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NATIONAL
GENERIC MEDICINES
FRAMEWORK

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NATIONAL **GENERIC MEDICINES** FRAMEWORK

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KEY TERMS

The following are the definition to some key terms used in this document:

Term	WHO Definition
Generic Medicines	Pharmaceutical product usually intended to be interchangeable with the originator brand product, manufactured without a licence from the originator manufacturer and marketed after the expiry of patent or other exclusivity rights. Generic medicines are marketed either under a non-proprietary name, or occasionally another approved name, rather than or brand name.
Brand Name	Name given to a pharmaceutical product by the manufacturer. The use of this name is reserved exclusively to its owner as opposed to the generic name. Brand names may also be used for generic products; they are then often called 'branded generics'. These brand names are different from innovator brand names.
Essential Medicines	Essential medicines are intended to be available within the context of functioning health systems at all times, in adequate quantities, in the appropriate dosage forms, with assured quality and adequate information, and at a price the individual and community can afford. The WHO model list of essential medicines is intended to be flexible and adaptable to many different situations; the precise definition of the medicines that are regarded as essential remains a national responsibility.
Innovator	Generally the product that was first authorised worldwide for marketing, normally as a patented product, on the basis of the documentation of its efficacy, safety and quality, according to requirements at the time of authorisation. The innovator product always has a brand name; this name may, however, vary between countries.

Term	WHO Definition
International non-proprietary name (INN)	A common, generic name selected by designated experts for the unambiguous identification of a new pharmaceutical substance. The selection process is based on a procedure and guiding principles adopted by the World Health Assembly. INNs are recommended for worldwide use. The system was introduced by WHO in 1950 as a means of identifying each pharmaceutical substance or active pharmaceutical ingredient by a unique name that is universally accessible as public property (non-proprietary). It is often identical to the generic name, e.g. diazepam. A brand name (trade name) should not be derived from the INN name.

1. INTRODUCTION

1.1 The Malaysian healthcare system runs as a two-tiered system consisting of public and private healthcare sectors (1), (2). In the public sector, healthcare costs are subsidised by the government through general taxation, whereas in the private sector, these costs are paid for by patient's out-of-pocket funds, private insurance or their employers (3), (4).

1.2 The principal objective of the Malaysian National Medicines Policy (MNMP) is to improve health outcomes of Malaysians by promoting equitable access to essential medicines, promoting rational use of medicines and ensuring quality, safety, effectiveness and affordability of medicines (5). The policy includes a range of measures, including procurement policies and price transparency mechanism, information and education, quality assurance, and monitoring and evaluation.

1.3 Part of the MNMP is the development of a National Generic Medicines Framework which aims to foster healthy competition in medicines pricing and achieve generic prescribing in both public and private healthcare institutions.

1.4 Generic Medicine is defined as a product that is essentially similar to a currently registered product in Malaysia. Generic medicines may be further classified into two groups; Scheduled Poisons and Non-Scheduled Poisons. However, the term generic is not applicable to Biologics (including biosimilars) (6). Therefore, the scope of this framework focuses on generic medicines and does not include biosimilars.

1.5 The Director General of Health has issued a directive on generic medicines labelling (Surat Pekeliling KPK Bil 17/1986) to call for all medicines dispensed in public healthcare facilities to be labelled by their generic names. Such practice has been implemented in all public healthcare facilities where generic medicines are widely used.

2. PRINCIPAL REASONING FOR GENERIC MEDICINES UTILISATION

2.1 Generic medicines are generally cheaper than their counterpart innovator medicines. By improving the uptake of generic medicines, the Malaysian healthcare system can be more sustainable as the use of more affordable generics may help to insulate budgets against future crises and improve patients' access to medicines (4).

2.2 With improved access and affordability of medicines, patients' adherence to medicines will also increase as they are more likely to take the medications prescribed.

2.3 Having more generics in the market will promote competition in the pharmaceutical industry and stimulate innovation and development of new and better treatments in the country.

2.4 The regulations governing the standards and guidelines for the registration of generic medicines in Malaysia, including the requirement to conduct bioequivalence (BE) studies, are established through a directive issued by the Senior Director of Pharmaceutical Services in accordance with the Control of Drugs and Cosmetics Regulations 1984 (7), (8).

3. ONGOING EFFORTS TO IMPROVE UTILISATION OF GENERIC MEDICINES

3.1 GENERIC MEDICINES AWARENESS PROGRAMME (GMAP)

3.1.1 In 2013, the Pharmaceutical Services Programme (PSP) launched the GMAP as an initiative to increase awareness and promote the use of generic medicines amongst healthcare professionals and the general public (9). This programme supports the MNMP's stance on the use of generic medicines to foster healthy competition in medicine pricing.

3.1.2 Both pharmacists and prescribers should have positive perceptions toward generic medicines as all generic medicines are required to undergo strict evaluation processes before being able to be marketed in the country.

3.1.3 The GMAP is a great initiative that should continue to run alongside the "Know Your Medicines" Programme as continuous education for the general public.

3.1.4 Efforts should be made to reinforce and sustain educational activities and awareness campaigns targeting healthcare professionals regarding generic medicines, particularly on bioequivalence (BE).

3.2 CONSUMER PRICE GUIDE

3.2.1 The Consumer Price Guide was introduced by the PSP as a reference for the consumer to make informed choices in purchasing medicines in the private

sector. This guide lists the suggested retail price for specific brands including generic medicines that is voluntarily declared by the Product Registration Holder (PRH). However, the actual retail prices of medicines in the market may differ from those displayed in the PSP portal.

3.2.2 Currently, the PSP has proposed a Medicines Price Transparency Mechanism to encourage the voluntary submission of prices for each supply chain and the display of medicine sales prices at private healthcare facilities (10). This initiative aims to empower the public to make informed choices, especially regarding generic medicines that are typically more affordable than innovators.

4. OBJECTIVES

4.1 The National Generic Medicines Framework is introduced to recommend best practice for generic medicines use in all healthcare facilities in Malaysia by emphasising the use of quality, safe and efficacious medicines.

4.2 This framework shall be used as a guide in procurement and distribution systems, prescribing, selling and supplying of medicines and rational use at every level of the healthcare system.

4.3 To ensure the accessibility and affordability of medicines for all Malaysians, this practice should be extended to private healthcare institutions and clinics, as well as community pharmacies.

5. RECOMMENDATIONS FOR IMPLEMENTATION

Synergistic collaborations and partnerships between stakeholders, including government, pharmaceutical industry, health insurance providers, academia, and civil society are required to improve access to generic medicines.

5.1 USING GENERIC TERMINOLOGIES AT ALL LEVELS OF HEALTHCARE **(Pharmaceutical industry, healthcare facilities, healthcare providers)**

5.1.1 This framework advocates for generic prescribing whenever possible using their International Non-Proprietary Names (INN), except where a change to a different manufacturer's product may compromise efficacy or safety.

5.1.2 Prescribers are recommended to indicate clearly in writing, where there is intention to prevent substitution, that no substitution shall be done or only a specific brand can be dispensed for that particular prescription (6), (9).

5.1.3 All dispensed medicines shall be labelled prominently with the generic INN of the medicine with or without the brand name to help patients to identify their medicines and avoid misunderstanding when substitutions occur.

5.1.4 This framework recommends the use of generic terminology in drug labelling, selling and supplying, and medication counselling to prevent polypharmacy and empower patients to identify their medicines and avoid misunderstanding when substitutions occur.

5.1.5 The use of integrated systems can eliminate discrepancies between the processes involved within patient care and enable systematic medicines management.

5.1.6 In selection for procurement, priority to domestically manufactured medicines can be considered where applicable.

5.1.7 This framework encourages healthcare professionals in both public and private sectors to offer generic options and promote the use of generic medicines in their respective facilities.

5.2 SHARED DECISION-MAKING BETWEEN HEALTHCARE PROVIDERS AND PATIENTS TO ACHIEVE PATIENT-CENTRED CARE

(Healthcare providers, patients)

5.2.1 Shared decision-making is a process in which healthcare professionals and patients or people using services work together to select tests, treatments, management or support packages, based on best available evidence and the person's informed preferences.

5.2.2 This framework encourages shared decision-making between prescribers and their patients in the selection between proprietary and generic medicines.

5.2.3 Patients should be given the option to receive proprietary or generic drugs as well as the right to obtain the medicine from other sources when either drug is unavailable (4).

5.2.4 It should be noted that, although the ultimate clinical decision lies on the prescriber, the views and rights of the patient shall be taken into consideration.

5.3 REGULAR MEDICATION REVIEWS AND CONTINUOUS PATIENT EDUCATION

(Healthcare providers)

5.3.1 Patients' medications should be regularly reviewed to ensure optimal treatment and avoid duplication of medications from multiple sources where patients get treatment or medication supplies.

5.3.2 Pharmacists can check for duplication of medicines through regular medication reviews in public, private and community settings (11). These sessions can be an opportunity for pharmacists to identify polypharmacy (12) and enhance public awareness and understanding of generic medicines as effective alternatives to innovator drugs, ensuring informed choices in medication selection.

5.3.3 Good communication between pharmacists and prescribers is essential to improve the management of patients' treatments in the public and private sectors.

5.4 INCREASING LOCAL GENERIC MANUFACTURING CAPACITY

(Government, other ministries/ agencies, pharmaceutical industry, academia)

5.4.1 To reduce the dependency on import of active pharmaceutical ingredients (API) from other countries by strengthening government-to-government agreements to ensure the security of API supply to the country (13). This is particularly crucial during crises where drug shortage pose a threat to national health.

5.4.2 Incentives shall be introduced to strengthen domestic manufacturing capabilities and the nation's self-sufficiency and security of supply of high-quality, affordable generic medicines, especially those in the National Essential Medicines List (14).

5.4.3 Malaysia shall continue to explore and increase the efforts in the promotion of halal generic medicines to penetrate the Middle East and other Muslim countries. Malaysia being a member of The Organisation of the Islamic Cooperation (OIC) and the Pharmaceutical Inspection Cooperation Scheme (PIC/S) (15), as well as having high regulatory standards are advantageous for moving into the export market (16).

5.4.4 There are initiatives relating to inter-ministerial (17) and other agencies pooled-procurement, as well as at ASEAN and regional levels. The Malaysian pharmaceutical industry should leverage on the efforts within this platform to promote Malaysia's local pharmaceutical industry.

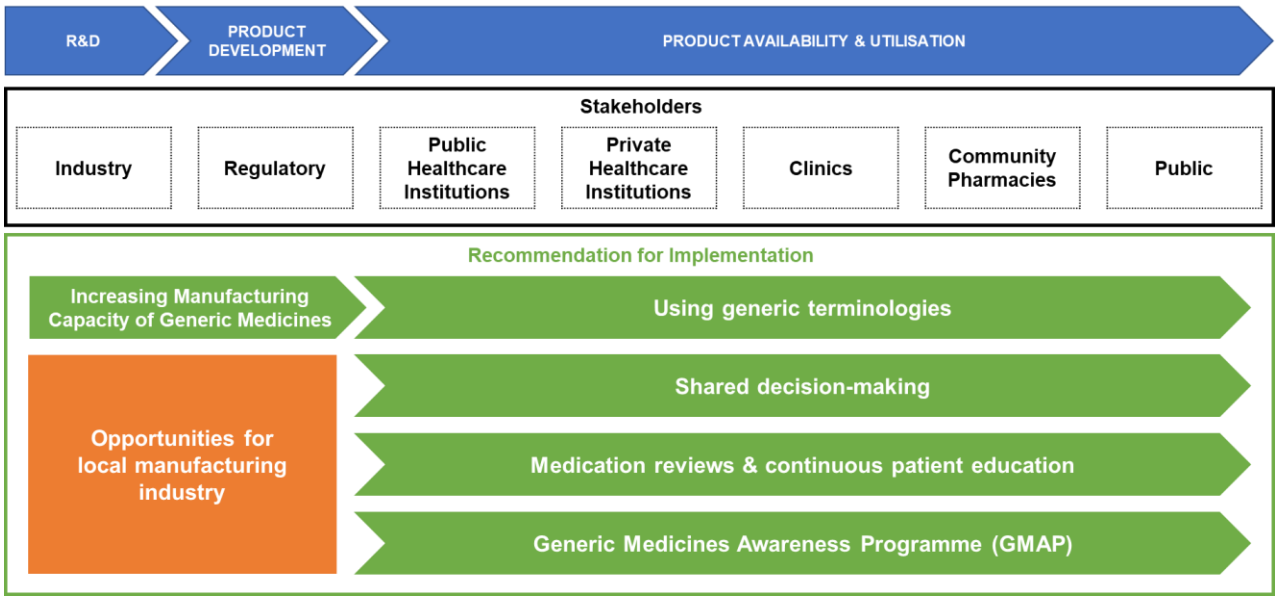
6. WAY FORWARD

6.1 The Health White Paper (HWP) for Malaysia aims at reforming the nation's health system towards realising better health and well-being for the people. The National Generic Medicines Framework can be used to support the implementations of initiatives under the HWP.

6.2 Malaysia should emulate the efforts that have been done in other developing and developed countries such as the Philippine's Generic Act 1988, South Africa's National Drug Policy and the UK's National Institute for Health and Care Excellence (NICE) Patient Decision Aids (PDAs) to promote the use of generic medicines for the benefit of the nation.

6.3 In the future, Malaysia could explore the possibility of generic substitution as done in many developed countries such as Finland, Sweden and Japan.

High-Level Diagram of
The National Generic Medicines Framework



7. SUMMARY

7.1 The National Generic Medicines Framework serves as a comprehensive and strategic approach towards promoting the accessibility, affordability, and quality of generic medicines within our nation. By implementing this framework, we aim to improve healthcare outcomes, reduce healthcare costs, and enhance the overall well-being of our population

7.2 Through this framework, we have established the importance of public awareness and education, enabling healthcare professionals and the public to make informed decisions regarding the use of generic medicines.

7.3 The framework recognises the significance of collaboration and partnerships among stakeholders, including healthcare professionals, pharmaceutical manufacturers, regulatory bodies, and patient advocacy groups. Together, we work towards creating an environment that fosters innovation, competition, and continuous improvement in the generic medicines sector.

7.4 As we move forward, this framework shall be monitored continuously to evaluate its effectiveness, making necessary adjustments to address emerging challenges and align with international best practices. The ultimate goal is to ensure that every individual has equitable access to affordable and high-quality generic medicines, supporting the delivery of optimal healthcare for all.

7.5 The National Generic Medicines Framework paves the way for a more sustainable, inclusive, and patient-centric healthcare system, in line with the Health White Paper, which aims to transform the healthcare system by enhancing accessibility, affordability, and quality of healthcare services. By promoting the use of affordable generic medicines, ensuring quality standards, and fostering collaboration, Malaysia strives to achieve universal health coverage and improved health outcomes for all its citizens.

REFERENCE

[1] D. K. L. Quek, “The Malaysian Health Care System: A Review,” 2014, [Online]. Available: https://www.researchgate.net/publication/237409933

[2] D. Ahmad, “Enhancing Sustainability in Healthcare Delivery - A Challenge to the New Malaysia,” *Malaysian Journal of Medical Sciences*, vol. 26, no. 1. Penerbit Universiti Sains Malaysia, pp. 1–4, 2019. doi: 10.21315/mjms2019.26.1.1.

[3] N. Z. Balqis-Ali, A. S. Jailani, W. H. Fun, S. Jawahir, S. Sararaks, and G. H. Y. Lee, “Effect of Supplementary Private Health Insurance on Inpatient Utilisation: Evidence from Malaysia,” *Heliyon*, vol. 9, no. 3, Mar. 2023, doi: 10.1016/j.heliyon.2023.e14025.

[4] C. S. Zin, N. S. A. Rahman, N. I. M. Nazar, A. Kurdi, and B. Godman, “Trends in the Cost of Medicines, Consultation Fees and Clinic Visits in Malaysia’s Private Primary Healthcare System: Employer Health Insurance Coverage,” *J Multidiscip Healthc*, vol. 16, pp. 1683–1697, 2023, doi: 10.2147/JMDH.S403589.

[5] MOH Malaysia, Pharmaceutical Services Programme, *Malaysian National Medicines Policy (MNMP) 2022-2026*. 2022. Accessed: Jan. 09, 2024. [Online]. Available: https://pharmacy.moh.gov.my/ms/entri/dasar-ubat-nasional-dunas-penggal-keempat.html

[6] MOH Malaysia, Pharmaceutical Services Programme, *Position Statements on the Use of Biosimilars in the Ministry of Health, Malaysia Healthcare Facilities*. 2022. [Online]. Available: http://www.pharmacy.gov.myWebsite:www.pharmacy.gov.my

[7] MOH Malaysia, National Pharmaceutical Regulatory Agency (NPRA), *Drug Registration Guidance Document (DRGD)*.

[8] “Control of Drugs and Cosmetics Regulations 1984”, Accessed: Jan. 09, 2024. [Online]. Available: https://pharmacy.moh.gov.my/ms/dokumen/akta-jualan-dadah-1952-peraturan-peraturannya.html

[9] MOH Malaysia, Pharmaceutical Services Programme, *What Prescribers Should Know About Generic Medicines*. 2022. Accessed: Jan. 09, 2024. [Online]. Available: https://pharmacy.moh.gov.my/sites/default/files/document-upload/gmap-book-2013.pdf

[10] MOH Malaysia, Pharmaceutical Services Programme, “Medicine Prices Monitoring In Malaysia Survey Report 2020,” 2020. Accessed: Jan. 09, 2024. [Online]. Available: https://pharmacy.moh.gov.my/ms/dokumen/kajian-pemantauan-harga-ubat-kphu-malaysia-2020.html

[11] C. T. Chang *et al.*, “Impact of Deprescribing intervention on Potentially Inappropriate Medications and Clinical Outcomes Among Hospitalized Older Adults in Malaysia: a Randomized Controlled Trial (REVMED RCT) Protocol,” *J Pharm Policy Pract*, vol. 16, no. 1, Dec. 2023, doi: 10.1186/s40545-023-00621-5.

[12] C. T. Chang *et al.*, “Polypharmacy and Potentially Inappropriate Medications Among Hospitalized Older Adults with COVID-19 in Malaysian Tertiary Hospitals,” *J Pharm Policy Pract*, vol. 16, no. 1, Dec. 2023, doi: 10.1186/s40545-022-00504-1.

[13] (MITI) Ministry of Investment, *New Industrial Master Plan 2030*. 2022. Accessed: Jan. 09, 2024. [Online]. Available: https://www.nimp2030.gov.my/

[14] MOH Malaysia, Pharmaceutical Services Programme, *National Essential Medicines List, 6th edition*. 2023. Accessed: Jan. 09, 2024. [Online]. Available: https://pharmacy.moh.gov.my/ms/dokumen/senarai-ubat-ubatan-penting-kebangsaan-neml.html

[15] Pharmaceutical Inspection Co-Operation Scheme (PIC/S), *Pharmaceutical Inspection Co-Operation Scheme (PIC/S)*. 2019. [Online]. Available: https://picscheme.org/en/members

[16] Malaysian Investment Development Authority (MIDA), “Malaysia’s Pharmaceutical Industry: A Fast-Growing Force,” 2022.

[17] KKM, Program Perkhidmatan Farmasi, “Laporan Eksekutif Kajian Penilaian Impak Harga Ubat-Ubatan Yang Dibeli Secara Perolehan Bersama (Pooled Procurement) di Sektor Awam,” 2023.