

PREAMBLE

The Malaysian National Medicines Policy (MNMP) which was revised in 2012 aims to promote equitable access and rational use of safe, effective and affordable essential medicines of good quality to improve the health outcomes of the people. Being a crucial commodity in healthcare, medicines have to be duly regulated and managed to ensure that the wellbeing of the public is safeguarded.

Malaysia has a dichotomous healthcare system where public healthcare expenditure is almost fully subsidised by the government while private healthcare spending is covered either through private health insurance, employers or out-of-pocket (OOP) payments. In the public health system, there is an indirect price control mechanism through the Ministry of Finance (MOF) policies and directives. However, in the private sector medicines are priced according to market forces and competition.

It has been reported that the prices of medicines in Malaysia are among the highest in the region despite the fact that medicines imported into the country are non-taxable. A prominent reason to this is the monopoly of new single source medicines which leads to high drug prices set by registration holders to recoup some or all of their initial investment. This has a direct impact on affordable access to new medicines.

However, high price of medicines is not the only issue in the private sector. The pharmaceutical market failures mainly in the form of information imbalance and failure of competition has led to price disparities within and between distribution channels. Price cutting between giant chains and independent pharmacies, market monopoly, creation of artificial demand, unfair bonusing, discounts and rebates and bundling of unwanted medicines has created an unhealthy and dysfunctional market and business environment.

Thus, it is timely for the introduction of a guideline on “Good Pharmaceutical Trade Practice (GPTP) for Private Sector” towards ensuring best trade practices across the pharmaceutical distribution chains. All pharmaceutical trade practices should be in line with existing laws and regulations and this guideline will address the finer details not spelt out under current legislations. It is hoped that this guideline shall serve its purpose well in ensuring that medicines needed for quality healthcare shall be affordable and accessible to all.

GOOD PHARMACEUTICAL TRADE PRACTICE

INTRODUCTION

GPTP is a guide towards ensuring good trade practice across the pharmaceutical distribution chain. All parties shall comply with existing legislations governing the pharmaceutical trade.

SCOPE OF PRODUCTS

GPTP applies to medicines in Group B and Group C as stated in the Poison Act 1952.

- Group B: Prescription Only Medicine (POM).
- Group C: Pharmacist Only Medicinal Product (POMP).
- Psychotropic substances, dangerous drugs and pseudoephedrine are excluded from this guideline.

DISTRIBUTION CHANNELS

GPTP covers all authorised pharmaceutical distribution channels of medicines, including, but not limited to manufacturer, importer, wholesaler, supplier, practitioner and retailer in pharmacies, clinics, hospitals and warehouses.

FIVE (5) COMPONENTS:

1. Standard price and bonus scheme to all channels and healthcare providers.

- Pharmaceutical companies should encourage and extend similar bonus scheme to all distributing channels.
- Reasonable bonus scheme is allowed.
- There should not be any inducement to purchase with extra gifts and benefits.
- Accessibility of product should not be impeded by trade terms such as additional charges, listing fees, additional trading terms from retail outlets, additional price discounts, advertisement fees, monetary or product incentives, sales and volume rebates and etc.

2. Provision of an official wholesale price list and formal announcement on price revision or any change of trading terms from suppliers to its consumers.

- Formal notification from the suppliers before any price revision should be sent to all relevant distributing channels and MOH at least 1 month before execution of the new price.
- Suppliers will be required to provide the wholesale price list to MOH once a year.

3. No market exclusivity for a product to any channel unless administratively advised or directed by MOH.

- There should not be any discriminatory sale practices to the various distribution channels for all products and their stock keeping unit (SKU).

4. Responsible promotion of products and services within the code of conduct/ practices.

- All associations and guilds should develop their own code of conduct/ practices in line with the Malaysian guideline on Good Governance in Medicine.

5. Establishment of an appropriate system of control and accountability of samples provided to healthcare professionals.

- Samples of medicines should not be sold by anyone and should be used as intended for market research, improve access or enable prescribers to gain experience with its use.
- Samples are only for newly launched medicines less than 2 years in market, unless justified.
- Samples distribution shall be discouraged.

CONCLUSION:

This guideline aims:

- To harmonize the current trading practices between/within all pharmaceutical distributing channels towards fair pricing and equitable access to quality medicines.
- To allow public to get the benefit from price discounts/ rebates thus increase their access to affordable medicines.
- To promote transparency in price information.

DEFINITIONS :

1. *Authorised pharmaceutical distribution channels:*

- Any distribution channels with appropriate licence or practising certificate issued by MOH related to their business or profession.

2. *Reasonable bonus:*

- Either bonus scheme of 30% or tier-pricing of 30% between the lowest-tier to the highest-tier.

3. *Newly launched medicinal products:*

- New product (new chemical entity and generic) marketed from the first date of commercial sales.

4. *Unless advised or directed by MOH:*

- Advice or directive given by MOH on a case to case basis for the condition as follows:
 - use of highly specialized product or treatment e.g. HIV case.
 - packaging for special requirement.
 - to safeguard public health.