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INITIAL REGULATEE PERCEPTION OF THE SELF-REGULATION APPROACH IN THE REGULATORY ENFORCEMENT OF MEDICINE ADVERTISEMENTS

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ABSTRACT

Medicine advertisements need to be controlled to ensure public interest is protected from harm and complications. This is because the medicine advertisements accessed could be misleading, untrue, and contain highly exaggerated advertising claims. The law in the control of medicine advertising is complex and advancements in technology has made advertising of medicines even more challenging. Typically, every public-policy problem will be solved through legislation or government action. However, the implementation of the self-regulation approach in regulatory enforcement of medicine advertisements has not been evidently shown and therefore, needs to be studied. This study is aimed at determining regulatees' initial perception in adopting the self-regulation approach in the regulatory

enforcement of medicine advertisements in Malaysia. A mixed method study was conducted using data collected from the feedback obtained through an evaluation form distributed at a seminar organised in 2015 and from library research. Data generated from the 2015 seminar was the only data available at the national level and this data could only be obtained from the Pharmacy Enforcement Division. The seminar, which was attended by regulators, government agencies, publishers, advertising agencies, companies from the pharmaceutical industry, and the relevant organisations who were stakeholders in the industry, was a way to advance new guidelines and a regulatory enforcement approach on medicine advertisement. The results from the survey revealed that 58 percent of the participants favoured the self-regulation approach. Their perceptions were found to be positive towards the self-regulation approach. Based on a thematic analysis, the results seemed to suggest that the concern of the regulatees about the self-regulation approach could be categorised into four important factors, which were the Malaysian industry's attitude and behaviour, government approval, government enforcement, and the management of the self-regulation approach. Nevertheless, in order to adopt the self-regulation approach, this study has highly recommended that the government should explicitly encourage self-regulatory bodies in Malaysia to implement the self-regulatory approach. For future studies, it is suggested that research be conducted to identify the effectiveness of the self-regulation approach among the various stakeholders of medicine advertisement.

Keywords: Pharmacy, advertisement, self-awareness, enforcement.

INTRODUCTION

Advertising is a valuable tool that can give consumers better information of the products or services being marketed. Advertisement is one of the essential elements of marketing strategies and in the present era of technological development, it is actively and innovatively used to promote products and to reach the masses (Advertising and promotion bans, 2018). Good advertisement has a strong impact on consumers and the ability to attract them to buy the products or services (Mackay (ed). John Wilmshurst, 2005). Accordingly, advertisements have a direct impact on business. The success of the advertisement for a

product or service can contribute greatly to a company's profit. Even companies that make small investments in effective advertisement can significantly increase their market and profit. However, advertisements can also be harmful to society. In the case of medicine advertisements, some of these advertisements can be misleading, untrue and can contain highly exaggerated advertising claims. Thus, there is a need for some kind of control and regulation of medicine advertisements to ensure that public interest is protected from the negative effects of such harmful advertising claims.

The need for control is even more critical since advertisements are everywhere; one does not even need to get out of one's house to be bombarded with advertisements. The rise in online shopping also calls for more control to be put in place. Various factors have influenced consumers to shop online and these included among others, the convenience of online shopping, the cheaper and more competitive price of goods compared to that in physical stores, the goods might not be available elsewhere, and it was trendy to shop online (Chua et al, 2017). These factors have resulted in a huge number of potential online shoppers in Malaysia. Research in 2013 showed that 91 percent of online users shopped online, while the other 9 percent of online shoppers was reluctant to do so (E-Commerce Infographic, 2018). This finding seemed to suggest that the public has been generally receptive to online shopping. The main reason consumers do not shop online may be related to the issue of TRUST, citing reasons like not being able to touch and feel the products and not trusting online shopping in terms of the aspects of security and credibility of the sellers. The danger is that consumers are surrounded with various kinds of information through the various online advertisements and are therefore, at risk of being exposed to false, deceptive, and misleading information.

In the case of misleading medicine advertisements or those with false information, these may not only result in the consumers losing their money, but it may also cause harm to them. The situation may worsen if the government is only concerned about developing the nation's economy at the expense of regulatory measures, as the lack of control or regulation would in the end only put the public at risk from the very serious danger of misleading medicine advertisements.

The rapid advancement of technology has placed a significant challenge in the monitoring and enforcement of medicine advertisements. The law of medicine advertisement in Malaysia has been seen as complex, out-dated, and contained strict rules (Youngman, 2016 and Penyata Rasmi Dewan Rakyat Parlimen, dated 3 November 2010). Since 1989, the Medicines (Advertisement and Sale Act 1956 [*Act 290*]) kept being revised and amended in which it was initially carried out mostly to facilitate health tourism especially for private hospitals, clinics, and laboratories (Penyata Rasmi Dewan Rakyat Parlimen, dated 30 June 1989 and personal communication, dated 3 July 2018). In 1994, Datuk Chua Jui Meng, the former Minister of Health, Malaysia commented on the need for amendments to be made to the Act to strengthen the control of medicine advertisements (Ministry to Review Medicines Act 1956, 1997).

On the same note, in 2001, there was a suggestion to develop guidelines for Act 290 to ensure that the requirements for promoting health tourism could be fulfilled (Penyata Rasmi Dewan Rakyat Parlimen, dated 29 October 2001). Since 1996 and until the present day, the Ministry of Health (MOH) based on that objective has been looking forward to drafting the final stage of a new comprehensive Bill to safeguard the public interest (Online Public Engagement on Pharmacy Bill, 2018). However, the journey in drafting the Bill has yet to reach an end and efforts are still continuing. The process of revising the legislation has been a long one and has met many challenges and difficulties. To date, such a Bill has not been tabled yet and this has made the actual work even more challenging.

In Malaysia, regulatory enforcement of medicine advertisement is governed by the Pharmacy Enforcement Division (PED) through its authorization under section 6A of Act 290. In addition, the Medicine Advertisement Board (MAB) has been established to ensure the governance of medicine advertisement controls under Act 290; its role has been to regulate the procedure and issuance of approval of advertisements. Other general legislation that might be relevant included the Communication and Multimedia Act 1998, the Printing Presses and Publication Act 1984, the Local Government Act 1976, and the Trade Descriptions Act 1972.

The MOH has planned several strategies for the improvement of medicine advertisement control system. Since 1989, guidelines

have been suggested to be developed, and in 2001 the guidelines of medicine advertisement have been established by the MOH through the approval of the MAB (Penyata Rasmi Dewan Rakyat Parlimen, dated 30 June 1989 and (Penyata Rasmi Dewan Rakyat Parlimen, dated 29 October 2001). In 2015, a new guideline was published to complement the provisions in Act 290 (Medicine Advertisements Board, 2018). However, Castro highlighted that not every public-policy problem should be solved with legislation or government action (Castro, 2011). He advocated self-regulation which he described as an essential tool for governing rapidly changing business in the information economy.

Currently, most of the countries practicing self-regulation have been the European countries such as the United Kingdom, Germany, the United States and Australia (Braithwaite, 2011 & Macrory, 2006). It has been one of the approaches that have successfully been proved on the quality of a resident's health in nursing homes in the United Kingdom and the United States (Braithwaite, 2011). By definition, self-regulation means the "regulatee party set and enforces rules and standards relating to the conduct of regulatees in the industry" (Castro, 2011 and Gupta & Lad, 1983). Thus, self-regulation was seen as the way forward for industries to 'self' regulate their 'own' standard, practice or code. As an organised group, it should regulate the behaviour of its members, for example, by establishing an industry-level code of practice (Braithwaite, Healy, & Dwan, 2005). As a result, regulatees comprised a group of stakeholders to the regulator and an important interest group by the National Regulatory Policy. Stakeholders could be a business community, employees, interest groups, professional organisations, and individuals involved in designing and reviewing regulations, such as consumer groups (Malaysia Productivity Corporation, 2013).

The MOH also undertook other initiatives such as educating and conducting dialogues with all the stakeholders, monitoring all the medium of medicine advertising, including the online platform; enforcing the law on illegal medicine advertisement, and conducting collaborations with other related agencies to ensure public interest was safeguarded (personal communication, dated 20 May 2018). Furthermore, the MOH also issued press releases to remind the public to be aware of illegal advertisements (Beware of illegal advertisement, 2015). The Ministry has lamented the uncontrolled advertising of

illegal health products in print and electronic media, in websites, on traffic light poles, and other public focus points. These were actions by unscrupulous parties who were only interested in making a profit without having any concern over the harm that their products could bring to the consumers. In Malaysia, these advertisements often included "magic bullet" promises such as 100 percent cure for cancer, immediate relief from diabetes, sustained weight loss, and often vulgar or embarrassing claims promising increased sexual performance to entice consumers to purchase the products. However, the advertising claims were often misleading and deceitful to the public. As an example, a customer mentioned in a newspaper reported that "*bila baca iklan yang menyatakan boleh kurus tanpa perlu bersenam, saya terus tertarik untuk membelinya"* (When I read advertisements that said I could become slim without having to exercise, I was immediately interested to purchase it (the product) (Masuk hospital kerana 'fat burner', 2017). Claims that consumers could reduce their weight without exercising or even losing weight within a short period of time were considered misleading claims. The worry is that these misleading claims can cause health problems or even death to the consumers who take such products.

The PED is responsible for the regulation of medicine advertisements under Act 290. In implementing the regulation**,** the MAB has even issued guidelines that explained the procedure for medicine advertising. The MAB has been authorised by the Act to set policies, directives, and guidelines for all advertisements containing medical and health claims (Medicine Advertisements Board, 2018). The MAB has established several guidelines to provide a more precise explanation of the format acceptable for medicine advertisements. These guidelines were aimed at ensuring responsible advertising in promoting the sale of medicines. The MAB would meet every two months and discuss each advertisement application (personal communication, dated 6 July 2018). The decision on each application was categorised according to the following outcomes: approval without any changes, approved with changes, rejected, or decision deferred until an expert opinion review (Annual Report Pharmaceutical Services Division, 2011).

The PED under the MOH is responsible for enforcing the Act (Annual Report Pharmaceutical Services Division, 2015). The PED has put in place enforcement measures to eradicate advertisements that breach the Act, so as to ensure that such advertisements do not mislead the

public. The monitoring programme conducted by the enforcement agency included observation of all publications from broadcast and non-broadcast media through the watchdog services provided by Isentia M Sdn. Bhd. (formerly known as MediaBanc Sdn. Bhd.), which now operating under the new name, investigate complaints, take precautionary measures on the potential harmful actions of the advertising industry and if need be, legal action against the offenders ("Annual Report Pharmaceutical Services Division," 2014). Laws and their enforcement are meant to ensure public order and deter future violation of crimes (Khalil et al., 2020). Nonetheless, there is still the urgent need to review and amend the law on medicine advertisement control to ensure that public interest is continuously protected from harm and other untoward consequences in light of the increasing number of misleading, false, and highly exaggerated advertisements being published in the country.

Over-reliance on the legal approach may however, undermine the necessary development of technologies in the advertising industry (Abdul Manap & Abdullah, 2020). It could be argued that in relation to the scope of regulatory enforcement of medicine advertisements, the MOH has taken all the necessary steps to ensure that public interest is protected. However, the implementation of the self-regulation approach in regulatory enforcement of medicine advertisements in the country is not clear-cut and therefore, needs to be re-examined. Thus, this study is aimed at determining the regulatees' initial perception in adopting the self-regulation approach in regulatory enforcement of medicine advertisements in Malaysia.

METHODOLOGY

This research has employed a mixed method approach, using a quantitative and qualitative research design to study data from evaluation forms which were distributed during a seminar organised in 2015 (Tanti et al., 2020, Walker, 2017, Nur Wahida et al., 2016 & Nur Wahida et al., 2016). Data were generated from the 2015 seminar evaluation because it was the only data available at the national level and which could only be obtained from the Pharmacy Enforcement Division. The evaluation forms were used as the questionnaire for the purpose of data collection in this study. Purposive sampling was utilised as the target population was the participants who attended the seminar.

The seminar which was organised by the Pharmaceutical Services Division (PSD) under the MOH and the Malaysian Pharmaceutical Society (MPS) took place on 26th March 2015 at the Tropicana Golf and Country Resort, Petaling Jaya. The participants were the various stakeholders of the industry, and they included regulators and people from government agencies, publishers, advertising agencies, and pharmaceutical industries (marketers). The participants have the expertise and knowledge, as well as the necessary experience in medicine advertisement control system of Malaysia.

The survey data was taken from the evaluation form questionnaire that had been developed by the PSD (seminar organiser) and validated by the top rank officers in the PED. The questionnaires were distributed to the participants during the registration session of the seminar. Each participant was given the questionnaire to complete and was then asked to submit the completed questionnaire to the seminar's secretariat at the end of the seminar. The questionnaire consisted of five closed-ended questions (Questions 1 to 4 and 6) and one open-ended question (Question 5). The structured questions were designed to obtain the perceptions of the stakeholders which were based on their experience of being involved in the medicine advertisement control system in Malaysia. Questions 1 to 3 were related to the current medicine advertisement system, while Question 6 was related to their rating of the level of satisfaction with the seminar. Data related to the participants' perception of the self-regulation approach were obtained through Questions 4 and 5.

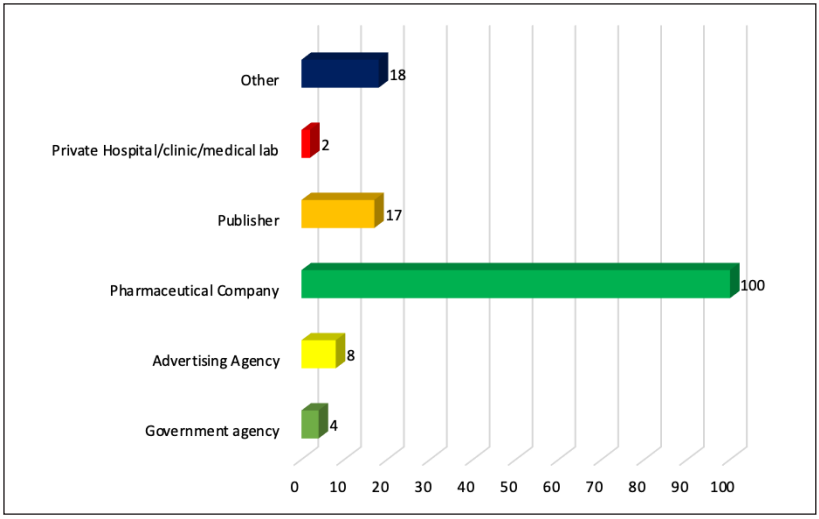
Data analysis was conducted by reviewing the feedback from each of the questions in the questionnaire. Data analysis for Questions 1 to 4 and Question 6 was quantitative in nature. The quantitative data were first calculated manually and later computed using Microsoft Excel software. Data for Question 5 were qualitatively analysed using the thematic analysis method (Walker, 2017). The researcher first read through the data to familiarise herself with the data before they were then assigned preliminary codes to describe the content. The coding was then analysed further to search for patterns or themes emerging across the participants' responses. The themes were then reviewed and refined to develop the main themes. It should be mentioned that the data presented in the study also included literature obtained through library research and official documents related to medicine advertisements in order to provide a better and more in-depth understanding of the issue being investigated.

THE SEMINAR ON MEDICINE ADVERTISEMENT

The seminar organised by the Pharmaceutical Services Division (PSD) under MOH and the Malaysian Pharmaceutical Society (MPS) was on the introduction of new guidelines for medicine advertisements. The seminar was well-participated with various stakeholders in the industry attending; however, the majority, 67.1 percent (100 participants) of the seminar participants were stakeholders from the pharmaceutical companies (marketers). Participation from other stakeholders were as follows: 12.1 percent (18 participants) were from the 'others' category, which comprised officers from the various branches and State Pharmacy Enforcement Divisions, while 11.4 percent (17 participants) were publishers, 5.4 percent (8 participants) were from the advertising agencies, 2.7 percent (4 participants) were officers from government agencies such as the National Pharmaceutical Regulatory Agency (NPRA), the Ministry of Domestic Trade and Consumer Affairs (KPDNHEP), and Food Safety and Quality Division (BKKM). The final 1.3 percent (2 participants) comprised participants from private hospitals/clinics/medical labs. The distribution of the seminar participants based on their background or affiliation is as presented in Figure 1.

Figure 1

Number of Participants in the Seminar



The main objectives of the seminar were to disseminate information on the new guidelines for medicine advertisements, to highlight and assist participants in the relevant advertising framework, and to increase awareness on medicine advertisement control. The objectives were appropriate for the participants because the participants were the regulated parties who should comply with the law. Analysis of the responses in Question 6 showed that after listening to the overview of Act 290 presented by the Secretary of the MAB and other briefing programmes related to the self-regulation approach in the seminar, 99.3 percent of the participants concluded that the seminar had met their expectations. In the overview, the Secretary highlighted the MOH's intention of withdrawing the medicine advertisement application provision under Medicine (Advertisement and Sales) Act 1956 and encouraging the regulated parties to rely on the self-regulation approach.

FINDINGS

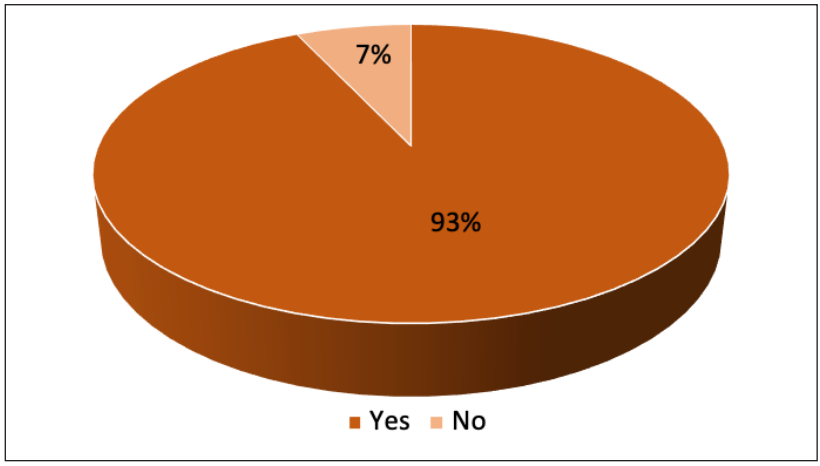
A total of 149 seminar evaluation forms were collected from the participants who attended the seminar. The data from the evaluation forms were compiled by the organisers and were later analysed by the author of this paper. Based on the data analysis of Question 1, which was on the participants interaction with the staff of the medicine advertisement unit, 72 percent of the seminar participants (107 participants) responded that they had dealt directly with the medicine advertisement unit staff, while another 28 percent (42 participants) declared that they had dealt with the medicine advertisement unit staff indirectly.

Satisfaction with the Current System

In relation to Question 1, which sought to know if the participants have dealt directly or indirectly with the staff of the medicine advertisement unit, the second question (Question 2) then went on to ask the participants if they were satisfied with the current medicine advertisement control system. A total of 142 participants answered this question. Based on the responses, 93 percent of the participants said that they felt satisfied with the current system, while the other 7 percent reported not feeling satisfied. Figure 2 displays the participants' responses in percentage regarding their level of satisfaction with the current system of medicine advertisement control.

Figure 2

Participants' Level of Satisfaction with the Current Medicine Advertisement Control System

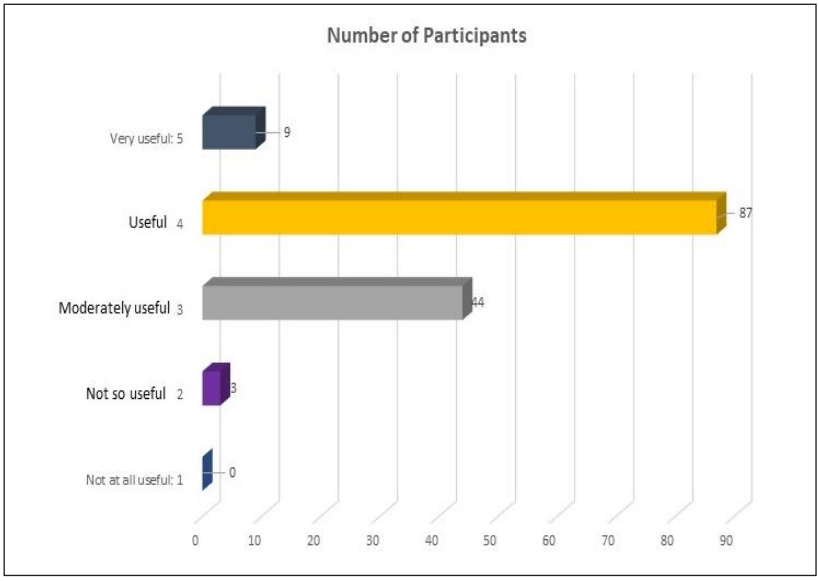


The Usefulness of the Current Guidelines on Medicine Advertisement

Question 3 was in relation to the participants' perception of the usefulness of the current guideline on medicine advertisement. In total, 143 respondents provided responses to the question. The responses showed that on the whole, the participants perceived the current guidelines positively. Based on the responses, the majority of the participants (87) felt that the current guideline is useful while another 44 participants perceived the current guideline as moderately useful and 3 participants perceived it as not so useful. In terms of the lowest and highest scale of 1 and 5 respectively, none of the participants perceived the current guideline as not at all useful while a total of 9 participants perceived the current guideline as very useful. Calculations of the average score in terms of usefulness of the current guideline on medicine advertisement generated a score of 3.71 which is located between scale 3 to scale 4, indicating many found the current guideline on medicine advertisement useful.

Figure 3

Participants' Perception Regarding the Usefulness of the Current Guidelines on Medicine Advertisement

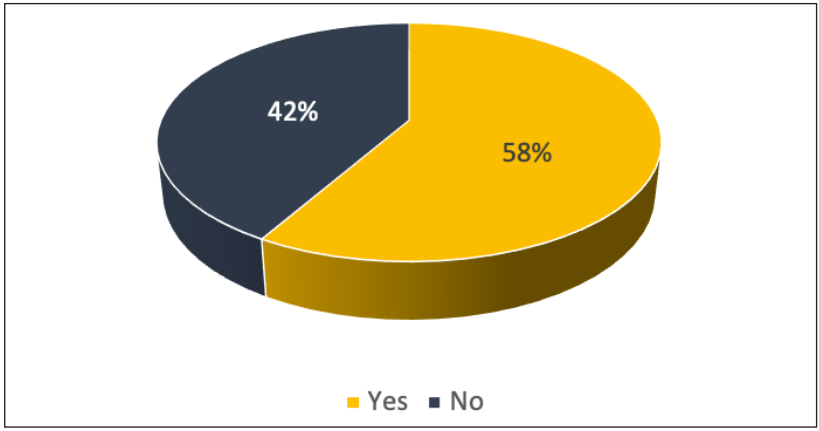


Preference Regarding the Move towards the Self-Regulation Approach

Question 4 asked the participants whether they would favour the move towards the self-regulation approach in medicine advertisement control. From a total of 139 participants who answered the question, the majority (58% of the participants) said that they were in favour of the move, while the other 42 percent were not in favour of the move. Figure 4 displays the participants' responses in percentage in relation to their preference in terms of the move towards the self-regulation approach.

Figure 4

Participants' Preference in Relation to the Move Towards the Self-Regulation Approach



Regulatees' Comments and Suggestions Regarding the Self-Regulation Approach in the Regulatory Enforcement of Medicine Advertisements

The evaluation form also contained a semi-structured question which was listed under Question 5. The question asked for any other comments or suggestions the participants would like to provide in relation to the seminar. However, many who responded to the question also provided comments and suggestions in relation to their perception of the self-regulation approach for medicine advertisement control in Malaysia. The number of participants who responded to Question 5 was small as only 30 participants (20%) provided comments or suggestions out of the total of 149 participants. It should be noted that the response to Question 5 was not compulsory, which explained the small number of responses. Nonetheless, from the 30 responses collected, 24 participants responded by giving their comments and suggestions on the self-regulation approach, and these comments were collected and then thematically analysed.

The responses to Question 5 from the 24 participants were coded and then categorised according to themes. All the categorised themes are as listed in Table 1. Based on the analysis, the participants' responses showed that some of them perceived the self-regulation approach

positively with comments such as the approach being a useful tool, and that they were looking forward to using the self-regulation approach. However, there were also many negative comments in relation to the participants' perception of self-regulation, such as Malaysians were not ready for it; advertisers were lacking in sincerity and honesty; the immaturity of the industry and market; the need for regulation approval by the government in Act 290; the MOH governing the advertisers; the need for more groundwork; and the possibility of advertisers/companies taking advantage of self-regulation. Overall, themes emerging from the thematic analysis revealed that the responses could be categorised into three important themes; concerns which had influenced the regulatees' suggestions or comments about the self-regulation approach, namely the management of the self-regulation approach, the attitude and behaviour of the industry, and the regulatory enforcement process.

Table 1

Themes Emerging from the Participants' Responses in Relation to their Perception of the Self-Regulation Approach in Medicine Advertisement Control System

Themes	Responses
Management of the self-regulation approach	1. Useful tool. 2. Need more groundwork. 3. We need clear and easy to understand regulations and guidelines. * 4. Need a neutral regulatory body. 5. Need to have talks with the manufacturers and advertisers. 6. Have a database where the public or interested organisations could consult applications/cases. 7. We are looking forward to the regulation based on the self-regulation approach. 8. By a professional body. 9. Save cost and time. 10. Allow application online. *
Industry attitude and behaviour	1. Malaysians are not ready. 2. Lack of sincere and honest advertisers. 3. Industry and market are not mature. * 4. Advertisers/ companies might take advantage. 5. Company awareness.
Regulatory enforcement process	1. Regulation approval provision by the government should be enforced and in place. * 2. MOH governs the advertisers.

Note. * Comments or suggestions contributed by more than one participant.

DISCUSSION: SELF-REGULATION IN THE REGULATORY ENFORCEMENT OF MEDICINE ADVERTISEMENT

Heijden, Wan Ahmad and Ariff Abdul Ghadas agreed that the meaning of self-regulation is impossible to define in a single standard definition (Heijden, 2009, Wan Izzat & Zuhairah, 2012). The subject or purpose and multiplicity of self-regulation depend on the approach taken in the industry or the respective areas. However, Castro citing Gupta and Lad defined self-regulation as "a regulatory process whereby an industry-level organisation (such as a trade association or a professional society), as opposed to a governmental- or firm-level organisation, sets and enforces rules and standards relating to the conduct of firms in the industry" (Castro, 2011).

In the regulatory spectrum, there were several types of regulation, namely no-regulation, self-regulation, co-regulation, and statutory regulation (Castro, 2011). Heijden found that a regulatory regime could be classified as public, prescribed co-regulation, conditional co-regulation, substitute co-regulation, and private (Heijden, 2009). Self-regulation itself has been categorised into five categories, namely co-operative, delegated, devolved, facilitated, and tacit where tacit self-regulation has been defined as having little explicit state or government support. Meanwhile, other self-regulation categories were more than explicitly supported by the government (Castro, 2011). Thus, most types of self-regulation required the intervention of government legislation regardless of how, and at what stage it was in (Wan Izzat & Zuhairah, 2012). It seemed that the code under self-regulation also required mandatory force (Wan Izzat & Zuhairah, 2012).

Hence, the need for government intervention in implementing or adopting the self-regulation approach in the medicine advertisement regulatory framework is vital. The following discussion is based on the findings on the regulatees' preference in relation to the move towards the self-regulation approach (Question 4) and their initial perception as evidenced in the analysis of their comments and suggestions (Question 5), which highlighted the three important themes or factors that emerged in relation to the self-regulation approach.

Regulatees Favoured the Self-Regulation Approach in a Medicine Advertisement Control System

In this study, it was found that 58 percent of the participants favoured the self-regulation approach. In contrast, only 42 percent of the regulatees showed preference for state regulation which is to be regulated and enforced totally by the government. The survey also showed that 93 percent of the regulatees were satisfied with the current medicine advertisement control system. Self-regulatory bodies play an essential role and are instrumental in the mechanism of the self-regulation approach. Thus, these self-regulatory bodies need to be established as they would enable the advertising industries to be guided in relation to medicine advertisements. It would help to ensure that the advertisements of medicines comply with the stipulated laws and regulations. Self-regulatory bodies must have members, and the members may include a specific professional body itself, or be made up of the various stakeholders of the medicine advertisement system.

Regulatees' Initial Perception of the Self-Regulation Approach in a Medicine Advertisement Control System

Even though the response rate for the comment and suggestion section of the evaluation form was low, with only 20 percent of the participants responding, the comments received were valuable as feedback on initial perception. The findings of this study showed that most of the regulatees who provided responses in the comments and suggestion section were concerned about the guideline; many admitted that the guideline was useful and has been a beneficial tool. Since the guideline is a part of a code or a standard of best practice in the self-regulatory organisation (SRO), this initial perception gleaned from the regulatees was an indispensable piece of information for future regulatory studies. It is quite tricky to generalise the self-regulation approach as a whole. However, this finding helps to build a structure for future studies such as in constructing interview questions. The discussion in the next few sections deals with the three essential themes or factors identified from the thematic analysis of the regulatees' responses in relation to the self-regulation approach, namely the management of self-regulation approach, the attitude and behaviour of the industry, and the regulatory enforcement process. The regulatees' perception

may have highlighted particularly, the regulators and regulatees' readiness towards the self-regulatory approach in the regulatory enforcement of medicine advertisement.

Management of the Self-Regulation Approach

First, the regulatees of medicine advertisement in Malaysia have shown their concern for having clear and transparent guidelines in self-regulation. In the management of self-regulation, the regulatory bodies or self-regulatory bodies should know how to produce guidelines. In the United Kingdom (UK), regulations have been supplemented with guidelines published by the Medicines and Healthcare Products Regulatory Agency (MHRA) on behalf of the licensing authority. The primary guidelines were contained in the Blue Guide – Advertising and Promotion of Medicines in the UK which was published in September 2014 and provided general guidance which has been published on the MHRA website.

Furthermore, most pharmaceutical companies operating in the UK have agreed to follow the industry's Codes of Practice, which offered the most precise and immediate oversight of the advertising of medicines, as part of the UK's medicine advertisement control scheme. In 2018, the Association of the British Pharmaceutical Industry (ABPI) released a new edition of its Code of Practice, known as the Proprietary Association of Great Britain (PAGB) Consumer Code. The PAGB Consumer Code governs the advertising of over-the-counter medicines to the community, while the PAGB Professional Code governs the advertising of over-the-counter medicines to people eligible to prescribe or supply. In the UK, the Codes of Practice are repeated in the law; however, in several respects, it goes beyond the law (Williams & Valverde, 2017). The MHRA monitors directly companies that have not committed to follow the relevant Codes of Practice and the related self-regulatory mechanisms.

In addition to the controls, the UK has, in theory, other general laws that could be applicable to medicines, such as the Trade Descriptions Act 1968. In terms of commercial practices (including advertising) relating to consumer goods are subject to a series of laws on consumer goods trades, including the Consumer Protection from Unfair Trading Regulations 2008/1277 (business-to-consumer practices)

and the Business Protection from Misleading Marketing Regulations 2008/1276 (business-to-business practices). To ensure high and consistent standards, the MHRA collaborates with the Advertisement Standards Authority (ASA) as the UK's independent regulator for general advertising in all media, and the Committee on Advertising Practice (CAP) as the body responsible for drafting and managing the UK Advertising Codes and providing authoritative guidance on the regulations.

Rules in Malaysia which consist of statutes, guidelines, and codes of practice regulate the advertising industries in the country. The existence of the statutes has resulted in some limitations or requirements that need to be adhered to in advertising to the public (Annual Report Pharmaceutical Services Division, 2012 & Siva, 2012). These statutes have provided some kind of guidelines which were assumed to make a more precise interpretation of the requirements in the legislation. The codes of practice identify the ethical values and responsibility of the advertisers in advertising practice (Siva, 2012). The rules were aimed at controlling the behaviour of the advertisers and acted as an instrument of social control of the public (Castro, 2011). A study highlighted that the combination of statutes and codes might help the industry to have a better understanding regarding poison advertisement (Khoo & Wan Ullok, 2008). The basic idea of self-regulation in advertising was for the advertising industry to set up a body that would represent the components of the advertising industry in drawing up a code of standards and practice (Draughn & Gray, 2003).

Codes set out a system of rules to control the conduct of certain specified activities for the specific professional body, particularly pharmacists. In Malaysia, there is a regulatory body called the Pharmacy Board which was established under the Registration of Pharmacists Act 1951. The Pharmacy Board has issued a code named 'Code of Conduct for Pharmacists and Bodies Corporate'. The code is statutory and has the force of law. A pharmacist who fails to abide by the code is liable to disciplinary action by the Board as deemed fit under the provisions of the Act (Code of Conduct for Pharmacists and Bodies Corporate, 2009). The Pharmacy Board in Malaysia is placed directly under the government, unlike in the UK where the Code is placed under the self-regulatory bodies. This statement leads

to the second point or issue which has been raised and that is the regulatees' perception on the need for a neutral regulatory body where these professional bodies will help to ensure every regulation made is logical and practical in the goal of achieving public interest.

Third, the regulatees admit that self-regulation is a useful tool to be implemented, would improve companies' awareness, and save cost and time. A self-regulation approach is a useful tool or initiative for the regulatory enforcement framework. It has been used as a part of the key initiatives in some government industry policy plans (Wan Izzat & Zuhairah, 2012). For example, in the Malaysian Construction Industry Master Plan 2006-2015 (CIMP) which consists of seven strategic thrusts, a self-regulation approach was needed and recommended for the second strategic thrust in order to achieve the thrust. Additionally, the initiatives for the construction industry have included self-regulation by the society, associations, or organisations (usually a professional body), tightening of the particular schemes, licencing, and establishment of a code of ethics by construction-related associations.

Due to hierarchy and nationalisation, the fourth aspect or point that needs to be taken into consideration involving the regulators and organisations is the need to carry out more groundwork and basic preparations where self-regulation is understood more in terms of avoiding contestation or disputes by the industry and prioritising public interest. Castro (2011) has supported self-regulation compared to statutory control which was seen as a faster way of dealing with the regulatory process as it was more readily accessible, informal, and flexible in responding to the fast-changing world of new media such as online advertising. Additionally, Bartle and Vass stated that self-regulation promoted flexibility, as it could quickly adopt new rules for the benefit of the public (Bartle & Vass, 2005). Through this informal procedure, complaints could be dealt with more rapidly compared to the court system (Walker, 2017). Fitzgerald also stated that the self-regulation system was much stricter and rigorous than statutory provisions in terms of the general rules and requirements to substantiate the factual claims. Furthermore, consumers could critically assess and discriminate against the claims in the advertisement (Siva, 2012).

Fifth, in terms of framing the self-regulation approach in the medicine advertisement control system, the regulatees were concerned about

getting more input from the manufacturers and advertisers in creating regulation. However, there were self-regulatory bodies that have come forward to bring up the issue and references to the MOH. In Malaysia, there exist self-regulatory bodies for pharmacists such as the Pharmaceutical Association of Malaysia (PhAMA), Malaysian Organisation of Pharmaceutical Industries (MOPI), Malaysian Pharmaceutical Society (MPS), Malaysian Community Pharmacy Guild (MCPG), and the Malaysian Association of Pharmaceutical Suppliers (MAPS) (personal communication, dated 3 July 2018). From the observation during the seminar and the responses gathered in the evaluation form as discussed earlier (see Question 3 and Figure 3), 93 percent of the seminar participants, the majority of whom were from the pharmaceutical industries, were satisfied with the current medicine advertisement control.

In Malaysia, even though there is a self-regulatory body known as the Pharmaceutical Association of Malaysia (PhAMA) that represents the pharmaceutical industry, and has as its goal to seek to improve viability and growth of the innovative pharmaceutical industry, as well as to ensure good marketing practice, there is no transparent system that complements and works synergistically with the Government as compared to the situation in the UK.

For example, the PhAMA, which is the self-regulatory body for the pharmaceutical industry, controls the advertisement published in the broadcast and non-broadcast media through their own established Code of Conduct; however, the control is only limited to their members. If the members breach the codes of conduct, action can be taken against them (PhAMA Code of Pharmaceutical Marketing Practices, 2019). Similar to co-regulation, the self-regulatory control would have been ratified by the government, resulting in a "soft power" instrument which had a top-down approach, as well as a bottom-up approach (Anguelov, 2015). This kind of soft policy instrument tended to be more flexible and subject to negotiations in the multi-stakeholder dialog to ensure consistency and efficiency with market approaches (Swallow et al., 2009).

Other organisations like the MCPG has set Good Pharmaceutical Trading Practices (GPTP) for their members to comply with (Good Pharmaceutical Trading Practices, 2018). Through the GPTP, the

MCPG encourages its members to make a report with evidence and details to be presented to the MCPG Council if they encounter cases of any other members not adhering to the GPTP. The investigation process will be initiated by the MCPG to ensure that corrective action is taken for such non-compliance.

Additionally, medicine advertisement regulation also needs input from other stakeholders such as the doctor's self-regulatory bodies like the Association of Private Hospitals Malaysia (APHM), Medical Practitioners Coalition Association of Malaysia (MPCAM), Malaysian Medical Association (MMA) and *Pertubuhan Doktor-Doktor Islam Malaysia* (PERDIM) (personal communication, dated 3 July 2018). Another stakeholder that comprises multiple professional stakeholders has been named the Medical Myth-buster Malaysia (3M) (personal communication, dated 3 July 2018).

Sixth, the regulatees suggested that the MAB creates a database for consultation so as to help them make decisions on self-regulation based on the experience of other organisations. As an example, the consultation needed by the regulatees included applications and cases to overcome every issue regarding medicine advertisement approval and prosecution cases. In self-regulation, the complaint unit is an important unit whose task or function is to accept all public, members or stakeholders' report, questions, and feedback.

The seventh issue or point raised was related to the adoption of the self-regulation approach. The regulatees expressed their eagerness for and expectations of the approach to be adopted and were looking forward to its implementation, and even suggested for further focus to be given to the online phase, particularly in the approval of applications of medicine advertisement. This suggestion or concern was expressed in the hope for the regulation to be expanded to the online phase, particularly in the approval of applications or any other kinds of advertisement issue.

Industry Attitude and Behaviour

The regulatees also had negative perceptions regarding the self-regulation approach. Firstly, the regulatees commented that Malaysians are not ready for the self-regulation approach. In the UK,

for example, there was introduced a mechanism for the advertising industries such as the advertisers, advertising agencies, and the media to work together in agreeing and complying with the advertising code as a system. It has been set up to ensure that misdemeanours in advertisements were quickly corrected or removed (Draughn & Gray, 2003). The situation is different in Malaysia. Although there is the existence of self-regulatory bodies in Malaysia, there have been no concurrent investigations conducted between the MAB and the self-regulatory bodies. Since there is no clear policies and laws, there is no formal implementation of the self-regulatory approach in the control of medicine advertisement in Malaysia.

Advertising is subject to several ethical controls in Malaysia. According to Hashim (2015) and Siva (2012), a system which has combined self-regulation and government regulation should be considered as an option in medicine advertisement control. These self-regulation controls could exist at the government level, the advertising industry level, and the firm level (Castro, 2011). Most types of self-regulation would require the intervention of government legislation regardless of how, and at what stage the industry found itself in (Wan Izzat & Zuhairah, 2012). At the industry level, there is the Advertising Standards Authority of Malaysia (ASAM), which is administered by the Advertising Standards Authority Malaysia (ASA) and whose members are drawn from the Malaysian Newspaper Publishers Association, the Association of Accredited Advertising Agents, Malaysia, the Malaysian Advertisers Association, and the Media Specialists Association (The Malaysian Code of Advertising Practice, 2008). The ASAM, which comprises a representative each from advertising agencies, advertisers, media owners, and the consumer association, formulated the Malaysian Code of Advertising Practice as a regulatory guide for advertisements that appear in Malaysian media (The Malaysian Code of Advertising Practice, 2008). However, in terms of medicine advertisement, there is a lack of sufficient information to provide a clear picture about the implementation of the system.

Several guidelines have been produced by the MAB through *www.pharmacy.gov.my* to provide a more explicit interpretation of the requirements in the legislation and to assist the medicine advertisement application process. Based on the medicine advertisement control system, the code set by the PhAMA or the MCPG does not have any

provision to enable corrective actions or the removal of advertisements that do not adhere to the regulations stipulated. This has been a preferable alternative mode to government regulation as a way of implementing and supplementing the legislation where the industry or private sectors could be carrying out the implementation instead of the government (Campbell, 1999).

Secondly, the regulatees are concerned about the advertisers whom they feel lack sincerity and honesty, since the advertising industry is a business concern and profit is their main goal. If the self-regulation in the industry is not controlled or monitored, they might not be too concerned about their social responsibilities and decide to ignore them. A study on taxation found that regulatory conversations could build a standard, reasonable behaviour for taxpayers and improve the taxation control system (Braithwaite, 2007). Meanwhile, based on the responsive regulation theory, the enforcement pyramid could be effectively applied if the regulators had the skills to read intention, were able to distinguish an honest mistake from a calculated choice being represented as a simple mistake, and were able to discern how regulatees' attitudes were affected by regulators' actions (Mascini, 2013).

Thirdly, there is the perception among the regulatees that the Malaysian industry and market are immature and that it is not yet time to let the medicine advertisement control system, particularly in the approval process to be based on a self-regulation approach. Indeed, self-regulation is something that everyone or every organisation should have, and it can be started and established at any time or in parallel. Nevertheless, the industry needs strong finances to enable them to act in a more active and aggressive manner. Perhaps, the government needs to give incentives to the people for self-regulation to take effect and for it to be effectively implemented.

Fourthly, the regulatees have the perception that the advertisers or companies might take advantage of the self-regulation approach. The implementation of self-regulation should work in tandem with the government's regulation, as stated in the responsive regulation theory where there was an enforcement pyramid that could have the impact of persuasion and deterrent in the model, in total, in the system (Mascini, 2013). If the system only adopted the persuasion model, the system therefore, has failed to recognise and act on the corrupt and unethical

advertisers or companies, and the public assumption was that there would still be those who were going to take advantage of the system.

Regulatory Enforcement Process

In Malaysia, the control of advertising includes statutory and self-regulatory control. However, the medicine advertisement control in Malaysia is mainly based on statutory control. Since the regulatory agency structure in Malaysia is a top-down one, the approach leads to a public regulatory regime. A public regime regulatory design would be more prone to forming regulators with enforcement powers (Hussein, 2011, Zainuddin, 2009). Regulatory instruments with a top-down approach tended to be implemented in a rigid manner, earning them the name or label of "hard policy instruments" (Swallow et al., 2009). In the top-down approach, a policy is designed based on the decisions of the statutes, executive orders, or court decisions. Even the hierarchy of regulatory enforcement by the government represented a top-down pattern of human interaction that has been built on the mechanism of 'command and control' of the government against the citizens (Sanders et al., 2014). Most of the Malaysian law on advertising imposed by the government which was called the statutory regulations had been too strict and had hindered the creativity of the advertisers and the freedom of commercial speech (Hashim, 2015).

Firstly, in relation to the regulatory enforcement process, the regulatees suggested that the status quo on the regulation of medicine advertisement approval under Act 290 be maintained and should be still placed under the government. Secondly, the regulatees wanted the MOH to govern the advertisers and that such provision should be placed in the legislation, particularly for medicine advertisements under the MOH (government).

In the general advertising industry, there is legislation related to consumer protection to monitor the advertisements in the broadcast and non-broadcast media. In addition, there were also regulatory bodies consisting of the advertisers, advertising agencies, and the media that have formulated self-regulatory systems by setting up their code to control the advertisements (Shad Salem Faruqi, 1998). However, specific to medicine advertisements, the authorities have played an essential role in vetting the advertisements under Act 290 before they can be published.

Unlike Malaysia, the advertising of medicines in the UK is controlled by a combination of legislation and codes of practice. Under the regulations, advanced approval has been given in the UK under the name of marketing authorisation, certificate of registration, traditional herbal registration, or Article 126a authorisation with the content of advertisement as listed in the summary of the product characteristics. Under section 304 of the Human Medicines Regulations 2012/1916 (the Regulations), the MHRA has the power to issue a notice ordering anyone involved in the publishing of medicinal product advertising to supply copies of the advertisements prior to publication and not to use such advertisements until they have been authorised (Williams & Valverde, 2017). Failure to comply with such a warning is punishable by law.

However, in the UK all promotional materials related the prescription-only medicines and over-the-counter goods must first receive prepublication authorization for consumer advertising from the respective self-regulatory bodies (such as the PAGB) for vetting to ensure its compliance to the Codes of Practice (Control of Over-The-Counter Medicines Advertising in the UK, 2018). At the same time, members or advertisers could gain any information from the complaint body, which is the MHRA and the ASA (Control of Over-The-Counter Medicines Advertising in the UK, 2018). Moreover, these bodies also provide free pre-publication copy-advice service to the advertisers to ensure the advertisement complies with the legislation before it is published (Control of Over-The-Counter Medicines Advertising in the UK, 2018). Such practices would therefore reduce the potential breach of legislation and Codes.

Currently, the PED is the only body doing the monitoring process in Malaysia and they have to meet the increasing number of non-compliant medicine advertisements every year. The government needs to spend more on the monitoring process through subscription to the services of Isentia M Sdn. Bhd., where all advertisements in printed and electronic media are kept and can be monitored or screened by the Headquarters and the State Pharmacy Enforcement Unit (personal communication, dated 6 July 2018). The PED also needs a huge budget to produce pamphlets and brochures meant for public consumption, promotional materials generated by health product companies, and any outdoor advertising such as banners, buntings, and posters. Clearly,

the self-regulation approach could help to reduce the constraints faced by the PED. As Castro has highlighted earlier, there were many benefits to the self-regulation approach compared to its limitations. He argued that self-regulation would improve companies' awareness because the firms would know more about their 'own' business, gain easy access, and obtain more information.

In Malaysia, if there is non-compliance in the monitoring stage, sanction will be imposed based on the compliance model, as opposed to the deterrent model which was previously practised. The PED may, at their discretion, not take any legal action against the advertisers if they breach the Act for the first time (personal communication, dated 6 July 2018). They will only issue a warning letter to inform the advertisers that their advertisements do not comply with the Act. The advertisers will only be given a warning as a reminder for their first offence, and if they repeat the same offence in the future, legal action will strictly be taken against them. However, if the advertisements involve a serious offence, legal action will be taken straight away against the advertisers (Annual Report Pharmaceutical Services Division, 2016 and personal communication dated 6 July 2018). In 2015, a total of 207 warning letters were issued to the media, editors, and advertisers, while 251 warning letters were issued in total to the media, editors, and advertisers in the year 2016 (Buku Statistik Penguatkuasa Farmasi Tahun, 2015 and (Annual Report Pharmaceutical Services Division, 2016).

After the monitoring stage, the next step of non-compliance of medicine advertisement is to advance to the sanction and prosecution stage (Annual Report Pharmaceutical Services Division, 2014). The sanction would include some hidden costs, such as the invisible cost of appearing in court, time spent for meetings, and others which would include the testing or operating cost (Russell et al., 1986). The investigation procedure, which includes the collection of exhibits (documents) and recording of statements, must be carried out quickly in order to complete the investigation with sufficient evidence. This is due to several reasons, such as the difficulty in obtaining the original documents, and the personnel in-charge is no longer with the company. However, as a result of the lack of manpower faced by the PED, the investigation process is often hampered (personal communication, dated 6 July 2018).

The investigation of any case that violates the Act that covers medicine advertisements and services from the broadcast and non-broadcast media is also based on public complaints. In 2016, a total of 313 cases were investigated by the PED (Annual Report Pharmaceutical Services Division, 2016). In addition, the PED has also taken the initiative to organise dialogues and engagement sessions with local authorities throughout the country, and also with media companies and advertising associations in order to enhance the effectiveness of medicine advertisement control (Annual Report Pharmaceutical Services Division, 2016). Dialogue is carried out continuously as a precautionary strategy to ensure constant co-operation from the industry. In 2016, the PED conducted 41 dialogues and engagement sessions (Annual Report Pharmaceutical Services Division, 2016). Thus, all the efforts were more in terms of the government's approach in relation to medicine advertisement control system of the regulatory process. In contrast, in the UK, all the complaint cases received by the MHRA in 2016 were resolved by voluntary agreements with the businesses involved, with most cases being dealt under self-regulation without the need to resort to statutory procedures (Williams & Valverde, 2017).

CONCLUSION: ARE WE READY?

Advertisement is one of the methods used to provide information about a product or service to the public. The medicine or pharmaceutical product industry uses advertisement as a tool to promote their products through the media. Accordingly, there must be a means of controlling medicine advertisements to ensure that public interest is protected from harm and complications as a result of misleading, untruthful, and highly exaggerated advertisements (Annual Report Pharmaceutical Services Division, 2011). However, in Malaysia, the provision in the legislation only empowers the government to control and monitor medicine advertisements.

The implementation or management of the self-regulation approach is not clearly stated in the legislation, and government intervention is implicit. The self-regulatory bodies for industry and community pharmacy, particularly medicine advertisements in Malaysia include the MPS, the MCPG, the PhAMA, the MOPI, and the MAPS. For a start, collaboration between the MPS and the government has been established through the support given to participation in the seminar,

showing that the advertising industries could work together to impose the self-regulation rules and improve medicine advertisement control in the industry. However, the initial perception of the regulatees showed that they were concerned about the issue of readiness. Self-regulation is not strange or uncommon in the pharmaceutical industries in terms of medicine advertisements; the only issue is that the role of the self-regulatory bodies and their use of information as the mechanism of self-regulation is not adequate enough. Each self-regulatory body does have its own code or best practice, but perhaps these codes and best practice are still unclear and insufficient; moreover, no monitoring strategies as a form of "watchdog" measures have been put in place in the context of Malaysia.

The behaviour and attitude of the regulatees, together with the complex and evolving technologies in the control medicine advertisement of Malaysia, clearly show that there is a need for all the bodies that determine compliance to sit together, share experiences and information. In a study in the Netherlands, it was found that the relationship between regulators and regulatees needs to be built on trust and that less agreement should be placed on output specifications to ensure the regulators could give more responsive behaviour and use persuasion in addition to deterrence application (Reynaers & Parrado, 2016). The findings showed that 58 percent of the stakeholders in the industry who participated in the seminar favoured self-regulation and this was a clear indication of a significant initial acceptance of the adoption of the self-regulation approach among the stakeholders. Since Malaysia has been practising the command-and-control regulation for quite some time, it is high time that the self-regulation approach is improved and primed with desirable self-regulation mechanisms so that it can be effectively implemented in the country.

The intervention of the self-regulatory bodies in collaboration with the government in the regulatory enforcement process is vital. In a show of support, Siva (2012) remarked that features of co-regulation might be suitably considered in the regulation of medicine advertisements in Malaysia, as it will help to ensure better and effective regulation. He also emphasised on the need for proactive monitoring, followed by severe sanctions when a violation of law is found. Participation of the private sector in the regulatory process should also be expanded, particularly in welcoming complaints. In fact, some complaints can become an idea contribution to the authorities in coming up with a way

to manage and develop better management in regulatory enforcement of medicine advertisements. Besides monitoring, the self-regulation approach should, together with stringent enforcement and sanction, be enforced by the authorities (Jong Ad. et al., 2005).

Nevertheless, in adopting the self-regulation approach, the initial findings from this study seemed to indicate that the government should explicitly encourage the self-regulatory bodies in Malaysia to implement the self-regulatory approach. This shows that the government is committed and supportive of enacting a better medicine advertisement regulation in Malaysia, as it is a developing nation moving towards becoming a more informed society that is prepared to face any new media challenges ahead. The law of medicine advertisement in Malaysia needs to be upgraded and expanded to ensure that the MOH's objectives for public safety can be achieved. It will be interesting to observe the way forward for the new legislation on medicine advertisement control and to see what challenges are ahead for the protection of consumers and responsible businesses from misleading medicine advertisements. As a conclusion, to better understand the situation in Malaysia, it is recommended that studies are conducted in the future to identify the effectiveness of the self-regulation approach in medicine advertisement control, as practised among the different medicine advertisement stakeholders in the country.

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