MOH/FAR/102.23(BP)-e

KEMENTERIAN KESIHATAN MALAYSIA
PROGRAM PERKHIDMATAN FARMASI

DASAR UBAT NASIONAL

DUNas

2022-2026

MALAYSIAN NATIONAL MEDICINES POLICY

DASAR UBAT NASIONAL

DUNas

2022-2026

DASAR UBAT NASIONAL
EDISI KEEMPAT (2022-2026)

No. Siri Penerbitan KKM: MOH/FAR/102.23(BP)-e
No. Pendaftaran Dokumen Program Perkhidmatan Farmasi: D-GU-105
No. ISBN: 978-967-2854-29-6

Terbitan oleh:
Program Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia
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Tel: 03-7841 3200
https://www.pharmacy.gov.my/v2/ms

ISBN 978-967-2854-29-6
9 789672 854296

KANDUNGAN

GLOSARI, TERMA, SINGKATAN DAN AKRONIM

GLOSARI, TERMA, SINGKATAN DAN AKRONIM

ACRPM	*Association of Clinical Research Project Managers*
ADSSR	*ASEAN Drug Security and Self-Reliance*
AGC	Jabatan Peguam Negara *Attorney General's Chamber*
AHMM	*ASEAN Health Ministers Meeting*
AMR	*Antimicrobial Resistance*
AMS	*Antimicrobial Stewardship*
API	Bahan Aktif Farmaseutikal *Active Pharmaceutical Ingredient*
APHM	*Association of Private Hospitals Malaysia*
ASEAN	*Association of Southeast Asian Nations*
BAPF	Bahagian Amalan dan Perkembangan Farmasi
BDPSF	Bahagian Dasar dan Perancangan Strategik Farmasi
BLFM	Bahagian Lembaga Farmasi Malaysia
BPF	Bahagian Penguatkuasaan Farmasi
BPKA	Bahagian Perkembangan Kesihatan Awam
BPM	Bahagian Pengurusan Maklumat
BPP | MDD	Bahagian Perkembangan Perubatan *Medical Development Division*
BPTK	Bahagian Perubatan Tradisional dan Komplementari
CGTP	Produk Terapi Sel dan Gen *Cell and Gene Therapy Product*
CKAPS	Cawangan Kawalan Amalan Perubatan Swasta
COVID-19	*Coronavirus Disease*
CPE	Pendidikan Profesional Berterusan *Continuous Professional Education*
CP	*Community Pharmacy*
CRC	*Clinical Research Centre*
CRM	*Clinical Research Malaysia*
CRO	*Clinical Research Organization*
DFIT	Dos, Frekuensi, Indikasi dan Masa *Dose, Frequency, Indication and Time*
DKUA	Duta Kenali Ubat Anda
DSAM	Persatuan Jualan Langsung Malaysia *Direct Selling Association of Malaysia*
DUNas | MNMP	Dasar Ubat Nasional *Malaysian National Medicines Policy*
e-DPF	Sistem Data Penguatkuasa Farmasi
FIH	*First In Human*
FOMCA	*Federation of Malaysian Consumer Associations*

FRIM	*Forest Research Institute Malaysia*
FRP	*Facilitated Registration Pathway*
FUKKM	Formulari Ubat Kementerian Kesihatan Malaysia
GA	*General Assembly*
GGM	*Good Governance of Medicines*
GMAP	*Generic Medicines Awareness Programme*
GRI	*Global Reporting Initiative*
HCF	Pembiayaan Penjagaan Kesihatan *Health Care Financing*
HECC	*Health Education Communication Centre*
HePiLI	*Health Promotion in Learning Institution*
HMR	Penilaian Ubat-ubatan di Rumah *Home Medication Review*
HUiTM	Hospital Al-Sultan Abdullah Universiti Teknologi MARA
HUKM	Hospital Universiti Kebangsaan Malaysia
HUPM	Hospital Universiti Putra Malaysia
HUSM	Hospital Universiti Sains Malaysia
HWP	Kertas Putih Kesihatan *Health White Paper*
ICH	*International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use*
ICT	Teknologi Maklumat dan Komunikasi *Information and Communication Technology*
IIR	*Industries Initiated Research*
IMR	*Institute for Medical Research*
JPNIN	Jabatan Perpaduan Negara dan Integrasi Nasional
KEMENTAH | MinDef	Kementerian Pertahanan *Ministry of Defence*
KASA	Kementerian Alam Sekitar dan Air
KK	Klinik Kesihatan
KKM | MOH	Kementerian Kesihatan Malaysia *Ministry of Health Malaysia*
KPDN	Kementerian Perdagangan Dalam Negeri dan Kos Sara Hidup *Ministry of Domestic Trade and Cost of Living*
KPT | MOHE	Kementerian Pendidikan Tinggi *Ministry of Higher Education*
KYM	Kenali Ubat Anda *Know Your Medicine*
LFM	Lembaga Farmasi Malaysia
MACT	*Malaysian Association for Cell Therapy*
MADSA	*Malaysian Dietary Supplement Association*
MAFS	Kementerian Pertanian dan Keterjaminan Makanan *Ministry of Agriculture and Food Security*
MAP	*Malaysian Academy of Pharmacy*

MAPS	*Malaysian Association of Pharmaceutical Suppliers*
MARDI	*Malaysian Agricultural Research and Development Institute*
MASA	Akta Ubat (Iklan dan Penjualan) *Medicines (Advertisement and Sale) Act*
MASc	*Medicines Access Scheme*
MCMC	Suruhanjaya Komunikasi dan Multimedia Malaysia *Malaysia Communication And Multimedia Commission*
MCPG	*Malaysian Community Pharmacy Guild*
MDSSR	*Malaysian Drug Security and Self-Reliance*
MIDA	*Malaysian Investment Development Authority*
MITI	Kementerian Pelaburan, Perdagangan dan Industri *Ministry of Investment, Trade and Industry*
MJM	*Memorandum Jemaah Menteri*
MKAK	Makmal Kesihatan Awam Kebangsaan *National Public Health Laboratory*
ML	*Maturity Level*
MMA	*Malaysian Medical Association*
MMC	*Malaysian Medical Council*
MOE	Kementerian Pendidikan Malaysia *Ministry of Education*
MOPI	*Malaysian Organisation Of Pharmaceutical Industries*
MOSTI	Kementerian Sains, Teknologi dan Inovasi *Ministry of Science, Technology and Innovation*
MoU	Memorandum Persefahaman *Memorandum of Understanding*
MPS	*Malaysian Pharmacist Society*
MTAPS	*Medicines, Technologies, and Pharmaceutical Services*
NEHAP	*National Environmental Health Action Plan*
NEML	*National Essential Medicines List*
NGO	Badan Bukan Kerajaan *Non-governmental Organisation*
NHMS	Tinjauan Kebangsaan Kesihatan dan Morbiditi *National Health & Morbidity Survey*
NIH	Institut Kesihatan Negara *National Institutes of Health*
NPRA	*National Pharmaceutical Regulatory Agency*
NRA	Badan Regulatori Negara *National Regulatory Authority*
NRECC	Kementerian Sumber Asli, Alam Sekitar dan Perubahan Iklim *Ministry of Natural Resources, Environment and Climate Change*
NVDR	*National Vaccine Development Roadmap*
OECD	*Organisation for Economic Co-operation and Development*
PBKD | DCA	Pihak Berkuasa Kawalan Dadah *Drug Control Authority*

PE	Farmakoekonomik *Pharmacoeconomic*
PEKA	Skim Peduli Kesihatan
PhAMA	*Pharmaceutical Association of Malaysia*
PhIS	*Pharmacy Information System*
PKD	Pejabat Kesihatan Daerah
PMS	*Post Marketing Surveillance*
PPF | PSP	Program Perkhidmatan Farmasi *Pharmaceutical Services Programme*
PPT	Pemberi Pendidikan Tinggi *Higher Education Provider (HEP)*
PPUM	Pusat Perubatan Universiti Malaya *University Malaya Medical Centre*
PPVN	Pelan Hala Tuju Pembangunan Vaksin Negara
PRH	*Product Registration Holder*
PRI	*Principles for Responsible Investment*
PRiSMA	*Pharmacist Registration Management System*
PRPM	Bidang Keutamaan Penyelidikan Farmasi di Malaysia *Pharmacy Research Priority Area in Malaysia*
PSI	*Pharmaceutical Security Institute*
PTI	Pelan Tindakan Induk *Master Plan of Action*
PUU	Penasihat Undang-undang
PV	Farmakovigilans *Pharmacovigilance*
QSE	Kualiti, Keselamatan dan Keberkesanan *Quality, Safety and Efficacy of Medicines*
QUM	*Quality Use of Medicines*
R&D	Penyelidikan dan Pembangunan *Research and Development*
RFI	*Request for Information*
RFP	*Request for Proposal*
RI	*Responsible Investment*
ROPA	Akta Pendaftaran Ahli Farmasi *Registration of Pharmacists Act*
RMK-12	Rancangan Malaysia ke-12 *Twelfth Malaysia Plan*
SDG	Matlamat Pembangunan Mampan *Sustainable Development Goals*
SODA	Akta Jualan Dadah *Sale of Drugs Act*
SOMHD	*ASEAN Senior Officials Meeting on Health Development*
T&CM	Perubatan Tradisional dan Komplementari *Traditional & Complementary Medicines*
TESMA	*Tissues Engineering & Regenerative Medicine Society of Malaysia*

TOT	*Training of Trainers*
UAT/ FAT	*User Acceptance Test/Final Acceptance Test*
UHC	*Universal Health Coverage*
UMBI	*UKM Medical Molecular Biology Institute*
UKAS	Unit Kerjasama Awam Swasta
UKK	Unit Komunikasi Korporat
UMBI	*UKM Medical Molecular Biology Institute*
USAID	*United States Agency for International Development*
WG	*Working Group*
WHA	Perhimpunan Kesihatan Sedunia *World Health Assembly*
WHO	Pertubuhan Kesihatan Sedunia *World Health Organization*

PENGHARGAAN

Program Perkhidmatan Farmasi, Kementerian Kesihatan Malaysia ingin merakamkan setinggi-tinggi penghargaan dan jutaan terima kasih kepada semua yang telah memberikan sokongan dan sumbangan secara langsung atau tidak langsung dalam penerbitan Dasar Ubat Nasional (DUNas) Edisi Keempat (2022-2026):

- Bahagian Dasar dan Perancangan Strategik Farmasi (BDPSF), KKM
- Bahagian Penguatkuasaan Farmasi (BPF), KKM
- Bahagian Amalan dan Perkembangan Farmasi (BAPF), KKM
- Bahagian Regulatori Farmasi Negara (NPRA), KKM
- Bahagian Lembaga Farmasi Malaysia (BLFM), KKM
- Bahagian Perubatan Tradisional dan Komplementari, KKM
- Jabatan Kesihatan Negeri
- Bahagian Perkhidmatan Kesihatan, Kementerian Pertahanan (KEMENTAH)
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- *Malaysian Community Pharmacy Guild* (MCPG)
- *Malaysian Academy of Pharmacy* (MAP)
- *Pharmaceutical Association of Malaysia* (PhAMA)
- *Malaysian Organisation of Pharmaceutical Industries* (MOPI)
- *Malaysian Association of Pharmaceutical Suppliers* (MAPS)
- *Association of Private Hospitals Malaysia* (APHM)
- Persatuan Perubatan Malaysia (MMA)
- Majlis Perubatan Malaysia (MMC)
- Gabungan Persatuan Pengguna Malaysia (FOMCA)
- Persatuan Jualan Langsung Malaysia (DSAM)
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PERUTUSAN MENTERI KESIHATAN

Dengan nama Allah yang Maha Pemurah lagi Maha Mengasihi

Alhamdulillah, syukur ke hadrat Ilahi, sepanjang 17 tahun pelaksanaan Dasar Ubat Nasional (DUNas), ia telah melalui pelbagai fasa pembangunan dan perubahan. Ini melambangkan komitmen berterusan Kementerian Kesihatan, khususnya Program Perkhidmatan Farmasi, yang sentiasa berusaha untuk menambah baik keberkesanan sistem farmaseutikal sedia ada bagi meningkatkan kebolehcapaian, kecekapan dan kesiapsiagaan perkhidmatan farmasi kepada rakyat

Pembangunan strategi dan inisiatif bagi DUNas Penggal Keempat telah dirangka melalui kolaborasi dengan pemegang taruh, agar ia sejajar dengan hala tuju Rancangan Malaysia Kedua Belas, iaitu bagi meningkatkan kesejahteraan rakyat. Pelaksanaan DUNas Penggal Keempat ini juga diselaraskan dengan hasrat dan perancangan kerajaan seperti yang terkandung dalam Kertas Putih Kesihatan dengan tujuan mereformasi sistem kesihatan negara agar lebih saksama, mampan dan berdaya tahan serta kalis masa depan.

Pada kesempatan ini, saya ingin merakamkan setinggi-tinggi penghargaan dan jutaan terima kasih kepada Program Perkhidmatan Farmasi, KKM dan semua agensi, organisasi serta kementerian yang terlibat secara langsung dan tidak langsung dalam merangka dan menjayakan pelaksanaan DUNas sejak 17 tahun yang lalu. Harapan saya agar DUNas diterjemahkan kepada pelaksanaan inisiatif dan strategi yang berimpak tinggi serta mewujudkan platform kepada pemegang taruh agar dapat berkolaborasi secara aktif. Semoga komitmen yang diberikan ini memberi manfaat kepada seluruh rakyat Malaysia. Semoga Allah SWT merahmati semua usaha murni kita bagi memantapkan pelaksanaan DUNas.

YB Dr. Zaliha Mustafa
Menteri Kesihatan Malaysia

PERUTUSAN KETUA PENGARAH KESIHATAN

DUNas adalah satu dasar yang menyeluruh dan dinamik kerana ia merangkumi semua isu semasa farmaseutikal di negara kita. Segala aktiviti yang dirancangkan memberi impak yang besar kepada sektor farmaseutikal. Dasar ini memberi panduan dan hala tuju yang lebih jelas bagi pelaksanaan aktiviti dan pengurusan farmaseutikal di sektor awam dan swasta dan perlu kekal relevan untuk masa hadapan.

Pelaksanaan DUNas telah meningkatkan akses yang saksama terhadap penggunaan ubat-ubatan yang selamat, berkesan dan mampu milik, di samping memastikan penggunaan ubat secara rasional ke arah meningkatkan tahap kesihatan rakyat. Selain itu, DUNas berjaya memantapkan sistem rangkaian pengedaran yang menyeluruh melalui integrasi sistem ICT agar akses kepada ubat-ubatan dipermudah. Melalui DUNas juga, impak dalam bidang penyelidikan dan pembangunan farmaseutikal juga telah menyokong dan meningkatkan kualiti perkhidmatan dan penjagaan farmaseutikal.

DUNas telah menyediakan satu platform yang membolehkan komunikasi berterusan bagi mewujudkan kolaborasi dan usaha sama antara pemegang taruh daripada pelbagai profesion meliputi sektor kesihatan awam dan swasta. Di samping itu, DUNas diselaraskan dengan dasar-dasar kerajaan yang berkaitan termasuk menyokong Matlamat Pembangunan Mampan (*Sustainable Development Goals* – SDG) untuk memastikan kesinambungan penyampaian perkhidmatan kesihatan dicapai serta menjamin akses dan kesaksamaan rakyat kepada ubat-ubatan. Ekosistem yang menyokong dan menggalakkan pengeluaran dan pemindahan teknologi perlu diwujudkan bagi membolehkan kesiapsiagaan dan kemandirian negara terutamanya dalam keadaan kecemasan.

Sekalung penghargaan kepada Program Perkhidmatan Farmasi atas usaha serta langkah proaktif dalam meneruskan pelaksanaan dasar ini. Ucapan tahniah kepada semua pihak yang terlibat atas komitmen dalam menghasilkan dokumen ini. Saya berharap agar dokumen DUNas Penggal Keempat ini dapat diterjemahkan dan dilaksanakan dengan jayanya serta memberi impak yang besar kepada kesejahteraan dan kesihatan rakyat.

YBhg. Datuk Dr Muhammad Radzi bin Abu Hassan
Ketua Pengarah Kesihatan
Kementerian Kesihatan Malaysia

PERUTUSAN PENGARAH KANAN PROGRAM PERKHIDMATAN FARMASI

DUNas Penggal Keempat ini adalah aspirasi dan komitmen daripada kerajaan dan pemegang taruh terhadap matlamat yang sama dalam sektor farmaseutikal. DUNas merupakan sebuah dokumen rangka kerja yang telus dan diselaraskan pelaksanaan strategi untuk menambah baik sektor farmaseutikal.

DUNas telah mencapai 17 tahun pelaksanaan dan merupakan usaha sama sektor awam dan swasta serta pemegang taruh. Dasar ini telah memberi transformasi positif dalam mewujudkan sistem regulatori yang komprehensif dan bertaraf antarabangsa, serta pengukuhan perundangan dan peraturan. Selain itu, dasar ini juga menggalakkan akses yang saksama kepada ubat-ubatan serta penggunaan ubat yang rasional, berkualiti, selamat, berkesan dan mampu milik demi meningkatkan tahap kesihatan rakyat

DUNas juga menekankan kepentingan kapasiti dan keupayaan tenaga kerja farmasi. Pelbagai inisiatif telah dilaksanakan untuk meningkatkan kompetensi dan pengiktirafan ahli farmasi bagi memastikan perkhidmatan farmasi yang berkualiti untuk meningkatkan taraf kesihatan rakyat. Polisi dan tadbir urus yang baik dalam pengurusan, amalan dan profesion farmasi yang jelas dan telus juga harus diutamakan. Dasar ini telah dihasilkan dengan teliti berpandukan strategi di peringkat global, selari dengan dasar dan pendekatan kebangsaan, menggambarkan wawasan Malaysia. Harapan saya agar kolaborasi sinergistik dan kerjasama dengan pelbagai pemegang taruh akan terus diperkukuh demi memastikan kesejahteraan rakyat.

Sekalung penghargaan dan tahniah kepada semua yang terlibat dalam memberikan input dan sumbangan bagi menghasilkan dokumen ini. Diharapkan agar semua sektor perkhidmatan farmasi termasuk regulatori, penguatkuasaan, amalan farmasi, industri farmaseutikal, akademik dan lain-lain menjadikan DUNas Penggal Keempat sebagai panduan dan rujukan dalam merangka serta melaksanakan perancangan agensi dan organisasi masing-masing demi memacu kecemerlangan perkhidmatan farmasi di Malaysia.

YBrs. Puan Norhaliza binti A Halim
Pengarah Kanan Program Perkhidmatan Farmasi
Kementerian Kesihatan Malaysia

KENYATAAN DASAR

Dasar Ubat Nasional (DUNas) merupakan sebuah dokumen rasmi Kerajaan Malaysia yang telah diluluskan oleh Kabinet pada tahun 2006. Dasar ini mengutamakan matlamat jangka masa sederhana dan panjang bagi sektor farmaseutikal di negara ini. Dokumen ini merupakan hala tuju negara untuk memastikan tadbir urus ubat-ubatan yang sistematik dan holistik demi mencapai hasil kesihatan yang lebih baik untuk rakyat Malaysia.

Objektif DUNas adalah untuk menggalakkan akses ubat-ubatan yang saksama dan penggunaan secara rasional ubat yang berkualiti, selamat, berkesan dan mampu milik ke arah meningkatkan tahap kesihatan rakyat. Sehubungan itu, tadbir urus sektor farmaseutikal yang baik perlu dititikberatkan bagi menjamin ubat-ubatan dalam pasaran adalah selamat, berkesan dan berkualiti untuk pengguna. Akses berterusan kepada ubat-ubatan juga perlu dipastikan bagi memenuhi keperluan penjagaan kesihatan rakyat. Ini termasuk memastikan semua ubat-ubatan dikecualikan daripada sebarang duti dan tarif bagi meningkatkan keperolehan dan kemampuan kepada ubat-ubatan. Selain itu, semua pihak harus memastikan ubat-ubatan digunakan secara rasional, sesuai, selamat dan efektif. Kolaborasi dan kerjasama strategik dalam kalangan pemegang taruh juga perlu diperkukuhkan bagi mencapai objektif dan matlamat sektor penjagaan kesihatan.

Dalam usaha memastikan kejayaan DUNas, perancangan dan pelaksanaan strategi yang komprehensif melalui kerangka kerja yang telus disokong oleh aspirasi dan komitmen kerajaan dan semua pemegang taruh dengan matlamat yang sama adalah penting ke arah memperkukuh sektor farmaseutikal negara. DUNas dibangunkan selari dengan objektif am polisi ubat-ubatan yang dicadangkan oleh *World Health Organization* (WHO). Terdapat lima (5) komponen keutamaan di bawah dasar ini:

- Tadbir Urus Ubat-Ubatan
- Kualiti, Keselamatan dan Keberkesanan Ubat-ubatan
- Akses kepada Ubat-ubatan
- Penggunaan Ubat Secara Berkualiti
- Kerjasama dan Kolaborasi bagi Industri Kesihatan

RINGKASAN EKSEKUTIF

Malaysia telah berjaya meningkatkan tahap kesihatan rakyat dan menunjukkan prestasi sistem penjagaan kesihatan baik serta penyampaian perkhidmatan farmasi yang berkualiti. Walau bagaimanapun, dengan peredaran masa, sektor farmaseutikal di negara ini perlu diperkukuh supaya lebih mampan untuk sentiasa bersedia menghadapi tekanan dan cabaran.

DUNas dirangka bertujuan meningkatkan tahap kesihatan rakyat melalui pengukuhan akses ubat-ubatan yang saksama dan penggunaan ubat secara rasional, selamat, berkesan serta mampu milik. Sehubungan itu, DUNas Penggal Keempat ini merupakan satu kerangka sistematik dan pelan berstruktur yang dibangunkan bertujuan menangani isu dan cabaran melalui strategi dan inisiatif yang dirangka bagi memastikan sektor farmaseutikal yang lebih produktif, berdaya tahan dan lestari.

Buku ini merangkumi tiga (3) bahagian utama iaitu kenyataan dasar, isu dan cabaran, dan Pelan Tindakan Induk (PTI) mengikut komponen-komponen DUNas. Bahagian kenyataan dasar menerangkan dokumen DUNas sebagai suatu hala tuju sektor farmaseutikal bagi memastikan tadbir urus ubat-ubatan yang sistematik dan holistik demi mencapai hasil kesihatan yang lebih baik untuk rakyat Malaysia. Ia juga menerangkan objektif dan lima (5) komponen yang terdapat di dalam DUNas.

Sektor farmaseutikal di Malaysia berhadapan dengan pelbagai cabaran dan jurang kesihatan. Antara cabaran dan isu utama yang dihadapi dalam sektor farmaseutikal adalah kawalan perundangan dan regulatori (ubat-ubatan tidak berdaftar termasuk ubat-ubatan palsu, sub-standard dan penjualan produk farmaseutikal/ubat di atas talian), pengukuhan sistem regulatori farmaseutikal (pengharmonian sistem regulatori dan penglibatan antarabangsa, meningkatkan kecekapan proses pendaftaran produk, memastikan produk berdaftar menepati syarat dan piawaian, terapi baharu muncul melalui kajian klinikal *First In Human* (FIH)), jurang akses dan ketersediaan kepada ubat-ubatan (paten, hak intelek dan ubat generik, kecekapan dan kelestarian rantaian bekalan ubat-ubatan), agihan serta kemahiran sumber manusia yang perlu dipertingkat, tahap literasi kesihatan yang rendah dan penggunaan ubat-ubatan secara tidak rasional dalam masyarakat.

Bahagian seterusnya akan menerangkan Pelan Tindakan Induk (PTI) bagi lima (5) komponen utama DUNas yang merangkumi matlamat, pendekatan, strategi dan inisiatif bagi setiap pelaksanaan dasar. Pelaksanaan PTI ini melibatkan semua pemegang taruh dalam sektor kesihatan. Justeru, agensi serta organisasi yang berkaitan perlu merujuk dokumen ini sebagai panduan dalam merangka serta melaksanakan perancangan masing-masing demi kecemerlangan sistem kesihatan farmaseutikal di Malaysia.

PENDAHULUAN

Dasar Ubat Nasional (DUNas) menggariskan objektif jangka masa sederhana dan panjang kerajaan, strategi dan pendekatan utama untuk mencapainya, serta peranan dan tanggungjawab pemegang taruh. DUNas juga menyediakan rangka kerja untuk menyelaraskan aktiviti utama dari sektor awam dan swasta, termasuk profesional kesihatan, agensi bukan kerajaan, pesakit, pengguna dan semua pemegang taruh yang berkaitan.

Konsep Dasar Ubat Negara mula diperkenalkan semasa Perhimpunan Kesihatan Sedunia (*World Health Assembly* (WHA)) ke-28 pada tahun 1975. Pertubuhan Kesihatan Sedunia (WHO) mengesyorkan agar semua negara membangun, melaksanakan sebuah dasar ubat negara yang komprehensif dan memantau pelan pelaksanaannya. Dasar ubat yang dibangunkan seharusnya konsisten dengan sistem penjagaan kesihatan negara atau dasar kesihatan negara.

Penggubalan dan pelaksanaan DUNas membuka ruang kepada semua pemegang taruh dalam sektor kesihatan untuk menyuarakan pandangan, memberikan input konstruktif dan berfungsi sebagai suatu dasar yang menyelaraskan peranan setiap pemegang taruh agar sektor kesihatan awam dan swasta mencapai matlamat yang sama.

Dasar Ubat Nasional (DUNas)

Strategi dan inisiatif di bawah DUNas dikaji dan disemak semula setiap lima (5) tahun demi memastikan program yang dilaksanakan kekal relevan serta memberi impak yang positif terhadap keterjaminan, kualiti ubat-ubatan dan penyampaian perkhidmatan farmasi di Malaysia. DUNas Penggal Keempat dibangunkan selari dengan polisi dan matlamat antarabangsa termasuk *Universal Health Coverage* (UHC) di bawah *Sustainable Development Goals* (SDG) dan Pertubuhan Kesihatan Sedunia (WHO). Pembangunan dasar ini juga bertepatan dengan dasar-dasar kebangsaan termasuk RMK-12, HWP dan Pelan Strategik Kementerian Kesihatan Malaysia serta dasar-dasar lain yang berkaitan.

Dasar ini bermula dengan lima (5) tahun penggal pertama, bermula pada tahun 2007 hingga 2011. Dasar ini telah dikaji dan disemak semula pada tahun 2012 untuk menghasilkan kerangka dasar penggal kedua pada tahun 2013 hingga 2017 dan penggal ketiga pada tahun 2017 hingga 2021. Pada penggal pertama hingga penggal ketiga DUNas, pelaksanaan dasar ini telah membuahkan hasil dan transformasi yang sangat positif. Kemajuan dan perubahan dapat diukur melalui sistem kawal selia yang komprehensif, pemerkasaan undang-undang dan peraturan, serta akses ubat-ubatan yang lebih meluas. Namun begitu, masih ada ruang penambahbaikan yang boleh dilakukan melalui pengukuhan dan penggabungan idea baharu yang sejajar dengan objektif dasar ini.

DUNas Penggal Keempat telah disemak semula dan diperkukuh selari dengan perubahan masa serta keperluan kesihatan rakyat. Pembangunan dan pelaksanaan DUNas bukan sahaja tertumpu kepada sektor awam malahan turut menggabungjalinkan usaha dan komitmen sektor farmaseutikal awam dan swasta.

TADBIR URUS
DASAR UBAT NASIONAL

JAWATANKUASA PEMANDU

1. Menasihati Menteri Kesihatan
2. Pengesahan Perancangan
3. Memutuskan Hala Tuju

Pengerusi
KETUA PENGARAH KESIHATAN

JAWATANKUASA PELAKSANAAN

Pemantauan dan semakan perancangan pelaksanaan

Pengerusi
PENGARAH KANAN
PERKHIDMATAN FARMASI

JAWATANKUASA TEKNIKAL

Merancang, mengenalpasti dan memantau pelaksanaan oleh jawatankuasa kerja

Pengerusi
PENGARAH /
TIMBALAN PENGARAH BAHAGIAN

JAWATANKUASA KERJA
Pelaksanaan Pelan Tindakan

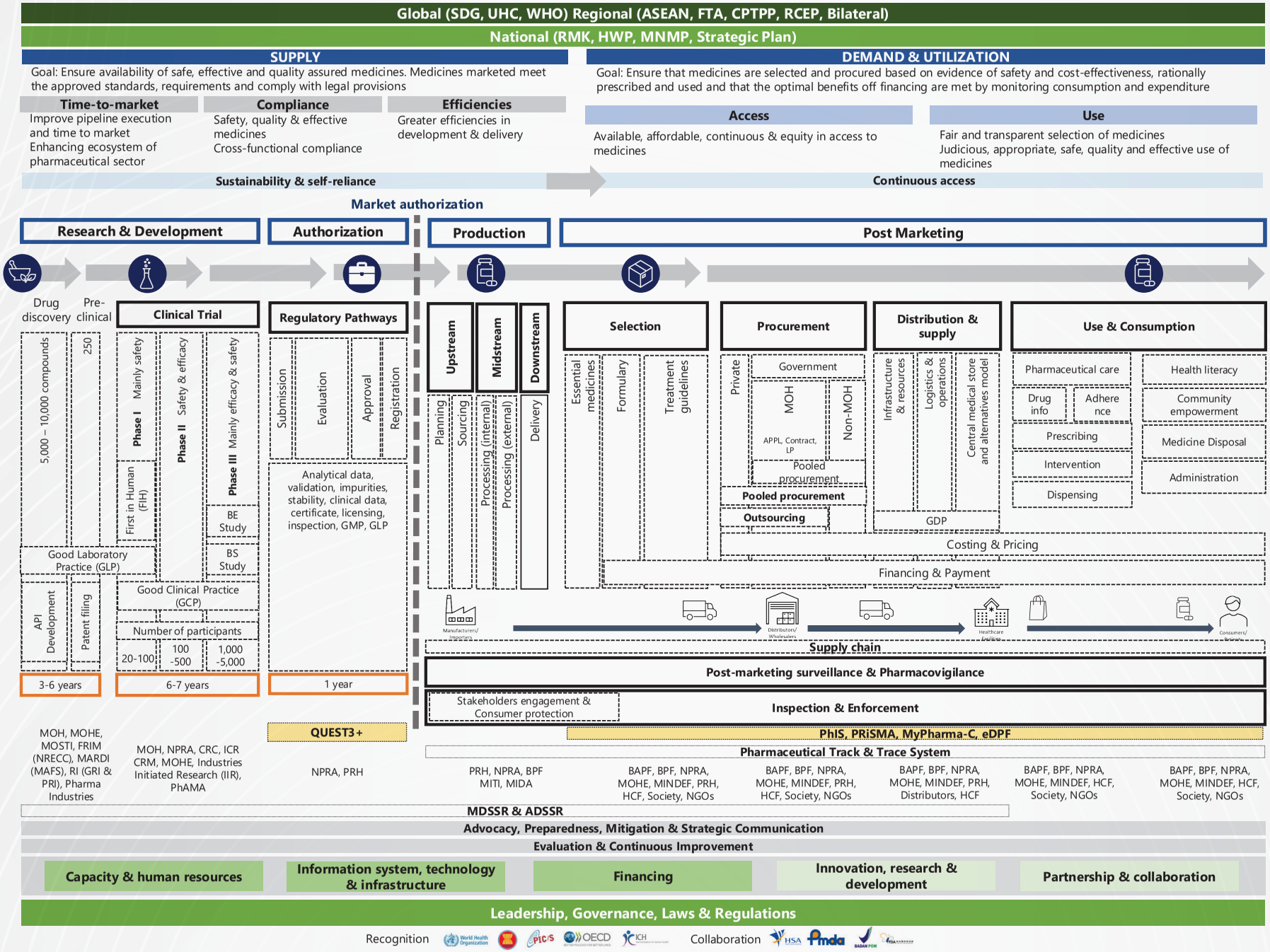
01 Tadbir Urus Ubat-ubatan

02 Kualiti, Keselamatan dan Keberkesanan Ubat-ubatan

03 Akses Kepada Ubat-ubatan

04 Penggunaan Ubat Secara Berkualiti

05 Kerjasama dan Kolaborasi bagi Industri Kesihatan


Global (SDG, UHC, WHO) Regional (ASEAN, FTA, CPTPP, RCEP, Bilateral)
National (RMK, HWP, MNMP, Strategic Plan)
SUPPLY
Goal: Ensure availability of safe, effective and quality assured medicines. Medicines marketed meet the approved standards, requirements and comply with legal provisions
Time-to-market
Improve pipeline execution and time to market
Enhancing ecosystem of pharmaceutical sector
Compliance
Safety, quality & effective medicines
Cross-functional compliance
Efficiencies
Greater efficiencies in development & delivery
DEMAND & UTILIZATION
Goal: Ensure that medicines are selected and procured based on evidence of safety and cost-effectiveness, rationally prescribed and used and that the optimal benefits off financing are met by monitoring consumption and expenditure
Access
Available, affordable, continuous & equity in access to medicines
Use
Fair and transparent selection of medicines
Judicious, appropriate, safe, quality and effective use of medicines
Sustainability & self-reliance
Continuous access
Market authorization
Research & Development
Authorization
Production
Post Marketing
Drug discovery
Pre-clinical
5,000 – 10,000 compounds
250
Clinical Trial
Phase I Mainly safety
First in Human (FIH)
Phase II Safety & efficacy
Phase III Mainly efficacy & safety
BE Study
BS Study
Good Laboratory Practice (GLP)
Good Clinical Practice (GCP)
API Development
Patent filing
Number of participants
20-100
100 -500
1,000 -5,000
3-6 years
6-7 years
Regulatory Pathways
Submission
Evaluation
Approval
Registration
Analytical data, validation, impurities, stability, clinical data, certificate, licensing, inspection, GMP, GLP
1 year
Upstream
Midstream
Downstream
Planning
Sourcing
Processing (internal)
Processing (external)
Delivery
Selection
Essential medicines
Formulary
Treatment guidelines
Procurement
Private
Government
MOH
APPL, Contract, LP
Non-MOH
Pooled procurement
Pooled procurement
Outsourcing
Distribution & supply
Infrastructure & resources
Logistics & operations
Central medical store and alternatives model
GDP
Use & Consumption
Pharmaceutical care
Drug info
Adherence
Prescribing
Intervention
Dispensing
Health literacy
Community empowerment
Medicine Disposal
Administration
Costing & Pricing
Financing & Payment
Manufacturers/ Importers
Distributors/ Wholesalers
Healthcare Facilities
Consumers/ Patients
Supply chain
Post-marketing surveillance & Pharmacovigilance
Stakeholders engagement & Consumer protection
Inspection & Enforcement
PhIS, PRiSMA, MyPharma-C, eDPF
Pharmaceutical Track & Trace System
MOH, MOHE, MOSTI, FRIM (NRECC), MARDI (MAFS), RI (GRI & PRI), Pharma Industries
MOH, NPRA, CRC, ICR CRM, MOHE, Industries Initiated Research (IIR), PhAMA
QUEST3+
NPRA, PRH
PRH, NPRA, BPF MITI, MIDA
BAPF, BPF, NPRA, MOHE, MINDEF, PRH, HCF, Society, NGOs
BAPF, BPF, NPRA, MOHE, MINDEF, PRH, HCF, Society, NGOs
BAPF, BPF, NPRA, MOHE, MINDEF, PRH, Distributors, HCF
BAPF, BPF, NPRA, MOHE, MINDEF, HCF, Society, NGOs
BAPF, BPF, NPRA, MOHE, MINDEF, HCF, Society, NGOs
MDSSR & ADSSR
Advocacy, Preparedness, Mitigation & Strategic Communication
Evaluation & Continuous Improvement
Capacity & human resources
Information system, technology & infrastructure
Financing
Innovation, research & development
Partnership & collaboration
Leadership, Governance, Laws & Regulations
Recognition
Collaboration

ISU DAN CABARAN

Sektor farmaseutikal memainkan peranan yang penting dalam memastikan ketersediaan dan kebolehcapaian ubat-ubatan yang selamat dan berkesan. Walau bagaimanapun, terdapat beberapa isu dan cabaran yang menjadi limitasi perkembangan sektor farmaseutikal.

Pengukuhan Kawalan Perundangan

Senarai perundangan di bawah Program Perkhidmatan Farmasi (PPF), KKM termasuk Akta Racun 1952, Akta Jualan Dadah 1952, Akta Pendaftaran Ahli Farmasi 1951, Akta Ubat (Iklan & Penjualan) 1956 dan Akta Dadah Berbahaya 1952 serta perundangan subsidiari masing-masing. Perundangan ini penting untuk mengawal amalan, substan, produk dan iklan berkaitan farmaseutikal bagi memastikan kesihatan dan keselamatan orang awam terjamin. Dengan itu, semakan perundangan telah dibuat secara berkala bagi memastikan peruntukan kekal relevan dengan amalan dan keperluan semasa. Pindaan kepada beberapa perundangan dicadangkan supaya tadbir urus yang lebih baik boleh dibuat bagi amalan, produk dan iklan farmaseutikal. Antara isu yang dihadapi dalam pengukuhan perundangan adalah polisi yang kurang jelas dan berubah-ubah serta kesukaran mendapat konsensus daripada semua pemegang taruh.

(i) Ubat Tidak Berdaftar, Palsu dan Substandard

Kemunculan ubat tidak berdaftar, palsu dan substandard dalam pasaran menimbulkan ancaman besar terhadap kesihatan awam. WHO menganggarkan bahawa 1 daripada 10 produk perubatan di negara berpendapatan rendah dan sederhana adalah palsu atau substandard. Ubat palsu merupakan produk yang dipalsukan sama ada dari segi identiti, kandungan dan sumbernya manakala ubat substandard pula adalah produk yang tidak memenuhi spesifikasi atau standard kualiti yang ditetapkan, atau kedua-duanya. Masih terdapat premis-premis seperti penjaja tepi jalan, pasar malam, media sosial, platform e-dagang dan lain-lain yang menjual produk tidak berdaftar, palsu dan substandard. Produk ini boleh menjejaskan keselamatan pesakit dan membawa kepada kegagalan rawatan. Tindakan lanjut perlu bagi memperkukuh langkah pengawalseliaan, meningkatkan sistem pengawasan, dan meningkatkan kesedaran awam adalah penting untuk memerangi ubat tidak berdaftar, palsu dan substandard demi menjaga kesejahteraan penduduk.

(ii) Penjualan Ubat Dalam Talian:

Perkembangan teknologi digital secara global telah mengubah cara perkhidmatan kesihatan masa kini termasuk di Malaysia. Perkhidmatan kesihatan secara dalam talian semakin mendapat tempat di Malaysia dengan percambahan pelbagai platform di media baharu yang dapat diakses dengan mudah termasuklah perkhidmatan farmasi secara dalam talian (*e-pharmacy*). Proses penjualan atau pembekalan produk farmaseutikal secara dalam talian ini adalah sebagai alternatif kepada pesakit atau pelanggan yang memerlukan perkhidmatan ini. Perkembangan teknologi berlaku dengan lebih cepat berbanding perubahan regulatori. Sejajar dengan perkembangan teknologi ini, pengetahuan, polisi dan garis panduan perlu seiring bagi memenuhi keperluan industri dan pengguna, di samping mematuhi undang-undang sedia ada.

Pengukuhan Sistem Regulatori Farmaseutikal

Memperkukuh sistem regulatori farmaseutikal adalah kunci untuk memastikan Bahagian Regulatori Farmasi Negara (NPRA) menyediakan perkhidmatan yang berkesan dan cekap kepada semua pemegang taruh serta memastikan bahan-bahan terapeutik yang dibenarkan di pasaran tempatan adalah berkualiti, selamat dan berkesan.

(i) Pengharmonian Regulatori dan Penglibatan Antarabangsa

Pada masa kini, pengharmonian dan penyelarasan aktiviti regulatori farmaseutikal di peringkat global adalah amat penting. Rangka kerja regulatori yang selari dengan piawaian antarabangsa dan amalan regulatori baik dapat mempercepatkan akses kepada ubat baharu, menggalakkan pelaburan dan memupuk inovasi. Usaha sama dengan pemegang taruh antarabangsa dalam penyelidikan, pembangunan dan perkongsian pengetahuan membolehkan Malaysia kekal di barisan hadapan dari segi kemajuan dalam sektor farmaseutikal.

Keahlian dalam *International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use* (ICH) amat bermakna kerana ia merupakan satu pengiktirafan bahawa kepakaran teknikal Bahagian Regulatori Farmasi Negara (NPRA) adalah setaraf dengan badan regulatori antarabangsa yang lain. Di samping itu, menjadi ahli ICH dapat memastikan bahawa piawaian regulatori yang digunakan adalah selaras dengan keperluan regulatori peringkat antarabangsa.

(ii) Meningkatkan Kecekapan Proses Pendaftaran Produk

Salah satu cabaran dalam mendapatkan kelulusan pendaftaran dan akses terhadap ubat-ubatan teknologi terkini di Malaysia adalah proses penilaian produk untuk tujuan pendaftaran yang rumit dan tempoh masa yang agak panjang. Sehubungan itu, NPRA telah mengambil inisiatif untuk mewujudkan mekanisme pendaftaran secara *Facilitated Registration Pathway* dengan menggunakan kaedah penilaian secara *collaborative and reliance* yang akan menambah baik proses penilaian bagi mempercepat akses kepada ubat yang berkualiti, selamat dan berkesan.

(iii) Memastikan Produk Berdaftar Menepati Syarat dan Piawaian

Bagi produk vaksin, aktiviti *Post Marketing Surveillance* (PMS) adalah terhad kerana kekangan kemudahan dan kepakaran dalam pengujian produk tersebut. Oleh itu, NPRA telah bekerjasama dengan Makmal Kesihatan Awam Kebangsaan (MKAK) Sungai Buloh untuk membangunkan tatacara pengujian potensi produk vaksin.

NPRA sentiasa mengikuti kemajuan teknologi dan terlibat secara aktif dengan rangkaian regulatori antarabangsa untuk menerima pakai amalan terbaik berkaitan pemantauan dan penilaian kelas ubat baharu. NPRA juga sentiasa bekerjasama dengan agensi antarabangsa, badan regulatori dan profesional penjagaan kesihatan untuk memanfaatkan kepakaran dan perkongsian sumber bagi meningkatkan usaha pengawasan pasca pemasaran.

(iv) Keperluan regulatori untuk kajian klinikal *First in Human (FIH)* dan produk *Cell and Gene Therapy (CGTP)*

Kemajuan dalam teknologi farmaseutikal dan penemuan ubat baharu memberikan cabaran baru dalam kawalan regulatori produk tersebut. Dalam Pelan Hala Tuju Pembangunan Vaksin Negara (PPVN) Malaysia telah mensasarkan untuk menjadi hub bagi kajian klinikal termasuk

kajian *First-In-Human* (FIH). Walaupun NPRA telah memulakan Program Akreditasi Unit Tahap 1 sejak tahun 2018, terdapat keperluan untuk membangunkan ekosistem penyelidikan klinikal memandangkan bilangan fasiliti yang berjaya mendapat akreditasi ini sangat terhad.

Bagi kawalan regulatori produk *Cell and Gene Therapy* (CGTP), didapati pemegang taruh yang terlibat memerlukan panduan dalam aspek pematuhan keperluan *OECD Good Laboratory Practice*, Amalan Perkilangan Baik, keperluan klinikal dan bukan klinikal untuk tujuan pendaftaran produk CGTP tersebut. Pada masa yang sama, NPRA juga perlu menambah baik aspek kepakaran dalam melaksanakan kawalan regulatori ke atas produk tersebut.

Jurang Akses dan Ketersediaan Kepada Ubat-ubatan

Akses kepada ubat-ubatan yang selamat, berkesan, berpatutan dan berkualiti merupakan komponen penting menuju ke arah *Universal Health Coverage* (UHC). Malaysia, sebuah negara berpendapatan sederhana dengan penduduk yang semakin menua juga menghadapi cabaran yang ketara untuk memastikan akses kepada ubat-ubatan yang mencukupi. Walaupun sistem penjagaan kesihatan Malaysia telah mencapai kemajuan yang membanggakan dalam menyediakan perkhidmatan penjagaan kesihatan, namun masih terdapat beberapa isu dan cabaran berkaitan kebolehcapaian ubat-ubatan.

(i) Paten, Harta Intelek dan Ubat Generik

Salah satu halangan utama kepada akses ubat-ubatan di Malaysia ialah kos produk farmaseutikal yang tinggi. Paten dan hak harta intelek menyumbang kepada kenaikan harga, terutamanya untuk ubat baharu dan dipatenkan. Kenaikan harga ubat yang dipatenkan, ditambah dengan peningkatan perbelanjaan penjagaan kesihatan, menimbulkan beban kewangan yang besar kepada individu dan sistem penjagaan kesihatan. Keadaan ini memberi kesan kepada kedua-dua sektor penjagaan kesihatan awam dan individu yang bergantung kepada perkhidmatan penjagaan kesihatan swasta. Pesakit yang menghidap penyakit kronik, yang memerlukan rawatan jangka panjang dan mereka yang tidak mempunyai perlindungan insurans kesihatan yang komprehensif sangat terkesan dengan isu ini. Walaupun paten diterima sebagai satu bentuk insentif dan ganjaran untuk inovasi, syarat paten yang berpanjangan merupakan antara sebab harga ubat-ubatan paten yang tinggi. Pelaksanaan mekanisme ketelusan harga ubat dan rundingan dengan syarikat farmaseutikal antara langkah yang dapat membantu mengurangkan kos ubat. Di samping itu, promosi penggunaan ubat generik, yang merupakan alternatif yang lebih berpatutan daripada ubat inovator, boleh mengurangkan perbelanjaan penjagaan kesihatan dengan ketara. Pelaksanaan kempen pendidikan dan mengurangkan potensi halangan kepada penggantian generik juga boleh menggalakkan penerimaan dan meningkatkan keyakinan terhadap alternatif yang juga kos efektif ini.

Jurang geografi di Malaysia turut menjejaskan akses kepada ubat-ubatan, terutamanya di kawasan luar bandar dan terpencil. Kemudahan dan infrastruktur penjagaan kesihatan yang terhad menyukarkan jangkauan akses kepada ubat-ubatan penting oleh komuniti seperti individu berpendapatan rendah, pelarian dan komuniti orang asli, sekaligus memburukkan lagi ketidaksamaan kesihatan kepada golongan ini.

(ii) Kecekapan dan Kelestarian Rantaian Bekalan Ubat-ubatan

Kecekapan dan kelestarian rantaian bekalan ubat-ubatan adalah penting untuk memastikan ketersediaan ubat yang berterusan dan stabil. Walau bagaimanapun, Malaysia sentiasa menghadapi cabaran berkaitan pengurusan rantaian bekalan, termasuk logistik, penyimpanan dan pengedaran.

Pandemik COVID-19, penutupan sempadan negara pengeksport utama seperti China dan India serta peperangan di Ukraine telah menyebabkan gangguan bekalan bahan mentah dan bahan farmaseutikal aktif (API) di peringkat global. Malaysia turut tidak terkecuali mengalami impak gangguan bekalan ubat-ubatan akibat kelewatan dalam pembekalan bahan farmaseutikal aktif (API), eksipien, standard analisis rujukan dan bahan pembungkusan. Keadaan ini ditambah buruk lagi dengan masalah kekurangan tenaga pekerja asing yang berlaku dalam kalangan pengilang tempatan.

Isu ini menyebabkan gangguan bekalan stok dan kelewatan penghantaran ubat ke fasiliti penjagaan kesihatan serta menjejaskan akses

pesakit terhadap ubat-ubatan yang diperlukan. Walaupun pelbagai pelan mitigasi telah dijalankan oleh kerajaan untuk menangani isu ini, terdapat keperluan untuk mewujudkan satu sistem pemantauan bekalan dan pengedaran ubat-ubatan di Malaysia dengan kerjasama pelbagai agensi Kementerian Kesihatan Malaysia bagi memantau ketersediaan stok ubat-ubatan. Selain itu, terdapat keperluan bagi merangka pelan keterjaminan dan kelestarian ubat-ubatan jangka panjang sebagai salah satu strategi kesiapsiagaan menghadapi krisis masa hadapan.

Agihan dan kemahiran sumber manusia yang perlu dipertingkatkan:

Perkhidmatan kesihatan yang baik juga bergantung kepada bilangan petugas dan tenaga kerja yang mencukupi, terlatih dan ditempatkan berdasarkan kemahiran mengikut keperluan. Ciri-ciri ini menyumbang kepada perkhidmatan yang berkualiti, berkesan, efisien, dan boleh diakses. Di samping itu, terdapat juga keperluan untuk mengoptimumkan kemahiran sumber manusia sedia ada kepada yang lebih pelbagai (*skill-mix*) bagi memenuhi keperluan perkhidmatan. Kualiti penjagaan kesihatan banyak bergantung kepada kewujudan tenaga kerja kesihatan mahir di setiap peringkat. Perancangan tenaga kerja yang berkesan juga akan memastikan keperluan dan tuntutan rakyat dipenuhi. Nisbah ahli farmasi kepada penduduk telah digunakan untuk mengira Indeks Kesihatan kerana dapat mencerminkan jumlah tenaga kerja ahli farmasi yang dapat memberi perkhidmatan kepada penduduk. Berdasarkan kepada statistik 2020, nisbah seorang (1) ahli farmasi kepada populasi adalah 1:2,413 (2018) dan 1:1,709 (2020) berbanding nisbah di Singapura iaitu 1:1,655 pada tahun 2020.

Meskipun wujud peningkatan ahli farmasi namun masih terdapat masalah agihan penempatan yang tidak seimbang di sektor awam dan swasta yang dipengaruhi oleh faktor geografi dan sosioekonomi. Contohnya, fasiliti kesihatan swasta lebih tertumpu di kawasan bandar kerana populasi yang tinggi serta perbezaan dari segi literasi kesihatan.

Situasi ketidakseimbangan sumber di antara sektor awam dan swasta juga disumbangkan oleh beban pesakit yang jauh lebih tinggi di sektor awam berbanding sektor swasta. Sebagai contoh, 64% daripada beban pesakit luar adalah dirawat di sektor awam berbanding hanya 36% di sektor swasta. Situasi ini menyebabkan kesesakan di fasiliti kesihatan awam dan masa menunggu yang lama untuk mendapatkan rawatan. Kekurangan kakitangan, kesesakan akibat beban bilangan pesakit yang tinggi, kekurangan dana dan peralatan yang tidak mencukupi yang perlu diganti serta fasiliti yang daif turut menjejaskan penyampaian perkhidmatan kesihatan terutamanya di sektor awam.

Tahap Literasi Kesihatan yang Rendah dan Penggunaan Ubat-ubatan Secara Tidak Rasional Dalam Masyarakat

Berdasarkan Tinjauan Kesihatan dan Morbiditi Kebangsaan (NHMS) 2019, didapati 35.1% golongan dewasa mempunyai tahap literasi kesihatan yang rendah. Berdasarkan penemuan tersebut, komuniti dan individu perlu diperkasakan untuk meningkatkan pengetahuan dan pemahaman terhadap pengurusan ubat-ubatan yang boleh membantu mereka dalam mencapai tahap kesihatan yang lebih baik. Penduduk Malaysia juga menuju ke arah populasi tua. Pertambahan rumah jagaan warga emas juga semakin ketara dalam masyarakat Malaysia. Bagi memastikan keselamatan warga emas ini, lebih banyak perhatian diperlukan untuk menyampaikan penjagaan kesihatan kepada mereka secara berkesan. Pengetahuan yang rendah berkenaan pengurusan ubat-ubatan di rumah dan institusi penjagaan akan mendedahkan masyarakat kepada risiko kesilapan pengubatan dan mengurangkan keberkesanan rawatan. Bilangan ahli farmasi kekal dalam nisbah rendah untuk memberi perkhidmatan kepada 32 juta penduduk. Terdapat platform yang terhad untuk menyebarkan maklumat yang tepat dan betul berkenaan ubat-ubatan kepada orang ramai. Dalam usaha memperluas liputan Program Kenali Ubat Anda, terdapat keperluan untuk mengenal pasti jurang ekonomi, kewangan, geografi dan sosial yang mempengaruhi penyebaran maklumat. Namun begitu, sepanjang pelaksanaan Program Kenali Ubat Anda, kita dapat mengenal pasti perspektif masyarakat terhadap penggunaan ubat-ubatan dapat dikenal pasti. Penglibatan awam memerlukan komitmen, usaha gigih, semangat, kerjasama dan persefahaman daripada ahli farmasi, profesional kesihatan, masyarakat awam dan semua pemegang taruh.

OBJEKTIF DUNas

Untuk menggalakkan AKSES kepada ubat-ubatan yang SAKSAMA dan penggunaan secara RASIONAL, ubat yang BERKUALITI, SELAMAT, BERKESAN dan MAMPU MILIK ke arah meningkatkan tahap kesihatan rakyat

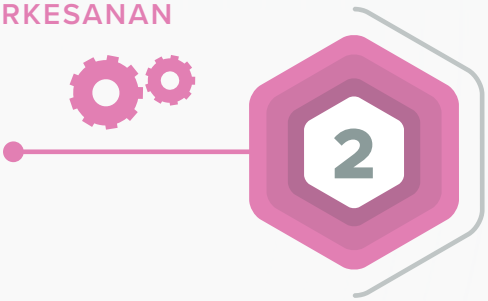
5 KOMPONEN UTAMA DUNas

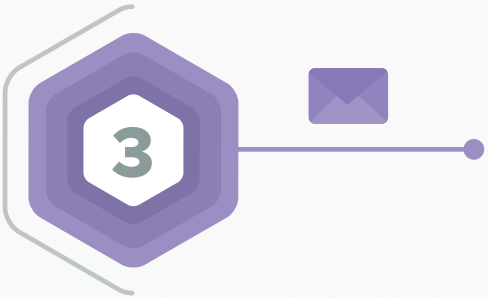
TADBIR URUS UBAT-UBATAN

Tadbir urus yang baik mengenai pengurusan farmaseutikal, amalan dan profesionalisme dititikberatkan

KUALITI, KESELAMATAN & KEBERKESANAN UBAT-UBATAN

Ubat-ubatan dalam pasaran adalah selamat, berkesan dan berkualiti untuk pengguna di Malaysia





AKSES KEPADA UBAT-UBATAN

Ketersediaan dan kesaksamaan ubat-ubatan ke arah memastikan akses berterusan bagi memenuhi keperluan penjagaan kesihatan rakyat pada setiap masa

PENGGUNAAN UBAT SECARA BERKUALITI

Penggunaan ubat secara berkualiti adalah tanggunggjawab semua pemegang taruh. Pemerkasaan pemegang taruh melalui penggunaan ubat-ubatan yang sesuai ke arah tahap kesihatan yang lebih baik

KERJASAMA DAN KOLABORASI BAGI INDUSTRI KESIHATAN

Kerjasama dan kolaborasi strategik dalam kalangan pemegang taruh hendaklah dipergiatkan untuk menyokong dan memupuk pelaksanaan matlamat dan hala tuju dalam sektor penjagaan kesihatan

TADBIR URUS UBAT-UBATAN

KOMPONEN PERTAMA 01

1.0. TADBIR URUS UBAT-UBATAN

1.1 DASAR

Tadbir urus yang baik mengenai pengurusan farmaseutikal, amalan, dan profesionalisme hendaklah dititikberatkan.

1.2 MATLAMAT

1.2.1 Memastikan dasar dan perundangan yang jelas dan telus dalam memudahkan dan menyokong tadbir urus, profesionalisme dan amalan terbaik.

1.2.2 Tadbir urus yang sesuai bagi memastikan penyediaan perkhidmatan penjagaan farmaseutikal dalam persekitaran amalan terbaik.

1.2.3 Memastikan semua pemegang taruh menjalankan tanggungjawab secara beretika dan profesional.

1.3 PENDEKATAN

1.3.1 Polisi, dasar, perundangan dan garis panduan (contoh: HWP, dasar, perundangan dan peraturan) yang berkaitan hendaklah dirangka dan disemak dengan sewajarnya bagi memastikan bekalan ubat yang mencukupi dan selamat sekaligus meningkatkan tahap kesihatan awam.

1.3.2 Perluasan penggunaan garis panduan semasa kepada pemegang taruh yang lain.

1.3.3 Memastikan ketersediaan sumber manusia yang berkelayakan dan cekap.

1.3.4 Pemegang taruh hendaklah mematuhi standard dan/ atau kod amalan yang dibangunkan oleh pihak berkuasa atau badan profesional yang berkaitan.

1.4 STRATEGI

1.4.1 Memupuk budaya tingkah laku yang beretika.

1.4.2 Menggalakkan ketelusan, akauntabiliti dan amalan beretika dalam kalangan profesional kesihatan.

1.4.3 Memperkukuh perundangan dan peraturan.

1.4.4 Memantapkan kapasiti dan keupayaan modal insan

STRATEGI 1: Memupuk budaya tingkah laku yang beretika					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
1.1	Semakan rangka kerja latihan GGM	a) Modul TOT GGM yang telah selesai disemak (sebelum atau pada Q2 2024)	2023-2024	Menyemak Modul TOT (2023)	BDPSF, KPT, KEMENTAH, Persatuan Farmasi / MPS, Sektor Swasta
				Menerbitkan TOT Modul pada Q2 2024	
		b) Bilangan jurulatih bertauliah diberikan latihan (bermula pada Q3 2024)	2024-2026	30 setiap tahun (2024-2026)	
		c) Bilangan peserta diberikan latihan (bermula Q1 2025)	2025-2026	500 (Minimum) (2025)	
				1,000 (Minimum) (2026)	
		d) Peningkatan peratusan dalam kefahaman terhadap konsep GGM (Penilaian Pra & Pasca)	2025-2026	20% setiap tahun (2025-2026)	
STRATEGI 2 : Menggalakkan ketelusan, akauntabiliti dan amalan beretika dalam kalangan profesional kesihatan					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
2.1	Mengemas kini dan memperluas pelaksanaan Garis Panduan Akreditasi Pendidikan Profesional Berterusan (CPE)	a) Penerbitan Garis Panduan Akreditasi CPE yang telah dikemaskini (sebelum atau pada Q3 2024)	2023-2024	1. Sesi libat urus bersama pemegang taruh 2. Garis Panduan Akreditasi Pendidikan Profesional Berterusan (CPE) yang telah dikemaskini (2023)	BDPSF, KPT, KEMENTAH, (contoh; MPS) Persatuan Farmasi
				Penerbitan Garis Panduan Akreditasi CPE yang telah dikemaskini (sebelum atau pada Q3 2024)	
		b) Peratusan institusi menerima pakai sepenuhnya Garis Panduan Akreditasi CPE	2025-2026	80% diterima pakai oleh hospital KKM, PKD dan KK (2025)	
				90% diterima pakai oleh hospital KKM, PKD dan KK (2026)	

STRATEGI 3 : Memperkukuh perundangan dan peraturan					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
3.1	Memperkukuh Akta Pendaftaran Ahli Farmasi 1951 (ROPA 1951) dan peraturan sedia ada untuk tadbir urus profesion yang lebih baik	Pembentangan Rang Undang-undang di Parlimen	2026	Pembentangan Rang Undang-undang di Parlimen (2026)	BLFM & BPF, PUU AGC, Persatuan Profesion, Persatuan Pengguna, Lain-lain Agensi
3.2	Memperkukuh Akta Jualan Dadah 1952 (SODA 1952) dan peraturan sedia ada untuk tadbir urus yang lebih baik bagi produk farmaseutikal	Pembentangan Rang Undang-undang di Parlimen	2023	Pembentangan Rang Undang-undang di Parlimen (2023)	BPF, PUU AGC, Persatuan Profesion, Persatuan Industri, Persatuan Pengguna, Lain-lain Agensi
3.3	Memperkukuh Akta Ubat (Iklan & Penjualan) 1956 (MASA 1956) dan peraturan untuk tadbir urus yang lebih baik bagi produk farmaseutikal	Pembentangan Rang Undang-undang di Parlimen	2026	Pembentangan Rang Undang-Undang di Parlimen (2026)	

STRATEGI 4: Memantapkan kapasiti dan keupayaan modal insan.					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
4.1	Penubuhan rangka kerja untuk pengiktirafan *credentialing* Ahli Farmasi dan Penolong Pegawai Farmasi di Malaysia	a) Penghasilan garis panduan pengiktirafan *credentialing* untuk Ahli Farmasi dan Penolong Pegawai Farmasi	2022-2024	Dapatkan kelulusan dasar / pengesahan mekanisme secara prinsip daripada Program Farmasi (2022)	BLFM, BDPSF, BAPF, NPRA, BPF **BUKAN KKM:** KEMENTAH, HUKM, HUSM, HUPM, PPUM, HUiTM, PPT dan sebagainya. **SWASTA:** MPS, MAP, Institusi Swasta contohnya KPJ Healthcare, IHH Healthcare, Farmasi Komuniti dan sebagainya.
				1. Kelulusan / Pengesahan mekanisme dari Lembaga Farmasi Malaysia (LFM) 2. Penubuhan Jawatankuasa *Credentialing* 3. Merangka dan menentukan dasar yang berkaitan dengan keperluan dan standard *credentialing* 4. Penubuhan Jawatankuasa Teknikal (2023)	
				1. Menghasilkan garis panduan berkaitan *credentialing* ahli farmasi (Bukan KKM) 2. Sesi libat urus bersama pemegang taruh yang berkaitan untuk memperkenalkan garis panduan (2024)	
		b) Bilangan bidang *credentialing* bagi institusi bukan KKM	2024-2026	1 bidang *credentialing* untuk diperaku oleh LFM (2024)	
				2 bidang *credentialing* untuk diperaku LFM (2025)	
				3 bidang *credentialing* untuk diperaku LFM (2026)	
		c) Bilangan Ahli Farmasi (dan Penolong Pegawai Farmasi) (KKM)	2023-2026	Peningkatan 10% setiap tahun (2023-2026)	
		d) Bilangan Ahli Farmasi (dan Penolong Pegawai Farmasi) (bukan KKM)	2025-2026	Minimum 5 (2025)	
				Minimum 10 (2026)	

KUALITI, KESELAMATAN DAN KEBERKESANAN UBAT-UBATAN

KOMPONEN KEDUA 02

2.0. KUALITI, KESELAMATAN DAN KEBERKESANAN UBAT-UBATAN

2.1 DASAR

Ubat-ubatan dalam pasaran adalah selamat, berkesan dan berkualiti untuk pengguna di Malaysia

2.2 MATLAMAT

Untuk memastikan ubat-ubatan yang dipasarkan mematuhi piawaian, keperluan yang diluluskan dan mematuhi peruntukan undang-undang untuk kesejahteraan pengguna.

2.3 PENDEKATAN

Memperkukuh sistem regulatori ubat dan aktiviti penguatkuasaan melalui rangka kerja perundangan ubat yang komprehensif, mempertingkatkan langkah-langkah keselamatan untuk jaminan kualiti farmaseutikal serta pengawasan pasca pemasaran yang berkesan dengan sokongan kolaboratif daripada pemegang taruh yang berkaitan

2.4 STRATEGI

2.4.1 Memastikan semua keperluan regulatori sejajar dengan amalan regulatori global semasa dan mematuhi piawaian antarabangsa

2.4.2 Memperkukuh aktiviti penguatkuasaan dan kawal selia di bawah akta dan peraturan yang berkaitan

2.4.3 Meningkatkan keselamatan produk dan aktiviti surveilans pasca pendaftaran produk

2.4.4 Memperkukuh kerjasama dengan badan regulatori negara (NRA) yang lain

STRATEGI 1 : Memastikan semua keperluan regulatori adalah sejajar dengan amalan regulatori global semasa dan mematuhi piawaian antarabangsa					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
1.1	Pengukuhan sistem regulatori menerusi Penilaian/ Penandaan aras Pihak Berkuasa Regulatori Kebangsaan (NRA) *[National Regulatory Authority (NRA) Assessment/ Benchmarking]* oleh WHO	Mencapai *maturity level* 4 (ML4) menjelang tahun 2024	2024	Mencapai *maturity level* 4 (2024)	WHO, NPRA, BPF, BAPF, BKP, BPKA
1.2	Pengukuhan sistem regulatori menerusi keahlian dalam *International Council of Harmonisation of Technical Requirement for Pharmaceuticals for Human Use* (ICH)	Mengenal pasti dan memenuhi keperluan untuk keahlian ICH	2023-2026	1. Mengenalpasti kepakaran untuk menjadi ahli ICH 2. Memohon peruntukan bagi menghadiri mesyuarat *Working Group* (WG) dan ICH *General Assembly* (GA) pada 2024 (2023) 1. Menyediakan MJM untuk mendapatkan kelulusan untuk menjadi ahli ICH dan memohon peruntukan untuk yuran tahunan ICH 2. Menghadiri mesyuarat WG dan ICH GA 3. Memohon peruntukan bagi menghadiri mesyuarat WG dan ICH GA pada 2025 (2024) 1. Menghadiri mesyuarat WG dan ICH GA 2. Memohon peruntukan bagi menghadiri mesyuarat WG dan ICH GA pada 2026 3. Menyusuli kelulusan MJM (2025) 1. Menghadiri mesyuarat WG dan ICH GA 2. Memohon peruntukan bagi menghadiri mesyuarat WG dan ICH GA pada 2027 3. Menyusuli kelulusan MJM (2026)	NPRA

1.3	Pelaksanaan Pendaftaran Produk Terapi Sel dan Gen (CGTP)	a) Semakan garis panduan CGTP	Selesai pada 2023	Garis Panduan CGTP Edisi ke-2 diterbitkan (2023)	NPRA, BPF, CKAPS, MACT, TESMA, Syarikat Bio-Ekonomi
		b) Bilangan sesi latihan untuk badan regulatori / NPRA	Selesai pada 2023	Sekurang-kurangnya satu sesi latihan (2023)	
		c) Bilangan latihan industri	2024-2026	Sekurang-kurangnya satu sesi latihan industri setahun (2024-2026)	
		d) Laporan permohonan pendaftaran produk dan pemeriksaan dihasilkan	2022-2026	Bilangan permohonan pendaftaran produk dan pemeriksaan GMP, GLP dan kajian klinikal dilaporkan (2022-2026)	
1.4	Promosi dan kesedaran kepada pemegang taruh untuk akreditasi tapak kajian klinikal *First-in-Human* (FIH) selari dengan *National Vaccine Development Roadmap* (NVDR)	a) Bilangan libat urus dengan pemegang taruh	2022-2026	3 setiap tahun (2022-2026)	NPRA, CRC, CRM, PRH, CRO, ACRPM, UMBI, Jawatankuasa Etika di Universiti, IMR, CKAPS
		b) Bilangan permohonan diterima untuk kajian FIH tempatan	2024-2026	Bilangan permohonan diterima untuk kajian FIH tempatan dilaporkan (2024-2026)	
1.5	Pelaksanaan *e-labelling* secara sukarela	a) Penyediaan kertas kerja dan garis panduan untuk dibentangkan dalam Mesyuarat Polisi PPF dan PBKD	Q1 2023	Dibentangkan dalam PBKD (2023)	NPRA, PPF, PhAMA, MOPI, MAPS
		b) Pelaksanaan *e-labelling* secara sukarela	2023-2026	1. Kajian rintis 2. Pelaksanaan *e-labelling* secara sukarela (Q3 2023)	
				Melaporkan bilangan produk yang menggunakan *e-labelling* (2024-2026)	
1.6	Penubuhan NPRA sebagai badan berkanun	MJM diangkat kepada Pengurusan Tertinggi KKM	2023-2025	Kertas Kerja dibentangkan dalam Mesyuarat Polisi PPF (2023)	NPRA
				Sesi Libat Urus bersama semua pemegang taruh (2024)	
				MJM diangkat kepada Pengurusan Tertinggi KKM (2025)	

STRATEGI 2 : Memperkukuh aktiviti penguatkuasaan dan regulatori di bawah akta dan peraturan yang berkaitan					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
2.1	Memerangi penjualan ubat haram dan palsu secara dalam talian	a) Bilangan iklan berkaitan penjualan ubat haram dan palsu dalam e-dagang yang dinotifikasi untuk diturunkan	2022-2026	4,000 setahun (2022)	BPF, MCMC, Interpol, WHO, *Pharmaceutical Security Institute* (PSI), Platform Media
				4,500 setahun (2023)	
				5,000 setahun (2024)	
				5,500 setahun (2025)	
				6,000 setahun (2026)	
		b) Peratus penjual ubat haram dan palsu dalam talian yang dikenal pasti dalam tempoh 30 hari dari pemprofilan dimulakan	2022-2026	90% setiap tahun (2022-2023)	
				95% setiap tahun (2024-2025)	
				100% (2026)	
		c) Peratus tindakan penguatkuasaan diambil ke atas penjualan dalam talian bagi produk haram dan palsu dalam tempoh 10 hari bekerja dari laporan pemprofilan yang lengkap	2022-2026	80% (2022)	
				85% (2023)	
				90% (2024)	
				95% (2025)	
				100% (2026)	
		d) Peratus operasi yang berjaya	2022-2026	50% setiap tahun (2022-2023)	
				75% setiap tahun (2024-2025)	
				80% (2026)	
2.2	Meningkatkan aktiviti penguatkuasaan untuk mengurangkan penjualan produk tidak berdaftar/ kosmetik tidak bernotifikasi/ produk, sediaan, dan kosmetik mengandungi racun dengan menggunakan pendekatan secara bersasar.	Peratus premis yang dikenal pasti menjual produk tidak berdaftar, produk dicampur palsu dan kosmetik tidak bernotifikasi secara terbuka, berkurangan setiap tahun secara kumulatif	2022-2026	Pengurangan 20% setiap tahun dan secara kumulatif 95% dalam masa 5 tahun (2022-2026)	BPF

2.3	Memperkukuh kawalan ke atas produk tidak berdaftar, palsu dan substandard melalui *Pharmaceutical Track and Trace System*	a) Kelulusan PBKD untuk *Pharmaceutical Track & Trace System*	2023-2025	Sesi Libat Urus bersama pemegang taruh dan pindaan regulatori (2023) Kajian Rintis Produk Rangkaian Sejuk (2024) Direktif PBKD dan Garis Panduan Pelaksanaan diluluskan (2025)	BDPSF, PPF, KKM, PhAMA, MOPI, MAPS, Lain-lain, Anggota kesihatan profesional
		b) Pelaksanaan *Pharmaceutical Track & Trace System*	2023-2026	1. Proses *Request for Information* (RFI): taklimat dan penyediaan laporan RFI untuk dihantar ke UKAS 2. Sesi Libat Urus bersama pemegang taruh (2023) 1. *Request for Proposal* (RFP), proses tender dan pemilihan pembekal 2. Pembangunan dan pelaksanaan MyMediTRACE (2024) 1. Kajian rintis MyMediTRACE 2. Pelaksanaan MyMediTRACE berdasarkan kategori produk (2025) Pelaksanaan MyMediTRACE (fasa sukarela bagi Racun Berjadual) (2026)	BDPSF, NPRA, BPF, BAPF, BPM, BPP

STRATEGI 3: Meningkatkan keselamatan produk dan aktiviti surveilans pasca pendaftaran produk

No.	Inisiatif	Indikator Pencapaian	Garis Masa Pelaksanaan	Sasaran (Tahun)	Pemegang Taruh Utama
3.1	Memperkukuh aktiviti farmakovigilans	a) Bilangan pemegang pendaftaran produk (PRHs) diperiksa	2023-2026	4 PRHs diperiksa (2023) 5 PRHs diperiksa (2024) 6 PRHs diperiksa (2025) 7 PRHs diperiksa (2026)	NPRA, MOPI, PRH, PhAMA, MAPS
		b) Bilangan latihan farmakovigilans dianjurkan	2023-2026	Minimum 1 latihan dianjurkan setiap tahun (2023-2026)	

3.2	Mempertingkatkan kepatuhan produk berdaftar kepada standard dan keperluan yang ditetapkan	a) Bilangan metodologi ujian vaksin dibangunkan	2023-2026	1. 1 metodologi ujian dibangunkan (Test 1) 2. 1 metolodogi ujian mula dibangunkan (Test 2) (2023)	NPRA, MKAK, UMBI, IMR, MOSTI, PRH, PhAMA, MOPI
				1. 1 metodologi ujian dibangunkan (Test 2) 2. 1 metodologi ujian mula dibangunkan (Test 3) (2024)	
				1. 1 metodologi ujian dibangunkan (Test 3) 2. 1 metodologi ujian dibangunkan (Test 4) (2025)	
				1 metodologi ujian dibangunkan (Test 4) (2026)	
		b) Bilangan jenis vaksin disampel dan diuji menggunakan metodologi yang telah dibangunkan		1 jenis vaksin disampel dan diuji setiap tahun (2023-2026)	NPRA, BKP, MKAK, IMR, PRH, PhAMA, MOPI

STRATEGI 4: Memperkukuh kerjasama antarabangsa dengan badan regulatori negara (NRA) yang lain

No.	Inisiatif	Indikator Pencapaian	Garis Masa Pelaksanaan	Sasaran (Tahun)	Pemegang Taruh Utama
4.1	Mengoptimumkan proses semakan regulatori	a) Semakan semula garis panduan	2023	Semakan garis panduan selesai (2023)	NPRA, MKAK, UMBI, IMR, MOSTI, PRH, PhAMA, MOPI
		b) Bilangan produk farmaseutikal yang dinilai melalui mekanisme *Facilitated Registration Pathway* (FRP)	2023-2026	Bilangan produk dinilai melalui FRP dilaporkan setiap tahun (2024-2026)	

AKSES KEPADA UBAT-UBATAN

KOMPONEN KETIGA 03

3.0. AKSES KEPADA UBAT-UBATAN

3.1 DASAR

Ketersediaan dan kesaksamaan ubat-ubatan ke arah memastikan akses berterusan bagi memenuhi keperluan penjagaan kesihatan rakyat pada setiap masa

3.2 MATLAMAT

Memastikan akses terhadap ubat yang berkualiti, selamat, efektif dan mampu milik adalah mencukupi, berterusan dan saksama ke arah mencapai keperluan penjagaan kesihatan

3.3 PENDEKATAN

3.3.1 Pemilihan ubat yang adil dan telus sesuai dengan keperluan kesihatan negara

3.3.2 Pengurusan rantaian bekalan ubat-ubatan yang optimum, efektif dan berterusan

3.3.3 Sistem pembiayaan dan harga ubat yang saksama bagi menjamin akses kepada perkhidmatan kesihatan

3.4 STRATEGI

3.4.1 Memperkukuh ketersediaan ubat berdasarkan keperluan negara

3.4.2 Memperkukuh pengurusan rantaian bekalan untuk memastikan bekalan ubat yang optimum, efektif dan berterusan

3.4.3 Mewujudkan mekanisme pembiayaan ubat-ubatan yang telus dan mampan

3.4.4 Memastikan ubat mampu milik di sektor awam dan swasta

3.4.5 Menggalakkan penggunaan ubat generik di sektor awam dan swasta

STRATEGI 1: Memperkukuh ketersediaan ubat berdasarkan keperluan negara					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
1.1	Memperkukuhkan *National Essential Medicines List (NEML)* berdasarkan keperluan semasa negara	Semakan NEML berdasarkan WHO EML	2022-2026	Semakan NEML berdasarkan WHO EML setiap tahun (2022, 2024, 2026)	BAPF
1.2	Memastikan ketersediaan ubat-ubatan NEML melalui pendaftaran produk dengan mematuhi elemen kualiti, keselamatan dan keberkesanan	Ubat-ubatan tidak berdaftar di bawah NEML diberikan keutamaan penilaian dan pendaftaran	2022-2026	1. Bilangan ubat-ubatan tidak berdaftar di bawah NEML yang diberikan keutamaan penilaian setiap tahun (2022-2026) 2. Bilangan ubat-ubatan yang tidak berdaftar di bawah NEML didaftarkan setiap tahun (2022-2026) 3. Status pemasaran akan dilaporkan apabila platform telah siap dan dasar-dasar pelaporan telah ditetapkan (2026)	NPRA, BAPF
1.3	Membangunkan garis panduan ubat-ubatan selaras dengan keperluan pengguna/ populasi yang bersesuaian	Pembangunan garis panduan ubat-ubatan selaras dengan perspektif pelbagai agama	2024	Analisis situasi (2024)	BDPSF
1.4	Memperkasakan penggunaan data farmakoekonomik (PE) tempatan dalam pemilihan ubat-ubatan	Penyediaan kerangka kerja penilaian PE dalam pemilihan ubat-ubatan untuk disenaraikan di dalam FUKKM/ Senarai *Reimbursement List*	2025	Kerangka kerja penilaian PE dalam pemilihan ubat-ubatan untuk disenaraikan di dalam FUKKM/ Senarai *Reimbursement List* dibangunkan (2025)	BAPF, PRH, PhAMA, MOPI
1.5	Membangunkan Formulari Ubat-ubat Tradisional & Komplementari (T&CM)	Pembangunan Formulari T&CM termasuk garis panduan penyenaraian dan pengguguran senarai produk T&CM di fasiliti KKM	2023	Formulari T&CM termasuk garis panduan untuk penyenaraian dan pengguguran senarai produk T&CM di fasiliti KKM dibangunkan (2023)	BPTK, PPF, NPRA, Unit T&CM di hospital kerajaan

STRATEGI 2: Memperkukuh pengurusan rantaian bekalan untuk memastikan bekalan ubat yang optimum, efektif dan berterusan					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
2.1	Membangunkan Sistem Pengurusan Stok Ubat-ubatan Kebangsaan yang komprehensif	a) Pembangunan kerangka kerja pelbagai pemegang taruh bagi pemantauan dan mitigasi gangguan bekalan ubat	2025	Platform pelaporan dan pemantauan yang melibatkan pelbagai pemegang taruh dibangunkan (2025)	NPRA, BAPF, BDPSF, BPF
		b) Pembangunan platform pelaporan dan pemantauan status pemasaran produk yang berdaftar melalui sistem atas talian QUEST5	2025	Pembangunan sistem berterusan sehingga UAT/ FAT pada Penggal 4 (2025)	NPRA, BDPSF, BAPF, BPF, MOPI, PhAMA, MAPS, MADSA
2.2	Memperkukuhkan proses perolehan untuk sektor awam dan swasta melalui Perolehan Bersama	Pembangunan Rangka Kerja Perolehan Ubat-Ubatan Secara Bersama Awam & Swasta	2024	1. Kajian kebolehlaksanaan Perolehan Bersama dikembangkan ke fasiliti kesihatan swasta 2. Rangka Perolehan Bersama antara fasiliti kesihatan awam dan swasta dibangunkan (2024)	BDPSF, BAPF, NPRA, BPF
2.3	Memastikan ketersediaan dan kelestarian bahan mentah ubat-ubatan di bawah senarai NEML	Pembangunan Rangka Kerja Pelan Sumber Bahan Mentah Farmaseutikal	2025	Rangka Kerja Pelan Sumber Bahan Mentah Farmaseutikal dibangunkan (2025)	PPF, MITI, NPRA, BDPSF, BPF, BAPF, MOPI, MAPS

STRATEGI 3: Mewujudkan mekanisme pembiayaan ubat-ubatan yang telus dan mampan					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
3.1	Memantapkan mekanisme bagi meningkatkan ketersediaan dan mampu milik ubat-ubatan	a) Menyediakan garis panduan berkaitan permohonan dan pengendalian *Medicines Access Scheme* (MASc) bagi fasiliti KKM	2023-2026	1. Bilangan MASc yang diluluskan setiap tahun (2023-2026) 2. Pemantauan pelaksanaan MASc di peringkat fasiliti berdasarkan garis panduan setiap tahun (2023-2026)	BAPF, PRH, PhAMA, MOPI
		b) Penilaian ekonomi berkaitan pelaksanaan *Medicines Access Scheme* (MASc) skim akses ubat-ubatan	2024-2026	Penilaian impak ekonomi berkaitan kelulusan ubat-ubatan di bawah skim MASc akses ubat-ubatan di KKM setiap tahun (2024-2026)	
3.2	Membangunkan rangka kerja fi dan *reimbursement* ubat-ubatan	Pembangunan rangka kerja fi dan *reimbursement* ubat-ubatan	2025	Memperluaskan skim *reimbursement* ubat di bawah PEKA B40 (dan lain-lain mekanisme pembiayaan yang diluluskan) (2025)	BDPSF, BAPF, Bahagian Perancangan KKM, Bahagian Kewangan KKM

STRATEGI 4: Memastikan ubat mampu milik di sektor awam dan swasta					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
4.1	Melaksanakan Mekanisme Ketelusan Harga Ubat	Pelaksanaan Mekanisme Ketelusan Harga Ubat	2024	Mekanisme Ketelusan Harga Ubat dilaksanakan (2024)	BAPF
4.2	Melaksanakan sesi libat urus bersama-sama pemegang taruh dalam pelaksanaan Mekanisme Ketelusan Harga Ubat	Bilangan libat urus dengan pemegang taruh yang terlibat dengan Pelaksanaan Mekanisme Ketelusan Harga Ubat	2022-2026	2 sesi libat urus setiap tahun (2022-2026)	BAPF, BDPSF, BPF, UKK, KPDN
4.3	Memantau impak pelaksanaan Mekanisme Ketelusan Harga Ubat	Penerbitan laporan berkaitan impak Mekanisme Ketelusan Harga Ubat	2025	Laporan diterbitkan (2025)	BAPF, NIH
STRATEGI 5: Menggalakkan penggunaan ubat generik di sektor awam dan swasta					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
5.1	Membangunkan Rangka Kerja Ubat Generik Kebangsaan	Pembangunan Rangka Kerja Ubat Generik & Biosimilar Kebangsaan	2024	Penerbitan dan penyebaran rangka kerja (2024)	BDPSF, NPRA, BAPF, MOPI, MAPS
5.2	Program Kesedaran Ubat Generik (GMAP)	Bilangan Program Kesedaran Ubat Generik dilaksanakan	2023-2026	2 libat urus setiap tahun (2023-2026)	BDPSF, BAPF, NPRA

PENGGUNAAN UBAT SECARA BERKUALITI

KOMPONEN KEEMPAT 04

4.0. PENGGUNAAN UBAT SECARA BERKUALITI

4.1 DASAR

Penggunaan ubat secara berkualiti adalah tanggungjawab semua pemegang taruh. Pemerkasaan pemegang taruh melalui penggunaan ubat-ubatan yang sesuai ke arah tahap kesihatan yang lebih baik.

4.2 MATLAMAT

Memastikan ubat-ubatan digunakan secara rasional, sesuai, selamat dan efektif

4.3 PENDEKATAN

4.3.1 Standard amalan terbaik hendaklah diaplikasi untuk memastikan penggunaan ubat-ubatan secara selamat dan berkualiti di semua peringkat penjagaan kesihatan termasuk sektor awam dan swasta.

4.3.2 Literasi kesihatan dan pemerkasaan semua pemegang taruh hendaklah dipertingkat untuk pengurusan ubat yang lebih baik.

4.4 STRATEGI

4.4.1 *Prescribing* dan pendispensan ubat hendaklah dilaksanakan selaras dengan garis panduan yang berkaitan.

4.4.2 Pengukuhan Amalan Pendispensan Baik di fasiliti kesihatan awam dan swasta

4.4.3 Meningkatkan literasi kesihatan dan memperkasakan masyarakat ke arah penggunaan ubat secara berkualiti

4.4.4 Pengukuhan strategi kerintangan antimikrob

STRATEGI 1: *Prescribing* dan pendispensan ubat hendaklah dilaksanakan selaras dengan garis panduan yang berkaitan					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
1.1	Memastikan Amalan Penjagaan Farmaseutikal selari dengan pelaksanaan standard amalan terbaik antarabangsa dan lokal	Peratus dokumen/ garis panduan berkaitan *prescribing* dan pendispensan ubat-ubatan disemak (sekurang-kurangnya setiap 5 tahun atau bila perlu)	2022-2026	65% (2022) 70% (2023) 75% (2024) 80% (2025) 85% (2026)	BAPF, APHM, MPS, MMA
1.2	Memastikan kepatuhan terhadap *Malaysian Patient Safety Goals No:7*: memastikan pelaksanaan Inisiatif Keselamatan Pengubatan di semua fasiliti kesihatan (awam & swasta)	Peratus fasiliti kesihatan mencapai lebih daripada 60% markah Penilaian Kendiri Inisiatif Keselamatan Pengubatan	2022-2026	1. 80% (KKM) 2. Semakan soal selidik (Bukan KKM) (2022) 1. 80% (KKM) 2. Dasar (Bukan KKM) 2023) 1. 85% setiap tahun (KKM) 2. Trend yang meningkat setiap tahun (Bukan KKM) (2024-2026)	BAPF, APHM, MPS, MMA, MCPG, NPRA
STRATEGI 2: Pengukuhan Amalan Pendispensan Baik di fasiliti kesihatan awam dan swasta					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
2.1	Membangunkan standard Amalan Pendispensan Baik di fasiliti kesihatan awam dan swasta	Dokumen rasmi bagi Standard Amalan Pendispensan Baik diterbitkan	2022-2026	1. Sesi Libat Urus bersama pemegang taruh dan membentuk Jawatankuasa bagi Standard Amalan Pendispensan Baik Sasaran: 1 Jawatankuasa 2. Analisis situasi (2022) 1. Analisis situasi Standard Amalan Pendispensan Baik di fasilii awam dan swasta Sasaran: 1 analisis 2. Pembangunan dokumen rasmi (2023) 1. Dokumen rasmi bagi Standard Amalan Pendispensan Baik diterbitkan Sasaran: 1 dokumen rasmi (2024) 2. Jerayawara (2024)	BAPF, CKAPS, APHM, MMC, MMA, MPS, MCPG

				Jerayawara untuk mewujudkan kesedaran dokumen rasmi mengenai standard dan senarai semak Amalan Pendispensan Baik di kemudahan Awam dan Swasta Sasaran: 6 jerayawara minimum (sekurang-kurangnya 1 di setiap zon) (2025)	
				Bilangan fasiliti yang mencapai standard dan senarai semak Amalan Pendispensan Baik 1. KKM (hospital utama negeri, hospital pakar major dan minor) = 100% 2. Bukan KKM = 50% (2026)	

STRATEGI 3: Meningkatkan literasi kesihatan dan memperkasakan masyarakat ke arah penggunaan ubat secara berkualiti					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
3.1	Melaksanakan sesi libat urus bersama-sama pemegang taruh berkaitan iklan ubat-ubatan dan perkhidmatan penjagaan kesihatan	Bilangan libat urus (Trend menaik)	2022-2026	5 (2022) 6 (2023) 7 (2024) 8 (2025) 10 (2026)	BPF, Platform e-dagang (Shopee/ Lazada dan sebagainya), Pempengaruh media sosial, penyedia perkhidmatan kesihatan, pemegang lesen, penjual, MCMC, Forum dan berkaitan
3.2	Melaksanakan program kesedaran dan pendidikan tentang ubat-ubatan kepada populasi OKU penglihatan	a) Memperluas pelaksanaan program kesedaran dan pendidikan kepada OKU penglihatan	2022-2026	Pembangunan Instrumen untuk Perbincangan Kumpulan Fokus (2022) Tinjauan ke atas orang buta dijalankan (2023) Pembangunan Modul Latihan (2024) Latihan kepada *Master Trainers* (2025) Pelaksanaan program (2026)	BAPF, Pertubuhan Pembangunan Orang Buta Malaysia, Persatuan bagi Orang Buta, KPM, MPS, MMA
		b) Menggalakkan PRH untuk mencetak label *Braille* pada bungkusan produk secara sukarela	2022-2026	1. *Baseline* (2022) 2. 1 (baru setiap tahun) (2023-2026)	BAPF, NPRA, MOPI, PhAMA, MAPS

3.3	Memperkukuh penggunaan ubat secara berkualiti dalam institusi pendidikan (*Health Promotion in Learning Institution* (HePiLI))	Peratus liputan	2022-2026	20% (2022) 40% (2023) 60% (2024) 80% (2025) 100% (2026)	BAPF, HECC, JPNIN
3.4	Memperkasakan wakil komuniti tentang penggunaan ubat secara berkualiti [Liputan Program Duta Kenali Ubat Anda (DKUA) yang dilaksanakan di seluruh negara]	a) Peratus liputan DKUA (trend menaik) b) Pelaksanaan program DKUA berdasarkan poskod (kawasan): 2778 sebagai denominator	2022-2026	a) *Baseline* b) 15.8% (2022) a) 5% b) 20% (2023) a) 10% b) 25% (2024) a) 15% b) 30% (2025) a) 20% b) 35% (2026)	BAPF
3.5	Memperkukuhkan penjagaan farmaseutikal melalui Perkhidmatan Farmasi Penilaian Ubat-ubatan di Rumah (*Home Medication Review* (HMR))	a) Bilangan sesi Perkhidmatan Farmasi Penilaian Ubat-ubatan di Rumah (HMR) dalam setahun	2022-2026	9000 (2022) 9200 (2023) 9400 (2024) 9600 (2025) 9800 (2026)	BAPF, MPS, MCPG, Akademik
		b) Penerbitan kajian HMR (seperti DFIT: dos, frekuensi, indikasi dan masa) dan *Compliance Score)*	2022-2026	Kemaskini protokol HMR (2022) Latihan dan jerayawara (2023) 1. Membangunkan instrumen kajian 2. *Baseline* (2024) 1. Kajian dijalankan 2. Penambahbaikan (2025) Analisis data & penerbitan laporan (2026)	

STRATEGI 4: Pengukuhan strategi kerintangan antimikrob					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
4.1	Membangunkan Pusat Latihan *Antimicrobial Stewardship* (AMS) yang bertauliah	a) Pusat Latihan *Antimicrobial Stewardship* (AMS) (kumulatif)	2022-2026	2 pusat latihan setiap tahun (2022-2023)	BAPF
				3 pusat latihan setiap tahun (2024-2025)	
				4 pusat latihan (2026)	
		b) Bilangan pegawai farmasi AMS yang dilatih dan diakreditasi	2022-2026	5 orang setiap tahun (2022-2026)	
4.2	Pemantauan dan surveilans antibiotik	Peratus fasiliti (awam & swasta) terlibat dalam surveilans antibiotik kebangsaan	2022-2026	95% setiap tahun (2022-2026)	BAPF, BPF, APHM, CKAPS, IMR, NIH
4.3	Menyebarkan maklumat yang tepat dan relevan tentang AMR kepada orang awam	Bilangan aktiviti kesedaran pendidikan berkaitan AMR kepada masyarakat	2022-2026	100 (2022)	BAPF, NPRA, MDD, HECC, Media
				Trend meningkat setiap tahun (2023-2026)	

KERJASAMA DAN KOLABORASI BAGI INDUSTRI KESIHATAN

KOMPONEN KELIMA 05

5.0. KERJASAMA DAN KOLABORASI BAGI INDUSTRI KESIHATAN

5.1 DASAR

Kerjasama dan kolaborasi bagi industri kesihatan dalam kalangan pemegang taruh hendaklah dipergiatkan untuk menyokong dan memupuk pelaksanaan matlamat dan hala tuju dalam sektor penjagaan kesihatan.

5.2 MATLAMAT

5.2.1 Menjalinkan kerjasama dan kolaborasi pragmatik dalam kalangan pemegang taruh dengan mematuhi amalan dan standard terbaik.

5.2.2 Memperkukuh polisi, sumber dan infrastruktur yang berkaitan.

5.2.3 Menggalakkan perkongsian pintar untuk meningkatkan daya saing.

5.3 PENDEKATAN

5.3.1 Melibatkan pemegang taruh yang berkaitan mengikut keperluan.

5.3.2 Memastikan ketersediaan dan kemampanan sumber manusia yang berkelayakan, cekap dan efektif.

5.3.3 Perkongsian maklumat, kepakaran, teknologi dan kemudahan secara optimum.

5.4 STRATEGI

5.4.1 Menggalakkan aktiviti penyelidikan dan pembangunan dalam kalangan pemegang taruh.

5.4.2 Mempergiat perkongsian pengetahuan dalam aktiviti penyelidikan dan inisiatif kualiti.

5.4.3 Pengurusan pelupusan ubat yang sistematik bagi menjamin kelestarian alam sekitar.

5.4.4 Mengoptimumkan keupayaan sumber manusia di farmasi komuniti bagi memastikan penyampaian perkhidmatan yang berterusan.

5.4.5 Meningkatkan akses pesakit kepada perkhidmatan farmasi melalui kerjasama sektor awam dan swasta.

5.4.6 Mempertingkatkan penglibatan pelbagai sektor ke arah penyampaian perkhidmatan kesihatan yang lebih baik.

5.4.7 Membangunkan platform digital untuk perkongsian maklumat.

5.4.8 Mewujudkan kerjasama serantau untuk menggalakkan akses ubat-ubatan yang saksama.

STRATEGI 1: Menggalakkan aktiviti penyelidikan dan pembangunan dalam kalangan pemegang taruh					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
1.1	Menggalakkan kolaborasi di antara sektor awam dan swasta dalam menjalankan aktiviti penyelidikan	a) Mewujudkan fokus untuk kolaborasi dalam bidang penyelidikan	2023	Bidang tumpuan bagi penyelidikan untuk kolaborasi dikenal pasti (2023)	BDPSF, Kolaborasi dengan sektor swasta termasuk universiti swasta
		b) Bilangan libat urus untuk kolaborasi di antara pemegang taruh	2022-2026	Sekurang-kurangnya satu (1) libat urus dengan pemegang taruh untuk mengenalpasti Bidang Keutamaan Penyelidikan Farmasi di Malaysia (PRPM) (2022)	
				Sekurang-kurangnya satu (1) libat urus dengan pemegang taruh untuk mengenalpasti bidang fokus bagi kerjasama penyelidikan (2023)	
				Sekurang-kurangnya satu (1) libat urus dengan pemegang taruh untuk mempromosikan kolaborasi penyelidikan antara sektor awam dan: 1. Sektor swasta 2. Bukan KKM dan akademik (2024)	
		c) Bilangan kajian yang dijalankan secara kolaborasi antara sektor awam dan swasta	2023-2026	Sekurang-kurangnya 1 libat urus setiap tahun (2025-2026)	

STRATEGI 2: Mempergiat perkongsian pengetahuan dalam aktiviti penyelidikan dan inisiatif kualiti					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
2.1	Mempertingkatkan perkongsian pengetahuan di dalam kajian dan inisiatif kualiti	a) Bilangan kajian multisektoral yang dikongsikan	2022-2026	1 setiap tahun (2022-2026)	BDPSF
2.2	Menyediakan platform bagi perkongsian maklumat dalam kajian yang dijalankan	b) Menghasilkan laporan kajian kebolehlaksanaan	2023	1. Melaksanakan kajian kebolehlaksanaan 2. Laporan Kajian Kebolehlaksanaan (2023)	
		a) Menghasilkan garis panduan dan platform perkongsian maklumat	2024	Menyediakan garis panduan dan platform (2024)	

STRATEGI 3: Pengurusan pelupusan ubat yang sistematik bagi menjamin kelestarian alam sekitar					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
3.1	Menyediakan prosedur terperinci bagi pengurusan pelupusan ubat dalam simpanan pesakit merentasi organisasi sektor awam, swasta, Badan Bukan Kerajaan (NGO) dan masyarakat	Pemantauan pelaksanaan	2022-2026	Menyediakan cadangan kertas kerja untuk dimasukkan ke dalam *National Environmental Health Action Plan* (NEHAP) (2022) 1. Sesi Libat Urus bersama-sama sektor awam dan swasta 2. Analisis situasi semasa (2023) 1. Memorandum Persefahaman antara agensi 2. Penyediaan polisi dan pelan strategik (2024) 1. Pelancaran 2. Jerayawara / Aktiviti kesedaran (2025) Pelaksanaan Projek (2026)	BAPF, KASA, Jabatan Alam Sekitar, MOPI, MPS, MMA, MCPG, Kualiti Alam, PhAMA, APHM
STRATEGI 4: Mengoptimumkan keupayaan sumber manusia bagi memastikan penyampaian perkhidmatan yang berterusan					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
4.1	Perluasan Program Kenali Ubat Anda melalui kerjasama sektor awam dan swasta	Bilangan ahli farmasi komuniti/ ahli farmasi di fasiliti swasta/ bukan KKM (contoh: hospital swasta, KEMENTAH, KPT dan sebagainya)	2022-2026	1. Sesi Libat Urus bersama MPS di peringkat Ibu Pejabat & Negeri 2. 133 orang ahli farmasi telah dilatih (2022) 1. Pelaksanaan program dalam komuniti 2. Perluasan program kepada ahli farmasi komuniti/ ahli farmasi di fasiliti swasta/ bukan KKM (contoh: hospital swasta, KEMENTAH, KPT, dan sebagainya (2023)	BAPF, MPS, Farmasi Komuniti Farmasi di Hospital Swasta / bukan KKM (contoh: KEMENTAH, KPM dan sebagainya)

				1. Pelaksanaan program dalam komuniti setiap tahun 2. Bilangan ahli farmasi komuniti/ ahli farmasi di fasiliti swasta/ bukan KKM (contoh: hospital swasta, KEMENTAH, KPT, dan sebagainya) setiap tahun (2024-2026)	
STRATEGI 5: Meningkatkan akses pesakit kepada perkhidmatan farmasi melalui kerjasama sektor awam dan swasta					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
5.1	Penyumberluaran (*Outsourcing*) dalam Pembekalan Ubat Susulan daripada Fasiliti KKM ke Farmasi Komuniti	Rangka kerja Penyumberluaran (*Outsourcing*) Perkhidmatan Farmasi dari KKM ke Farmasi Komuniti disiapkan	2024	1. Melaksanakan kajian kebolehlaksanaan bagi Pembekalan Ubat Susulan daripada Fasiliti KKM ke Farmasi Komuniti. 2. Rangka kerja Penyumberluaran (*Outsourcing*) Perkhidmatan Farmasi ke Farmasi Komuniti disiapkan (2024)	BDPSF
STRATEGI 6: Mempertingkatkan penglibatan pelbagai sektor ke arah penyampaian perkhidmatan kesihatan yang lebih baik					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
6.1	Pengiktirafan makmal swasta berdasarkan keperluan regulatori semasa	Bilangan makmal swasta yang diiktiraf mampu menjalankan pengenalpastian dan pengesahan bahan aktif herba di dalam produk tradisional	2023-2026	1 makmal (kumulatif) (2023) 2 makmal (kumulatif) (2024) 3 makmal (kumulatif) (2025) 4 makmal (kumulatif) (2026)	NPRA, Makmal swasta, PRH, Pengilang produk tradisional tempatan, Persatuan produk tradisional

STRATEGI 7: Membangunkan platform digital untuk perkongsian maklumat					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
7.1	Penilaian persekitaran yang kondusif untuk perkongsian maklumat pendigitalan antara sektor awam dan swasta	Menjalankan kajian kebolehlaksanaan untuk mempertimbangkan tahap sokongan dan pelaksanaan platform digital tersebut	2023-2025	1. Mengenal pasti pemegang taruh 2. Membentuk Jawatankuasa Kerja bagi membincangkan pembentukan parameter bagi kajian kebolehlaksanaan (2023)	BDPSF
				1. Analisis situasi dijalankan 2. Kajian Kebolehlaksanaan dijalankan (2024)	
				1. Kajian kebolehlaksanaan dijalankan 2. Laporan Kajian Kebolehlaksanaan disediakan (2025)	
STRATEGI 8: Mewujudkan kerjasama serantau untuk menggalakkan akses ubat-ubatan yang saksama					
No.	**Inisiatif**	**Indikator Pencapaian**	**Garis Masa Pelaksanaan**	**Sasaran (Tahun)**	**Pemegang Taruh Utama**
8.1	Menyediakan pelan tindakan bagi strategi kolaborasi serantau untuk Keterjaminan dan Kemandirian Ubat-Ubatan ASEAN (ADSSR)	Dokumentasi bagi pelaksanaan ADSSR disediakan	2022-2025	1. Rangka Kerja strategi kolaborasi serantau untuk keterjaminan dan kemandirian ubat-ubatan ASEAN (ADSSR) diterimapakai oleh AHMM 2. Senarai cadangan ubat bagi pembelian ubat secara pukal dicadangkan oleh Malaysia di SOMHD (2022)	BDPSF
				Pembentukan deklarasi ASEAN *Leader Commitment* bagi ADSSR (2023)	
				Pelan Tindakan ADSSR disediakan (2024)	
				Kertas konsep bagi pelan tindakan ADSSR disediakan (2025)	

RUJUKAN

RUJUKAN

[1] Dr. Soccoro Escalante, Technical Meeting on Regional Collaborative Strategy for ADSSR

[2] Product Life Cycle Management in Life Sciences Industry, Deloitte Consulting AG, 2012

[3] Clinical Research in Malaysia, CRC MOH Malaysia

[4] Pharmaceutical Supply Chain Mapping, MITI

[5] Management Sciences for Health, Section 29: Governance in Pharmaceutical Systems, 2015

[6] USAID The Medicines, Technologies, and Pharmaceutical Services (MTAPS) Program

MALAYSIAN NATIONAL MEDICINES POLICY

MNMP

2022-2026

NATIONAL MEDICINES POLICY
FOURTH EDITION (2022-2026)

Published by:
Pharmaceutical Services Programme
Ministry of Health Malaysia
Lot 36, Jalan Prof Diraja Ungku Aziz,
46200 Petaling Jaya, Selangor.
Tel: 03-7841 3200
https://www.pharmacy.gov.my/v2/ms

ISBN 978-967-2854-29-6
9 789672 854296

CONTENT

GLOSSARY, TERMS, ABBREVIATIONS AND ACRONYMS

GLOSSARY, TERMS, ABBREVIATIONS AND ACRONYMS

ACRPM	*Association of Clinical Research Project Managers*
ADSSR	*ASEAN Drug Security and Self-Reliance*
AGC	Jabatan Peguam Negara *Attorney General's Chamber*
AHMM	*ASEAN Health Ministers Meeting*
AMR	*Antimicrobial Resistance*
AMS	*Antimicrobial Stewardship*
API	Bahan Aktif Farmaseutikal *Active Pharmaceutical Ingredient*
APHM	*Association of Private Hospitals Malaysia*
ASEAN	*Association of Southeast Asian Nations*
BAPF	Bahagian Amalan dan Perkembangan Farmasi
BDPSF	Bahagian Dasar dan Perancangan Strategik Farmasi
BLFM	Bahagian Lembaga Farmasi Malaysia
BPF	Bahagian Penguatkuasaan Farmasi
BPKA	Bahagian Perkembangan Kesihatan Awam
BPM	Bahagian Pengurusan Maklumat
BPP | MDD	Bahagian Perkembangan Perubatan *Medical Development Division*
BPTK	Bahagian Perubatan Tradisional dan Komplementari
CGTP	Produk Terapi Sel dan Gen *Cell and Gene Therapy Product*
CKAPS	Cawangan Kawalan Amalan Perubatan Swasta
COVID-19	*Coronavirus Disease*
CPE	Pendidikan Profesional Berterusan *Continuous Professional Education*
CP	*Community Pharmacy*
CRC	*Clinical Research Centre*
CRM	*Clinical Research Malaysia*
CRO	*Clinical Research Organization*
DFIT	Dos, Frekuensi, Indikasi dan Masa *Dose, Frequency, Indication and Time*
DKUA	Duta Kenali Ubat Anda
DSAM	Persatuan Jualan Langsung Malaysia *Direct Selling Association of Malaysia*
DUNas | MNMP	Dasar Ubat Nasional *Malaysian National Medicines Policy*
e-DPF	Sistem Data Penguatkuasa Farmasi
FIH	*First In Human*

FOMCA	*Federation of Malaysian Consumer Associations*
FRIM	*Forest Research Institute Malaysia*
FRP	*Facilitated Registration Pathway*
FUKKM	Formulari Ubat Kementerian Kesihatan Malaysia
GA	*General Assembly*
GGM	*Good Governance of Medicines*
GMAP	*Generic Medicines Awareness Programme*
GRI	*Global Reporting Initiative*
HCF	Pembiayaan Penjagaan Kesihatan *Health Care Financing*
HECC	*Health Education Communication Centre*
HePiLI	*Health Promotion in Learning Institution*
HMR	Penilaian Ubat-ubatan di Rumah *Home Medication Review*
HUiTM	Hospital Al-Sultan Abdullah Universiti Teknologi MARA
HUKM	Hospital Universiti Kebangsaan Malaysia
HUPM	Hospital Universiti Putra Malaysia
HUSM	Hospital Universiti Sains Malaysia
HWP	Kertas Putih Kesihatan *Health White Paper*
ICH	*International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use*
ICT	Teknologi Maklumat dan Komunikasi *Information and Communication Technology*
IIR	*Industries Initiated Research*
IMR	*Institute for Medical Research*
JPNIN	Jabatan Perpaduan Negara dan Integrasi Nasional
KEMENTAH | MinDef	Kementerian Pertahanan *Ministry of Defence*
KASA	Kementerian Alam Sekitar dan Air
KK	Klinik Kesihatan
KKM | MOH	Kementerian Kesihatan Malaysia *Ministry of Health Malaysia*
KPDN	Kementerian Perdagangan Dalam Negeri dan Kos Sara Hidup *Ministry of Domestic Trade and Cost of Living*
KPT | MOHE	Kementerian Pendidikan Tinggi *Ministry of Higher Education*
KYM	Kenali Ubat Anda *Know Your Medicine*
LFM	Lembaga Farmasi Malaysia
MACT	*Malaysian Association for Cell Therapy*
MADSA	*Malaysian Dietary Supplement Association*
MAFS	Kementerian Pertanian dan Keterjaminan Makanan *Ministry of Agriculture and Food Security*

MAP	*Malaysian Academy of Pharmacy*
MAPS	*Malaysian Association of Pharmaceutical Suppliers*
MARDI	*Malaysian Agricultural Research and Development Institute*
MASA	Akta Ubat (Iklan dan Penjualan) *Medicines (Advertisement and Sale) Act*
MASc	*Medicines Access Scheme*
MCMC	Suruhanjaya Komunikasi dan Multimedia Malaysia *Malaysia Communication And Multimedia Commission*
MCPG	*Malaysian Community Pharmacy Guild*
MDSSR	*Malaysian Drug Security and Self-Reliance*
MIDA	*Malaysian Investment Development Authority*
MITI	Kementerian Pelaburan, Perdagangan dan Industri *Ministry of Investment, Trade and Industry*
MJM	*Memorandum Jemaah Menteri*
MKAK	Makmal Kesihatan Awam Kebangsaan *National Public Health Laboratory*
ML	*Maturity Level*
MMA	*Malaysian Medical Association*
MMC	*Malaysian Medical Council*
MOE	Kementerian Pendidikan Malaysia *Ministry of Education*
MOPI	*Malaysian Organisation Of Pharmaceutical Industries*
MOSTI	Kementerian Sains, Teknologi dan Inovasi *Ministry of Science, Technology and Innovation*
MoU	Memorandum Persefahaman *Memorandum of Understanding*
MPS	*Malaysian Pharmacist Society*
MTAPS	*Medicines, Technologies, and Pharmaceutical Services*
NEHAP	*National Environmental Health Action Plan*
NEML	*National Essential Medicines List*
NGO	Badan Bukan Kerajaan *Non-governmental Organisation*
NHMS	Tinjauan Kebangsaan Kesihatan dan Morbiditi *National Health & Morbidity Survey*
NIH	Institut Kesihatan Negara *National Institutes of Health*
NPRA	*National Pharmaceutical Regulatory Agency*
NRA	Badan Regulatori Negara *National Regulatory Authority*
NRECC	Kementerian Sumber Asli, Alam Sekitar dan Perubahan Iklim *Ministry of Natural Resources, Environment and Climate Change*
NVDR	*National Vaccine Development Roadmap*
OECD	*Organisation for Economic Co-operation and Development*
PBKD | DCA	Pihak Berkuasa Kawalan Dadah *Drug Control Authority*

PE	Farmakoekonomik *Pharmacoeconomic*
PEKA	Skim Peduli Kesihatan
PhAMA	*Pharmaceutical Association of Malaysia*
PhIS	*Pharmacy Information System*
PKD	Pejabat Kesihatan Daerah
PMS	*Post Marketing Surveillance*
PPF | PSP	Program Perkhidmatan Farmasi *Pharmaceutical Services Programme*
PPT	Pemberi Pendidikan Tinggi *Higher Education Provider (HEP)*
PPUM	Pusat Perubatan Universiti Malaya *University Malaya Medical Centre*
PPVN	Pelan Hala Tuju Pembangunan Vaksin Negara
PRH	*Product Registration Holder*
PRI	*Principles for Responsible Investment*
PRiSMA	*Pharmacist Registration Management System*
PRPM	Bidang Keutamaan Penyelidikan Farmasi di Malaysia *Pharmacy Research Priority Area in Malaysia*
PSI	*Pharmaceutical Security Institute*
PTI	Pelan Tindakan Induk *Master Plan of Action*
PUU	Penasihat Undang-undang
PV	Farmakovigilans *Pharmacovigilance*
QSE	Kualiti, Keselamatan dan Keberkesanan *Quality, Safety and Efficacy of Medicines*
QUM	*Quality Use of Medicines*
R&D	Penyelidikan dan Pembangunan *Research and Development*
RFI	*Request for Information*
RFP	*Request for Proposal*
RI	*Responsible Investment*
ROPA	Akta Pendaftaran Ahli Farmasi *Registration of Pharmacists Act*
RMK-12	Rancangan Malaysia ke-12 *Twelfth Malaysia Plan*
SDG	Matlamat Pembangunan Mampan *Sustainable Development Goals*
SODA	Akta Jualan Dadah *Sale of Drugs Act*
SOMHD	*ASEAN Senior Officials Meeting on Health Development*
T&CM	Perubatan Tradisional dan Komplementari *Traditional & Complementary Medicines*
TESMA	*Tissues Engineering & Regenerative Medicine Society of Malaysia*

TOT	*Training of Trainers*
UAT/ FAT	*User Acceptance Test/Final Acceptance Test*
UHC	*Universal Health Coverage*
UMBI	*UKM Medical Molecular Biology Institute*
UKAS	Unit Kerjasama Awam Swasta
UKK	Unit Komunikasi Korporat
UMBI	*UKM Medical Molecular Biology Institute*
USAID	*United States Agency for International Development*
WG	*Working Group*
WHA	Perhimpunan Kesihatan Sedunia *World Health Assembly*
WHO	Pertubuhan Kesihatan Sedunia *World Health Organization*

ACKNOWLEDGEMENT

The Pharmaceutical Services Program, Ministry of Health Malaysia would like to express our highest appreciation and gratitude to all those who have provided support and contributions directly or indirectly in the publication of the Fourth Edition of the Malaysian National Drug Policy (MNMP) (2022-2026):

- Pharmacy Policy & Strategic Planning Division, MOH
- Pharmacy Enforcement Division, MOH
- Pharmacy Practice & Development Division, MOH
- National Pharmaceutical Regulatory Agency (NPRA), MOH
- Pharmacy Board Malaysia Division, MOH
- Traditional & Complementary Medicine Division, MOH
- State Health Department
- Health Services Division, Ministry of Defence (MINDEF)
- Malaysian Pharmacists Society (MPS)
- Malaysian Community Pharmacy Guild (MCPG)
- Malaysian Academy of Pharmacy (MAP)
- Pharmaceutical Association of Malaysia (PhAMA)
- Malaysian Organisation of Pharmaceutical Industries (MOPI)
- Malaysian Association of Pharmaceutical Suppliers (MAPS)
- Association Of Private Hospitals Malaysia (APHM)
- Malaysian Medical Association (MMA)
- Malaysian Medical Council (MMC)
- Federation of Malaysian Consumer Associations (FOMCA)
- Direct Selling Association of Malaysia (DSAM)
- Healthcare professionals from both public and private healthcare facilities/ agencies/ organisations

EDITORIAL COMMITTEE

PREFACE FROM THE MINISTER OF HEALTH

Praise be to Allah, over the course of the past seventeen years, the Malaysian National Medicines Policy (MNMP) has been through a remarkable journey of development and progress. This is reflective of the commitment shown by the Ministry of Health, and the Pharmaceutical Services Programme in particular, in working towards enhancing the accessibility, efficiency, and preparedness of pharmaceutical services in Malaysia.

The strategies and initiatives outlined in the Fourth Term MNMP have been formulated in collaboration with stakeholders, thus ensuring that it remains aligned with the goals of the 12th Malaysia Plan, which emphasizes the rakyat's wellbeing. The implementation of the Fourth Term MNMP is also aligned with the aspirations espoused in the Health White Paper (HWP), which seeks to reform the nation's health system towards greater equitability, sustainability, resilience.

I would like to express my deepest appreciation to the Pharmaceutical Services Programme and all agencies, organisations and ministries involved for their unwavering support throughout the implementation of MNMP for the past 17 years. I hope that this document will be translated into impactful initiatives and activities, subsequently building a platform where all stakeholders can actively collaborate towards improving pharmaceutical services for the nation. May Allah SWT bless all our sincere efforts to strengthen the implementation of MNMP.

YB Dr. Zaliha Mustafa
Minister of Health of Malaysia

PREFACE FROM THE DIRECTOR-GENERAL OF HEALTH

Malaysian National Medicines Policy (MNMP) is a comprehensive and dynamic policy that addresses current pharmaceutical issues in Malaysia. The strategies and initiatives mapped out under MNMP have a tremendous impact on the country's pharmaceutical sector. This policy provides clearer guidance and direction for the implementation of pharmaceutical activities and management in both public and private sectors and needs to remain relevant for the future.

The implementation of MNMP has increased equitable access to the use of safe, effective and affordable medicines, in addition to ensuring the rational use of medicines towards improving people's health. MNMP successfully strengthened a comprehensive distribution network system through the integration of ICT systems where access to medicines is simplified. Through MNMP, the advancement of pharmaceutical research and development has also supported and improved pharmaceutical services and care.

MNMP has provided a platform that enables continuous communication and collaboration amongst multi-profession stakeholders in the public and private healthcare sectors. Additionally, MNMP is aligned with relevant policies in support of the Sustainable Development Goals (SDG) to ensure a full continuum of essential health services and equitable access to medicines. An ecosystem that supports and encourages the production and transfer of technology needs to be established to enable the country's preparedness and sustainability, especially in emergency situations.

My gratitude to the Pharmaceutical Services Programme for the efforts and proactive steps to develop this MNMP document. Congratulations to all parties involved for their commitment to produce this document. I hope that the Fourth Term MNMP can be translated and implemented successfully and have a great impact on the well-being and health of the people.

YBhg. Datuk Dr Muhammad Radzi bin Abu Hassan
Director-General of Health
Ministry of Health Malaysia

PREFACE FROM THE SENIOR DIRECTOR OF PHARMACEUTICAL SERVICES

This Fourth Term Malaysian National Medicines Policy (MNMP) is an aspiration and commitment from the government and stakeholders towards a common goal in the pharmaceutical sector. MNMP is a transparent and coordinated framework document for the implementation of strategies to improve the pharmaceutical sector.

MNMP has reached 17 years of implementation and is a collaboration between the public and private sectors and stakeholders. This policy has produced transformation in creating a comprehensive and international regulatory system, as well as strengthening legislation and regulations. In addition, this policy also promotes equitable access to medicines as well as the use of rational, quality, safe, effective and affordable medicines in order to improve the health of the nation.

MNMP emphasises the importance of the capacity and capability of the pharmacy workforce. Various initiatives have been implemented to improve the competence and accreditation of pharmacists to ensure quality pharmacy services to improve the health of the nation. Good policies and governance in the management, practice and profession of pharmacy that are clear and transparent should also be prioritised. This policy has been carefully produced based on global strategies, in line with national policies and approaches, reflecting Malaysia's vision. It is my hope that synergistic collaboration and partnership amongst various stakeholders will continue to strengthen, shape and ensure the well-being of the people.

My heartiest congratulations to those who have contributed to produce this document. Hopefully, all pharmaceutical sectors can utilise the fourth term of MNMP as a point of reference and guidance for the planning and implementation of respective agencies and organisations to achieve pharmaceutical services delivery excellence.

YBrs. Puan Norhaliza binti A Halim
Senior Director of Pharmaceutical Services
Ministry of Health Malaysia

POLICY STATEMENT

The Malaysian National Medicine Policy (MNMP) is an official document by the Malaysian Government that was granted Cabinet approval in 2006. This policy prioritises medium and long-term goals for the Malaysian pharmaceutical sector. This document is a directive to ensure systematic and holistic governance of medicines to achieve better health outcomes for Malaysians.

The objectives of the MNMP are to promote equitable access to medicines and rational use of medicines that are safe, effective and affordable towards improving the health of the nation. Therefore, good governance in the pharmaceutical sector has to be emphasised to ensure the quality, safety and efficacy of medicines in the market. Continuous access to medicines is crucial to meet the healthcare needs of the nation. This includes ensuring that all medicines are exempted from any duties and tariffs to increase availability and affordability of medicines. Additionally, all stakeholders shall ensure that medicines are used rationally, appropriately, safely and effectively. Collaboration and partnership among stakeholders shall be intensified to achieve the objectives and goals of the healthcare sector.

In an effort to ensure its success, a comprehensive planning and strategy implementation through a transparent framework, supported by the aspirations and commitments of the Government and all stakeholders towards common goals is vital to strengthen the country's pharmaceutical sector. MNMP was developed in parallel with the general objective of the medicine policy proposed by World Health Organization (WHO). There are five (5) components under this policy:

- Governance in Medicines
- Quality, Safety and Efficacy of Medicines
- Access to Medicines
- Quality Use of Medicines
- Partnership and Collaboration for the Healthcare Industry

EXECUTIVE SUMMARY

Malaysia has successfully enhanced the health of the nation and demonstrated one of the best healthcare systems globally, as well as provision of high quality pharmacy services. But as time goes on, the pharmaceutical sector in this country needs to be strengthened to improve its resilience, ensuring it is continuously prepared to handle pressure and obstacles.

MNMP aims to improve the health of the nation through strengthening equitable access and promoting the rational use of safe, effective and affordable medicines. The Fourth Term MNMP is a framework and structured plan developed to tackle issues and challenges through strategies and initiatives meant to promote a more productive, robust, and sustainable pharmaceutical sector.

This document consists of three (3) main sections; policy statement, issues and challenges, and the Master Action Plans (PTI) for each of the components under MNMP. The policy statement section elaborates the role of MNMP as a directive for the pharmaceutical sector to ensure a systematic and holistic governance of medicines to achieve better health outcomes for Malaysians. It also explains the objectives of MNMP and its five (5) components.

The Malaysian pharmaceutical sector faces various challenges and health gaps. Among the main challenges and issues faced in the pharmaceutical sector are legislation and regulations (unregistered medicines, substandard and online medicine sales), strengthening the pharmaceutical regulatory system (regulatory harmonisation and international involvement, improving the efficiency of the product registration process, ensuring that registered products meet the requirements and emerging standards and therapies and First In Human (FIH)) clinical studies, gaps in access and availability to medicines (patents, intellectual rights and generic medicines, efficiency and sustainability of medicine supply chains), distribution and necessary human resource skills to be improved and the low level of health literacy and the irrational use of medicines in the community.

The next section elaborates the implementation of Master Action Plans (PTI) of the five (5) main components of MNMP which include goals, approaches, strategies and initiatives. The implementation of this PTI involves numerous stakeholders in the health sector. Thus, all related agencies and organisations shall refer to this document as a guide in formulating and implementing their respective plans for the excellency of pharmaceutical services in Malaysia.

INTRODUCTION

The Malaysian National Medicines Policy (MNMP) outlines the Government's medium and long-term goals, strategies and initiatives to achieve them, as well as the roles and responsibilities of relevant stakeholders. Additionally, MNMP provides frameworks for coordinating important initiatives for these stakeholders, from the public and private sectors, including healthcare professionals, nongovernmental organisations, patients, consumers and relevant stakeholders.

The concept for medicines policy was first introduced during the 28th World Health Assembly (WHA) in 1975. The World Health Organization (WHO) recommends that all developing countries implement a comprehensive national medicines policy and monitor its implementation plan. The developed policy should be consistent with the national health care system or national health policy.

The establishment of MNMP provides a platform for all relevant stakeholders in the healthcare sector to voice out their concerns and provide constructive feedback. MNMP serves as a policy that coordinates the role of each stakeholder in order for both the public and private healthcare sectors to achieve a common goal.

Malaysian National Medicines Policy (MNMP)

The strategies and initiatives under MNMP are analysed and reviewed every five (5) years to ensure the implementation of the policy remains relevant and has a positive impact on the quality, safety and efficacy of medicines and the delivery of pharmacy services in Malaysia. The Fourth Term MNMP was developed in line with international policies and objectives such as the Universal Health Coverage (UHC) under Sustainable Development Goals (SDG) and the World Health Organization (WHO). The MNMP is in line with national policies including the Twelfth Malaysia Plan (RMK-12), Health White Paper (HWP), MOH Strategic Plan and other relevant policies.

The MNMP began its first five (5) years of the term starting in 2007 to 2011. This policy was studied and revised in 2012 to produce the policy framework for the second term in 2013 to 2017 and the third term in 2017 to 2021. During these terms, the implementation of MNMP has yielded substantial outcomes and transformation within the pharmaceutical sector. The progress and change can be measured through the existence of a comprehensive regulatory system, the empowerment of laws and regulations, and the extensive pharmaceutical distribution network. However, there is still room for improvement by strengthening and incorporating new ideas that align with the objectives of this policy.

The Fourth Term of MNMP has been reviewed and improved in line with the changing times and country's health needs. The development and implementation of MNMP is not only focused on the public sector but also combines the efforts and commitments of the public and private pharmaceutical sectors.

NATIONAL MEDICINES POLICY GOVERNANCE

STEERING COMMITEE

1. Advise The Health Minister
2. Authorise plans
3. Decide the direction

Chair
DIRECTOR GENERAL OF HEALTH

IMPLEMENTATION COMMITTEE

Monitor and review the development of the implementation

Chair
SENIOR DIRECTOR OF PHARMACEUTICAL SERVICES

TECHNICAL COMMITTEE

Plan, identify and monitor the implementation done by the Working Committees

Chair
DIRECTOR OF DIVISION / DEPUTY DIRECTOR

WORKING COMMITTEES
Implementation plan of action

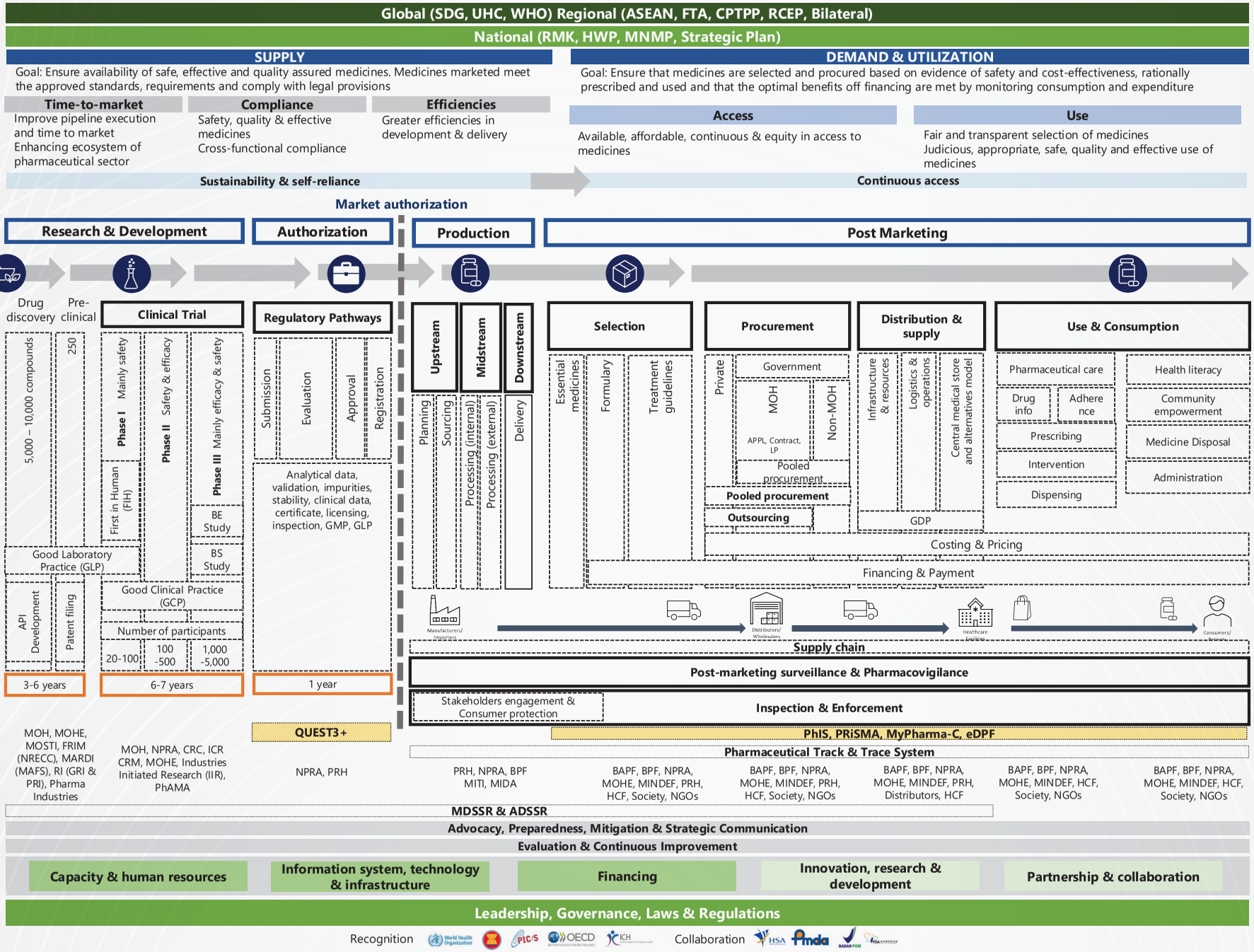
01 Governance in Medicines

02 Quality, Safety & Efficacy of Medicines

03 Access to Medicines

04 Quality use of Medicines

05 Partnership and Collaboration for the Healthcare Industry


Global (SDG, UHC, WHO) Regional (ASEAN, FTA, CPTPP, RCEP, Bilateral)
National (RMK, HWP, MNMP, Strategic Plan)
SUPPLY
Goal: Ensure availability of safe, effective and quality assured medicines. Medicines marketed meet the approved standards, requirements and comply with legal provisions
Time-to-market
Improve pipeline execution and time to market
Enhancing ecosystem of pharmaceutical sector
Compliance
Safety, quality & effective medicines
Cross-functional compliance
Efficiencies
Greater efficiencies in development & delivery
DEMAND & UTILIZATION
Goal: Ensure that medicines are selected and procured based on evidence of safety and cost-effectiveness, rationally prescribed and used and that the optimal benefits off financing are met by monitoring consumption and expenditure
Access
Available, affordable, continuous & equity in access to medicines
Use
Fair and transparent selection of medicines
Judicious, appropriate, safe, quality and effective use of medicines
Sustainability & self-reliance
Continuous access
Market authorization
Research & Development
Authorization
Production
Post Marketing
Drug discovery
Pre-clinical
5,000 – 10,000 compounds
250
Clinical Trial
Phase I Mainly safety
First in Human (FIH)
Phase II Safety & efficacy
Phase III Mainly efficacy & safety
BE Study
BS Study
Good Laboratory Practice (GLP)
Good Clinical Practice (GCP)
API Development
Patent filing
Number of participants
20-100
100 -500
1,000 -5,000
3-6 years
6-7 years
Regulatory Pathways
Submission
Evaluation
Approval
Registration
Analytical data, validation, impurities, stability, clinical data, certificate, licensing, inspection, GMP, GLP
1 year
Upstream
Midstream
Downstream
Planning
Sourcing
Processing (internal)
Processing (external)
Delivery
Selection
Essential medicines
Formulary
Treatment guidelines
Procurement
Private
Government
MOH
APPL, Contract, LP
Non-MOH
Pooled procurement
Pooled procurement
Outsourcing
Distribution & supply
Infrastructure & resources
Logistics & operations
Central medical store and alternatives model
GDP
Use & Consumption
Pharmaceutical care
Drug info
Adherence
Prescribing
Intervention
Dispensing
Health literacy
Community empowerment
Medicine Disposal
Administration
Costing & Pricing
Financing & Payment
Manufacturers/ Importers
Distributors/ Wholesalers
Healthcare Facilities
Consumers/ Patients
Supply chain
Post-marketing surveillance & Pharmacovigilance
Stakeholders engagement & Consumer protection
Inspection & Enforcement
PhIS, PRiSMA, MyPharma-C, eDPF
Pharmaceutical Track & Trace System
MOH, MOHE, MOSTI, FRIM (NRECC), MARDI (MAFS), RI (GRI & PRI), Pharma Industries
MOH, NPRA, CRC, ICR CRM, MOHE, Industries Initiated Research (IIR), PhAMA
QUEST3+
NPRA, PRH
PRH, NPRA, BPF MITI, MIDA
BAPF, BPF, NPRA, MOHE, MINDEF, PRH, HCF, Society, NGOs
BAPF, BPF, NPRA, MOHE, MINDEF, PRH, HCF, Society, NGOs
BAPF, BPF, NPRA, MOHE, MINDEF, PRH, Distributors, HCF
BAPF, BPF, NPRA, MOHE, MINDEF, HCF, Society, NGOs
BAPF, BPF, NPRA, MOHE, MINDEF, HCF, Society, NGOs
MDSSR & ADSSR
Advocacy, Preparedness, Mitigation & Strategic Communication
Evaluation & Continuous Improvement
Capacity & human resources
Information system, technology & infrastructure
Financing
Innovation, research & development
Partnership & collaboration
Leadership, Governance, Laws & Regulations
Recognition
Collaboration

ISSUES AND CHALLENGES

The pharmaceutical sector plays an important role in ensuring availability and accessibility of safe and effective medicines. However, there are several issues and challenges that may hinder the growth of the pharmaceutical sector.

Legislative Strengthening

The list of legislation under the Pharmaceutical Services Programme (PSP), MOH, includes the Poisons Act 1952, the Sale of Drugs Act 1952, the Pharmacists Registration Act 1951, the Medicines (Advertisement & Sale) Act 1956, and the Dangerous Drugs Act 1952, and their respective subsidiary acts. These laws are important in controlling pharmaceutical practices, ingredients, products and advertising to ensure the health and safety of the public. Therefore, the legislation is reviewed periodically to ensure that the provisions continue to meet current practices and needs. Amendments to legislation are proposed to provide better oversight of pharmaceutical practices, products, and advertising. Among the issues faced in the strengthening of legislation include policies that are unclear and uncertain and the difficulty of getting consensus from all stakeholders.

(i) Unregistered, falsified and substandard medicines:

The circulation of unregistered, falsified and substandard medicines poses a significant threat to public health. WHO estimates that 1 in 10 medical products in low- and middle-income countries is either false or substandard. Falsified medicines are medical products that deliberately/ fraudulently misrepresent their identity, composition or source, while substandard medicines are authorised medical products that fail to meet either their quality standards or specifications, or both. These medicines can be obtained from roadside vendors, night markets, social media, e-commerce platforms, and others. These products can jeopardise patient safety and lead to treatment failure. Strengthening regulatory measures, enhancing surveillance systems, and increasing public awareness are crucial in combating the presence of unregistered, substandard and falsified medicines and to safe guard the well-being of the population.

(ii) Online Medicine Sales:

The global advancement of digital technology has transformed the healthcare landscape, including in Malaysia. Online healthcare services have gained traction in Malaysia with the emergence of various platforms on new media that are easily accessible, including online pharmacy services (e-pharmacy). The online sale or supply of pharmaceutical products serves as an alternative for patients or customers in need of such services. Technological advancements occur at a faster pace than regulatory changes. In line with these technological developments, knowledge, policies, and guidelines have to keep pace to meet the needs of the industry and consumers, while adhering to existing laws.

Strengthening the Pharmaceutical Regulatory System

Strengthening regulatory systems is key to ensuring that the National Pharmaceutical Regulatory Agency (NPRA) provides effective and efficient services to their stakeholders and the therapeutic substances approved for the local market are of high quality, safe, and effective.

(i) Regulatory Harmonisation and International Collaboration

In an increasingly global pharmaceutical landscape, harmonisation and coordination of regulatory activities are critical. Aligning the regulatory framework with international standards and good regulatory practices can accelerate access to new medicines, encourage investment and foster innovation. Collaborating with international partners in research, development and knowledge sharing enables Malaysia to remain at the forefront of progress in the pharmaceutical sector.

Expertise in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is significant as it reperesents a recognition that the technical expertise of the National Pharmaceutical Regulatory Agency (NPRA) is on par with other international regulatory bodies. Furthermore, being a member of ICH ensures that the regulatory standards used are in line with international regulatory requirements.

(ii) Optimising Product Registration Process

One of the challenges in obtaining registration approval and access to the latest technological medicines in Malaysia is the complex product assessment process for registration purposes, along with a relatively lengthy time period. NPRA has taken the initiative to establish a Facilitated Registration Pathway mechanism by employing collaborative and reliance assessment methods, which will enhance the assessment process to expedite access to quality, safe and effective medicines.

(iii) Ensuring Registered Products Conform to Standards and Requirements

For vaccine products, Post Marketing Surveillance (PMS) activities are limited due to constraints on facilities and expertise in testing. Therefore, NPRA has collaborated with the Sungai Buloh National Public Health Laboratory to develop a procedure for testing the potential of vaccine products.

The NPRA remains vigilant in keeping up with technological advancements and actively engages with international regulatory networks to adopt best practices for monitoring and evaluating new drug classes. NPRA also continuously collaborates with international organisations, regulatory bodies, and healthcare professionals to leverage expertise and sharing of resources to enhance post-marketing surveillance efforts.

(iv) Regulatory Requirements for First in Human (FIH) Clinical Studies and Cell and Gene Therapy Products (CGTP)

Advancements in pharmaceutical technology and the discovery of new drugs pose new challenges in regulatory control of these products.

In the National Vaccine Development Roadmap (PPVN) of Malaysia, the goal is to establish the country as a hub for clinical studies, including First-In-Human (FIH) trials. Although NPRA has initiated Level 1 Unit Accreditation Program since 2018, there is a need to develop the clinical research ecosystem since the number of facilities successfully accredited is limited. Regarding the regulatory control of Cell and Gene Therapy Products (CGTP), it has been observed that stakeholders involved require guidance in aspects of compliance with OECD

Good Laboratory Practice, Good Manufacturing Practice, Clinical and Non-Clinical requirements for the registration of CGTP products. Simultaneously, NPRA also needs to enhance its expertise in implementing regulatory controls over such products.

Gaps in Access to and Availability of Medicines

Access to safe, effective, affordable and quality medicines is a vital component of the progress towards Universal Health Coverage (UHC). Malaysia, a middle-income country with a rapidly ageing population also faces a significant challenge to ensure adequate access to medicines. While the Malaysian healthcare system has made commendable progress in providing healthcare services, several issues and challenges concerning the accessibility of medicines still exist.

(i) Patent, Intellectual Property and Generic Medicines

One of the primary obstacles to accessing medicines in Malaysia is the high cost of pharmaceutical products. Patents and intellectual property rights contribute to the inflated prices, particularly for newer and patented medicines. The rising prices of patented medicines, coupled with increasing healthcare expenditure, pose a significant financial burden on individuals and the healthcare system. This situation affects both the public healthcare sector and individuals who rely on private healthcare services. The burden falls heavily on patients with chronic diseases, who require long-term medication and those without comprehensive health insurance coverage. While patents are accepted as a form of incentive and reward for innovation, prolonged patent terms can be one reason for the continued high price of these medicines. Implementing medicine price transparency mechanisms and negotiations with pharmaceutical companies can help lower the cost of medicines. In addition, promoting the use of generic medicines, which are more affordable alternatives to innovator medicines, can significantly reduce healthcare expenditure. Implementing education campaigns and removing potential barriers to generic substitution can increase acceptance and confidence in these cost-effective alternatives.

Geographical disparities exist in Malaysia, particularly in rural and remote areas where there are limited healthcare facilities and infrastructure. This results in inadequate access to essential medicines within these communities. Additionally, vulnerable populations, such as low-income individuals, refugees, and indigenous communities, face additional barriers in accessing medicines, exacerbating health inequities.

(ii) Efficient and Reliable Supply Chain of Medicines

Efficiency and sustainability of the medicine supply chain are essential to ensuring continuous availability of medicines. However, Malaysia is constantly facing challenges related to supply chain management, including logistics, storage and distribution.

The COVID-19 pandemic, closure of the borders of major exporting countries such as China and India, as well as the war in Ukraine, have caused disruptions in the supply of raw materials and active pharmaceutical ingredients (API) globally. Malaysia is also not exempted from the impact of medicines supply disruptions due to delays in the supply of APIs, supplements, reference analysis standards and packaging materials. This situation is further aggravated by the problem of the shortage of foreign labour that occurs among local manufacturers.

This leads to disruption of stock supply and delays in delivery of medicines to health care facilities, thus affecting patient access to essential medicines. Although various mitigation plans have been implemented by the government to address this issue, there is a need to establish a system for monitoring the supply and distribution of medicines in Malaysia, in cooperation with various agencies under the Malaysian Ministry of Health to monitor the availability of medicines. In addition, there is a need for a long-term guarantee and sustainability plan for medicines as one of the strategies of preparedness for future crises.

(iii) The distribution and skills of human resources that need to be improved:

Good health services also depend on an adequate number of officers and workforce, trained and distributed according to needs. These features contribute to quality, effective, efficient, and accessible services. In addition, there is a need to optimise the existing human resource to skill mix in order to fulfil needs for the service. The quality of healthcare depends largely on the presence of skilled health workers at each level. Effective workforce planning will also ensure that the needs and demands of the people are met. The pharmacist-to-population ratio has been used to calculate the Health Index because it can reflect the extent to which pharmacists can provide services to the population. Based on 2020 statistics, the ratio of one (1) pharmacist to the population is 1:2,413 (2018) and 1:1,709 (2020) compared to Singapore's ratio which is 1:1,655 in 2020.

Despite an increase in the number of pharmacists, socioeconomic and geographical considerations have an impact on the issue of unequal placements in the public and private sectors. For instance, due to the high population density and disparities in health literacy, private health facilities are more prevalent in urban areas.

The maldistribution of resources between the public and private sectors is contributed by the higher number of patients in the public sector than in the private sector. For example, 64% of the outpatient burden is treated in the public sector versus only 36% in the private sector. This has resulted in shortages in public health facilities and long waiting times in order to get treatment. Staff shortages, overcrowding due to high patient loads, underfunding and insufficient equipment that needs to be replaced as well as inadequate facilities affected the delivery of health services especially in the public sector.

Low Level Health Literacy and Irrational use of Medicines in the Society

Based on the findings from the National Health & Morbidity Survey (NHMS) 2019, 35.1% of Malaysian adults have limited health literacy. In light of the findings, communities and individuals must be empowered to increase knowledge and understanding towards medications management which may aid them in achieving better health outcomes. Malaysia is moving fast towards having an ageing population. The elderly nursing homes or home care institutions are becoming significant in the society. Whilst ensuring the safety of the elderly people, more attention is also needed to deliver health care to them effectively. Lack of attention may result in mismanagement of medications at those homes and institutions and hence put their health at risk. The number of pharmacists remained low in ratio to serve a population of 32 million. There are limited platforms to disseminate reliable information regarding medications to the public. Expanding the reach of the 'Know Your Medicine' (KYM) Programme is a primary priority in improving health awareness. However, expanding coverage is not straightforward, and it is necessary to identify the economic, financial, geographical and social limitations affecting the dissemination of information. Nevertheless, through years of implementing the KYM Programme, understanding from the consumers' perspective when it comes to utilising medications has been established. Public engagement requires commitment, hard work, passion, cooperation and understanding from pharmacists, healthcare professionals, the community as well as stakeholders.

OBJECTIVES OF MNMP

Promoting equitable ACCESS and RATIONAL use of SAFE, EFFECTIVE and AFFORDABLE essential medicines of good QUALITY to improve health outcomes of the people

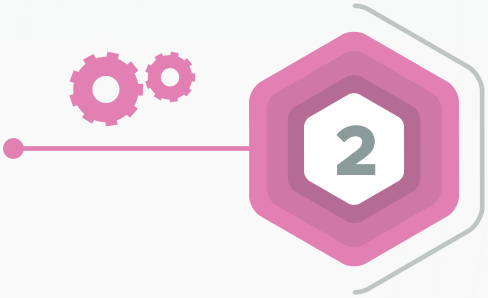
5 MNMP MAIN COMPONENTS

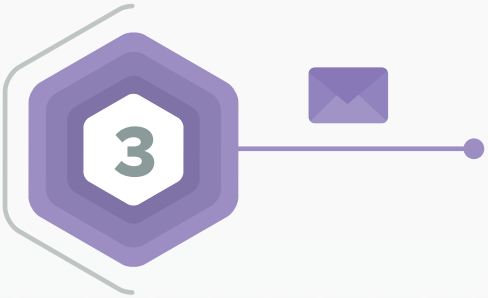
GOVERNANCE IN MEDICINES

Good governance on pharmaceutical management, practices, and professionalism shall be emphasized

QUALITY, SAFETY & EFFICACY OF MEDICINES

Safe, efficacious and quality medicines for consumers in Malaysia





ACCESS TO MEDICINES

Medicines shall be made available and affordable to ensure continuous access to meet healthcare needs of the nation at all times

QUALITY USE OF MEDICINES

Quality use of medicines is the responsibility of all stakeholders. Empowerment of all stakeholders through the appropriate use of medicines towards better health outcomes

PARTNERSHIP & COLLABORATION FOR THE HEALTHCARE INDUSTRY

Strategic partnership and collaboration among stakeholders shall be invigorated to support and foster the implementation of current and future goals in the healthcare sector

GOVERNANCE IN MEDICINES

COMPONENT ONE 01

1.0. GOVERNANCE IN MEDICINES

1.1 POLICY

Good governance on pharmaceutical management, practices, and professionalism shall be emphasised.

1.2 AIM

1.2.1 To ensure clear and transparent policies and legislations in facilitating and supporting the governance, professionalism and current practices

1.2.2 To have appropriate governance that ensures the provision of pharmaceutical care services within the best practice environment

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

1.3 APPROACH

1.3.1 Relevant policies, legislation and guidelines shall be developed and reviewed accordingly to ensure an efficient and safe supply of medicines in order to improve public health outcomes

1.3.2 Expansion of implementation of current guidelines to other stakeholders

1.3.3 Ensuring availability and sustainability of qualified and competent human resource

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

1.4 STRATEGY

1.4.1 Inculcate a culture of ethical conduct

1.4.2 Promote transparency, accountability and ethical practices among health professionals

1.4.3 Strengthen legislation and regulation

1.4.4 Strengthening human capital, capacity and capability

STRATEGY 1 : Inculcate a culture of ethical conduct					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
1.1	Revision of Good Governance for Medicines (GGM) training framework	a) Revised GGM Training of Trainers (TOT) module completed (by Q2 2024)	2023-2024	Revise TOT Module (2023)	BDPSF, MOHE, MinDef, Organisation / MPS, Private sector
				Published TOT Module by Q2 (2024)	
		b) Number of certified trainers trained (starting from Q3 2024)	2024-2026	30 per year (2024-2026)	
		c) Number of participants trained (starting from Q1 2025)	2025-2026	500 (Minimum) (2025)	
				1,000 (Minimum) (2026)	
		d) Percentage increment in understanding towards GGM concept (Pre & Post evaluation)	2025-2026	20% per year (2025-2026)	
STRATEGY 2 : Promote transparency, accountability and ethical practices among health professionals					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
2.1	Reviewing and expanding the implementation of Continuous Professional Education (CPE) Accreditation Guideline	a) Publish revised CPE Accreditation Guideline (by Q3 2024)	2023-2024	1. Engagement with stakeholders 2. Revise CPE Accreditation Guidelines (2023)	BDPSF, MOHE, MinDef, Pharmacy association (i.e. MPS)
				Published revised guidelines (Q3 2024)	
		b) Percentage of institutions fully adopted the CPE accreditation guideline	2025-2026	80% adoption by MOH hospitals, PKD and KK (2025)	
				90% adoption by MOH hospitals, PKD and KK (2026)	
STRATEGY 3 : Strengthen legislation and regulation					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
3.1	Strengthening the existing Registration of Pharmacists Act 1951 (ROPA 1951) and regulation for better governance to the profession	Tabling of Bill in Parliament	2026	1. Approval of draft Bill by Attorney General's Chambers 2. Approval by Cabinet 3. Tabling of Bill in Parliament (2026)	BLFM, BPF, Legal Advisor, Attorney General's Chambers, Pharmaceutical association, Professional association, Industry association, Other agency

3.2	Strengthening the existing Sales of Drugs Act 1952 (SODA 1952) and regulation for better governance of the pharmaceutical products	Tabling of Bill in Parliament	2023	Tabling of Bill in Parliament (2023)	BPF, Legal Advisor, Attorney General's Chambers, Pharmaceutical association, Professional association, Industry association, Other agency
3.3	Strengthening the existing Medicines (Advertisement & Sale) Act 1956 (MASA 1956) and regulation for better governance of the pharmaceutical products	Tabling of Bill in Parliament	2026	Tabling of Bill in Parliament (2026)	
STRATEGY 4 : Strengthening human capital, capacity and capability					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
4.1	Establishment of framework for credentialing of pharmacists (and pharmacists assistants) in Malaysia	a) Establishment of credentialing guideline for pharmacists (and pharmacists assistants)	2022-2024	Get policy approval / endorsement of the mechanism in principle from Pharmacy Programme (2022)	BLFM, BDPSF, BAPF, NPRA, BPF **NON-MOH:** MINDEF, HUKM, HUSM, HUPM, PPUM, HUiTM, PPT etc. **PRIVATE:** MPS, MAP, Private institution e.g KPJ Healthcare, IHH Healthcare, Community Pharmacy etc.

			2022-2024	1. Approval / endorsement of the mechanism from Pharmacy Board of Malaysia (LFM) 2. Establishment of Credentialing Committees 3. Formulate and determine policies pertaining to credentialing requirements and standards 4. Establishment of Technical Committees (2023)	
				1. Develop guidelines to credentialing of pharmacists (Non-MOH) 2. Engagement with relevant stakeholders to introduce the guideline (2024)	
		b) Number of credentialed area for non MOH institutions	2024-2026	1 credentialed area to be certified by board (2024)	
				2 credentialed area to be certified by board (2025)	
				3 credentialed area to be certified by board (2026)	
		c) Number of credentialed pharmacists (and pharmacist assistants) (MOH)	2023-2026	10% increment per year (2023-2026)	
		d) Number of credentialed pharmacists (and pharmacist assistants) (non MOH)	2025-2026	Minimum 5 (2025)	
				Minimum 10 (2026)	

QUALITY, SAFETY AND EFFICACY OF MEDICINES

COMPONENT TWO 02

2.0. QUALITY, SAFETY AND EFFICACY OF MEDICINES

2.1 POLICY

Safe, efficacious and quality medicines for consumers in Malaysia

2.2 AIM

To ensure medicines marketed meet the approved standards, requirements and comply with legal provisions for the well-being of consumers

2.3 APPROACH

Strengthening the medicine regulatory system and enforcement activities 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

2.4.1 Ensuring all regulatory requirements are aligned with current global regulatory practice and international standards

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

2.4.3 Enhancing post-market surveillance activities and product safety

2.4.4 Strengthening international collaboration with other National Regulatory Authorities (NRAs)

STRATEGY 1 : Ensuring all regulatory requirements are aligned with current global regulatory practice and international standards					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
1.1	Regulatory system strengthening through National Regulatory Authority (NRA) Assessment/ Benchmarking by the World Health Organization (WHO)	Achieve maturity level 4 by 2024	2024	Achieve maturity level 4	WHO, NPRA, BPF, BAPF, BKP, BPKA
1.2	Regulatory system strengthening by working towards becoming a member of the International Council of Harmonisation of Technical Requirement for Pharmaceuticals for Human Use (ICH)	Mapping of ICH membership requirement and complete identified needs	2023-2026	1. Identify experts to be members of ICH technical working groups (WG) 2. Apply for funds to attend WG meetings and ICH General Assembly (GA) in 2024 (2023)	NPRA
				1. Prepare MJM to obtain approval to become ICH member and to request funds for ICH annual fee 2. Attend WG meetings and ICH GA 3. Apply for funds to attend WG meetings and ICH GA in 2025 (2024)	
				1. Attend WG meetings and ICH GA 2. Apply for funds to attend WG meetings and ICH GA in 2026 3. Follow-up on MJM approval (2025)	
				1. Attend WG meetings and ICH GA 2. Apply for funds to attend WG meetings and ICH GA in 2027 3. Follow-up on MJM approval (2026)	

1.3	Implementation of Cell and Gene Therapy Product (CGTP) registration	a) Revision of CGTP guideline	Completed by 2023	Publication of 2nd edition of CGTP guideline (2023)	NPRA, BPF, CKAPS, MACT, TESMA, Bio-economy Corporation
		b) Number of training sessions for regulators/ NPRA)	Completed by 2023	At least one training session (2023)	
		c) Number of industry trainings	2024-2026	Minimum one industry training per year (2024-2026)	
		d) Number of product registrations and inspection applications received to be reported	2022-2026	To report GMP, GLP, Clinical Trial inspection applications and Registration applications received (2022-2026)	
1.4	Awareness and promotion with stakeholders on accreditation of First-in-Human (FIH) clinical trial sites to be in line with National Vaccine Development Roadmap (NVDR)	a) Number of engagements with stakeholders	2022-2026	3 per year (2022-2026)	NPRA, CRC, CRM, PRH, CRO, ACRPM, UMBI, Ethics Committee of universities, IMR, CKAPS
		b) Number of applications received for FIH studies conducted locally	2024-2026	To report number of applications received for FIH studies conducted locally (2024-2026)	
1.5	Establishment and voluntary implementation of e-labelling	a) Preparation of the concept paper and guideline to be presented in PSP Policy Meeting and Drug Control Authority Meeting	Q1 2023	Presented in DCA Meeting (2023)	NPRA, PSP, MOH, PhAMA, MOPI, MAPS
		b) Voluntary e-labelling implementation	2023-2026	1. Pilot 2. Voluntary e-labelling implementation (Q3 of 2023)	
				To report: Number of products implementing e-labelling (2024-2026)	

1.6	Establishment of National Pharmaceutical Regulatory Agency (NPRA) as a Statutory Body	MJM submitted to MOH top management	2023-2025	Concept paper presented in PSP Policy Meeting (2023)	NPRA
				Engagement with all relevant stakeholders (2024)	
				MJM submitted to MOH top management (2025)	
STRATEGY 2 : Strengthening enforcement and regulatory activities under the relevant acts and regulations					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
2.1	Combating online sales of illegal and falsified medicines	a) Number of online advertisements related to sales of illegal and falsified medicines notified for removal in local e-marketplace	2022-2026	4,000 per year (2022)	BPF, MCMC, Interpol, WHO, Pharmaceutical Security Institute (PSI), New media platform
				4,500 per year (2023)	
				5,000 per year (2024)	
				5,500 per year (2025)	
				6,000 per year (2026)	
		b) Percentage of illegal and falsified medicines online sellers identified within 30 working days from profiling started	2022-2026	90% per year (2022-2023)	
				95% per year (2024-2025)	
				100% (2026)	
		c) Percentage of enforcement actions taken on online sales of illegal and falsified medicines within ten (10) working days after completion of profiling reports	2022-2026	80% (2022)	
				85% (2023)	
				90% (2024)	
				95% (2025)	
				100% (2026)	
		d) Percentage of operation successfully conducted	2022-2026	50% per year (2022-2023)	
				75% per year (2024-2025)	
				80% (2026)	
2.2	Enhancing enforcement activities to reduce sales of unregistered products/unnotified cosmetics/ products, preparations, and cosmetics containing poisons using targeted approach	Percentage of identified premises selling unregistered products, adulterated product and un-notified cosmetics openly, reduced per year cumulatively	2022-2026	Reduction by 20% per year and cumulative of 95% for 5 years (2022-2026)	BPF

2.3	Strengthening control on unregistered and substandard products through Pharmaceutical Track and Trace System	a) DCA approval for Pharmaceutical Track & Trace System	2023-2025 (On-going)	Stakeholders engagement and regulatory amendment (2023)	BDPSF, PSP, MOH, PhAMA, MOPI, MAPS, Other healthcare professionals
				Pilot implementation for cold chain items (2024)	
				DCA directive and implementation guidelines approved (2025)	
		b) Implementation of Pharmaceutical Track & Trace System	2023-2026 (On-going)	1. Request for Information (RFI) process: briefing and preparation of RFI reports for submission to UKAS 2. Stakeholders engagement (2023)	BDPSF, NPRA, BPF, BAPF, BPM, BPPs
				1. Request for Proposal (RFP), tendering process & selection of solution provider 2. MyMediTRACE development and implementation (2024)	
				1. Pilot project of MyMediTRACE 2. Implementation of MyMediTRACE based on category of products (2025)	
				Implementation of MyMediTRACE (voluntary stages for Scheduled Poison) (2026)	

STRATEGY 3 : Enhancing post-market surveillance activities and product safety					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
3.1	Strengthening of Pharmacovigilance (PV) activities	a) Number of product registration holders (PRHs) inspected	2023-2026	4 PRHs inspected (2023)	NPRA, MOPI, PRH, PhAMA, MAPS
				5 PRHs inspected (2024)	
				6 PRHs inspected (2025)	
				7 PRHs inspected (2026)	
		b) Number of pharmacovigilance (PV) trainings conducted	2023-2026	Minimum 1 training conducted per year (2023-2026)	

3.2	Enhancement of registered products conforming to standards and requirements	a) Number of methodologies developed for vaccine testing	2023-2026	1. 1 test method developed (Test 1) 2. 1 test method development initiated (Test 2) (2023)	NPRA, MKAK, UMBI, IMR, MOSTI, PRH, PhAMA, MOPI
				1. 1 test method developed (Test 2) 2. 1 test method development initiated (Test 3) (2024)	
				1. 1 test method developed (Test 3) 2. 1 test method development initiated (Test 4)(2025)	
				1 test method developed (Test 4) (2026)	
		b) Number of vaccine types sampled and tested using the developed method	2023-2026	1 type of vaccine sampled and tested per year (2023-2026)	NPRA, BKP, MKAK, IMR, PRH, PhAMA, MOPI

STRATEGY 4 : Strengthening international collaboration with other National Regulatory Authorities (NRAs)

No.	Initiative	Performance Indicator	Implementation timeline	Target (Year)	Stakeholders
4.1	Optimising the Regulatory Review Process	a) Revision of guidelines	2023	Guidelines revision completed (2023)	NPRA, MKAK, UMBI, IMR, MOSTI, PRH, PhAMA, MOPI
		b) Number of pharmaceutical products evaluated through Facilitated Registration Pathway (FRP)	2024-2026	To report number of products evaluated through Facilitated Registration Pathway (FRP) per year (2024-2026)	

ACCESS TO MEDICINES

COMPONENT THREE 03

3.0. ACCESS TO MEDICINES

3.1 POLICY

Medicines shall be made available and affordable to ensure continuous access to meet healthcare needs of the nation at all times

3.2 AIM

To ensure adequate, continuous and equitable access to quality, safe, effective and affordable medicines towards achieving healthcare needs

3.3 APPROACH

3.3.1 A fair and transparent selection of medicines in accordance with the country's health needs

3.3.2 An optimum, effective and continuous medicines supply chain management

3.3.3 An equitable medicines financing and pricing system that safeguards access to healthcare

3.4 STRATEGY

3.4.1 Strengthening the availability of medicines based on country's needs

3.4.2 Strengthening the supply chain management to ensure optimum, effective and continuous supply of medicines

3.4.3 Establishing a reliable and sustainable medicines financing mechanism

3.4.4 Ensuring affordable medicines in both public & private sectors

3.4.5 Encouraging use of generic medicine in both public & private sectors

STRATEGY 1: Strengthening the availability of medicines based on country's needs					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
1.1	Enhancing the National Essential Medicines List (NEML) based on the country's current needs	Revision of NEML in accordance with WHO EML	2022-2026 (On-going)	NEML revised in accordance with WHO EML (2022, 2024, 2026)	BAPF
1.2	Ensuring the availability of medicines listed under NEML by encouraging product registration without compromising the elements of quality, safety and efficacy (QSE)	Unregistered medicines under NEML granted priority review and registered	2022-2026 (On-going)	1. Number of unregistered medicines under NEML that have been granted priority review per year (2022-2026) 2. Number of unregistered medicines under NEML registered per year (2022-2026) 3. Marketing status to be reported if platform is ready and policies to ensure reporting is in place (2026)	NPRA, BAPF
1.3	Developing guidelines on medicines that caters to consumer/ population needs & requirements where appropriate	Development of guidelines for medicines that caters to various religious perspectives	2024	Situational analysis (2024)	BDPSF
1.4	Strengthening the use of local Pharmacoeconomics (PE) data in the selection of medicines	Development of framework for PE evaluation in medicines selection for MOH Medicines Formulary/ Reimbursement List	2025	Framework for PE evaluation in medicine selection for MOH Medicines Formulary/ Reimbursement List developed (2025)	BAPF, PRH, PhAMA, MOPI
1.5	Developing MOH Traditional & Complementary Medicines (T&CM) Formulary	Development of T&CM Formulary with a guideline for listing and de-listing of T&CM products used in MOH facilities	2023	T&CM Formulary with a guideline for listing and de-listing of T&CM products used in MOH facilities developed (2023)	BPTK, PSP, NPRA, T&CM in MOH facilities

STRATEGY 2: Strengthening the supply chain management to ensure optimum, effective and continuous supply of medicines					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
2.1	Developing a comprehensive National Medicines Stock Management System	a) Development of multi-stakeholder framework to monitor and mitigate medicines shortage and unavailability	2025	Multi-stakeholder platform for reporting and monitoring medicines shortage developed (2025)	NPRA, BAPF, BDPSF, BPF
		b) Development of platform for reporting and monitoring of the marketing status of registered products through the QUEST5 online system	2025	System continues to be developed up to Q4 for UAT / FAT to be done (2025)	NPRA, BDPSF, BAPF, BPF, MOPI, PhAMA, MAPS, MADSA
2.2	Strengthening the procurement process for private and government partnership through pooled procurement	Development of framework for pooled procurement among public and private healthcare facilities	2024	1. Conduct feasibility study on pooled procurement expansion to private healthcare facilities 2. Framework for pooled procurement among public and private healthcare facilities developed (2024)	BDPSF, BAPF, NPRA, BPF
2.3	Ensuring continuous availability & self-sustainability of raw material of medicines under the NEML list	Development of Pharmaceutical Raw Material Sourcing Plan Framework	2025	Pharmaceutical Raw Material Sourcing Plan Framework developed (2025)	PSP, MITI, NPRA, BDPSF, BPF, BAPF, MOPI, MAPS

STRATEGY 3: Establishing a reliable and sustainable medicines financing mechanism					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
3.1	Enhance mechanisms to improve accessibility and affordability of medicines	a) Development of guidelines on submission and implementation of Medicines Access Schemes (MASc) for MOH facilities	2023-2026 (ongoing)	1. Number of MASc approved per year (2023-2026) 2. Monitor the implementation of MASc at facility level according to guideline per year (2023-2026)	BAPF, PRH, PhAMA, MOPI
		b) Economic assessment of medicines access schemes implementation	2024-2026 (ongoing)	Evaluation on economic impact of the medicines access schemes approved in MOH per year (2024-2026)	
3.2	Developing medicines fees and reimbursement framework	Development of medicines fees and reimbursement framework	2025	Expanding of the reimbursement scheme for medicines under PEKA B40 (and any financing mechanism approved) (2025)	BDPSF, BAPF, Planning Division, KKM, Finance Division, KKM

STRATEGY 4: Ensuring affordable medicines in both public & private sectors					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
4.1	Initiating Medicines Price Transparency Mechanism	Implementation of Medicines Price Transparency Mechanism	2024	Medicines Price Transparency Mechanism implemented (2024)	BAPF
4.2	Engagement with all stakeholders involved in the pricing mechanism on the implementation of Medicines Price Transparency Mechanism	Number of Engagements with all stakeholders involved in the pricing mechanism on the implementation of Medicines Price Transparency Mechanism	2022-2026 (ongoing)	2 engagement sessions per year (2022-2026)	BAPF, BDPSF, BPF, UKK, KPDN
4.3	Monitoring the impact of Medicines Price Transparency Mechanism	Publish report on the impact of Medicines Price Transparency Mechanism	2025	Report published (2025)	BAPF, NIH

STRATEGY 5: Encouraging use of generic medicine in both public & private sectors					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
5.1	Development of the National Generic Medicines Framework	National Generic Medicines & Biosimilars Framework developed	2024	Publication and dissemination of the Framework (2024)	BDPSF, NPRA, BAPF, MOPI, MAPS
5.2	Generic Medicines Awareness Programme (GMAP)	Number of Generic Medicines Awareness Programmes conducted	2023-2026 (on-going)	2 engagements per year (2023-2026)	BDPSF, BAPF, NPRA

QUALITY USE OF MEDICINES

COMPONENT FOUR 04

4.0. QUALITY USE OF MEDICINES

4.1 POLICY

Quality use of medicines is the responsibility of all stakeholders. Empowerment of all stakeholders through the appropriate use of medicines towards better health outcomes.

4.2 AIM

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

4.3 APPROACH

4.3.1 Best practices shall be applied to ensure the provision of safe and quality use of medicines at all levels of healthcare inclusive of public and private sectors.

4.3.2 Health literacy and empowerment of all stakeholders shall be enhanced for better management of medicines.

4.4 STRATEGY

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

4.4.2 Strengthening of good dispensing practice in public and private healthcare facilities

4.4.3 Enhancing health literacy and empowering the community towards quality use of medicines

4.4.4 Strengthening of antimicrobial resistance strategies

STRATEGY 1: Prescribing and dispensing of medicines shall be implemented in accordance with relevant guidelines					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
1.1	Ensuring Pharmaceutical Care Practices are in line with current international and local best practices approach and implemented	Percentage of documents/ guidelines related to prescribing and dispensing of medicine reviewed (at least every 5 years or when necessary)	2022-2026	65% (2022) 70% (2023) 75% (2024) 80% (2025) 85% (2026)	BAPF, APHM, MPS, MMA
1.2	Ensuring adherence to Malaysian Patient Safety Goals No. 7: To ensure Medication Safety initiative implemented in all healthcare facilities (public and private)	Percentage of healthcare facilities achieving more than 60% marks in medication safety initiatives survey	2022-2026	1. 80% (MOH) 2. Questionnaire review (non MOH) (2022) 1. 80% (MOH) 2. Baseline (non MOH) (2023) 1. 85% per year (MOH) 2. Increasing trend per year (non MOH) (2024-2026)	BAPF, APHM, MPS, MMA, MCPG, NPRA
STRATEGY 2: Strengthening of good dispensing practice in public and private healthcare facilities					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
2.1	Developing standards of Good Dispensing Practice in Public and Private healthcare facilities	Formal document for standards of Good Dispensing Practice published	2022-2026	1. Engagement with stakeholders (Public and Private) and form a taskforce in standards of Good Dispensing Practice Target = 1 taskforce 2. Situational analysis (2022) 1. Situational analysis of basic standards of Good Dispensing Practice at public and private Target = 1 analysis 2. Development of formal document (2023) 1. Development of formal document for standards of Good Dispensing Practice and checklist Target = 1 formal document 2. Roadshow (2024)	BAPF, CKAPS, APHM, MMC, MMA, MPS, MCPG

				Roadshow to create awareness for formal document on standards of Good Dispensing Practice and checklist among Public and Private facilities Target = minimum 6 roadshow (at least in 1 in each zone) (2025)	
				Number of facilities achieving standards of Good Dispensing Practice and checklist 1. MOH (Main state hospital, major and minor specialist hospital) = 100% 2. Non MOH = 50% (2026)	
STRATEGY 3: Enhancing health literacy and empowering the community towards quality use of medicine					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
3.1	Engagement with stakeholders on medicines and healthcare services advertisements	Number of engagements (Increasing trend)	2022-2026	5 (2022)	BPF, E-commerce platforms (Shopee/ Lazada etc), social media influencers, healthcare service providers, licence holders, sellers, MCMC, Content Forum, and others
				6 (2023)	
				7 (2024)	
				8 (2025)	
				10 (2026)	
3.2	Implementation of awareness and education programme on medicines amongst blind population	a) Expand the implementation of awareness and education programme on medicines amongst blind population	2022-2026	Development of Instrument for Focus Group Discussion (2022)	BAPF, Visually Impaired Community, Association Society for the blind, MOE, MPS, MMA
				Conduct survey on the blind population (2023)	
				Development of training module (2024)	
				Training master trainers using the modules developed (2025)	
				Project implementation (2026)	
		b) Encourage PRH to incorporate braille voluntarily onto the product packaging	2022-2026	1. Baseline (2022) 2. 1 (new per year) (2023-2026)	BAPF, NPRA, MOPI, PhAMA, MAPS

3.3	Enhancing quality use of medicines for consumers in learning institution (Health Promotion in Learning Institution, HePiLI)	Percentage of coverage	2022-2026	20% (2022) 40% (2023) 60% (2024) 80% (2025) 100% (2026)	BAPF, HECC, JPNIN
3.4	Empowering community leaders on the quality use of medicines [Coverage of Duta Kenali Ubat Anda (DKUA) programme conducted nationwide]	a) Percentage of coverage (Increasing Trends) b) Programme conducted by DKUA based on postcodes (area) : 2778 as denominator	2022-2026	a) Baseline b) 15.8% (2022) a) 5% b) 20% (2023) a) 10% b) 25% (2024) a) 15% b) 30% (2025) a) 20% b) 35% (2026)	BAPF
3.5	Enhancing Pharmaceutical Care through Home Medication Review Pharmacy Services	a) Number of Home Medication Review sessions per year	2022-2026	9000 (2022) 9200 (2023) 9400 (2024) 9600 (2025) 9800 (2026)	BAPF, MPS, MCPG, Academia
		b) Report of Dose,Frequency, Indication and Time (DFIT) and Compliance Score published	2022-2026	Update protocol HMR (2022) Training & roadshow (2023) 1. Develop Research Instrument 2. Baseline data (2024) 1. Research conducted 2. Intervention (2025) Data Analysis & Publish report (2026)	

STRATEGY 4: Strengthening of antimicrobial resistance strategies					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
4.1	Establishing accredited Antimicrobial Stewardship (AMS) Training Centres	a) Number of accredited AMS Training Centres (cumulative)	2022-2026	2 training centres per year (2022-2023)	BAPF
				3 training centres per year (2024-2025)	
				4 training centres (2026)	
		b) Number of accredited trained AMS Pharmacists	2022-2026	5 new per year (2022-2026)	
4.2	Monitoring and surveillance of antibiotics	Percentage of facilities (public & private) involved in national surveillance of antibiotics	2022-2026	95% per year (2022-2026)	BAPF, BPF, APHM, CKAPS, IMR, NIH
4.3	Providing the public with accurate and relevant information on AMR (Relevant and accurate Information dissemination on AMR to the public)	Number of awareness and education activities related to Antimicrobial Resistance (AMR) given to the public	2022-2026	100 (2022)	BAPF, NPRA, MDD, HECC, Media
				Increasing trend per year (2023-2026)	

PARTNERSHIP AND COLLABORATION FOR THE HEALTHCARE INDUSTRY

COMPONENT FIVE 05

5.0. PARTNERSHIP AND COLLABORATION FOR THE HEALTHCARE INDUSTRY

5.1 POLICY

Strategic partnership and collaboration among stakeholders shall be invigorated to support and foster the implementation of current and future goals in the healthcare sector.

5.2 AIM

5.2.1 To incorporate pragmatic partnership and collaboration among stakeholders by conforming to the best practices and standards

5.2.2 To strengthen relevant policies, resources and infrastructure

5.2.3 To encourage and promote smart partnership to boost competitiveness

5.3 APPROACH

5.3.1 Timely engagement with relevant stakeholders

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

5.3.3 Sharing and optimising information, expertise skills, technology and facilities

5.4 STRATEGY

5.4.1 Encouraging research and development among stakeholders

5.4.2 Intensifying knowledge sharing in research and quality improvement

5.4.3 Drug disposal management for healthy environment

5.4.4 Optimise human resource capacity to ensure continuous service delivery

5.4.5 Improving patient access to pharmacy services through public-private partnership

5.4.6 Enhancing multi-sectoral technical engagement towards better health service delivery

5.4.7 Establishment of digital platform for information exchange

5.4.8 Initiating regional collaboration to promote equitable access to medicines

STRATEGY 1: Encouraging research and development among stakeholders					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
1.1	Encouraging collaboration in conducting research between public and private sectors	a) Establishment of focus area for research collaboration	2023	Focus area for research collaboration established (2023)	BDPSF, To collaborate with private sectors including private universities
		b) Number of engagements for collaboration among stakeholders	2022-2026	At least 1 engagement with stakeholders to identify the Pharmacy Research Priority Area in Malaysia (PRPM) (2022)	
				At least 1 Engagement with stakeholders to determine the focus area for research collaboration (2023)	
				At least 1 engagement with stakeholders to promote research collaboration between public and: 1. private sector 2. non-MOH & academia (2024)	
		c) Number of studies conducted in collaboration between the public and private sectors	2023-2026	At least 1 engagement per year (2025-2026)	
STRATEGY 2: Intensifying knowledge sharing in research and quality improvement					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
2.1	Intensifying knowledge sharing in research and quality improvement	a) Number of events for multi-sectoral research sharing	2022-2026	1 event per year (2022-2026)	BDPSF
2.2	Establishment of platform for information sharing in research	b) Feasibility study report produced	2023	1. Conduct feasibility study 2. Feasibility study report (2023)	
		c) Development of guideline and platform for information sharing	2024	Guidelines and platform developed (2024)	

STRATEGY 3: Drug disposal management for healthy environment					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
3.1	Establishing comprehensive procedures for medicines disposal management at the consumer level	Implementation Progress	2022-2026	Produce a proposal to be included in the National Environmental Health Action Plan (NEHAP) (2022) 1. Engagement with public & private sector 2. Situational analysis (2023) 1. Memorandum of Understanding (MoU) inter-agency 2. Establishment of strategic plan and policy (2024) 1. Launching 2. Roadshow / Awareness (2025) Implementation (2026)	BAPF, KASA, Jabatan Alam Sekitar, MOPI, MPS, MMA, MCPG, Kualiti Alam, PhAMA, APHM
Strategy 4: Optimise human resource capacity to ensure continuous service delivery					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
4.1	Expansion of Quality Use of Medicines (QUM) Programme through public-private partnership	Number of community pharmacists (CP)/ pharmacists at private hospital/ non-MOH (i.e. private hospital, MinDef, MOE etc.) collaborated	2022-2026	1. Engagement with MPS Headquarters and state-level 2. Trainings conducted (133 pharmacists) (2022) 1. Implementation of programme in community 2. Expansion to community pharmacists (CP)/ pharmacists at private hospitals/ non-MOH (i.e. private hospitals, MinDef, MOE etc.) (2023)	BAPF, MPS, Community pharmacists, Pharmacists at private hospital / non-MOH (i.e. MinDef, MOE etc.)

				1. Implementation programme in community per year 2. Number of community pharmacists (CP)/ pharmacists at private hospital/ non-MOH (i.e. MinDef, MOE etc.) collaborated per year (2024-2026)	
STRATEGY 5: Improving patient access to pharmacy services through public-private partnership					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
5.1	Outsourcing of Patient Follow-up Medicines Supply from MOH Facilities to Community Pharmacies	Framework for Outsourcing of Patient Follow-up Medicines Supply from MOH Facilities to Community Pharmacies developed	2024	1. Conduct feasibility study on outsourcing of medicines supply to community pharmacies 2. Framework for Outsourcing of Patient Follow-up Medicines Supply from MOH Facilities to Community Pharmacies developed (2024)	BDPSF
STRATEGY 6: Enhancing multi-sectoral technical engagement towards better health service delivery					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
6.1	Recognition of private laboratories based on current regulatory requirement	Number of recognised private laboratories that are capable of conducting identification and authentication test for herbal raw material to be used in traditional products	2023-2026	1 lab (cumulative) (2023) 2 labs (cumulative) (2024) 3 labs (cumulative) (2025) 4 labs (cumulative) (2026)	NPRA, Private Testing laboratories, PRH, local traditional manufacturers, traditional product association

STRATEGY 7: Establishment of digital platform for information exchange					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
7.1	Evaluation of conducive environment for the digitalisation of information sharing between public and private sector	Conduct feasibility study to consider the level of support and implementation of such a digital platform	2023-2025	1. Identify the stakeholders 2. Establish Task Force to discuss and consider issues to create the parameter of the feasibility study (2023)	BDPSF
				1. Situational analysis 2. Conduct feasibility study (2024)	
				1. Conduct feasibility study 2. Feasibility Study report (2025)	
STRATEGY 8: Initiating regional collaboration to promote equitable access to medicines					
No.	**Initiative**	**Performance Indicator**	**Implementation timeline**	**Target (Year)**	**Stakeholders**
8.1	Developing regional collaborative strategy for ASEAN Drug Security and Self-Reliance (ADSSR) plan of action	Documentation on Implementation of ADSSR developed	2022-2025	1. The framework on regional collaborative strategy of ADSSR is endorsed and adopted by AHMM 2. A list medicines for pool procurement proposed by Malaysia SOMHD (2022)	BDPSF
				Development of ASEAN Leader Commitment on ADSSR (2023)	
				Plan of Action on ADSSR developed (2024)	
				Concept note on Plan of Action of ADSSR (2025)	

REFERENCE

REFERENCE

[1] Dr. Soccoro Escalante. 2019. Technical Meeting on Regional Collaborative Strategy for ADSSR

[2] Product Life Cycle Management in Life Sciences Industry. 2012. Deloitte Consulting AG.

[3] Clinical Research in Malaysia, CRC MOH Malaysia

[4] Pharmaceutical Supply Chain Mapping, MITI

[5] Management Sciences for Health. 2015:(29). Governance in Pharmaceutical Systems.

[6] USAID The Medicines, Technologies, and Pharmaceutical Services (MTAPS) Program

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