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ASSESSMENT OF GENERIC MEDICINES DEVELOPMENT AND ENTRY DECISIONS BY THE MALAYSIAN GENERIC PHARMACEUTICAL INDUSTRIES

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ABSTRACT

The Malaysian government has in place policy and regulatory measures aimed at promoting generic medicines development and production.[1] This mechanism is in place mainly to ensure drug affordability and accessibility for the population. However, despite the cost-saving advantage of generic medicines, generic pharmaceutical industry consider several factors before taking decisions to develop and introduce a new generic drug into the market following patent expiration of innovator products. Therefore, this study assesses the factors determining decisions by Malaysian generic manufacturers to develop and introduce a generic version of an innovator product into the pharmaceutical market. Data was gathered by using a mail survey approach. The pre-validated questionnaire was mailed to members of the Malaysian Organization of Pharmaceutical Industries (MOPI). From the total mailing of 26 questionnaires, a total of 16 manufacturers responded to the survey (response rate of 61.5 %). Based on the mean score, market size of the innovator product before patent expiration had the highest and significant mean score (mean=4.15, SD=1.07, p=0.03) and time to develop and obtain marketing approval for a new generic medicine had the lowest mean score (mean =3.23, SD=1.30, p=0.76). Consistent with studies[2,3] in other countries, this present study revealed that pre-patent expiration market value of the innovator product is the major and significant factor Malaysian generic manufacturers consider before developing and introducing a new generic medicine into the market. Decision making process for the potential generic entrant is also attributed to the existence and strength of any barriers surrounding the entry process.