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Community pharmacist's perceptions towards the quality of locally manufactured generic medicines: A descriptive study from Malaysia

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ABSTRACT

This study aimed to explore the perceptions of Malaysian community pharmacist towards locally manufactured generic medicines. A cross-sectional descriptive study involving entire population (N = 270) of Practicing community pharmacists in the State of Penang, Malaysia was undertaken using a self-completed anonymous mail questionnaire. Responses were received from 48 pharmacists (response rate 17.8%). Majority of the respondents (97.9%) actively dispensed generic medicines in their practice. Only 37.5% of the respondents viewed locally manufactured generic medicines as equal in quality compared to the imported generics from international manufacturers. However, approximately 60% of the respondents agreed that domestic generics are equal in safety and efficacy as the imported generic medicines. About half of the respondents (47.9%) believed that imported generic products need to pass more stringent approval process. Majority of the respondents (68.8%) urged that the Malaysian regulatory authorities should convince pharmacists about the quality of domestic generic medicines. The Malaysian pharmacists have lack of confidence with the generic medicines produced by local pharmaceutical companies.

Keywords: Generic medicines, community pharmacist, perception, knowledge, local pharmaceutical companies.

INTRODUCTION

In the recent years, the utilization of generic medicines has increased steadily around the globe as a consequence of economic pressure on drug budgets (Allenet and Barry, 2003; Andersson *et al.*, 2007; King and Kanavos, 2002; Suh, 1999). A generic medicine refers to a pharmaceutical product, usually intended to be interchangeable with the innovator product and marketed after the expiry of patent or other exclusivity rights (WHO, 1997). Although generic drugs are chemically identical to their branded counterparts, they are cheaper than their original branded equivalents. When medicines are no longer protected by the patents, the intense competition among generic manufacturers resulted in the relatively low price of generic medicines (Lofgren, 2004; McGavock, 2001). As generic companies incur fewer costs in creating the generic products, they are able to maintain their profit while charging lower price to consumers (Kirking and Ascione, 2001). The price differential between generic and innovator medicines could range from 10% to 90% (Karim *et al.*, 1996; King *et al.*, 2002). In Malaysia, consumers can save up to 60% if they opt for generics (Chong *et al.*, 2011).

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Although cost is the main driver for generic medicine use, pharmacist's role in generic medicine selection is multifaceted (Mott and Cline, 2002). It includes the selection of a bioequivalent medicine, educating patients on issues relating to generic substitutions such as compliance with therapy and avoidance of potential confusion that may arise due to changes in brands of same medication. Besides, they also provide information about the quality and safety of generic medicines to both the consumers and healthcare providers (Kirking *et al.*, 2001). In Malaysia, there are many generic drugs manufacturing companies which manufacture wide range of both over the counter and prescription products. Although the pressure of containing consumers' expenditures may lead pharmacists to concentrate on medicines prices when performing product selection, a more comprehensive evaluation is needed when selecting the products as there are high proliferations of different generic brands in the market. Consumers tend to use generic medicines if they received reassurance from the pharmacists about the quality of the products (Gossell-Williams and Harriott, 2007; Hassali *et al.*, 2005; Kjoenniksen and Lindbaek, 2006). Within this context, pharmacists must have good understanding about generic medicines in order for them to proficiently guide the consumers in the selection of generic pharmaceutical products (Raynu and Agnes, 2009).

Studies from various countries indicates that pharmacists are generally in favour of generic substitution and view generic medicines as being efficacious and safe (Al-Gedadi and Hassali, 2008; Allenet *et al.*, 2003; Chong *et al.*, 2010; Kirking *et al.*, 2001). However, a recent study found that the Malaysian community pharmacists may have particularly lack of confidence with the generic medicines produced by local pharmaceutical companies (Chong *et al.*, 2011). This in return may affect the community pharmacists' support towards domestic generics which generally priced lower than the generics from global pharmaceutical companies. Nevertheless, further investigation is needed to assess about this issue, including factors contributing to the negative views about local generic products. Understanding perceptions held by community pharmacists regarding domestic generic medicines are very important in establishing a sound generic medicine policy in Malaysia (MOH, 2007). Therefore, this study aimed to explore Malaysian community pharmacists' perceptions of locally manufactured generic pharmaceutical products including issues around quality, safety, efficacy and factors influencing the pharmacists' choice of generic medicines.

METHODS

This was a cross-sectional descriptive study using data obtained from a self-completed anonymous questionnaire. The questionnaire was tested for face and content validity by two experts. It was further revised after pilot testing with ten community pharmacists. There are three sections in the questionnaire. The first section is to characterize the respondent demographics. The following section evaluates the trends in generic medicines dispensing and stocking among the community pharmacists. In this section, a question was set to assess whether

the pharmacists actively dispense generic medicines in their practice. Besides, a list of generic medicines manufacturers was developed based on findings from a previous study (Chong and Hassali, *et al.*, 2011) and the pharmacists were asked to identify the companies which they obtained their generic medicines supply. The third section contains ten questions exploring pharmacists' perceptions of locally manufactured generic medicines, including issues around quality, efficacy, safety and factors which influence them to stock the domestic generic products. The responses were framed as a five-point Likert scale (1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree and 5 = strongly disagree).

The entire population (N = 270) of Practicing community pharmacists in the State of Penang, Malaysia was invited to participate in this survey. An invitation letter along with the questionnaire and a prepaid return envelop were sent to the respondents. A week later, a reminder letter was sent to all non-respondents in order to improve the response rate. The participation of pharmacists approached was strictly voluntary. The informed consents of the participants were obtained and no personal data of the participants were reported. Data were collected from 1st July 2010 to 31st July 2010. All the collected data were entered into SPSS® 16.0 for descriptive analysis using frequency and cross-tabulation.

RESULTS

Demographic characteristics of responding pharmacists

A total of 48 responses were received with a response rate of 17.8% as described in table 1. The majority of the respondents were female (56.2%) and aged between 30 to 40 years (60.4%). The respondents mostly graduated from local universities (77.1%).

Table 1: Demographic characteristics of the respondents.

<i>Characteristic</i>	<i>N (%)</i>
<i>Gender</i>	
Male	21 (43.8)
Female	27 (56.2)
<i>Age group (years)</i>	
< 30	6 (12.5)
30 – 40	29 (60.4)
41 – 50	11 (22.9)
> 50	2 (4.2)
<i>Year of graduation</i>	
< 1980	4 (8.3)
1981 – 1990	9 (18.8)
1991 – 2000	20 (43.8)
> 2001	14 (29.2)
<i>Year of practice in community pharmacy</i>	
< 10	26 (54.2)
11 – 20	19 (39.6)
21 – 30	2 (4.2)
Missing data	1 (2.1)
<i>Country of graduation</i>	
Malaysia	37 (77.1)
Overseas	9 (18.7)
Missing data	2 (4.2)

Trends in generic medicines dispensing and stocking

Nearly all of the responding pharmacists (97.9%) indicated that they actively dispense generic medicines in their practice. When assessing the pharmacists' trend in generic medicines stocking, most of the respondents (93.8%) purchase their generic products from Yung Shin Pharmaceutical (Y.S.P.) Industries Ptd Ltd, a local generic pharmaceutical company (Table 2). Another three popular generic pharmaceutical companies among the respondents were Apotex Inc. (89.6%), CCM Pharmaceutical Ptd Ltd (89.6%) and Hovid Pharmaceutical Ltd (89.6%). In contrast, the respondents were less likely to stock the generic products from Cipla Pharmaceutical Ltd (58.3%) and Sandoz (29.2%).

Table 2: Pharmaceutical companies that the pharmacists choose to obtain their generic medicines supply.

Pharmaceutical company (country of origin)	N (%) ^a
Yung Shin Pharmaceutical (Y.S.P.) Industries Ptd Ltd (Local)	45 (93.8)
Apotex Inc. (Canada)	43 (89.6)
CCM Pharmaceutical Ptd Ltd (Local)	43 (89.6)
Hovid Pharmaceutical Ltd (Local)	43 (89.6)
Cipla Pharmaceutical Ltd (India)	28 (58.3)
Sandoz (Germany)	14 (29.2)
Others	12 (25.0)

The respondents can choose more than one answer

Community pharmacists' perceptions of locally manufactured generic medicines

When assessing the pharmacists' views on domestic generic medicines, only 37.5% of the respondents agreed that local generics are equal in quality as compared to the imported generic products (Table 3). Further analysis found that 58.4% of the pharmacists perceived local generics as equal in safety and efficacy as the imported products. The respondents mostly agreed that the manufacturers of local generic products have a reliable logistic supply system (72.9%). The pharmacists were further evaluated on the factors that influence their generic medicines stocking practice. Half of the respondents preferred to stock and dispense domestic generics if the companies provide good bonuses. However, majority of the respondents (85.5%) were concerned about credibility of generic suppliers when stocking medicines. About four in ten of the responding pharmacists would stock only locally manufactured generics which is well advertised. Interestingly, approximately half of the respondents (47.9%) thought that imported generics need to pass more stringent approval process. Most of the respondents (66.6%) agreed that domestic generics are cheaper than the imported products. The pharmacists predominantly agreed with the establishment of brand substitution policy in Malaysia (73.0%) and urged that the Malaysia regulatory authorities should convince the pharmacists about the quality of locally produced generic medicines (68.8%).

Table 3: Community pharmacists' views on issues around locally manufactured generic medicines.

Question	Survey questions/Statement	Frequency (%)					Did not answered
		1	2	3	4	5	
1	Locally manufactured generics are equal in their quality compared to the imported generics.	2 (4.2)	16 (33.3)	19 (39.6)	9 (18.8)	2 (4.2)	0 (0.0)
2	Locally manufactured generics are equal in their safety and efficacy compared to the imported generic.	2 (4.2)	26 (54.2)	17 (35.4)	3 (6.2)	0 (0.0)	0 (0.0)
3	Manufacturers of local generic products have a reliable logistic and supply system.	4 (8.3)	31 (64.6)	10 (20.8)	2 (4.2)	0 (0.0)	0 (0.0)
4	I prefer to stock and dispense locally manufactured generics because the companies provide good bonus scheme compared to suppliers importing them.	2 (4.2)	22 (45.8)	10 (20.8)	12 (25.0)	1 (2.1)	1 (2.1)
5	Credibility of the generic manufactures / suppliers are my concern when stocking medicines in my pharmacy.	20 (41.7)	21 (43.8)	5 (10.4)	1 (2.1)	1 (2.1)	0 (0.0)
6	I will only stock locally manufactured product which is well advertised through medical representatives and medicine related references.	3 (6.2)	16 (33.3)	11 (22.9)	17 (35.4)	1 (2.1)	0 (0.0)
7	Imported generics need to pass more stringent approval process compared with locally manufactured ones.	4 (8.3)	19 (39.6)	13 (27.1)	10 (20.8)	2 (4.2)	0 (0.0)
8	Locally manufactured generics are cheaper compared to imported generics.	10 (20.8)	22 (45.8)	6 (12.5)	8 (16.7)	2 (4.2)	0 (0.0)
9	I believe we need to establish brand substitution policy in Malaysia.	9 (18.8)	26 (54.2)	12 (25.0)	1 (2.1)	0 (0.0)	0 (0.0)
10	The Malaysian regulatory authorities need to convince pharmacists that registered locally manufactured generics are of high quality and standards.	9 (18.8)	24 (50.0)	11 (22.9)	2 (4.2)	1 (2.1)	1 (2.1)

1= strongly agree, 2= agree, 3 = neutral, 4 = disagree and 5 = strongly disagree.

DISCUSSION

Implementing generic medicines and substitution policy is one of the future plans of Malaysian Government to improve the medicines affordability among the nations (Chong *et al.*, 2010; MOH, 2007). This study revealed that majority of the Malaysian community pharmacists supported generic substitution policy implementation and they are actively promoting generics in their current practice. These findings are consistent with data from other countries where pharmacists are generally in favour to generic medicines (Al-Gedadi and Hassali, 2008; Allenet, *et al.*, 2003; Chong *et al.*, 2011; Eriko *et al.*, 2011; Suh, 1999).

Specific obstacle to generic medicines utilization was observed among the responding Malaysian pharmacists in relation to their negative views on domestic generics. High proportion of pharmacists was doubt about the quality, efficacy and safety of locally produced generic medicines. These pharmacists believed that the imported generics need to pass more astringent approval process. These results suggested that pharmacists may have a lack of information and/or understanding about generic manufacturing and approval system in Malaysia. In fact, the Malaysian Drug Control Authority (DCA) strictly regulates the registration and production of pharmaceutical products to ensure their quality, efficacy and safety (Hassali *et al.*, 2009; MOH, 2000). Good Manufacturing Practice (GMP) requirements, guidelines for pharmaceutical development, conduct of stability as well as bioequivalent studies and the content of Common Technical Document for regulatory submission are adopted from competent regulatory agencies in the European Union, the USA as well as the International Conference on Harmonisation (ICH) (Hassali *et al.*, 2009; MOH, 2000). The same quality control criteria are applied to both domestic generics and imported generic medicines from international manufacturers. Despite negative perceptions of domestic generics, the responding pharmacists demonstrated high tendency of choosing local generic pharmaceutical companies as their sources of generic medicines supply (Table 2). This reflects that there might be a gap between pharmacists' views on domestic generics and their real generic stocking practices. In this study, credibility of the generic manufacturers, reliable supply system and good bonus scheme found to be the main reasons for pharmacists to stock the domestic products. Studies from USA found similar trend where manufacturers' reputation, supplier consistency and unit price of the generic products were among the major criteria that influence pharmacists' decisions to stock generic pharmaceuticals in pharmacies (Kirking *et al.*, 2001; Segal *et al.*, 1989). In the context of promoting generic medicines utilization, pharmacists must have a sound knowledge about generics. The misconceptions about domestic generics as revealed in the present study may affect pharmacists' role in facilitating both physician and patient's choice of generic medicines. Hence, interventions are needed to improve the Malaysian pharmacists' understanding about generic medicines. The pharmacy curricula may need to be enhanced in the areas of generic medicines, especially the regulatory, quality control and bioequivalent requirements applied to the registration and production of generic medicines in

Malaysia. Additionally, continuing pharmacy education for Practicing pharmacists needs to be strengthened to correct any negative views about domestic generic medicines. The Malaysian Government can consider adopting educational strategies used by countries with generic medicines policy to improve the pharmacists' knowledge of generis. For instance, in Australia, the community pharmacists frequently received educations and guidelines on generic medicines through newsletters, webpage and campaigns organized by the National Prescribing Service and the Pharmaceutical Society of Australia (NPS, 2006, 2007a, 2007b, 2008a, 2008b, 2009). These educational activities are intent to develop pharmacists' competency in facilitating both the prescriber and consumer about appropriate use of generic medicines.

Apart from education interventions, establishing a national formulary of interchangeable medicines would help in removing the pharmacists' doubt about the quality of domestic generics. The Malaysian Government needs to develop a formulary which includes all the marketed innovator medicines and its interchangeable bioequivalent generic brands. In countries with generic medicines policy in place, such formulary acts as an important tool to guide the pharmacists in the selection of generic products which demonstrated to be therapeutically equivalent with the innovator brands (ADHA, 2009; USFDA, 2009). The "Schedule of Pharmaceutical Benefits Scheme (PBS)" established by the Australian Government (ADHA, 2009) and the "Approval Drug Products with Therapeutic Equivalence Evaluation (Orange Book)" developed by US FDA (USFDA, 2009) are good examples of formulary of interchangeable medicines. A previous survey in Australia confirmed the influence of such formulary as majority of the pharmacists were confident in substituting generics for innovator medicines whenever permitted by the Schedule of PBS (Chong *et al.*, 2010).

STUDY LIMITATIONS

This study has limitation where the low response rate in this survey may lead to non-responder bias. The responding pharmacists may have more positive attitudes towards generic medicines and this in return may reduce the validity of the study results. Further, the ability to generalize the findings to Malaysian community pharmacists is somewhat limited as this survey only conducted among pharmacists in the state of Penang, Malaysia. However, this survey can serve as a preliminary study and is valuable in providing insights into perceptions of Malaysian pharmacists on issues around locally manufactured generic medicines.

SUGGESTIONS FOR FUTURE STUDY

A nationwide survey should be conducted to obtain a clearer picture on Malaysian community pharmacists' views on locally produced generic medicines. Further, a qualitative interview is needed to research in depth about the reasons behind the pharmacists' lack of confident with the domestic generic medicines.

CONCLUSIONS

Although it appears that the responding Malaysian pharmacists have largely accepted the use of generic medicines, they still have concerns and misleading about the reliability and quality of domestic generic products. Pharmacists need to be educated and reassured about generic manufacturing and approval system in Malaysia concerning quality, efficacy and safety.

CONFLICT OF INTEREST

All the authors have no conflict of interest in connection with this paper. The present study did not receive any funding or fees from any organization.

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