

3RD EDITION • 2017-2021





PHARMACEUTICAL SERVICES PROGRAMME

MINISTRY OF HEALTH MALAYSIA

MALAYSIAN NATIONAL MEDICINES POLICY

3RD EDITION • 2017-2021

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Malaysian National Medicines Policy (MNMP)

1st Edition, 2007



Malaysian National Medicines Policy (MNMP)

2nd Edition, 2012



Malaysian National Medicines Policy (MNMP)

3rd Edition, 2017

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- Hospital Kuala Lumpur
- Hospital Melaka
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- Traditional and Complementary Medicine Division, MoH
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- Federation of Malaysian Consumer Associations (FOMCA)
- Malaysian Pharmaceutical Society (MPS)
- Malaysian Community Pharmacy Guild (MCPG)
- Pharmaceutical Association of Malaysia (PhAMA)
- Malaysian Organisation of Pharmaceutical Industries (MOPI)
- Malaysian Association of Pharmaceutical Suppliers (MAPS)
- Malaysian Dietary Supplement Association (MADSA)
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INTRODUCTION

The Malaysian National Medicines Policy (MNMP) is an official document of the Government that defines and prioritises the medium and long-term goals of the country's pharmaceutical sector. The policy is a commitment of the Government and stakeholders in the public and private sector towards achieving the goals. The MNMP establishes framework and strategy plans for the implementation in the public and private sector. The principal objective of the 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.

The MNMP has entered into its third term (2017-2021) after a full review of its implementation conducted in September 2016. The Policy focuses on five main components which are the:

- 1. Governance in Medicines
- 2. Quality, Safety and Efficacy of Medicines
- 3. Access to Medicines
- 4. Quality Use of Medicines
- 5. Partnership and Collaboration for the Healthcare Industry

The policy implementation for the first and second term has shown tremendous positive outcomes and transformation. Achievements in establishing a comprehensive regulation system, strengthening of the laws and regulations, creating a robust pharmaceutical industry as well as developing an extensive pharmaceutical distribution network were observed. Nevertheless, improvement can still be adopted in several areas through reinforcement and embracing new ideas aligned with the policy objective.

With the revision of the MNMP, new policy statements and strategies are introduced for the pharmaceutical and health sectors to move forward and to provide for the present needs of the nation. The MNMP is also pre-emptive to address essential issues and areas for improvement to support existing government policies in order to meet future healthcare needs of the country.

Alongside the formation of the revised edition of MNMP, an appropriate and practical Plan of Action was developed based on the existing components and the newly-organised strategies outlined in the policy. With the concerted efforts from all the stakeholders, it is very much anticipated that the implementation of the Plan of Action will bring a remarkable impact to the health of the nation.



GOVERNANCE IN MEDICINES

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1. GOVERNANCE IN MEDICINES

1.1 POLICY

Good governance practices, conduct and professionalism shall be emphasised within the healthcare industry.

1.2 AIM

To have appropriate governance that ensures the provision of safe, quality, effective and affordable medicines within the best practice environment.

To ensure all stakeholders are responsible for conducting themselves in an ethical and professional manner.

To ensure regulations facilitate and support the governance, professionalism and practice.

1.3 APPROACH

Health professional bodies and relevant stakeholders shall have codes of conduct and be responsible for ensuring compliance by its members with the code.

Stakeholders shall perform in accordance with the standards and/or code of practice developed by appropriate authorities or relevant professional bodies.

Relevant legislation shall be developed and reviewed when needed to ensure an efficient and safe supply of medicines.

1.4 STRATEGY

1.4.1 Implementation of the Good Governance in Medicines (GGM) framework

The GGM Framework provides a national guide to implementing GGM in the pharmaceutical sector. The activities enlisted in the Framework shall be carried out by both the government and private sector.

Strategy 1: Implementation of the Good Governance in Medicines Framework

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
1.1	To review and update the GGM framework	Ongoing	Revised GGM framework	Implementation of GGM framework	GGM Committee Member
1.2	To review governance training module	Ongoing	Revised governance training module	Implement training module and monitor GGM training	GGM Committee Member
1.3	To inculcate a culture of high ethical conduct	2019	Number of stakeholders that has a code of conduct	Develop COC survey and send out to all companies to obtain baseline data	Private GGM Committee Member
		2020	Develop an action plan based on the results from the COC survey on the pharmaceutical companies	Create awareness on the importance of COC in the pharmaceutical industry	GGM Seminar Committee Member



QUALITY, SAFETY AND EFFICACY OF MEDICINES

MALAYSIAN NATIONAL MEDICINES POLICY

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2. QUALITY, SAFETY AND EFFICACY OF MEDICINES

2.1 POLICY

Ensuring medicines are of quality, safe and efficacious for consumers in Malaysia.

2.2 AIM

To ensure medicines marketed meet the approved standards and are in compliance with legal provisions for the well-being of consumers.

2.3 APPROACH

The aim shall be achieved by strengthening the medicines regulatory system through a comprehensive medicines legislation framework, enhanced measures for pharmaceutical quality assurance and effective post-marketing surveillance with collaborative support from the relevant stakeholders.

2.4 STRATEGY

LEGISLATION AND REGULATION

2.4.1 Ensuring all regulatory requirements are aligned with international standards

Regulations shall be strengthened and managed through judicious and transparent criteria and processes in accordance with relevant international standards and agreements. The level of regulation shall be consistent with potential benefits and risks to the community.

The NPRA shall collaborate with the industry and other stakeholders in order to strengthen the regulatory framework.

The NPRA shall play a prominent role in facilitating regional and international harmonisation of technical requirements for the registration of medicines.

2.4.2 Strengthening enforcement and regulatory activities under the relevant acts and regulations

Drug legislation and regulation shall be supported by adequate and effective enforcement to ensure that all activities in the manufacturing and supply of medicines comply with existing legislations, regulations, guidelines and directives.

Premises that manufacture, import, supply or dispense medicines shall be inspected regularly to ensure compliance to existing regulatory requirements.

PHARMACEUTICAL QUALITY ASSURANCE

2.4.3 Enhancing post-marketing surveillance activities and product safety

There shall be continuous monitoring on products available in the market in order to ensure conformity of the products to the current standards and requirements.

Strategy 1: Ensuring all regulatory requirements are aligned with international standards

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
1.1	Enhance regulatory control of vaccine in the aspects of laboratory testing	On-going	Number of methodology developed for vaccine testing	Three (3) vaccine testing methods developed	Bahagian Regulatori Farmasi Negara
1.2	Regulatory system strengthening through the National Regulatory Authority Assessment/ Benchmarking by World Health Organization (WHO)	2020	Achieved Maturity Level 4 and above	Obtain Level 5 Maturity	Bahagian Regulatori Farmasi Negara
1.3	1.3 Awareness engagement with stakeholders for regulation of Cell Gene Therapy Products (CGTP)	2017-2021	Number of awareness programme with stakeholder	Two sessions per year	Bahagian Regulatori Farmasi Negara
		2017-2021	Percentage of engagement with stakeholder	100% of engagement requested by stakeholder completed	
		2019	Baseline report survey (to identify CGTP in market and assess industry preparedness) done	Baseline report survey completed	

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
		2017-2021	 i. Involve in program workshop on regulatory science of CGTP ii. Build networking among regulators, for e.g. CORE, ISCT, APEC 	i. Involve in CoRE activities on CGTP iii. 1 workshop in 2019 and 2020 each for evaluators and stakeholder	
1.4	Establishment and implementation of guideline on therapeutic claims for herbal products	2021	Guideline approved by the DCA and implemented in 2020	100% evaluation of therapeutic claims for herbal products	Bahagian Regulatori Farmasi Negara
1.5	Strengthening Regulatory Capacity and Standards through Pharmaceutical Track and Trace System	2020	Implementation of 1st Phase of Pharmaceutical Track and Trace System	1st phase Track & Trace System by 2020	Pharmacy Policy and Strategic Planning Division

CoRE: Centre of Regulatory Excellence ISCT: International Society of Cell and Gene Therapy

APEC: Asia-Pacific Economic Cooperation

Strategy 2: Strengthening enforcement and regulatory activities under the relevant acts and regulation

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
2.1	Combating online sales of illegal and illicit medicines	On-going	Percentage of illegal and illicit medicines online sellers identified within 30 working days from profiling started	95%	Pharmacy Enforcement Division
		On-going	Number of actions taken on online sales of illegal and illicit medicines	400	Pharmacy Enforcement Division
2.2	Expand the "Didik, Pantau and Serbu (DiPS)" approach to the hotspot areas	On-going	Percentage of identified premises selling unregistered drugs openly, reduced each year cumulatively	Reduction by 95%	Pharmacy Enforcement Division
2.3	Enhancement of inspection coverage and compliance level to premises dealing with medicinal products	On-going	Percentage of premises dealing with medicinal products are in compliance with Pharmacy related Acts and Regulations	85%	Pharmacy Enforcement Division
		On-going	Number of inspections on premises dealing with medicinal products	15,000	Pharmacy Enforcement Division

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
2.4	Expansion of inspection scope to importers and wholesalers dealing with vaccines and blood products	On-going	Percentage of importers and wholesalers inspected are in compliance with Good Distribution Practice (GDP) guideline	100%	Bahagian Regulatori Farmasi Negara

Strategy 3: Enhancing post-marketing surveillance activities and product safety

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
3.1	Strengthening of Pharmacovigilance Activities through Pharmacovigilance Inspection	2016-2020	Implementation of Pharmacovigilance Inspection in phases	1 st Phase Implementation in 2021	Bahagian Regulatori Farmasi Negara
3.2	Enhancement of registered products conforming to standards and requirements	On-going	Percentage of registered products sampled conforming to standards and requirements	90%	Bahagian Regulatori Farmasi Negara



ACCESS TO MEDICINES

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3. ACCESS TO MEDICINES

3.1 POLICY

Medicines shall be accessible and affordable to meet healthcare needs of the nation at all times.

3.2 AIM

To ensure adequate, continuous and equitable access to quality medicines in line with healthcare needs.

3.3 APPROACH

Policy makers and all relevant stakeholders shall ensure a viable healthcare system for equitable access to medicines.

Suppliers and healthcare providers shall have a well-managed logistics system to provide adequate and continuous supply of medicines.

3.4 STRATEGY

3.4.1 Establish a reliable and sustainable financing mechanism to achieve universal access to medicines

A reliable, affordable and sustainable financing mechanism shall be established to achieve universal access to medicines. There shall be planning, budgeting and securing of sufficient funding for the supply of medicines with emphasis on cost-containment measures.

Financing mechanism shall ensure that the poor and underprivileged are not deprived of access to essential medicines.

3.4.2 Enhance collaboration amongst relevant stakeholders to ensure equitable access to medicines

Collaboration among various stakeholders and key players in the healthcare sector shall be enhanced to promote the effective use of resource and strengthen national and regional policies in ensuring equitable access to medicines.

3.4.3 Strengthen medicines selection mechanism in accordance with the country's health needs

A fair and transparent medicines selection mechanism in accordance with the country's health needs by emphasising clinical effectiveness and cost-effectiveness of treatments based on available standard of clinical practice/standard treatment guidelines.

Drug and Therapeutic Committee (DTC) shall be made available in health facilities to ensure medicines are of clinical and cost effective based on available resources. All health facilities are encouraged to refer to DTC guidelines published by MoH for establishment of DTC.

3.4.4 Enhancing the National Essential Medicines List (NEML) based on the country's need

The NEML shall be revised and updated regularly to serve as the national reference for domestic medicines industry for the purpose of production, procurement, distribution, utilisation and research as well as to the healthcare academia in their teaching curriculum.

3.4.5 Ensuring the availability of orphan medicines and non-commercially viable products without compromising the elements of quality, safety and efficacy

There shall be appropriate procedures to enhance the accessibility of life-saving products, orphan medicines and non-commercially viable products, without compromising its quality, safety and efficacy.

3.4.6 Ensuring the availability of medicines that caters to consumer/population needs and requirements where appropriate

This strategy serves the purpose to enable patients/consumers of certain religion/belief to use medicinal products that are suitable and allowed in their context. Guideline shall be developed as guidance for the use of these medicines.

3.4.7 All medicines shall continue to be given exemption of tariff and duties

Controlled medicines and listed essential medicines shall continue to be exempted from tariff and duties to reduce price and improve accessibility and affordability.

3.4.8 Implementation of Generic Medicines Policy

This initiative aims to foster healthy competition in medicines pricing and achieve generic prescribing in both public and private healthcare institutions.

This policy also shall be used as a guide in procurement and distribution systems, prescribing and dispensing of medicines and rational use at every level of the healthcare system both in public and private healthcare institutions.

3.4.9 Strengthening the procurement and supply system in order to ensure adequate and timely availability of medicines

An efficient, effective and transparent procurement and economical distribution network shall be strengthened to ensure timely availability of medicines and distribution of adequate quantities of quality medicines to end users.

Storage, inventory control and quality assurance in facilities and throughout the supply chain network shall comply with Good Distribution Practice requirement to ensure quality and security of medicines.

The disposal of medicines shall be done in accordance with existing regulations and guidelines.

3.4.10 Ensuring manageable and timely supply of medicines in emergency situations and donations

This strategy aims to ensure a systematic supply of medicines in national emergency situations and timely supplies of these medicines without compromising its quality, safety and efficacy.

Management of medicines as donation and in emergency situation shall be based on expressed needs as recommended by the WHO Guidelines for Medicines Donations from donor to the recipients or related guidelines.

3.4.11 Rationalisation of medicines pricing system in the public and private sector

Effort shall be taken to promote healthy competition towards fair and transparent medicines pricing, and sustainable cost-effective treatment. This initiative shall encompass the principles of equity, affordability and transparency.

This strategy aims to promote the availability of the quality, safe and effective medicines at affordable cost. Cost shall not become a barrier to ensure that medicines are available to the population.

All stakeholders shall collaborate to ensure transparency on medicines price in Malaysia.

3.4.12 Ensuring availability of quality and safe traditional and complementary medicines

A formulary of traditional and complementary medicines shall be developed by an expert advisory committee under the auspices of the Ministry of Health.

This formulary shall serve as a guide to ensure quality and safety of traditional and complementary medicines utilised in the Ministry of Health facilities.

Strategy 1: Establish a reliable and sustainable financing mechanism to achieve universal access to medicines

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
1.1	To propose reimbursement list/medicines tariff for claims made through public coverage/private health insurance providers/other payers	To revisit this initial system is confirm	ative after national m ed	edicines financing	Pharmacy Practice and Development Division
1.2	1.2 Improving access to affordable medicines through Patient Access Scheme (PASc)	2018	Guideline for PASc developed	Guideline developed and disseminated	Pharmacy Practice and Development
		2019-2021	Number of drugs approved for PASc	Increasing trend	Division

Strategy 2: Enhance collaboration amongst relevant stakeholders to ensure equitable access to medicines

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
2.1	To ensure that Ministry of Health (MoH) is referred before any pharmaceutical patent applications approval	2021	Number of pharmaceutical patent application referred to NPRA	Subject to application submitted	Bahagian Regulatori Farmasi Negara
2.2	2.2 To conduct a survey (situational analysis) within the ASEAN countries in improving access to medicines through the regional perspective	2020	Report presented to the ASEAN committee	Development of regional strategy proposal	Pharmacy Policy and Strategic
		2021	Regional strategy proposal developed		Planning Division

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
2.3	Implementation of innovative pharmacy service delivery/ mechanism through expansion of Integrated Drug Delivery System	2021	Number of centres established (cumulative)	Increasing trend	Pharmacy Practice and Development Division

ASEAN: Association of Southeast Asian Nations

Strategy 3: Strengthen medicines selection mechanism in accordance with the country's health needs

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
3.1	3.1 To promote the utilisation of local pharmacoeconomic data in selection of medicines	2020	Pharmacoeconomic Guideline 2 nd Edition published	Pharmacoeconomic Guideline 2 nd Edition completed and disseminated	Pharmacy Practice and Development Division
		Ongoing	Percentage of dossier received with pharmacoeconomic study	Increasing trend	
3.2	To enhance the functions of Drugs and Therapeutic Committees of institutions and local health facilities (focus on private hospitals)	2021	Percentage of Drug and Therapeutic Committee (DTC) formed in public and private health facilities	Increasing trend (more than 90%)	Pharmacy Practice and Development Division Pharmacy Policy and Strategic Planning Division

Strategy 4: Enhancing the National Essential Medicines List (NEML) based on the country's need

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
4.1	To update National Essential Medicines List (NEML) based on country's current needs	2017-2021	Number of revision done	Two periodic revisions done	Pharmacy Practice and Development Division
4.2	To ensure availability of essential medicines in the public and private healthcare facilities	2017-2021	Number of 'Kajian Pemantauan Harga Ubat' (KPHU) report published	Two periodic reports published	Pharmacy Practice and Development Division

Strategy 5: Ensuring the availability of orphan medicines and non-commercially viable products without compromising the elements of quality, safety and efficacy

No.	Activities	lmplementation Timeline	Indicator	Final Target	Stakeholder
5.1	To update the list of orphan drugs	2020	Official list available	Official list published	Pharmacy Practice and Development Division
5.2	To facilitate the registration, manufacturing and importation of noncommercially viable products	2021	Mechanism to facilitate registration, manufacturing and importation of non- commercially viable products established	Development of regional strategy proposal (mechanism proposed)	Pharmacy Policy and Strategic Planning Division

Strategy 6: Ensuring the availability of medicines that caters to consumer/population needs and requirements where appropriate

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
6.1	To develop a guideline on the use of medicines/ pharmaceuticals of animal origin	2018	Guidelines developed	Guideline published and disseminated	Pharmacy Policy and Strategic Planning Division Pharmacy Practice and Development Division

Strategy 7: Supply of controlled medicines and medicines listed under NEML will continue to be given exemption from tariffs and duties

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
7.1	To ensure newly registered controlled medicines being given continuous exemption from tariffs and duties	On-going	Number of medicines being imposed tariffs and duties	No medicines being imposed tariffs and duties	Pharmacy Policy and Strategic Planning Division

Strategy 8: Implementation of Generic Medicines Policy

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
8.1	To develop a National Generic Medicines Policy	2020	National Generic Medicines Policy developed	Publication and dissemination of the policy	Pharmacy Policy and Strategic Planning Division

Strategy 9: Strengthening the procurement and supply system in order to ensure adequate and timely availability of medicines

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
9.1	To develop a mechanism to provide healthcare professionals and consumers the current information on shortage of medicines	2021	Mechanism established	Establishment of the mechanism	Pharmacy Practice and Development Division

Strategy 10: Ensuring manageable and timely supply of medicines in emergency situations and donations

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
10.1	To develop a guideline specific to handling of medicines supply in emergency situations	2021	Guideline developed	Development of the guideline	Pharmacy Practice and Development Division
10.2	To develop a guideline on the medicines donation	2020	Guideline published	Publication of the guideline	Pharmacy Policy and Strategic Planning Division

Strategy 11: Rationalisation of drug pricing system in the public and private sector

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
11.1	To enhance the availability of medicines price information for public reference	2021	Percentage of medicines price data reported through MyPharma-C	Increasing trend	Pharmacy Practice and Development Division
11.2	To implement Medicines Price Setting Mechanism	2020	Medicines Price Setting Mechanism implemented	Implementation of Medicines Price Setting Mechanism	Pharmacy Practice and Development Division

Strategy 12: Ensuring availability of quality and safe traditional and complementary medicines (T&CM)

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
12.1	To develop the Ministry of Health T&CM List	2021	T&CM List developed	Implementation of T&CM List	Traditional and Complementary Medicine Division



QUALITY USE OF MEDICINES

MALAYSIAN NATIONAL MEDICINES POLICY

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4. QUALITY USE OF MEDICINES

4.1 POLICY

Quality use of medicines is the responsibility of all stakeholders. Activities by relevant stakeholders in support of informed and appropriate use of medicines shall be promoted.

4.2 AIM

To ensure judicious, appropriate, safe and effective use of medicines.

4.3 APPROACH

Best practice shall be applied to ensure the provision of safe and quality use of medicines at all levels of healthcare.

Education, training and continuous professional development of all healthcare professional involved in medication management shall include safe, appropriate and quality use of medicines.

Health literacy and empowerment of consumers shall be enhanced to better manage their medicines.

All personnel involved in medicines sales, promotion and media reporting shall have adequate knowledge in quality use of medicines.

4.4 STRATEGY

4.4.1 Prescribing and dispensing of medicines shall be in accordance with relevant guidelines

This strategy is to ensure that prescribing and dispensing of medicines shall adhere to existing guidelines. This can be achieved through implementation of good practices and periodical audits or surveys.

4.4.2 Strengthening of Antimicrobial Stewardship (AMS) programme

This strategy aims to optimize antimicrobial therapy in order to maximize clinical cure or prevent infections and to limit the unintended consequences such as the emergence of antimicrobial resistance and adverse drug events.

4.4.3 Strengthening of pharmaceutical care practices in non-MoH and private health facilities

This strategy is to encourage non-MoH and private health facilities to provide basic pharmaceutical care services according to existing benchmarks and standards.

4.4.4 Enhanced community engagement to encourage safe and effective use of medicines by consumers

This strategy is to educate and create awareness on safe and effective use of medicine by consumers. This will increase their knowledge and skill so they are able to make informed decisions.

4.4.5 Engaging media personnel on quality use of medicines

This strategy is to ensure responsible reporting of health-related article and advertisement.

Strategy 1: Prescribing and dispensing of medicines shall be in accordance with relevant guidelines

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
1.1	.1 Ensuring pharmaceutical care practices are in line with current international and local best practices approach	At least every 5 years or when necessary	Percentage of documents reviewed related to prescribing and dispensing of medicine	60%	Pharmacy Practice and Development Division
		On-going	Number of documents developed related to prescribing and dispensing of medicine (if necessary)	When necessary	
1.2	Monitoring and surveillance activities of drugs utilisation	Every 2 years	Number of surveillance audit on drugs/ group of drugs	1 surveillance audit every 2 years	Pharmacy Practice and Development Division
1.3	Ensure adherence to Malaysian Patient Safety Goals No.7: To Ensure Medication Safety initiative implemented in all healthcare facilities	On-going	Percentage of healthcare facilities achieving more than 60% marks in medication safety initiatives survey	Increasing trend MoH facilities: 80% Non-MoH facilities: 60%	Pharmacy Practice and Development Division

Strategy 2: Strengthening of Antimicrobial Stewardship (AMS) programme

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
2.1	Establishment of accredited AMS Training Centres	2018-2021	Number of accredited AMS Training Centres established (cumulative)	Increasing trend of number of pharmacists from State Hospitals trained in AMS Increasing trend of number of AMS Training Centres established	Pharmacy Practice and Development Division Medical Development Division Family Health Development Division
2.2	Monitoring and surveillance of antibiotics	On-going	No. of facilities involved in the national surveillance audit	Increasing trend	Pharmacy Practice and Development Division

Strategy 3: Strengthening of pharmaceutical care practices in non-MoH and private health facilities

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
3.1	Developing minimum standards of pharmaceutical care services in non- MoH healthcare facilities	2020	Standards of pharmaceutical care services in non-MoH healthcare facilities developed	Standards published dan disseminated	Private healthcare facilities Pharmacy Policy and Strategic Planning Division

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
3.2	Enhancement of pharmaceutical care services in community pharmacy	2019-2021	Number of facilities providing dispensing, counselling, public health promotion and medication utilisation review services	Increasing trend	Pharmacy Policy and Strategic Planning Division

Strategy 4: Enhanced community engagement to encourage safe & effective use of medicines by consumers

No.	Activities	Implementation	Indicator	Final Target	Stakeholder
		Timeline			
4.1	Engaging non- governmental organisations (NGOs)/professional society etc. to reach specific group towards quality use of medicines (QUM) & customer protection	On-going (yearly data)	Number of new project focusing on effort to educate and increase awareness of the public about QUM	1 new project per year	Pharmacy Practice and Development Division
4.2	Enhance quality use of medicines by consumers	On-going (yearly data)	Number of educational and promotional activities carried out by MoH	Increasing trend	Pharmacy Practice and Development Division
		2019-2021	Number of educational and promotional activities carried out by the private sector	Increasing trend	Pharmacy Practice and Development Division
		On-going (yearly data)	Number of educational and promotional activities carried out in school	Increasing trend	Pharmacy Practice and Development Division
			& institutes of higher education		

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
4.3	Empower community leaders on the quality use of medicines	On-going (yearly data)	Number of training of trainer (ToT) session	8 sessions (yearly)	Pharmacy Practice and Development Division
		On-going (yearly data)	Number of trainers trained	140 trainers (yearly)	Pharmacy Practice and Development Division
4.4	Provision of timely and accurate information on medicines to consumers	On-going (yearly data)	Number of educational materials disseminated	Increasing trend	Pharmacy Practice and Development Division

Strategy 5: Engaging media personnel on the quality use of medicines

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
5.1	Engaging media personnel on quality use of medicines	On-going	Number of engagements with local medias on medicines advertisement (cumulative)	Increasing trend	Pharmacy Enforcement Division



PARTNERSHIP AND COLLABORATION FOR THE HEALTHCARE INDUSTRY

MALAYSIAN NATIONAL MEDICINES POLICY

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5. PARTNERSHIP AND COLLABORATION FOR THE HEALTHCARE INDUSTRY

5.1 POLICY

Smart partnership and collaboration among stakeholders in the implementation and strengthening of relevant areas in the healthcare sector.

5.2 AIM

To ensure that partnership and collaboration of all stakeholders conform to the best practices and standards pertaining to medicines.

To ensure relevant policies, resources and infrastructure are in place.

To facilitate and accelerate smart partnership to boost competitiveness.

5.3 APPROACH

Timely engagement with relevant stakeholders.

Ensuring availability and sustainability of qualified, competent and effective human resource based on needs.

Sharing and optimizing information, expertise, skills, technology and facilities.

5.4 STRATEGY

5.4.1 Developing human capital, capacity and capability

Training providers shall be transformed to produce quality healthcare professionals who are able to function effectively and efficiently in meeting the country's healthcare needs.

Career pathways for healthcare providers shall be identified and implemented for future career development.

5.4.2 Promoting Research and Development among stakeholders

This strategy is to promote research collaboration between public and private pharmaceutical sectors that are aligned with the current Malaysia Plan and the Pharmacy Strategic Plan.

5.4.3 Enhancing Multi Sectoral Technical Engagement towards better health service delivery

This strategy shall be achieved through recognition of private laboratory based on current needs, privatisation of pre-registration testing for traditional products and engagement with local council in reducing unapproved medical advertisement.

Strategy 1: Developing human capital, capacity and capability

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
1.1	Develop a projection of manpower needs for each domain within the pharmaceutical sector (1st stage: for Pharmacists and Pharmacist Assistants)	Ongoing	A report on the projection of manpower needs within the Pharmaceutical Sector developed	Develop report on projection of manpower needs for each domain within the pharmaceutical sector	Pharmaceutical Services Programme
1.2	Enhance human resource competency and performance (Pharmacists only)	2020	Mandatory minimum Continuous Professional Development (CPD) points for renewal of Annual Certificate for Pharmacists	Fully enforced	Pharmaceutical Services Programme
1.3	Establishment of Subject Matter Expert (SME) Programme and profession recognition in pharmacy	2020	Establishment of SME certification/ recognition body in the private sector	Implementation of the SME Framework	Malaysian Pharmaceutical Society (MPS)

Strategy 2: Promoting Research and Development among stakeholders

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
2.1	Promote collaboration in conducting research between public and private sectors	On-going	Number of requests to conduct research collaboratively with private sector received by Pharmaceutical Services Programme	Increasing trend	Pharmaceutical Services Programme

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
		On-going	Number of researches conducted in collaboration between the public and private sectors	Increasing trend	Pharmaceutical Services Programme
2.2	Intensify knowledge sharing in research and innovation through multiple platforms	On-going	Number of research and innovation projects presentation	Increasing trend	Pharmacy Policy and Strategic Planning Division

$Strategy\,3: Enhancing\,Multi\,Sectoral\,Technical\,Engagement\,towards\,better\,health\,service\,delivery$

No.	Activities	Implementation Timeline	Indicator	Final Target	Stakeholder
3.1	Recognition of private laboratory based on current needs	2017-2020	Number of recognised private laboratories that are capable of conducting all required test for traditional products	6 laboratories recognised by 2020	Bahagian Regulatori Farmasi Negara
3.2	Privatisation of pre- registration testing for traditional products	2020	Privatisation of pre-registration testing for traditional products by year 2020	Implementation of the privatisation	Bahagian Regulatori Farmasi Negara
3.3	Engagement with local council in reducing unapproved medical advertisement	2020	Percentage of local council covered (cumulative)	100% of local council covered	Pharmacy Enforcement Division



REVIEW OF THE MALAYSIAN NATIONAL MEDICINES POLICY

MALAYSIAN NATIONAL MEDICINES POLICY

3RD EDITION • 2017-2021

REVIEW OF THE MALAYSIAN NATIONAL MEDICINES POLICY

THE EVERLY, PUTRAJAYA 1-3 NOVEMBER 2016

Chairperson

Dr. Ramli bin Zainal

Director
Pharmacy Policy & Strategic Planning Division

Organising Committee

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Senior Principal Assistant Director Pharmacy Policy & Strategic Planning Division

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Principal Assistant Director Pharmacy Policy & Strategic Planning Division

Zainuddin bin Ma'amor

Principal Assistant Director
Pharmacy Policy & Strategic Planning Division

Mohd Saufa bin Mohamed

Administration Unit Pharmaceutical Services Programme

List of Participants

COMPONENT 1: GOVERNANCE IN MEDICINES

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COMPONENT 5: PARTNERSHIP AND COLLABORATION FOR THE HEALTHCARE INDUSTRY

No.	Name	Stakeholder/Agency/Organisation Representative
1.	Dr. Ramli bin Zainal	Pharmacy Policy and Strategic Planning Division, MoH
2.	Tan Ann Ling	Pharmacy Enforcement Division, MoH
3.	Fuziah binti Rashid	Malaysian Pharmacy Board, MoH
4.	Siti Aisah binti Bahari	Pharmacy Policy and Strategic Planning Division, MoH
5.	Nur'Ain Shuhaila binti Shohaimi	Pharmacy Policy and Strategic Planning Division, MoH
6.	Ezatul Rahayu binti Anuar	Pharmacy Practice and Development Division, MoH
7.	Nor Aza binti Hassan	Pharmacy Enforcement Division, MoH
8.	Nurrul Salwa binti Saleh	Pharmacy Practice and Development Division, MoH
9.	Mary Chok Chiew Fong	Pharmacy Policy and Strategic Planning Division, MoH
10.	Leona Tan Sze Ping	Pharmacy Policy and Strategic Planning Division, MoH
11.	Cho Hui Yin	Pharmacy Policy and Strategic Planning Division, MoH
12.	Hj. Abu Bakar bin Ibrahim	Pharmacy Policy and Strategic Planning Division, MoH
13.	Zarina binti Rosli	Bahagian Regulatori Farmasi Negara, MoH
14.	Nor Hafizah binti Potri	Bahagian Regulatori Farmasi Negara, MoH
15.	Azlina binti Ismail	Bahagian Regulatori Farmasi Negara, MoH
16.	Aida Haryati binti Abdul Rahim	Bahagian Regulatori Farmasi Negara, MoH
17.	Dr. Nour Hanah binti Othman	Hospital Kuala Lumpur
18.	Shaik Nurudin bin Shaik Shahrudin	Kelantan State Health Department
19.	Amrahi bin Buang	Malaysian Pharmaceutical Society (MPS)
20.	Ewe Kheng Huat	Pharmaceutical Association of Malaysia (PhAMA)
21.	Dr. Choe Tong Seng	Malaysian Association of Pharmaceutical Suppliers (MAPS)
22.	Nik Jah Nik Ab Kadir	Malaysian Community Pharmacy Guild (MCPG)
23.	James Pereira	Malaysian Dietary Supplement Association (MADSA)

COMPONENT 2: QUALITY, SAFETY AND EFFICACY OF MEDICINES

No.	Name	Stakeholder/Agency/Organisation Representative
1.	Dr. Salmah binti Bahri	Bahagian Regulatori Farmasi Negara, MoH
2.	Siti Aida binti Abdullah	Bahagian Regulatori Farmasi Negara, MoH
3.	Datin Dr. Faridah Aryani binti. Md. Yusof	Bahagian Regulatori Farmasi Negara, MoH
4.	Muhammad Lukmani bin Ibrahim	Bahagian Regulatori Farmasi Negara, MoH
5.	Wan Mohaina binti Wan Mohammad	Bahagian Regulatori Farmasi Negara, MoH
6.	Noorul Akmar binti Mohd Nur	Bahagian Regulatori Farmasi Negara, MoH
7.	Nicholas Leow Chun Wei	Bahagian Regulatori Farmasi Negara, MoH
8.	Fatkhiah binti Khalil	Pharmacy Policy and Strategic Planning Division, MoH
9.	Ainul Salhani binti Abdul Rahman	Pharmacy Policy and Strategic Planning Division, MoH
10.	Somiyaton binti Mohd Dahalan	Bahagian Regulatori Farmasi Negara, MoH
11.	Siti Fatimah binti ldris	Pharmacy Enforcement Division, MoH
12.	Nursyila Roziana binti Mohd Radzi	Pharmacy Enforcement Division, MoH
13.	Nurhazwani binti Mohd Noor	Pharmacy Enforcement Division, MoH
14.	Nurul Islah binti Muzakir	Pharmacy Policy and Strategic Planning Division, MoH
15.	Azura binti Abdullah	Bahagian Regulatori Farmasi Negara, MoH
16.	Yee Lai Jiuan	Bahagian Regulatori Farmasi Negara, MoH
17.	Belinna binti Abu Bakar	Bahagian Regulatori Farmasi Negara, MoH
18.	Lam Kai Kun	Malaysian Pharmaceutical Society (MPS)
19.	Alice Chee Seat Mee	Pharmaceutical Association of Malaysia (PhAMA)
20.	Fazidah binti Mohamed Noor	Pharmaceutical Association of Malaysia (PhAMA)
21.	J.S. Sunitha Dewi Shanmugam	Pharmaceutical Association of Malaysia (PhAMA)
22.	Sabrina binti Haron	Malaysian Organisation of Pharmaceutical Industries (MOPI)
23.	Zarrah Banu Hulwani binti Abdul Rahim	Direct Selling Association of Malaysia (DSAM)

COMPONENT 3: ACCESS TO MEDICINES

No.	Name	Stakeholder/Agency/Organisation Representative
1.	Abida Haq binti Syed M Haq	Pharmacy Practice and Development Division, MoH
2.	Rosminah binti Mohd Din	Pharmacy Practice and Development Division, MoH
3.	Salbiah Mohd Salleh	Pharmacy Practice and Development Division, MoH
4.	Fatimah binti Abdul Rahim	Pharmacy Practice and Development Division, MoH
5.	Norhaliza binti A. Halim	Pharmacy Practice and Development Division, MoH
6.	Dr. Azuana binti Ramli	Pharmacy Practice and Development Division, MoH
7.	Rosliza binti Lajis	Pharmacy Practice and Development Division, MoH
8.	Saimah binti Mat Noor	Pharmacy Practice and Development Division, MoH
9.	Dazlinawati binti Daud	Pharmacy Practice and Development Division, MoH
10.	Norazlin binti A.Kadir	Pharmacy Practice and Development Division, MoH
11.	Rosilawati binti Ahmad	Bahagian Regulatori Farmasi Negara, MoH
12.	Farahwahida binti Mohd Kassim	Pharmacy Practice and Development Division, MoH
13.	Bibi Faridha binti Mohd Salleh	Pharmacy Policy and Strategic Planning Division, MoH
14.	Lee Kah Seng	Pharmacy Practice and Development Division, MoH
15.	Seetha a/p Ramasamy	Bahagian Regulatori Farmasi Negara, MoH
16.	Tan Kee Leong	Traditional and Complementary Medicine Division, MoH
17.	Teoh Sheh Ki	Traditional and Complementary Medicine Division, MoH
18.	Brigedier Jeneral Dato' Dr. A. Halim bin Basari	Ministry of Defence (MINDEF)
19.	Muhammad Hawari bin Hassan	Malaysian Department of Islamic Development (JAKIM)
20.	Wan Hwei Yen	Malaysian Pharmaceutical Society (MPS)
21.	Aileen Chong	Malaysian Pharmaceutical Society (MPS)
22.	Loh Peng Yeow	Malaysian Community Pharmacy Guild (MCPG)
23.	Kathleen Yeoh Hui Chin	Pharmaceutical Association of Malaysia (PhAMA)
24.	Hong Li Wen	Pharmaceutical Association of Malaysia (PhAMA)

No.	Name	Stakeholder/Agency/Organisation Representative
25.	Azwar binti Kamarudin	Pharmaceutical Association of Malaysia (PhAMA)
26.	Keh Song Hock	Malaysian Organisation of Pharmaceutical Industries (MOPI)
27.	Lai Yeo Lian	Malaysian Organisation of Pharmaceutical Industries (MOPI)
28.	Lim Teng Chyuan	Malaysian Association of Pharmaceutical Suppliers (MAPS)
29.	Mathew John	Malaysian Association of Pharmaceutical Suppliers (MAPS)
30.	Lee Seng Dee	Association of Private Hospitals of Malaysia (APHM)
31.	Prof. Dr. Mohamed Azmi bin Ahmad Hassali	Universiti Sains Malaysia (USM)
32.	Assoc Prof. Dr. Asrul Akmal bin Shafie	Universiti Sains Malaysia (USM)

COMPONENT 4: QUALITY USE OF MEDICINES

No.	Name	Stakeholder/Agency/Organisation Representative	
1.	Che Pun binti Bujang	Pharmacy Practice and Development Division, MoH	
2.	Mazlan bin Ismail	Pharmaceutical Services Programme	
3.	Noraini binti Mohamad	Pharmacy Practice and Development Division, MoH	
4.	Munira binti Mohamad	Pharmacy Practice and Development Division, MoH	
5.	Fajaratunur binti A. Sani	Pharmacy Practice and Development Division, MoH	
6.	Mohd Azuwan bin Mohd Zubir	Pharmacy Practice and Development Division, MoH	
7.	Syazana Akmal binti Ahmad Kamal	Pharmacy Enforcement Division, MoH	
8.	Muhammad Syahnizam bin Kassim	Pharmacy Enforcement Division, MoH	
9.	Lau Ling Wei	Pharmacy Policy and Strategic Planning Division, MoH	
10.	Rohana binti Hassan	Hospital Kuala Lumpur	
11.	Saidatul Raihan binti Ibrahim	Hospital Melaka	
12.	Norharlina binti Sulaiman	Klang District Health Office	
13.	Akmalyatun Kamal binti Kamaruddin	Selangor State Health Department	
14.	Che Zuraini binti Sulaiman	University Malaya Medical Centre (UMMC)	
15.	Shariffah Norasmah binti Syed Mustaffa	UKM Medical Centre (UKMMC)	
16.	Yip Sook Ying	Malaysian Pharmaceutical Society (MPS)	
17.	Lim Shi Hao	Pharmaceutical Association of Malaysia (PhAMA)	
18.	Andy Lee Kuan Min	Pharmaceutical Association of Malaysia (PhAMA)	
19.	Kothandaraman a/l Nathan	Pharmaceutical Association of Malaysia (PhAMA)	
20.	Ahmad Kamal bin Ahmad Suhaimi	Malaysian Organisation of Pharmaceutical Industries (MOPI)	
21.	Lovy Beh	Malaysian Community Pharmacy Guild (MCPG)	
22.	Dr. Azizan binti Abdul Aziz	Malaysian Medical Association (MMA)	
23.	Zarihasyum binti Md Zain	Association of Private Hospitals of Malaysia (APHM)	
24.	Sharvin a/l A. Subramaniam	Federation of Malaysian Consumer Associations (FOMCA	
25.	Wan Mun Yi	Sunway Medical Centre	



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