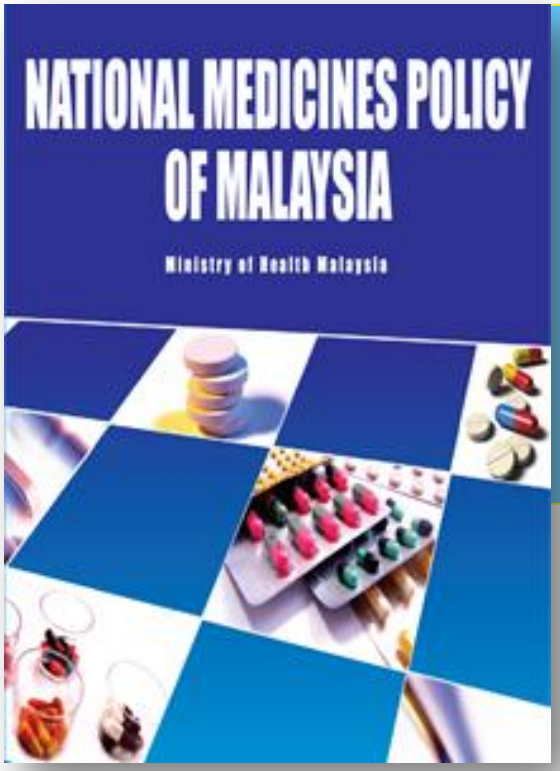

NATIONAL MEDICINES POLICY OF MALAYSIA (DUNas): 2nd Edition 2013

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OUTLINE

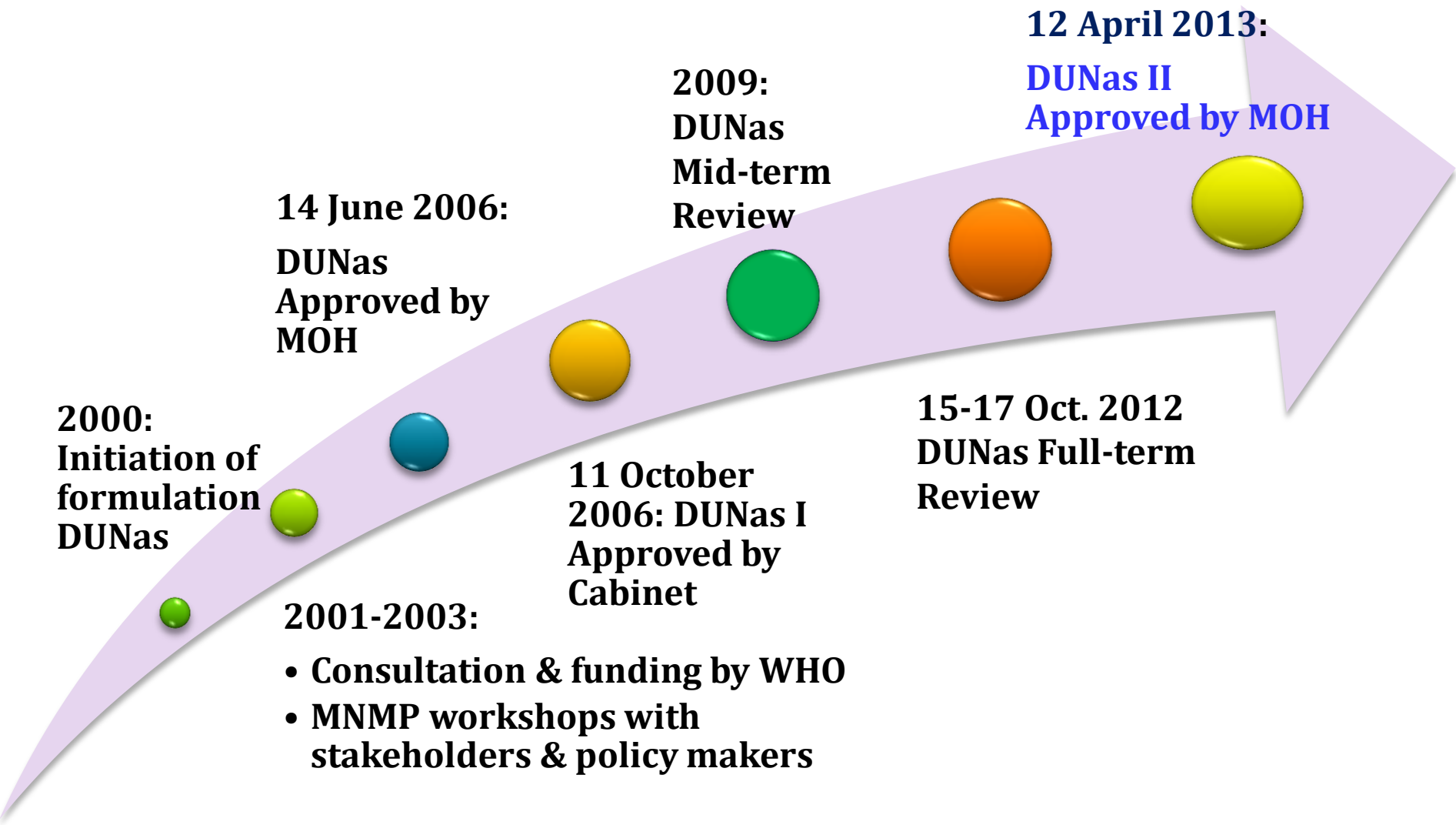
1. • Background of DUNas
2. • DUNas 2013: Strategies for Pharmacy Transformation
3. • Tasks Ahead

BACKGROUND OF DUNas

National Medicines Policy of Malaysia – DUNas

- A clear and official government statement that defines and prioritises the medium to long term-goals set by the government for the pharmaceutical sector
- A formal record of aspirations, aims, decisions and commitments of the government and all stakeholders in both public and private sectors to a common goal for the pharmaceutical sector
- Identifies strategies and provides a transparent framework for the coordinated implementation of these strategies by stakeholders in the public and private sectors
- Existing legislation can provide the executive power and legal framework to implement the DUNas
- Ministry of Health (MOH) to oversee, monitor and administer the legislation

Roadmap of DUNas



DUNas Full Term Review (Oct. 2012)

- To reflect achievements and outcomes attained from strategies implemented
- Serves as platform to obtain input and consensus from all stakeholders on new propositions and strategies
- The intitial objectives of *DUNAS* were maintained
- Introductions of new strategies and revision of current strategies to fulfill the current needs of the country.

DUNas Components

DUNas I (2006)

Core Components

- Quality, Safety and Efficacy of Drugs
- Drug Availability
- Drug Affordability
- Quality Use of Drugs

Supporitng Components

- Human Resource Development
- Research and Development
- Technical Co-operation
- Management of the National Medicines Policy

DUNas II (2013)

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

OBJECTIVES OF DUNas 2013

To improve health outcomes of Malaysians through:

- **Promoting equitable access to essential medicines**
- **Ensuring availability of safe, effective and affordable medicines of good quality**
- **Promoting quality use of medicines by healthcare providers and consumers**

DUNas 2013

Strategies For Pharmacy Transformation

POLICY 1

QUALITY, SAFETY & EFFICACY

Policy 1: Quality, Safety and Efficacy of Medicines

Only safe, efficacious and quality medicines that meet approved standards and specifications shall be registered and made available for sale and use by the consumers in Malaysia

Policy 1: Quality, Safety and Efficacy of Medicines

STRATEGIES

Legislation & Regulations

Strengthened to ensure appropriate practices in development, production, importation, supply, marketing, sale and management (including prescribing, dispensing, administration and disposal) of medicines

Level of regulation shall be consistent with potential benefits and risks to the community

- **National Pharmaceutical Control Bureau**
- **Regulating Premises that Supply Medicines**
- **Effective Enforcement**
- **Medicines Advertisement & Promotion**
- **Counterfeit Medicines**

Pharmaceutical Quality Assurance

- **Post Marketing Surveillance**
- **Management of Complaints about Medicines**

QUALITY, SAFETY & EFFICACY
Drug Control Authority

Responsible for Pharmaceutical Regulatory Control in Malaysia

- Licensing of manufacturers, importers and wholesalers
- Registration of medicines
- Quality control of medicines
- Good Laboratory Compliance
- Post Marketing Surveillance Activities
- Control of medicines used in clinical trials

- Collaborate with industry and other stakeholders to:-
  - strengthen regulatory framework & community engagement
  - ensure enhanced communication and effective use of medicines by the consumers.
- Play a prominent role in facilitating regional and international harmonisation of technical requirements of registration of medicines

QUALITY, SAFETY & EFFICACY

Regulating Premises that Supply Medicines

- **Only licensed manufacturers, importers and wholesalers shall handle registered medicines**
- **The sale, supply and dispensing of medicines shall be carried out at premises regulated according to the appropriate legislations.**

Effective Enforcement

- **Ensure all activities in the manufacture, import, supply or dispense medicines comply with legislations, regulations, guidelines and directives**
- **Premises involved in these activities shall be inspected regularly to ensure compliance to existing regulatory requirements.**

QUALITY, SAFETY & EFFICACY

Medicines Advertisement and Promotion

All relevant stakeholders shall comply with existing legislations, guidelines and relevant codes of ethics for advertising and promotion

Counterfeit Medicines

- **An appropriate legal and technical framework for concurrent enforcement of laws and regulations by MOH together with other relevant authorities for market surveillance shall be enhanced to manage and control the problem of counterfeit medicines**
- **Suitable security measures for authentication, traceability of counterfeit medicines and public education shall be implemented and enhanced.**

QUALITY, SAFETY & EFFICACY
Pharmaceutical Quality Assurance

Post Marketing Surveillance

- Continuous monitoring on products available in the market to ensure products conform to standards and requirements
- Necessary punitive action will be instituted on non-conforming products

Management of Complaints about Medicines

All complaints pertaining to medicines shall be investigated and appropriate action shall be taken in a timely manner

POLICY 2

ACCESS TO MEDICINES

Policy 2: Access to Medicines

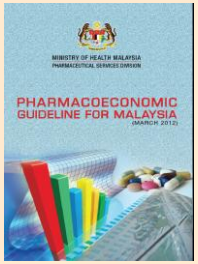
- **An efficient and integrated medicines management and supply network shall be maintained**
- **The pharmaceutical industry shall be organised and regulated to create incentives and foster competition in medicine prices**
- **Appropriate financing mechanisms shall be developed to ensure essential medicines needed for quality healthcare are affordable**

Policy 2: Access to Medicines

STRATEGIES

1. Availability of Medicines

- **Selection of Medicines**
- Transparent & based on quality, safety, efficacy, clinical effectiveness & cost effectiveness of treatment

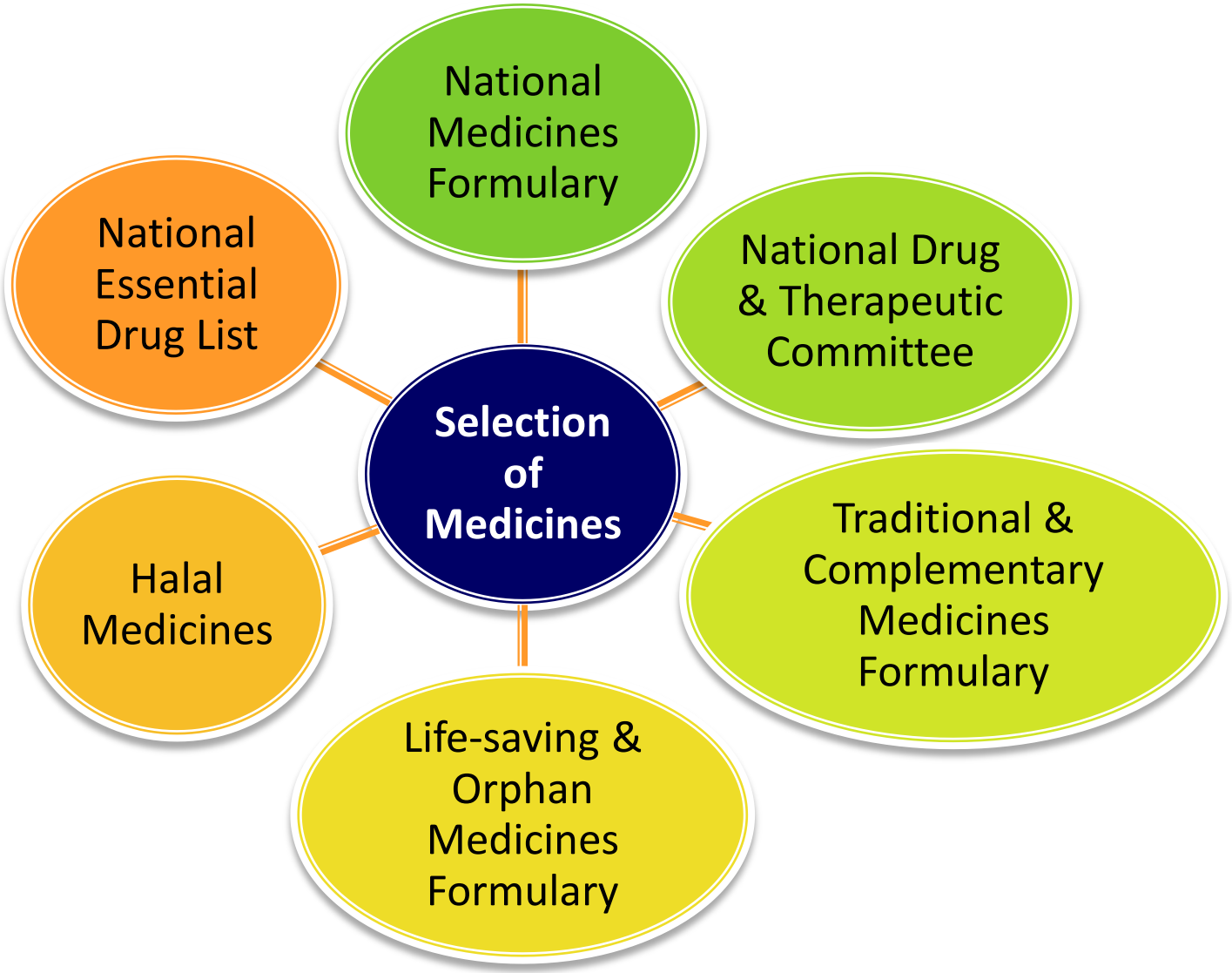


- **Supply of Medicines**
- Strengthen Medicines Supply Chain Network -TQM,GDP & ICT

2. Affordability of Medicines

- **National Pricing Reference for Malaysia**
  - Transparency on Price Information
  - Monitoring of Price Information
  - Tariffs and Duties
- **Financing of Medicines**
- **Generic Medicines Policy**

Policy 2: Access to Medicines
Strategy 1 – Availability of Medicines



Policy 2: Access to Medicines
Strategy 1 – Availability of Medicines

SELECTION OF MEDICINES

National Medicines Formulary

- National Essential Medicines List
- Developed by National Drug & Therapeutic Committee
- Standard reference for prescribing in Malaysia

Traditional & Complementary Medicines Formulary

- Shall be developed by an expert advisory committee under MOH
- Serves as a guide for use of registered TCM by health providers

Life-saving Medicines and Orphan Medicines

- To develop appropriate procedures for the accessibility of live-saving and orphan medicines without jeopardising elements of safety, quality & efficacy

National Essential Drug List

- National reference for domestic medicines industry for:
  - *Production, procurement, distribution & utilisation*
  - *Research*
  - *Teaching curriculum*

National Drug & Therapeutic Committee

- Under MOH & represented by all relevant stakeholders
- All local drug and therapeutic Committee shall be established and function based on the guidelines developed by MOH

Halal Medicines

Strategic partnerships with the relevant authorities to make certified halal medicines available in Malaysia

Policy 2: Access to Medicines
Strategy 1 – Availability of Medicines

Supply of Medicines

Procurement

- Strengthen efficient, effective and transparent procurement system to ensure adequate & timely availability of medicines

Distribution & Storage of Medicines

- Strengthen efficient & economical distribution network
- Storage, inventory control and quality assurance to comply to GDP
- Establish integrated ICT network for logistic, inventory and financial transaction in all health facilities

Medicines Supply in Emergency & Medicines Donations

- Collaboration and coordination of all organisations to manage national emergency situation
- WHO Guidelines on managing drug supplies in emergency situations and receiving donations

Disposal of Medicines

- Disposal of medicines to be in accordance with prevailing laws and regulations

Policy 2: Access to Medicines

Strategy 2 – Affordability of Medicines

Price of Drugs

- **National Pricing Reference**
  - Transparency on price information
  - Develop database
  - RRP for public
  - Compulsory itemised billing
  - Availability of patent info data
- **Monitoring price info**
- **Tariff and duties (exempted)**

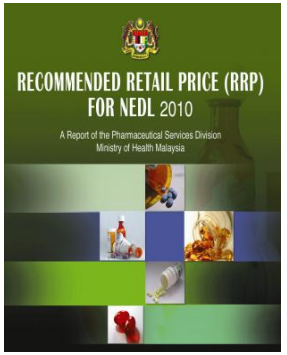
Generic Policies

Implemented to foster healthy competition in medicines pricing

- Shall be practiced at all channels.
- Procurement of all medicines by generic International Non-proprietary Name (INN) In selection of procurement, priority to domestically manufactured medicines.
- All dispensed medicines: labelled with the generic INN name
- A list of interchangeable and non-interchangeable (NI) medicines
- Generic substitution shall be permitted and legislated except for those in NI list
- Appropriate incentives to promote the use of generic medicines

Drug Financing

- Reliable & sustainable National Financing Mechanism
- To ensure the poor and underprivileged are not denied access to essential medicines



POLICY 3

QUALITY USE OF MEDICINES

Policy 3: Quality Use of Medicines

Quality use of medicines is the responsibility of all stakeholders.

Activities by the relevant stakeholders' in support of informed and appropriate use of medicines shall be encouraged and promoted.

Policy 3: Quality Use of Medicines

STRATEGIES
Development & Implementation of Models of Best Practice
Education & Training - Healthcare Providers, Consumers, Pharmaceutical Industry, Media
Provision of Timely & Accurate Information on Medicines - Healthcare Providers, Consumers, Pharmaceutical Industry, Media
Strengthening Seamless Care Between Healthcare Providers
Research & Development in Quality Use of Medicines
Engagement of Payers involved in Reimbursements for Medicines Use

Policy 3: Quality Use of Medicine

Quality Use of Medicines

Models of best practice

- Prescribing & dispensing medicines accordance to CPGs, STGs, Good Dispensing Practice, others (relevant)
- Guidelines made available
- Review & updating guidelines
- Audit, monitoring & surveillance activities (compliance to guidelines)

Education & Training

• ***Health Provider***: curricula of education & training
• ***Consumers:*** Health literacy & consumer empowerment
•***Pharmaceutical industries & Media***: Training in QUM

Strengthen Seamless Care Between Healthcare Providers

•Development of comprehensive information & ICT
•Access to adequate Patient Medical Records
•Smart partnership & collaboration

Timely & Accurate Information on Medicines

• ***Health Provider***: Evidence-based info made available
• ***Consumers***: Access to accurate info
• ***Pharmaceutical industries***: Balance & responsible promotion, packaging & PILs, ethical advertising
• ***Media***: Accurate & responsible reporting on medicines, timely response in misinformation cases

R&D in QUM

Conducting studies to evaluate effectiveness of QUM programs

Engagement of Payers – involves in Reimbursements for Medicines Use

Responsibility of payers: support & engage in QUM activities

QUM ACTIVITIES

On going QUM activities in Malaysia

www.knowyourmedicines.gov.my

QUALITY USE OF MEDICINES
R&D in QUMC Programmes

Research in QUM Activities:

National Study on Use of Medicines by Consumers in 2012 done by PSD, MOH in collaboration with USM :

- 56.5% understand the proper use of their medicines (2008 - 44.4%)
- 49.7% unable to differentiate brand/generic name of their medicines (2008 – 65.7%)
- 64% were aware on their medicine's side effects (2008 – 61%)
- 67% agreed that medicine counselling sessions with pharmacists were necessary in order to understand and overcome problems.

POLICY 4

PARTNERSHIP & COLLABORATION FOR THE HEALTHCARE INDUSTRY

Policy 4: Partnership & Collaboration for the Healthcare Industry

Partnerships and collaboration in the implementation and strengthening of relevant areas in the healthcare industry shall be established with various stakeholders at the national, regional and international levels

Policy 4: Partnership & Collaboration for the Healthcare Industry

STRATEGIES

To achieve aim by:

- **Early and continuous engagement of all relevant stakeholders.**
- **Ensuring sustainability of qualified, competent and effective human resource based on needs through:**
  - Training and development
  - Development and advancement of professional career pathway
- **Sharing of information, expertise, skills and facilities.**
- **Developing a viable domestic and maintaining a responsible medicines industry.**

Human Resource Development

Research & Development

Technical Collaboration & Partnership

A Viable & Responsible Pharmaceutical Industry

- Domestic Medicines Manufacturing

Policy 4: Partnership & Collaboration for the Healthcare Industry

Partnership & Collaboration

Human Resource Development

- Development, review & enforcement on quality assurance mechanism (comply with policies & standards)
- Training providers
- Training programs for health providers & relevant stakeholders
- Career pathway

Viable & Responsible Pharmaceutical Industry

- Co-ordination of policies (industry & health)
- Intellectual property: in-line with international standards
- Harmonization of medicines manufacturing standards
- Suitable supports & incentives
- Domestic Manufacturing: cost-effectives medicines, production in sufficient quantities, incentives, export local produced medicines

Technical Collaboration & Partnership

- Technical collaboration and partnership: areas in regulatory practices, training and human resource, medicines accessibility, quality use, R&D.
- Effective networking: provide framework for exchange and sharing of information.
- Best practices & standards
- Partnerships, coordination & co-operation with relevant stakeholders

Research & Development

- Co-ordination between research institutions and the relevant Ministries
- Research in priority areas
- Innovative research: encouraged and incentivised.
- Transfer, acquisition and development of technology between foreign and local companies

POLICY 5

GOVERNANCE IN MEDICINES

Policy 5: Governance in Medicines

Good governance, practices, conduct and professionalism shall be emphasized within the healthcare industry towards promoting and facilitating optimal health outcomes

Policy 5: Governance in Medicines

STRATEGIES

- Health professional bodies and relevant stakeholders shall have codes of conducts and be responsible to ensure compliance by its members with the code.
- Stakeholders shall perform in accordance with the standard of practice developed by appropriate authorities/relevant professional bodies.
- Compliance with the standards shall be supported by legislation where appropriate.
- Relevant legislations / regulations shall be developed and / or reviewed to ensure an efficient supply chain network and integrated medicines management to safeguard the public.

Accountability, Transparency & Good Governance

WHO Good Governance for Medicines (GGM) - Implementation (Phase III) stage

Access to information

- Transparent data and information sharing on medicines in the health sector
  - Medicine prices, drug registration status, all transactions and decisions of committees on medicines

Managing Conflicts of Interest

- Clear criteria in the selection and appointment of members to decision-making committees-
  - *DCA, Panel Review of MOH Formulary, Expert Committees, Procurement Technical Committee, Tender Board*
- Policy of transparency through declaration of relations with drug companies
- Guidelines on Receiving Gifts
- Guidelines on Managing with Sales Representative

Accountability, Transparency & Good Governance

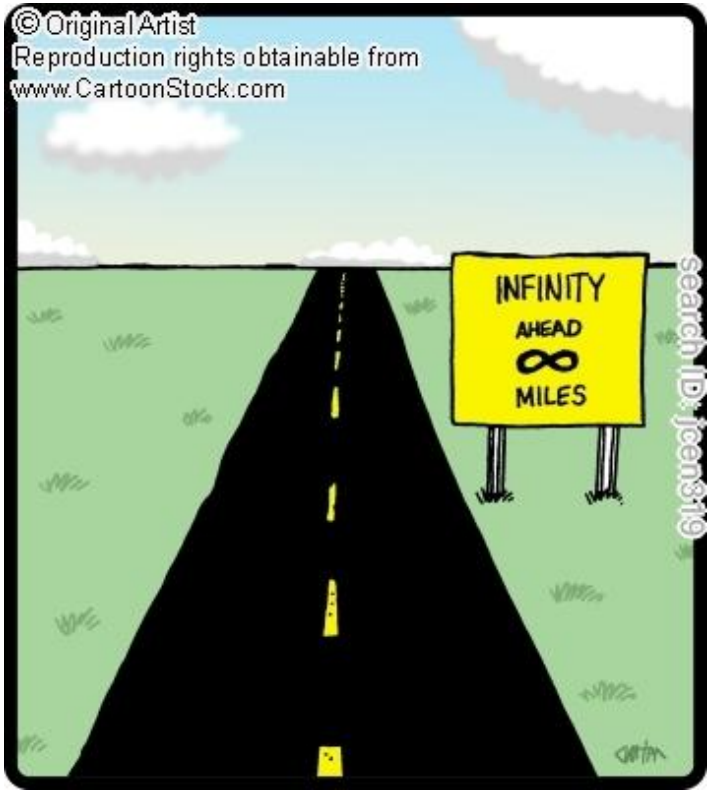
Efficient, transparent & accountable processes

- Improved protocols for licensing and inspection of drug establishments, selection, procurement, distribution, conduct of clinical trials and control of medicines promotions
- Compliance of industry and other stakeholders to regulatory/ethical standards

Standards of Good Governance

- Malaysian Guideline on GGM
- Rewards and incentives system for GGM
- Performance audit of health facilities, industry with regard to GGM and efforts to improve access to medicines

TASKS AHEAD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INFINITY
AHEAD
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MILES
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- New Pharmacy Bill
- Transparency & mechanism to regulate Medicines Price
- Halal Hub – explore OIC market
- Benchmarking & Accreditation
- Liberalization & Harmonization

TASKS AHEAD

- **Continuous Engagement &Partnership With All Stakeholders During Planning And Implementation Process**
  - ***Foster ownership, commitment and responsibility for the actions***
- **Getting Political Master Support**

THANK YOU

BETTER HEALTHCARE FOR OUR FUTURE GENERATION