IFPMA/PhAMA EVENT ON ETHICAL PROMOTION OF HEALTHCARE PRODUCTS: NEED FOR MULTI-STAKEHOLDER COLLABORATION

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Keynote Address

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"Ethical Standards in Healthcare Product Promotion -The Government Perspective"

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Distinguished guests, Ladies & Gentlemen,

Salam Sejahtera, Salam 1Malaysia and a very good morning to all.

First and foremost, I would like to thank the organisers, namely, the International Federation of Pharmaceutical Manufacturers & Association (IFPMA) and the Pharmaceutical Association of Malaysia (PhAMA) for inviting me to speak on Ethical Standards in Healthcare Product Promotion – The Government Perspective at this IFPMA/PhAMA event on Ethical Promotion of Healthcare Products, which is being held for the first time in Malaysia.

On behalf of the Ministry of Health Malaysia, it is my great pleasure to welcome all of you to Kuala Lumpur, Malaysia and we are deeply honoured that you have chosen Kuala Lumpur as the venue for the event. I also wish to congratulate and commend the efforts taken by IFPMA & PhAMA for organising this event and involving relevant healthcare stakeholders, both local and international.

Ladies and Gentlemen,

The pharmaceutical industry is one of the fastest-growing sectors in Malaysia. Over the last decade, it is encouraging to see that the Malaysian pharmaceutical market had grown steadily, maintaining at between 8 to 10% annually. In tandem with the national agenda on economic transformation, pharmaceuticals have been identified as one of the Entry Point Projects (EPP) to stimulate growth and economy.

In expanding businesses in this highly competitive industry, pharmaceutical companies' success depends on the sales and marketing of their drugs to healthcare professionals. Nevertheless, marketing in any industry should follow basic ethical standards at all times. In the healthcare industry, it is important that marketing efforts comply with ethical standards and practices to ensure that product safety, efficacy and quality are not compromised.

Healthcare product marketing and promotion includes all form of interactions with healthcare professionals and public. Thus, communication between pharmaceutical companies and healthcare professionals is important as it creates awareness about new therapy options and ultimately benefits patients with these new treatment regimes. Promotion involves disseminating information about a product, product line, brand or company. Advertisement is a pivotal tool in marketing and promotion of product or services.

According to the Medicines (Advertisement & Sale) Act 1956 (MASA), advertisement includes any notice, circular, report, commentary,

pamphlet, wrapper or other document and any announcement made orally or by any means of producing or transmitting light or sound.

It is undeniable that advertisements draw attention from the potential buyers or customers. While the importance of communication with healthcare professionals is undeniable, it must be conducted in an ethical and professional manner to ensure integrity and credibility. It is the social obligation of the advertisers/marketers to provide unbiased information in their advertisements to assist consumers to make informed choices when they purchase any goods or services. To protect consumers and ensure marketing campaigns are ethically conducted, MASA prohibits certain advertisements relating to medical matters and regulates the sale of substances recommended as a medicine.

Currently, MASA confers power to the Medicine Advertisement Board (MAB), established under Medicine Advertisement Regulations 1976 to monitor and regulate advertisements. Generally, the MAB is empowered to set policies and guidance on related advertisements to ensure its integrity; without annoying people, without manipulation and without deception, with regards to promoting the sale of medical products, skills and services. To facilitate the process, the MAB offers guidance for medical products and services aimed at improving marketing messages and adherence to provisions of MASA. Relevant requirements and information related to advertisements are available and accessible at our official website, www.pharmacy.gov.my.

Over the years the number of advertisements applications has shown an increasing trend. In 2012, the MAB received a total number of 2133 applications for approvals. This figure represents an increase of 23% in comparison to 2011 in which the total number of applications received then was 1639.

Recognising the great magnitude of advertisements and the crucial lead time needed to place products or services in the market, as an impact of the economic transformation, the MAB secretariat has reviewed existing procedures to shorten the approval for a complete application of an advertisement from 7 to 5 working days, beginning 2013.

Ladies and Gentlemen,

The Pharmacy service came into existence in the country since 1951 and the division was officially named the Pharmaceutical Services Division (PSD) in 1974 in recognition of the expanding role of the pharmaceutical services in the health sector. As custodian of medicines and the country's healthcare regulator, the PSD is responsible for ensuring the public gets access to safe, efficacious and quality pharmaceutical products, protecting their interest via enforcement of relevant legislations, and ensuring rational use of medicines by both healthcare providers and patients.

As the pharmaceutical industry progresses, the dynamics of relationship amongst healthcare stakeholders certainly has to adapt to the changing business environment. While the role of regulation and enforcement has been perceived as being solely under the purview of healthcare authorities, evolving over the years, the pharmaceutical industry must be ready to shoulder shared responsibilities and practices self-regulation diligently and be a key partner in ensuring ethical promotion.

Self-regulation can be defined as the controlling of a process or activity by the people or organisations that are involved in it rather than by an outside organisation such as the government. Effective self-regulation offers consumers a double layer protection. It does not replace statutory legislation but complements an existing framework of law to provide robust and proportionate consumer protection with advantages not only for consumers, but also the business and governments. With regards to pharmaceutical advertising, an element of self regulation is the **Code of Conduct,** in which marketers must abide in terms of how they advertise.

I am happy to note that the pharmaceutical industry in Malaysia together with PhAMA has been working closely with the MAB to ensure compliance of the industry code and to establish an appropriate channel of communication when non-compliance occurs. Such efforts should be extended to other healthcare sectors like medical devices and generic pharmaceuticals. Indeed, this will create a conducive business environment; ensuring the best available healthcare for the patients.

In our pursuit for better healthcare, the Ministry of Health has always emphasised the importance of quality services. Key Performance Indicators (KPIs) have been introduced to ensure targets set meet customers satisfaction. Value-added services have been implemented to provide various options for patients to obtain their medications from hospitals and health clinics, efficiently and effectively. While embarking on a proposed national healthcare transformation, the Pharmaceutical Services Division is working together with the relevant stakeholders to plan and make recommendations in all important aspects related to medicines.

Ladies and Gentlemen,

The Malaysian National Medicines Policy (MNMP), established since 2006 puts in place a comprehensive guide related to medicines, incorporating key elements such as quality, safety, efficacy, affordability, availability and quality use. The growing importance of ethics and governance was given due consideration during the full term review last year, hence recommending it to be a new element in the MNMP.

In tandem with the Government's efforts to establish integrity as an important element in the public services to curb corruption, the Pharmaceutical Services Division has been working on the Good Governance of Medicines (GGM), a project initiated by the World Health Organisation (WHO). The Phase I of the GGM project, involving the assessment of ethical practices in medicine registration, selection and procurement was done in 2004. The aim of the assessment was to determine the degree of vulnerability to corruption in the registration,

selection and procurement processes of pharmaceuticals and to highlight areas where the current system is most prone or vulnerable to corruption.

The Phase II of the program was the development of GGM framework, which outlined the basic components needed in the GGM programme to address and prevent corruption in the pharmaceutical sector. The framework integrates the two basic strategies necessary to promote good governance and to reduce corrupt practices. We are currently in the Phase III which is the Implementation of National GGM. In preparation for this phase, a GGM Training of Trainers (TOT) module and 2 GGM related guidelines were developed. The 2 GGM guidelines published are: Guidelines on Giving and Receiving Gifts for Civil Servants under the Pharmacy program and Guidelines for Pharmacy Members in Dealing with Pharmaceutical Company Representatives and Suppliers.

Malaysia's involvement in the GGM programme was to further strengthen transparency in medicines management practice and contribute to World Health Organization (WHO) global initiatives in preventing corruption in healthcare systems. Governance of Medicines has also been included in the reviewed National Medicines Policy, whereby ethics and code of conduct will be the emphasis of this component. With this, health professional bodies and relevant stakeholders shall have codes of conduct and be responsible for ensuring compliance by its members with the code. Additionally, stakeholders shall perform in accordance with the standards of practice developed by appropriate authorities or relevant professional bodies. Relevant legislation/regulations shall also be developed and reviewed regularly to ensure an efficient supply chain network and integrated medicines management to safeguard the public.

In the future, PSD plans to conduct more studies to assess the level of transparency and implementation of GGM in Malaysia. While we are working to strengthen and institutionalise good governance of medicines

in the public sector, the next step is to further extend it to the private sector. This is one of the initiatives that will lift all industry players a notch higher, ensuring all stakeholders continue to operate within a high level of business ethical standards. And we hope to embark in such innovative programmes in the near future.

Ladies and Gentlemen,

One of the challenges that we face in enforcing MASA is the emergence of various innovative products of *food-drug*, *device-drug* and *cosmetic-drug inter-phase* categories. The current situations whereby these interface products are currently governed by different set of laws and regulations pose some difficulty. Led by the Pharmaceutical Services Division, the Ministry of Health is now exploring and studying the possibility of establishing a single enforcement entity to coordinate and integrate issues related to control and regulation of products and services.

In this day and age, online advertising are developing at an incredible pace, changing the scenario significantly for consumers, giving them access to potentially unlimited loads of information, creating a global marketplace, and offering more shopping convenience. Nevertheless, the fact that online advertising is borderless by nature has made it more complicated for us as law enforcement authorities to deal and track their business activities and modus operandi.

In the light of rapid expansion in ICT, moving forward, we have revised our regulations and guides. Our new Pharmacy Bill, when enacted will provide an avenue for self regulation in the control of medicines advertisement. The bill has undergone public consultations and hopefully it will be tabled in parliament in due time.

While a lot of work still needs to be done, self regulation needs a through commitment from all the stakeholders. It needs a strong legal framework to enforce penalties, punish offenders and impose deterrent sanctions. New standards and guidelines for ethical promotion of pharmaceutical products shall also be developed. Thus, I would like to urge the industry to prepare themselves and work together with us towards the implementation of self regulation. After all, safety, efficacy and quality of drugs as well as well beings of patients are our utmost priority.

Interactions between the healthcare industry and healthcare professionals, public and private, to promote better understanding are essential to ensure the appropriate use of healthcare products. Ethical and responsible promotion of healthcare products requires commitment from both healthcare professionals and the industry, which is essential for patient health and safety. For that reason, the need for multi stakeholder collaboration through engagements and consultations becomes very crucial to ensure that patients and consumers receive the best available medical treatments and health care.

Ladies and Gentlemen,

Before I conclude, once again I would like to express my sincere appreciation to IFPMA and PhAMA for their continuous efforts in upholding and promoting ethical practices amongst players of the pharmaceutical industry by abiding to the Code of Conduct. Indeed, it is an exemplary partnership which benefits all stakeholders involved - healthcare professionals, patients, caretakers, caregivers and members of the public. I believe we will achieve our desired goals through such a symbiotic relationship.

Finally, let me wish IFPMA and PhAMA every success in their keen endeavours to champion ethics and best business practices within the pharmaceutical industry.

Thank you.