PhAMA Position Paper on Generic Medicines
May 2010

1. Background

Malaysia's robust healthcare system, responsible for the significantly improved health status of the nation, has elicited widespread commendation by countries and global health organisations, including the World Health Organisation. It has the distinction of being referred to as a healthcare model for other developing countries to emulate.

The integral pillar of this healthcare system is the country's National Medicines Policy, formulated to coordinate healthcare stakeholders' commitment and efforts to ensure that only safe, efficacious and quality medicines of approved standards are registered and approved for sale and use in Malaysia.

Rising healthcare costs continues to challenge the sustainability of the Malaysia's healthcare system. The Ministry of Health (MOH) Malaysia and healthcare stakeholders are looking for available options to ensure continued affordability by the payors, comprising the Government, insurers or private individuals. Therefore, it is imperative that medicines remain affordable to payors.

In support of this objective, PhAMA acknowledges the role of quality generic medicines, existing alongside innovator medicines, in a country's progressive healthcare system.

For the reasons stated above, PhAMA strongly believes that quality generic medicines can contribute significantly to increasing access to medicines and supporting the aspirations of healthcare providers to achieve the best quality of care for patients whilst, managing costs.

2. PhAMA's Position

PhAMA firmly believes that there is a role for both innovator and quality generic medicines in Malaysia's healthcare system. Innovator medicines are registered and approved for sale and use in Malaysia pursuant to approved standards outlined National Medicines Policy. PhAMA advocates that generic medicines shall adhere to approved standards and must be safe, efficacious and quality generic medicines which are registered and approved for sale and use in Malaysia. This ensures that patient safety is always at the forefront of the endeavours of the pharmaceutical industry and Government.

In order for the pharmaceutical industry and Government to achieve the objective stated above for quality generic medicines ("Generics"), PhAMA puts forth the following recommendations for consideration:

2.1 Clearly Defined Standards for Generics

a. Generics must be produced by Manufacturing facilities that adhere strictly to Good Manufacturing Practice (GMP) standards using Active Pharmaceutical Ingredients (APIs) and excipients from duly audited sites that conform to International GMP standards.
b. Generics must be granted licenses only after they are able to prove bioequivalence with the innovator product. To this end, PhAMA supports the MOH Malaysia's call for the accreditation of more Bioequivalance (BE) centers to ensure the standardisation of the conduct of BE studies in order to generate high quality data required for the registration of generics;
c. Generics, whether manufactured in Malaysia or imported, shall not in any way infringe any intellectual property rights of innovator medicines;

d. Generic manufacturers must commit to a robust pharmacovigilance framework that will enable diligent regular monitoring, tracking and reporting of adverse events (AEs) to the Malaysian Drug Control Authority;
e. As with innovator products, Generics must be subject to the rigorous supervision of the Drug Control Authority and therefore subject to the same rules in relation to maintenance of quality standards;
f. Pharmaceutical companies, both innovator and Generics, must adhere to a strict code of conduct that espouses only the highest ethical promotions of medicines to Healthcare Professionals; as well as a comprehensive framework within its trade organisation for ensuring compliance among its members, including sanctions for those found to be in violation of these codes.

2.2 *That Patient Care Remains a Healthcare Professional's Discretion*

The role of a doctor is to diagnose and determine for their patients, which treatments will help them and how these treatments will work. Doctors remain at the forefront of helping patients understand their respective medical conditions, the treatments available and the risks and benefits of the recommended treatments. As such, patient care remains with doctors who have the relevant expertise and have been educated and trained on diagnosing and treating patients.

The role of the pharmacist, being qualified by examination, registered and authorised to dispense medicines, is to dispense the medication to patients and counsel them on the proper use and adverse effects of that medications thus ensuring safe and effective use of medications.

Therefore, PhAMA believes that both roles are valuable and need to be respected, in order to protect the patient's safety at all times.

PhAMA is not in support of interchangeability or substitution of generic medicines at the pharmacy level without prior consultation with a patient's physician.

2.3 *The Importance of a Level Playing Field*

Malaysia has a long established history of promoting an environment that encourages investment, among foreign and local companies alike.

The establishment of clearly defined standards for Generics will create a level playing field for innovator and generic medicine manufacturers and/or suppliers. This level playing field encourages foreign and local companies to continue investing in Malaysia. Such an environment will be conducive in promoting a sustainable and competitive Generics industry that contributes to increasing access to drugs and improving quality of healthcare delivery while keeping healthcare costs manageable.

It is therefore important that only quality generic medicines that meet the requisite legal and regulatory requirements be allowed distribution rights in Malaysia, including but not limited to the participation in Government tenders.

The promotion of an open and transparent environment where innovators and Generics can compete effectively will ultimately result in a win-win situation for manufacturers, suppliers, payors, and ultimately and most importantly, the patient.

Prepared by: PhAMA Policy Committee