poison, includes products containing substances listed in the First Schedule under the Poisons Act 1952. Non-scheduled Poison, also known as Non-Poison or "Over-the-Counter" (OTC), consists of products containing active ingredients not listed in the First Schedule under the Poisons Act 1952, excluding those categorized under health supplements, natural products, or cosmetics. Non-Schedule Poison undergoes evaluation through two methods: Full Evaluation and Abridge (Generic Medicine, n.d.).

Original drug formulations are protected by patents, typically lasting between 10 to 20 years (Clark & Beadle, 2012 ; Berger *et al.*, 2017), varying with the chemical composition. Consequently, once the patent expires, many pharmaceuticals, particularly life-saving ones, are produced and sold as generics. Additionally, generic medicines are less expensive than their brand-name counterparts because they are not required to undergo animal and clinical studies. Brand-name drugs, in contrast, incur significant costs for conducting these studies to demonstrate safety and efficacy.

Understanding the knowledge and perceptions of generic medications among final year diploma in pharmacy students in Malaysia is of paramount importance due to several key factors. Firstly, pharmacy students represent the future healthcare professionals who will be directly involved in dispensing medications and providing guidance to patients. Therefore, their understanding and attitudes towards generic drugs can significantly influence patient education and adherence. Additionally, as Malaysia's healthcare system increasingly relies on generic medications to improve affordability and accessibility, it is crucial for pharmacy students to possess comprehensive knowledge about these drugs to effectively contribute to healthcare delivery. Furthermore, by assessing the perceptions of pharmacy students towards generic medications, insights can be gained into potential barriers or misconceptions that may impact their acceptance and utilization in clinical practice. Hence, studying the knowledge and

perceptions of generic medications among pharmacy students can inform educational strategies and better prepare the readiness of the students at promoting rational prescribing and enhancing patient care, upon entering the job market in Malaysia.

Literature Review

The Original Drug Formulations

Original drug formulations are novel pharmaceutical products developed through extensive research and development (R&D) processes. These formulations address unmet medical needs, improve patient outcomes, and contribute to advancements in medical science. According to Grabowski et al. (2012), original drug formulations often provide breakthrough therapies for diseases with limited treatment options, leading to significant improvements in patient care.

The development of original drug formulations is a multifaceted process that integrates various stages, each crucial for bringing a new therapeutic agent from conception to market availability. This process involves a comprehensive and interdisciplinary approach, as highlighted by Hughes et al. (2011). Initially, researchers embark on target identification and validation, aiming to pinpoint biological targets relevant to the disease of interest. Subsequently, assay development facilitates the screening of compound libraries through high throughput screening, enabling the identification of potential hits with therapeutic potential. These hits undergo lead optimization, a phase focused on enhancing their pharmacological properties and minimizing potential side effects, ultimately culminating in the selection of a candidate molecule for clinical development.

Building upon this foundation, the development journey progresses through preclinical testing and clinical trials, as elucidated by Narayan (2011). Preclinical studies constitute a critical stage wherein the safety and efficacy of the candidate molecule are rigorously assessed using *in vitro* and *in vivo* models. These studies provide essential insights into the pharmacokinetic and pharmacodynamics profiles of the drug candidate, guiding dose selection and formulation optimization for subsequent clinical trials.

Phases Of Clinical Trials

Clinical trials represent the pinnacle of drug development, serving as the final validation of the candidate molecule's therapeutic potential in human subjects. Phases of clinical trials in drugs formulation are generally classified into Phases I to IV (Wright, 2017). These trials, conducted in phases, evaluate the drug's safety, efficacy, and tolerability across diverse patient populations. Phase I trials focus on establishing safety and pharmacokinetic profiles, while Phase II trials delve deeper into efficacy and optimal dosage regimens. Phase III trials involve large-scale patient populations to confirm the drug's efficacy and safety under real-world conditions, paving the way for regulatory approval. Phase IV to simplify is after drug approval (Derhaschnig & Jilma, 2016).

Throughout this intricate process, researchers harness innovative techniques such as high-throughput screening and rational drug design to expedite drug discovery and optimization. Their efforts are underpinned by stringent regulatory oversight to ensure patient safety and adherence to ethical standards. In summation, the development of original drug formulations epitomizes a collaborative endeavour, blending scientific ingenuity with regulatory diligence to deliver transformative therapies for unmet medical needs. Overall, the process of bringing a

new drug from concept to market launch is intricate, spanning an average duration of 12 to 15 years and often exceeding a financial investment of \$1 billion (Hughes et. al, 2011).

Generic Medications

Generic medications are pharmaceutical products that closely resemble their branded counterparts in several key aspects, encompassing dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use (Rana & Roy, 2015; Seeley & Kanavos, 2008). These medications attain the same level of bioequivalence as their brand-name counterparts, thereby providing equivalent clinical benefits and enabling interchangeability with the original product (Garattini & van de Vooren, 2015). Despite potential variations in names, generic drugs carry comparable risks and benefits to their branded counterparts.

Generic Medicines in Malaysia

Generic medicines become available in Malaysia once the patent protection expires, provided they meet the NPRA criteria and guideline (Ling, 2022). The approval hinges significantly on the concepts of bioequivalence, reference product, and therapeutic equivalence. To obtain NPRA approval, pharmaceutical manufacturing entities in Malaysia are mandated to adhere to the provisions outlined in Appendix 5, denoted as the "Guideline on Registration of Generics." This directive is to be comprehensively interpreted alongside the Drug Registration Guidance Document (DRGD), ensuring alignment with the regulatory mandates delineated within the ambit of the Sale of Drugs Act 1952 and the Control of Drugs and Cosmetics Regulations 1984 (Drug registration guidance document, n.d.).

The NPRA mandates that pharmaceutical companies seeking approval for generic medications must demonstrate bioequivalence to the corresponding reference product through comprehensive comparative pharmacokinetic studies. These studies aim to establish that the generic drug exhibits similar rates and extents of absorption in the body as the reference product, ensuring equivalent clinical effects. The reference product serves as the benchmark against which the bioequivalence of the generic medication is assessed, providing a standard for safety and efficacy. Moreover, demonstrating therapeutic equivalence is crucial to ensure that the generic medicine produces the same therapeutic effect as the reference product when administered to patients under the same conditions. Adherence to stringent bioequivalence and therapeutic equivalence criteria is integral to the approval process for generic medicines in Malaysia, as it assures healthcare professionals and patients alike of the quality, safety, and efficacy of these cost-effective treatment options.

Perceptions and Attitudes Towards Generic Medicine

In Malaysia, the utilization of generic medicines is a critical component of the healthcare system, aimed at improving affordability and accessibility of essential medications. However, the perceptions and attitudes of pharmacy students towards generic drugs play a pivotal role in shaping their future prescribing practices and patient counselling behaviours. Research has shown that pharmacy students' attitudes towards generic medications can vary significantly. For example, a study by Lee et al. (2014) found that pharmacy students in Malaysia have mixed perceptions about the efficacy, safety, and comparability of generic medicines, and demand more information on bioequivalence testing. Upon embarking into the working world, it is not surprising to see that this uncertainty is translated into only 37.5% of Malaysian community pharmacists viewed locally manufactured generic medicines as equal in quality compared to

imported generics from international manufacturers (Hassali et al. 2012). In a different study, only 50.2% of Malaysian pharmacists agreed that all approved generic equivalents can be considered therapeutically equivalent with the innovator medicines, and 21% thought that generic medicines were of inferior quality. This trend is also seen elsewhere in the medical field and the world whereby a high proportion of doctors, pharmacists, and lay people hold negative perceptions of generic medicines, with doctors believing they cause more side effects and pharmacists believing they have inferior quality.

Methodology

The research employed a cross-sectional survey design to gauge final-year pharmacy students' knowledge and perspectives on generic medication use in Malaysia. The study was conducted among students enrolled in the Diploma in Pharmacy program at Universiti Teknologi MARA, Cawangan Pulau Pinang, Kampus Bertam. The study employed a purposive sampling technique, determining a sample size of 84 participants based on a 95% confidence level and a 5% margin of error. Data was then collected via a self-administered questionnaire disseminated online, eliciting feedback from 107 participants.

The questionnaire comprised three sections. The first section gathered demographic information, encompassing gender, age, current semester, and location of their respective hospital attachment. In the second section, students responded to questions assessing their knowledge of generic medicines, with 10 items rated on a scale from 1 (strongly disagree) to 5 (strongly agree). Similarly, the third section focused on students' perceptions of generic medicines, with 10 questions also rated on a scale from 1 to 5. The final section, section 4, invited students to provide suggestions for enhancing knowledge and perception of generic medicines through short-answer responses. The calculated mean score was interpreted based on Mcleod's Likert scale interpretations (Mcleod, 2023).

Ethical approval was obtained from the Universiti Teknologi MARA, Cawangan Pulau Pinang Research Ethics Committee (BERC) BERC/5/2023 (UG/MR/178). Participants were informed of the study's purpose, gave consent, and were assured of confidentiality and anonymity.

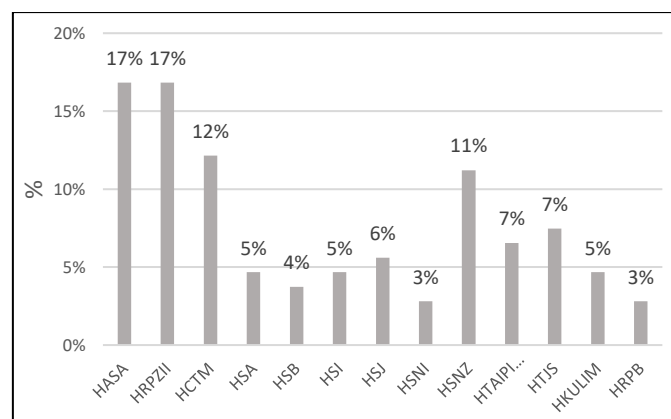
Results and Discussion

In this analysis, it was observed that the number of female respondents exceeded that of male respondents. Specifically, out of the total respondents, 85 students were identified as female, constituting approximately 79% of the survey participants. Conversely, male respondents comprised a smaller portion, with only 22 students, accounting for approximately 21% of the total respondents. Respondents' age is one of the demographic factors considered. There were three age groups among the students who answered the questions. The highest number of respondents, totalling 96 participants and accounting for 90% of the total, were aged 21, making it the majority age group. The age group of 22 had 10 respondents, representing about 9% of the total participants. Conversely, only one respondent fell into the age group of 20, comprising just 1% of the total respondents. The data is in line with the fact that all students are in their semester 6, with females making up the majority. Slight variations for with their age is mostly like dependent on the month of their birthday during which the study was conducted.

Table 1: Demographic of Respondents (n=107)

Demographic	Frequency (n)	Percentage (%)
Gender		
Male	22	20.6
Female	85	79.4
Age		
20	1	0.9
21	96	89.7
22	10	9.4
Semester 6	107	100

In this analysis, the final demographic data pertains to the internship locations of the participating students, encompassing a total of 13 hospitals. These hospitals include Hospital Al-Sultan Abdullah (HASA), Hospital Canselor Tuanku Mukhriz (HCTM), Hospital Kulim (HKULIM), Hospital Raja Permaisuri Bainun (HRPB), Hospital Raja Permaisuri Zainab II (HRPZII), Hospital Sultanah Aminah (HSA), Hospital Sultanah Bahiyah (HSB), Hospital Sultan Ismail (HSI), Hospital Seberang Jaya (HSJ), Hospital Sultanah Nora Ismail (HSNI), Hospital Sultanah Nur Zahirah (HSNZ), Hospital Taiping (HTAIPING), and Hospital Tunku Ja'afar (HTJS).

**Figure 1: The Distribution of Internship Locations Among Participating Students**

Notably, two hospitals, HASA and HRPZII, emerged with the highest number of respondents, each totalling 18 students. These figures correspond to approximately 17% of the total respondents each. Following closely, HCTM recorded the second-highest number of respondents, with 13 students contributing to about 12% of the total respondents. Conversely, two hospitals, namely HRPB and HSNI, had the lowest participation rates, with only three students from each hospital completing the questionnaire. This accounts for merely 3% of the total respondents for each respective hospital.

The distribution of internship locations among participating students is primarily attributed to their selection based on hometown preferences, rather than any deliberate pattern or significance. As students typically opt for internships in hospitals close to their hometowns for convenience and familiarity, the distribution observed in the data reflects this natural tendency rather than any intentional bias. Therefore, while certain hospitals may have higher participation rates, it is important to recognize that these distributions are largely a result of

chance and individual preferences, rather than indicating any particular trend or significance in the context of the study.

The analysis presented in Table 2 below serves as a tool to gauge the perceived knowledge of the respondents regarding generic medications. By examining their responses to a series of 10 statements related to various aspects of generic medicines, such as efficacy, recognition, side effects, affordability, and quality, insights into their understanding and beliefs regarding generic medications are obtained.

Table 2: Analysis Of Students' Knowledge Towards A Generic Medicine

Statement	Strongly Disagree (1) N (%)	Disagree (2) N (%)	Neutral (3) N (%)	Agree (4) N (%)	Strongly Agree (5) N (%)	Mean	Interpretation
Generic medicines have the same efficacy as branded medicines.	2 (1.9)	7 (6.5)	23 (21.5)	35 (32.7)	40 (37.4)	3.99	Positive
Generic medicines are more recognizable compared to original formulations.	4 (3.7)	19 (17.8)	26 (24.3)	36 (33.6)	22 (20.6)	3.50	Positive
Generic medications give bad side effects to the users more than branded medicines.	18 (16.8)	28 (26.2)	41 (38.3)	12 (11.2)	8 (7.5)	2.66	Neutral
Generic names are used widely.	1 (0.9)	14 (13.1)	21 (19.6)	42 (39.3)	29 (27.1)	3.79	Positive
Generic names should be used as the first line name for all medicines.	1 (0.9)	3 (2.8)	35 (32.7)	35 (32.7)	33 (30.8)	3.90	Positive
Pharmacist normally use generic names when dispensing	1 (0.9)	16 (15.0)	28 (26.2)	37 (34.6)	25 (23.4)	3.64	Positive
I can differentiate between generic medication and original drug formulations.	1 (0.9)	5 (4.7)	31 (29)	45 (42.1)	25 (23.4)	3.82	Positive
All original drug formulations have their generic version	5 (4.7)	7 (6.5)	26 (24.3)	31 (29.0)	38 (35.5)	3.84	Positive
Generic medicine has better quality than brand medicines.	5 (4.7)	15 (14.0)	54 (50.5)	21 (19.6)	12 (11.2)	3.19	Neutral
Generic medicines are affordable to Malaysians	4 (3.7)	3 (2.8)	25 (23.4)	41 (38.3)	34 (31.8)	3.92	Positive

A notable finding from Table 2 is from the first statement, whereby there is the strong belief among respondents that generic medicines have the same efficacy as branded medicines. With a total of 70.1% respondent agreeing, this positive perception indicates a level of confidence

in the effectiveness of generic medications, which is crucial for their acceptance and utilization in healthcare settings. It is understandable that this finding shows higher percentage compare to a previous report as patients or common people only shows 53.5%, (Wong et. al, 2014) as pharmacy students would have this knowledge during their study.

Overall, 8 out of 10 statements show positive mean score on perceived knowledge on generic medicine bar two statements, which are the third (Generic medications give bad side effects to the users more than branded medicines) and the ninth (Generic medicine has better quality than brand medicines) statements. In the third statement, the responses are distributed across different categories, with a mean of 2.66 indicating mixed perceptions regarding the incidence of side effects between generic and branded medicines. This suggests that respondents have varying levels of knowledge or uncertainty about the potential side effects associated with generic medications compared to their branded counterparts. The neutral interpretation implies that there is no clear consensus among respondents regarding the safety profile of generic drugs, highlighting the need for further education and awareness on this topic.

Meanwhile for the ninth statement, the responses indicate that while some respondents agree or strongly agree with the statement with a combined percentage of 30.8% indicating a belief in the superior quality of generic drugs, others remained neutral (50.5%), disagree or strongly disagree (combined percentage of 18.7%). This mixed perception suggests that there is no clear consensus among respondents regarding whether generic medicines exhibit better quality than their branded counterparts. The finding is in line with a previous account of 38% of the respondents (who were medical representatives) were also neutral in their opinion that generic medicine is therapeutically equivalent to innovator brand medicine. This highlights the complexity of assessing medication quality and underscores the need for further education and research in this area to clarify misconceptions and ensure accurate understanding among healthcare consumers.

Based on the findings derived from the mean score of 3.62, with a standard deviation of 0.537, among the 107 participants who engaged in this survey, it is evident that the majority of respondents possess a commendable understanding of generic medicines.

The following Table 3 presents a summary of responses from pharmacy students regarding their perceptions and experiences regarding generic medicines. The data collected through a survey includes responses to various statements related to the affordability, recommendation, confusion, confidence, and educational aspects of generic medications.

Table 3: Analysis Of Students' Perception Towards A Generic Medicine

Statement	Strongly Disagree (1) N (%)	Disagree (2) N (%)	Neutral (3) N (%)	Agree (4) N (%)	Strongly Agree (5) N (%)	Mean	Interpretation
Do you agree that generic medicines are cheaper than brand name medicines?	7 (6.5)	6 (5.6)	19 (17.8)	45 (42.1)	30 (28.0)	3.79	Positive
I would suggest patients to use generic medicines over brand name medicines.	1 (0.9)	6 (5.6)	40 (37.4)	38 (35.5)	22 (20.6)	3.69	Positive

I am confused between both generic and brand names.	10 (9.3)	20 (18.7)	37 (34.6)	30 (28.0)	10 (9.3)	3.09	Neutral
I felt wrong for taking brand names over generic medicines.	4 (3.7)	4 (3.7)	18 (16.8)	48 (44.9)	33 (30.8)	2.67	Neutral
Do you have any training on generic medicines as part of your pharmacy education?	0 (0.0)	8 (7.4)	18 (16.8)	10 (9.3)	71 (66.4)	3.95	Positive
Patients need to be educated about brand name medicines.	0 (0.0)	4 (3.7)	18 (16.8)	46 (43.0)	39 (36.4)	4.12	Positive
I feel confident when taking generic medicines over brand name medicines.	5 (4.7)	9 (8.4)	36 (33.6)	42 (39.3)	15 (14.0)	3.50	Positive
It is easier to remember brand name medicines over generic medicines.	1 (0.9)	10 (9.3)	26 (24.3)	37 (34.6)	33 (30.8)	3.85	Positive
Do you agree that generic medicines take a longer treatment time compared to brand name?	9 (8.4)	24 22.4	54 (50.5)	12 (11.2)	8 (7.5)	2.87	Neutral
Do you agree that among pharmacy's students use generic names in their studies?	1 (0.9)	1 (0.9)	25 (23.4)	45 (42.1)	35 (32.7)	4.05	Positive

Overall, the responses reflect a generally positive perception (with 7 out of 10 statements) of generic medicines among the surveyed pharmacy students. The majority of respondents agree or strongly agree (70.1%) that generic medicines are cheaper than brand name medicines, and they would recommend patients to use generic medicines over brand name ones (56.1%). Additionally, majority of the respondents express confidence in taking generic medicines (53.3%) and believe that pharmacy students use generic names in their studies (74.8%).

However, there are areas of ambiguity or mixed perceptions. For instance, some respondents express confusion between generic and brand names with a mean score of 3.09, while others are unsure if they feel wrong for taking brand names over generic medicines (mean, 2.67). Similarly, opinions are divided on whether generic medicines take a longer treatment time compared to brand name ones (mean 2.87).

Based on the analysis of perception data and the mean score of 3.56, with a standard deviation of 0.516, among the 107 respondents who participated in this survey, it is evident that the majority of respondents hold a favourable perception towards generic medicines. The overall finding reflects previous reports i.e. where 60% of doctors, all nursing and pharmacy professionals, and 72% of others accepted that generic medicines are safe as like branded medicines (Gupta et. al) indicating positive view. Another report also supports this as most

doctors believe that generics are therapeutically (59.6%) and safety wise (71.9%) equivalent to branded drugs, and 89.5% believe that generics are cheaper than branded ones (Desai et. al 2017).

Conclusion

In conclusion, the comprehensive analysis of the data pertaining to knowledge and perception of generic medicines among pharmacy students reveals several significant findings. Firstly, there is a commendable level of understanding demonstrated by the respondents, as evidenced by their positive perception towards generic medicines, reflected in the majority of responses indicating agreement with statements regarding the efficacy, affordability, and recommendation of generic medications. Additionally, while some areas of ambiguity and mixed perceptions were identified, such as confusion between generic and brand names, overall, the data suggests a prevailing confidence and trust in the quality and utility of generic drugs. These findings underscore the importance of continued education and awareness initiatives to further enhance understanding and promote the safe and effective utilization of generic medicines among pharmacy students and healthcare professionals alike. In summary, the study achieved its objectives by demonstrating that final-year pharmacy students have a good understanding and generally positive perceptions of generic medications, although some areas for improvement remain. Moving forward, targeted interventions aimed at addressing areas of uncertainty and fostering informed decision-making regarding medication choices are warranted to ensure optimal patient outcomes and healthcare delivery.

Future studies on pharmacy students' knowledge and perceptions of generic medications should consider several key areas. Longitudinal studies can track changes in students' understanding and attitudes over time and after specific educational interventions. Expanding the research to include students from different universities or regions would provide a broader perspective. Evaluating the effectiveness of educational programs, such as workshops and curriculum changes, can help identify the best methods for improving knowledge and perceptions of generic medications. Additionally, investigating how improved student knowledge affects patient outcomes, like adherence to generic medications and treatment satisfaction, would offer practical insights. These studies can lead to better strategies for promoting the use and acceptance of generic medicines in Malaysia.

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