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Original Article

Generic industry's perceptions of generic medicines policies and practices in Malaysia

Omotayo Fatokun [a,b,*], *Mohamed Izham Mohamed Ibrahim* [c], *Mohamed Azmi Ahmad Hassali* [a]

[a] *Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, 11800 Penang, Malaysia*

[b] *Faculty of Pharmaceutical Sciences, UCSI University, Kuala Lumpur, Malaysia*

[c] *College of Pharmacy, Qatar University, Doha, Qatar*

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ABSTRACT

Objectives: Post-patent entry of generic medicines has been shown to reduce overall drug expenditure and increase access to medicines. However, the implementation of pro-generic policies and practices are needed to create incentives for generic medicines production by the generic industry. This study assesses the views of the Malaysian generic drug manufacturers on existing policies and generic demand-sides practices in Malaysia.

Methods: Data was gathered by using a mail survey approach. The questionnaire was mailed to all the members ($N = 26$) of the Malaysian Organization of Pharmaceutical Industries (MOPI) licensed to manufacture prescription medicines in Malaysia.

Results: Usable response rate was 53.8% following four successive mailings. Majority of the respondents (64.3%) were dissatisfied with generic prescribing in Malaysia, while majority of the respondents (57.1%) were satisfied with generic dispensing. Fifty-percent of the respondents were dissatisfied with generic public awareness and equal proportions (21.4%) were either very dissatisfied or unsure. A majority of the respondents (69.2%) were dissatisfied with generic medicines education and information to healthcare professionals in Malaysia. The relationship between respondents' perceived level of generic public awareness and generic prescribing was positive and significant ($r_s = 0.59$, $p = 0.03$). Government policies and regulations were perceived to be fairly effective in promoting generic medicines in Malaysia by 42.9% and 35.7% of the respondents respectively. A positive and significant relationship was observed between respondents' scores on government policies and regulations ($r_s = 0.55$, $p = 0.04$).

Conclusions: Overall, the generic industry perceived generic dispensing in Malaysia to be somewhat satisfactory. However, generic prescribing, generic public awareness and education of healthcare professionals on generics need to be enhanced to foster generic uptake in Malaysia. The generic industry expressed ambiguous perceptions on effectiveness of government policies and regulations in promoting generic medicines in Malaysia.

* *Corresponding author*. Discipline of Social and Administrative Pharmacy, School of Pharmaceutical Sciences, Universiti Sains Malaysia, 11800 Penang, Malaysia. Tel.: +60 176442807.
E-mail address: tayofatokun@gmail.com (O. Fatokun).

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1. Introduction

The entry and availability of generic medicines following patent expiration on innovator products have been associated with increased drug accessibility and remarkable healthcare cost savings in several countries.[1] However, to ensure a continuous supply and availability of generic medicines, there must be in place enabling policies and complimentary demand-side practices of generic prescribing, generic dispensing and generic awareness.[2] These measures foster the uptake of generic medicines and thus create a conductive market environment for an efficient production of generic medicines.

Policies and practices related to generic medicines are highly diverse in nature with various policy measures implemented to meet the overall objectives of drug affordability and accessibility, including promoting the domestic industry.[3,4] These policy measures are generally classified into supply-side and demand-side policies. However, both policy sides are complementary and the optimal mix of the two ensure the availability and increased utilization of generic medicines, which in turn promote competition in the pharmaceutical market and a potential reduction in drug costs.[1,5] On the supply side, generic medicines policies include regulations that assure the efficacy, safety and quality of generic medicines; and regulatory measures that facilitate market entry of generic medicines such as simplified registration procedures and differential registration fees. Others include pharmaceutical pricing policies and the implementation of regulatory exception or "Bolar provision" that allows the development of generic medicines while the innovator's product is still under patents, so that generic equivalent can enter the market as soon as the innovator's product patent expires.[1,2] The demand-side policies largely focus on measures that encourage generic prescription, generic dispensing, generic awareness and generic consumption.[1,2]

In Malaysia, the government has long embraced the promotion of generic medicines usage in order to ensure drug affordability and containment of pharmaceutical expenditure, particularly with the launch of the national essential drugs list (NEDL) in 2000 and the publication of the Malaysia national medicines policy in 2007.[6] Section 3.2 of the Malaysian national medicines policy under generic medicines policy aimed to encourage generic production, generic prescribing, generic dispensing, generic substitution and generic use in Malaysia.[6] Another regulatory measure related to generic medicines is the incorporation of the regulatory exception provision in the Malaysian patent law, a provision that can potentially facilitate the early entry of generic medicines after patent expiration.[7] Although these measures have improved the outlook of the Malaysian generic medicines industry, there remain some challenges especially with respect to dominance of branded innovator products in the Malaysian pharmaceutical market.[8,9]

While several studies that have examined the views of prescribers, pharmacists and consumers on issues related generic medicines policies and practices in Malaysia and elsewhere,[4] studies examining the views of generic medicines producers are yet to be reported in Malaysia and are generally scanty elswhere.[10] Therefore, the overall aim of this study is to provide the views of the Malaysian generic industry "insiders" on generic medicines policies and practices in Malaysia, given that similar studies have not been carried out in Malaysia. Specifically, the objective of this paper, a part of a larger study aimed to explore the perceptions of the Malaysian generic manufacturers on the effectiveness of policies and regulations in promoting generic drugs in a Malaysia, and their level of satisfaction with generic dispensing, prescription and awareness in Malaysia.

2. Methods

This was a cross-sectional descriptive national study using data obtained from a mailed self-completed anonymous questionnaire. The questionnaire was tested for face and content validity by two faculty members with expertise in survey research and in-depth knowledge of the Malaysian generic medicines industry. The final questionnaire was further evaluated by two generic drug manufacturers for content and clarity. The questionnaire contains three sections of five-point single-item Likert scale responses that examined the study's objectives.[11] The first section assesses respondent's views on the effectiveness of the regulatory exception provision in the Malaysian patent law in facilitating early market entry of new generic medicines. The second section assesses respondent's views on the effectiveness of government policies and regulations in promoting generic medicines in Malaysia. The third section assesses respondent's level of satisfaction regarding the level of generic prescribing; generic dispensing; generic public awareness; and generics education and information to healthcare professionals in Malaysia. A final section contains questions on respondent's engagement in generic manufacturing and the market sector of generic sales.

The questionnaire along with a cover letter and a prepaid return envelope was mailed to the entire members ($N = 26$) of the Malaysian Organization of Pharmaceutical Industries (MOPI) licensed to manufacture prescription medicines in Malaysia. MOPI is the national official representative body of generic drugs manufacturing firms in Malaysia. The chief executive officers or managing directors of all the generics firms were the target audiences of the questionnaire. Non-responders were again mailed the questionnaire materials after the initial mailing three times over three months. Follow-up telephone calls were made to non-responders in two successive months following the last reminder mailing. The entire data collection period was from January 2010 to December 2010. All data collected were entered into SPSS 20.0 for analysis.

3. Results

Out of the 26 questionnaires mailed to all potential respondents, a total 17 firms returned the questionnaire, giving an overall response rate of 65.4% (17/26). However, three of the respondents indicated that they do not manufacture