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## Original Article

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

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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.

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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.<sup>1</sup> 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.<sup>2</sup> These measures foster the uptake of generic medicines and thus create a conducive 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.<sup>3,4</sup> 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.<sup>1,5</sup> 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.<sup>1,2</sup> The demand-side policies largely focus on measures that encourage generic prescription, generic dispensing, generic awareness and generic consumption.<sup>1,2</sup>

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.<sup>6</sup> 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.<sup>6</sup> 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.<sup>7</sup> 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.<sup>8,9</sup>

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,<sup>4</sup> studies examining the views of generic medicines producers are yet to be reported in Malaysia and are generally

scanty elsewhere.<sup>10</sup> 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.

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## 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.<sup>11</sup> 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.

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## 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

prescription generic medicines and therefore excluded for further analysis. Thus, a usable response rate of 53.8% (14/26) was achieved following four successive questionnaire mailings. The non-responders that were reachable on telephone follow-ups indicated that they were either “busy” or “do not engage in surveys”.

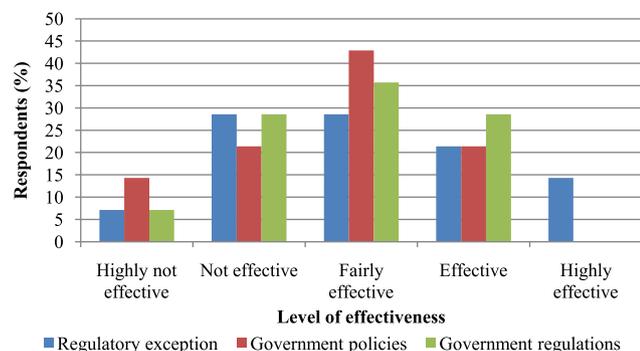
Potential non-response bias to the survey was investigated using response wave analysis, by comparing early responders with late responders on the study key variables.<sup>12,13</sup> The result indicated there was no significant difference between the early and late responders for any of the variables under investigation. Thus suggesting that non-response bias is unlikely to have a significant effect on the study findings.<sup>12,13</sup> The reliability of the questionnaire responses was established on the basis of their predictive validity, given the sample size of the study.<sup>14,15</sup>

### 3.1. Characteristics of surveyed respondents

Majority of the respondents (78.6%,  $n = 11$ ) are focused mainly on the Malaysian domestic pharmaceutical market for their generic sales, while only two (14.3%) are focused mainly on export markets. Almost all of the respondents (92.9%,  $n = 13$ ) have been manufacturing generic medicines in Malaysia for more than 10 years. One respondent did not respond to these two variables.

### 3.2. Effectiveness of the regulatory exception provision in promoting early post-patent entry of generic medicines

The perception of the generic firms on the effectiveness of the regulatory exception provision in promoting early entry of generic medicines in Malaysia was examined descriptively [Fig. 1]. Equal proportions of respondents (28.6%) indicated that the provision is either not effective or fairly effective; while lower proportions of the respondents indicated that the provision is either effective (21.4%) or highly effective (14.3%). In sum, the results indicated the respondents have an unclear view of the regulatory exception provision in promoting early entry of generic medicines.



**Fig. 1 – Ranking of the level of effectiveness of the regulatory exception patent provision, government policies and regulations in promoting generic medicines in Malaysia.**

### 3.3. Effectiveness of government policies and regulations in promoting generic medicines in Malaysia

As shown in Fig. 1, equal proportions (21.4%) of the respondents held the view that the policies are either effective or not effective in promoting generic medicines in Malaysia, while a higher percentage (42.9%) indicated that government policies is fairly effective. With regard to government regulations, equal percentage (26.8%) viewed the regulations as either not effective or effective, while a higher percentage (35.7%) of the respondents indicated that government regulations are fairly effective in promoting generic medicines in Malaysia [Fig. 1]. Overall, the respondents expressed ambiguous perceptions on the effectiveness of government policies and regulations in promoting generic medicines in Malaysia. The relationship between the respondents’ perceptions on government policies and regulations was further explored using Spearman’s rho correlation analysis. The result revealed a positive and significant relationship between government policies and government regulations ( $r_s = 0.55$ ,  $p = 0.04$ ) in promoting generic medicines in Malaysia.

### 3.4. Satisfaction with generic prescribing, generic dispensing and generic awareness in Malaysia

Given that increased uptake of generic medicines through generic prescribing, dispensing and generic awareness can potentially promote generic production and availability, the level of satisfaction among the respondents regarding these practices in Malaysia were examined. Table 1 presents the results.

Majority of the respondents (64.3%) were dissatisfied with generic prescribing in Malaysia and a lower proportion (21.4%) were satisfied. Majority of the respondents (57.1%) were satisfied with generic dispensing in Malaysia, while equal proportions (21.4%) were dissatisfied or unsure about their perception on generic dispensing in Malaysia. Half of the respondents (50%) 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 relationships between these measures were further explored using Spearman’s rho correlation analysis. The result showed that generic public awareness was positively and significantly related to generic prescribing ( $r_s = 0.59$ ,  $p = 0.03$ ).

## 4. Discussion

The response rate of 65.4% (usable 53.8%) achieved in this study following four successive mailings is considered satisfactory, given the typically low response rates to mail surveys among organizations and top industrial executives.<sup>16,17</sup> Furthermore, the present study’s response rate is comparable to the response rate of 52% achieved in a related study among the top executives of pharmaceutical firms in Greece.<sup>10</sup>

The findings of this study revealed that Malaysian generic manufacturers have an ambiguous and ambivalent perception on the effectiveness of government regulations and

**Table 1 – Frequency ranking on generic prescribing, generic dispensing and generic awareness in Malaysia.**

Study variables	n (%)					Total, N (%) <sup>a,b</sup>
	1	2	3	4	5	
Generic prescribing	0 (0.0)	9 (64.3)	2 (14.3)	3 (21.4)	0 (0.0)	14 (100)
Generic dispensing	0 (0.0)	3 (21.4)	3 (21.4)	8 (57.1)	0 (0.0)	14 (100)
Generic public awareness	3 (21.4)	7 (50.0)	3 (21.4)	1 (7.1)	0 (0.0)	14 (100)
Generic education and information to healthcare professionals	1 (7.7)	9 (69.2)	2 (15.4)	1 (7.7)	0 (0.0)	13 <sup>c</sup> (100)

1 = Very dissatisfied, 2 = dissatisfied, 3 = unsure, 4 = satisfied, 5 = very satisfied.

a Valid percent.

b Row percentages have been corrected to the nearest one decimal place and total percentage may not add to exactly 100%.

c One responding firm did not answer this item.

policies in promoting the entry and uptake of generic medicines in Malaysia. These findings are similar to the findings from a related study in Greece that found that the pharmaceutical industry players in Greece viewed negatively the government policies in promoting generic medicines and concluded that the Greece pharmaceutical industry is “sceptical” regarding the strategies of generics promotion.<sup>10</sup> It thus appears that the perception of the Malaysian generic manufacturers on generic medicines promotion in Malaysia could be a reflection of the gaps between generic policy formulation and implementation in Malaysia, even as it has been noted in earlier studies in Malaysia<sup>9,18,19</sup> and in other countries.<sup>4,20</sup> This present study also noted a positive and significant relationship between perceived effectiveness of government policies and regulations. A finding that is found consistent with the literature which indicated that policies and regulations are intertwined and interdependent.<sup>21</sup> Thus indicating that ensuring policy and regulations coherence is of importance in promoting generic medicines in Malaysia.

With regard to generic prescribing, dispensing and awareness, the findings of this study revealed that a high majority of generic manufacturers were dissatisfied with generic prescribing, generic public awareness and generic education and information to healthcare professionals in Malaysia, while slight majority were satisfied with generic dispensing. These results reflect the findings in earlier studies in Malaysia that reported lack of confidence in generic prescribing, generic dispensing and low level of generic awareness in Malaysia.<sup>18,19,22–25</sup> In addition, the positive and significant relationship between perceived level of satisfaction with generic prescribing and generic public awareness suggests that from the perspective of the Malaysian generic manufacturers, generics public awareness is positively linked with generic prescribing, and vice-versa. This finding is found consistent with the literature which indicated that generic prescribing is influenced by consumers’ knowledge and awareness about generic medicines, and generic prescribing and communication with consumers contribute to increased awareness and use of generic medicines by consumers.<sup>1,18,26</sup> Accordingly, it has been noted that “physician and consumers perceptions are interlinked”.<sup>4</sup> Therefore, the findings of this present study show that the low level of generic prescribing in Malaysia could be increased by intensifying generic knowledge, education and public awareness.

This could be achieved by ongoing mass education and campaign and education of healthcare professionals about generic medicines.

One limitation of this study was the inability to obtain response from all the study’s potential respondents despite repeated mailings and telephone calls. Although the response wave analysis revealed no significant difference between early and late responders on all the study variables of interest, because late non-responders are only “proxy” non-responders, their being similar to responders does not conclusively indicate an absence of non-response bias.

## 5. Conclusion

Overall, Malaysian generic industry perceived the level of generic dispensing to be satisfactory but the level of generic prescribing, generic education and information to healthcare professional and generic public awareness were unsatisfactory. The generic drug industry in Malaysia expressed an ambiguous perception on the effectiveness of government regulations and policies in promoting generic medicines in Malaysia.

Therefore, in order to benefit fully from the cost-lowering advantages of generic medicines, it is necessary to bridge the gap between generic policy intent and implementation in Malaysia. Additionally, there is a need to enhance the levels of generic prescribing, education and public awareness on generic medicines in Malaysia, in order to create a right market environment for generic medicines production and market availability.

## Conflicts of interest

All authors have none to declare.

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