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A Challenge Facing the Malaysian Pharmaceutical Sector: Quality and Affordability of the National Medications

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ABSTRACT

Background: Enhancing public satisfaction of the quality and affordability of medicines is an important task in health services.

Objective: This study was intended to assess the trust and acceptance of public concerning quality and affordability of locally manufactured medicines in Malaysia.

Methodology: A cross sectional study was performed, and a validated Likert scale questionnaire was used in this study. The results were analyzed using the statistical package for social sciences (SPSS) software version 20. A total of 544 questionnaires were collected from three major cities in Malaysia (Kuala Lumpur, Penang and Kota Baru). The respondents aged between 20 and 60 years.

Results: Most of the respondents were satisfied with the quality (65.1%) and affordability (66%) of manufactured medicines in Malaysia. Furthermore, (45%) of respondents in Malaysia prefer locally manufactured medicines. However, there is concern about the escalating prices and hence demonstrates the need for price regulation, as asserted by the majority in Malaysia (88.9%).

Conclusion: Medicine's price control is one of the demands declared by Malaysian public. Moreover, majority of public have an opinion that quality of life, quality of medicines and prices are correlated.

INTRODUCTION

During the past five decades, drug development achieved notable successes. However, no single therapy so far can be prescribed as fully and entirely safe and effective. The patients treated with commercially available drugs are satisfied despite the variable beneficial outcome that relies starkly on the prevailing perception. The actual efficacy depends on the therapy endpoint used and mostly on the patient response and expectation. One of the manifested consequence of this standard practice is the continuous production of a substandard drugs ^[1]; In Thailand, a cross section study revealed the high incidence of substandard drugs in the pharmaceutical market and the financial and medical impacts of their trading on the individual and society ^[2]. About 36.5% medicines out of 96 samples were proved substandard reflecting an obvious shortage of the capacity of the regulatory authorities to control and enforce the GMP standards compliance ^[3]. Another example from the western world was reported in regards to receiving angiotensin converting enzyme (ACE) inhibitors as a treatment for chronic heart failure. The drug was insufficient for 21-36% of the cardiac patients and 40% were forced to discontinue due to angioedema and other health risks ^[4]. The reason was attributed to genetic background where some of the ethnic groups showed more susceptibility to exacerbate a secondary illness rather than healing effect. The magnitude of the problem outweighs the expected predictability of the clinical trials and causes a substantial economic loss due to the withdrawal and second turn of clinical investigations ^[5].

The pharmaceutical sectors globally are pressurized to afford medicines for the estimated ninety pillion population, while simultaneously addressing the quality and safety. In Malaysia, the pressure is increasing as the country new policy, in regards to medical care, is to standardize the existing GMP guidelines, disseminate the medical information and evaluate the pharmaceutical products, implement knowledge transfer when it comes to public service. The implementation of GMP is challenging in terms of how to centralize the patients benefit and overcome the burden between the manufacturers and institutional borders. The policy should review the conflict of interest and reveal the financial ties to pharmaceutical leaders and sponsors and oversight the outcome versus the costs. The total sale of locally manufactured medicines in 2006 in Malaysia was about 272 million USD. 65%-80% of the Malaysian pharmaceutical needs are still imported from Germany, England and France, including the new generation of antibiotic, cholesterol lowering, diabetic, cardiovascular and anticancer medicines ^[6].

To face the challenge, the Malaysian regimen is investing into efficient implementation of GMP and to assure the impact of drug quality are contemplated. Integrated strategies to address these aims are ongoing and the safety factors are revised. However, it is unclear if all the partners/stakeholders within this process benefit equally from the available therapeutics roles and if they are aware about the appropriate indications and possible limitations. One more interesting question, if the access to the entire related information is guaranteed and if the statistical records are actual figures or underestimate. Yet there is no updated studies of how close are the Malaysian practice to the global GMP standards. According to data published in 2012 by ministry of health (MOH), Planning and Development Division, Health Informatics Centre, that in 2011 the total population used the public health facilities was 33,379,603 (Health, 2012).

In the current study, we performed a comprehensive survey aiming at the general promotion of the systematic GMP and the improvement of the health care quality. According to my best knowledge, this is the first kind of study which assessed the opinions of general public on quality and affordability of medicines in Malaysia. The study encourages positive contribution of public in pharmaceutical practices and interaction between regulatory bodies and people. The study declared the importance of pricing system in the country.

METHODOLOGY

The present study was designed to find solutions to the challenges facing the pharmaceutical sectors and consumers of the medicine. This study has been approved by the University of Malaya Medical Ethics Committee, Faculty of Medicine, and Kuala Lumpur, Malaysia.

Reliability Tests for Questionnaire

Questionnaires were distributed and collected from thirty respondents. The data were inserted into Excel sheet and reliability tests were conducted. The reliability test results for questions for respondents show that the Cronbach's Alpha is 0.713 which considered acceptable for the instrument to be reliable. The spearman Rho correlation test for respondents show that most of correlation coefficients are 1.000 indicating strong reliability. The values range from 1.000 to 0.940 which are greater than 0.65 and significant at the level 0.01. Therefore the instrument is reliable.

Questionnaire Validation

Content and face validity was conducted by firstly sending the questionnaires to national pharmaceutical control bureau (NPCB) to comment and obtain feedback since they are the professionals in GMP implementation. Secondly a pilot stuc

done in two stages: first, the copies were distributed personally to three respondents to ascertain their thoughts on the questions and their capability of understanding the questions and answering them; then, it was distributed personally to a larger group of twenty respondents to do the pilot test, and this excluded the workers in the medical field in the case of public [7]. Some of the questions were removed as a result of pilot test.

Questionnaire Design

The questionnaire was designed according to the Likert scale method [8]. These types of scales used for measuring opinions and attitudes [9]. Questionnaire was designed to maintain the flow and consistence of the questions.

Questionnaires were distributed in Malay and English language. Back to back translation was performed to ensure quality of translation and again another person the review the translated version to double check. Therefore, this process enhanced accuracy and quality of translation [10].

Questionnaires Distribution

According to data published in 2012 by MOH, Planning and Development Division, Health Informatics Centre, that in 2011 the total population used the public health facilities was 33,379,603 (Health, 2012).

The sample size was estimated as 385 with confidence level 95% according to equation in OpenEpi site for epidemiologic statistics for public health. Questionnaires were distributed in three main cities in Malaysia: Kuala Lumpur, Penang and Kota Bharu. Kuala Lumpur is the national capital city of Malaysia with the highest population in Malaysia. It is located in the west of the country. Other city is Penang with second highest population in Malaysia and located in the northwest direction of the country. The third city Kota Bharu is located in the north-eastern part. These cities were chosen because they have high number of population, located in different parts of Malaysia and have different ethnic groups. A total of 600 questionnaires were distributed to people in Malaysia out of which 570 were received back while a total of 544 were usable with a response rate of 90.7%.

Data Analysis

SPSS version 20, software was used to analyse the data. Descriptive and analytical analyses were performed.

RESULTS

Table 1 shows the demographic characteristics of the respondents in Malaysia.

Table 1. Demographic characteristics

Characteristics		N (%)
Gender	Male	291(53.5)
	Female	253(46.5)
Age	20-29	362(66.5)
	30-39	98(18.0)
	40-49	60(11.0)
	50-59	24(4.0)
Education level	Post graduated	34(6.3)
	University Graduated	298(54.8)
	Secondary school graduated	195(35.8)
	Primary school graduated	2(0.4)
	Non educated	15(2.8)
Current position	Unemployed	93(17.1)
	Student	112(20.6)
	Professional	124(22.8)
	Support staff	106(19.5)
	Business	105(19.3)
	Retired	4(0.7)
	Labor	

The number of males and females who participated in the study is close to each other; 53.5% are males while 46.5% are females. The majority of the respondents were aged between 20- and 30 years (66.5%) and were university graduates (54.8%).

Table 2 shows the preference of local manufactured medicines for Malaysian. Around 71% of the Malaysian respondents took local manufactured medicines and 48.6% have taken medicines without a doctor's prescription.

Table 2. Preference for local manufactured medicines

Scale items	N (%)			
	Yes	No	Don't know	Not applicable
Do you ever take local manufacturing medicine?	387 (71.1)	55 (10.1)	100 (18.4)	2 (0.4)
If yes, do you take it directly from pharmacy without doctor prescription?	188 (48.6)	199 (51.4)	0	0
Do you prefer the local manufacturing medicines?	245 (45)	201 (36.9)	67 (12.3)	31 (5.7)
Do you take medicines according to the doctor prescription without looking in to the manufacturer?	381 (70.0)	124 (22.8)	28 (5.1)	11 (2.0)
Do you consider the medicine price when you are taking the medicines from the pharmacy?	383 (70.4)	146 (26.8)	9 (1.7)	6 (1.1)
Do you have any case of a problem related to a medicine manufactured inside Malaysia?	14 (2.6)	412 (75.7)	112 (20.6)	6 (1.1)

Only 45% of Malaysian respondents preferred locally manufactured medicines and 36.9% preferred imported ones. The majority (70.4%) also considered the price of the medicines when purchasing from the pharmacy. Only 14 of the respondents (2.6%) in Malaysia were found to have faced problems with locally manufactured medicines as shown in same Table.

Table 3 reveals that the respondents' opinions, regarding the quality and affordability of Malaysian manufactured medicines. In Malaysia (16.9%) strongly agreed and (48.5%) fairly agreed that Malaysian manufactured medicines are meeting the required quality. Majority of respondents in Malaysia have an opinion that Malaysian manufactured medicines have clear labels (18.1% strongly agreed and 48.2% agreed) and strong and safe packaging (15.6% strongly agreed and 43.2% agreed). 13.2% of Malaysian respondents strongly agreed and 52.8% agreed that the prices of Malaysian manufactured medicines are affordable, while only 9.2% disagreed. This was asserted by the results that local manufactured medicines are cheaper than imported ones in Malaysia (23.9% strongly agreed and 43.9% agreed).

Table 3. Opinions of public in Malaysia on locally manufactured medicines.

Scale Items	N (%)				
	Strongly agree	Agree	Don't know	Dis-agree	Strongly disagree
To what extent do you agree that the locally manufacturing drugs have the required quality?	92 (16.9)	264 (48.5)	171 (31.4)	16 (2.9)	1 (0.2)
To what extent do you agree that the locally manufactured medicines labels are clear?	100 (18.4)	262 (48.2)	139 (25.6)	43 (7.9)	0
To what extent do you agree that the local manufacturing medicines have a safe and strong packaging?	85 (15.6)	235 (43.2)	187 (34.4)	37 (6.8)	0
To what extent do you agree that the people are not care about the name of the manufacturer?	142 (26.1)	213 (39.2)	136 (25.0)	45 (8.3)	8 (1.5)
To what extent do you agree that the Malaysian manufactured medicines have affordable price?	72 (13.2)	287 (52.8)	128 (23.5)	50 (9.2)	7 (1.3)
To what extent do you agree that the quality of the drug is related to quality of the life?	134 (24.6)	262 (48.2)	114 (21.0)	30 (5.5)	4(0.7)
To what extent do you agree that the price of medicines is directly proportional to the quality?	197 (36.2)	258 (47.4)	68 (12.5)	16 (2.9)	5 (0.9)
To what extent do you agree that the regulatory body should control the medicines prices?	264 (48.5)	220 (40.4)	53 (9.7)	5 (0.9)	2(0.4)
To what extent do you agree that the local manufactured medicines are cheaper than the imported ones?	130 (23.9)	239 (43.9)	148 (27.2)	24 (4.4)	3(0.6)

As displayed in the same tables' majority (88.9%) of respondents in Malaysia strongly agreed that the price control should be conducted by the regulatory body. In Malaysia, 24.6% strongly agreed and 48.2% agreed that quality of medicines is correlated to price. Higher percentage of respondents in Malaysia strongly agreed (36.2%) and agreed (47.4%) that quality is strongly correlates with the price. Moreover majority of respondents in Malaysia (47.7% strongly agreed and 21% agreed) agreed that quality of the drug is proportional to the quality of life as presented in **Table 3**.

Table 4 shows perception on local medicines among different age groups and gender in Malaysia. There were no significant differences were found between the opinion and perception of local medicine among different age groups and gender, except for the relation between price and the quality of medicine. Females were more likely to agree or strongly agree (86.2%) that the price of medicines is directly proportional to the quality compared to males (81.4%). Where respondents age 40 and above were more likely to agree or strongly agree (89.3%) that the price of medicines is directly proportional to the quality compared to younger participants (82.6%).

Table 4. Comparison on perception on local medicine among different age groups and gender in Malaysia.

Scale items	p-Value (Chi-square test; *Fisher's Exact test)	
	Age group (<40 vs ≥40)	Gender (Male Vs Female)
To what extent do you agree that the Malaysian manufacturing drugs have the required quality?	0.183*	0.886*
To what extent do you agree that the locally manufactured medicines labels are clear?	0.221	0.345
To what extent do you agree that the local manufacturing medicines have a safe and strong packaging?	0.103	0.868
To what extent do you agree that the people are not care about the name of the manufacturer?	0.095	0.163
To what extent do you agree that the Malaysian manufactured medicines have affordable price?	0.137	0.141*
To what extent do you agree that the quality of the drug is related to the quality of the life?	0.607*	0.352*
To what extent do you agree that the price of medicines is directly proportional to the quality?	0.014*	0.047*
To what extent do you agree that the regulatory body should control the medicines prices?	0.133*	0.586*
To what extent do you agree that the local manufactured medicines are cheaper than the imported ones?	0.009*	0.206*

The participants who did not receive university level education preferred to have local medicines (58.5%) while the opposite is true for university graduates (36.4%), $p < 0.001$ (*chi-square* test). In Malaysia 69.4% of participants who did not receive university level education agreed and strongly agreed that local medicines have the required quality, and it is the opposite for the university graduates (62.9%), $p = 0.001$ (*chi-square* test). Most of the participants (70.3%) who did not go to university also agreed and strongly agreed that local medicines are cheaper than imported medicines ($p < 0.001$) (*chi-square* test).

DISCUSSION

The rising demand of a reasonable health care witnessed a great attention to the pharmaceuticals industry in Malaysia and worldwide. The society attaches the medicines expenditure to the better health. Malaysia launched the first GMP Act in 1952, which focused on the visibility of the GMP compliance and licensing provisions, and the feasibility of inspection of manufacturing facilities; it culminated in a compact and critical review of the various approaches. The last edited versions, dated 1989 and 2009, ensured how the pharmaceuticals will continue to benefit the society, taking into consideration the means to implement critical control concerning standardization, organization and innovation.

In 1985, the NPCB was given the task to ensure the quality, efficacy and safety of pharmaceuticals through the registration and licensing scheme ^[11]. In 1996, the NPCB was given international recognition by the WHO as a WHO collaborating centre for regulatory control of pharmaceuticals. Furthermore, it is a member of the pharmaceutical inspection cooperation scheme, PIC/S since 2002.

The NPCB introduced the drug control authority (DCA) as an executive body established under the control of drugs and cosmetics regulations 1984. The main task of the DCA is to ensure the safety, quality and efficacy of pharmaceuticals by making GMP compulsory for all levels of pharmaceutical manufacturing through the implementation of drug regulations ^[12].

The generic pharmaceutical industry supports the economy of the country and helps the public in attaining essential and vital medicines ^[13,14]. This indicates poor availability of generic medicines in public facilities, which, consequently, would increase the financial burden of Malaysian citizens, as they have to use the innovator brand, which, according to the results of the same study, costs 2.4 times higher in the Malaysian public sector and 16 times higher in the private pharmacies.

Particularly in Malaysia and although the general public is the main consumer of medicines produced in the pharmaceutical industry, there is scarce attention to their opinions. Thus to find out if the participants approve directly or indirectly the usage condition and handling consent of the pharmaceutical products, we investigate their perception of the national versus imported products, the pricing versus the affordability. It was observed that most of the people in Malaysia 65.4% were satisfied with the quality of locally manufactured medicines. Only low percentage of the public (2.6%) had faced problems related to locally manufactured medicines. Surprisingly preference for locally manufactured medicines in Malaysia 45% slightly higher than for the imported medicines (37%). Moreover the results from this study affirm that most people in Malaysia agreed that local manufactured medicines have the required packaging quality. Then the answer to our question if the guidelines fairly simplified to meet the participants background was unexpected as the majority of respondents in Malaysia 70% did not care about the name of the manufacturer upon taking their doctor's prescription. This probably because they trust the doctor, pharmacist and the medicine quality regardless of the manufacturer name. This perception also will enhance the use of generic medicine ^[15].

Pharmaceuticals are inevitable elements to human kind and primary tools to restore our health, nevertheless the quality

standards are still rigorous and it calls for a major public health concern. Poor quality such as substandard production, intoxication and counterfeiting are a ticking alarm to seek better understanding of the key factors in the process in terms of specific practice prohibitions, restricted activities and financial disclosure. To address the question whether higher medicines prices prohibited public from attaining their needs ^[146], we asked the participants of their experience and expectations regarding the drug prescriptions, manipulation and storage. It is believed that the variation in cost is a result of the variety of quality grades, which may be due to the broad concept of the selected standards ^[147], in which the highest grade has the highest quality, cost and price and that the GMP implementation cost which is evaluated to be 25% of the total manufacturing process expenditures ^[148]. Results from this study show that the majority of the Malaysian general public have taken local manufactured medicines. Taking medicines without doctor consultation is not recommended, but it indicates the trust in the local medicines by Malaysians. Majority of Malaysian respondents (70.4%) consider the medicine price. The results displayed a higher percentage of public's acceptance of the affordability of Malaysian medicines compared with the imported medicines. Although majority of respondents has perception that quality is strongly correlates to the price and quality of life, this does not influence their positive opinion about locally manufactured medicines. Results from this study demonstrate that we cannot separate good manufacturing practice from manufacturing costs and consequently price of medicines.

A previous study was carried out to assess the availability of medicines in Malaysia; the findings showed that merely 25% of generic medicines are available in the public sector ^[144]. Another study emphasized that the authorities agreed that the quality assurance is tightly linked to the pharmacodynamics and pharmacokinetics and by the public it was the sole condition to fully accept the product and take it into the practice and marketing ^[149]. In response to the critical need for new update on the criteria of efficacy, safety and quality, it was sensible to evaluate the tools operating and if it meets the high professional standards to effectively enforce that the production of pharmaceutical entities are moving within the international commerce. It seems that the infrastructures are devoted to ensure sufficient and effective production and that the country policy is supporting the local manufacturer.

Public satisfaction does not give an accurate and scientific status of the quality but it is rather an indicator to monitor and revise policies based on the analysis of people's opinion. The system could be unique in the way it afford direct interaction with the public and be committed to make changes for a better life and health.

CONCLUSION

The survey outcome showed a positive trend that the pharmaceutical practices in Malaysia satisfy the public throughout the affordable high quality medicines. Furthermore, the study found that the product brand name does not influence the acceptance of use, although there is a perception that medicine quality is directly proportional to the price. Consequently, this supports the use of generic medicines in developing countries. In particular, medicine prices are increasing in Malaysia, which decreases the affordability of medicines, especially for poor people. Hence, a pricing system needs to be implemented and controlled by the regulatory body in Malaysia.

There was an evident shortage of the primary education on the pharmaceutical products and the interaction between the regulatory authorities and the public was not appropriate except those with the professional and medical staff where clear guidance was provided. Therefore, it is recommended to free pharmaceutical production from any possible empiricism and move it towards a multi-partner and stakeholder-tailored venture. A new initiative would be to develop a channel to announce the validation of old and new products and provide the tools to agree contribute and comment on the public response.

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