A STUDY ON MALAYSIAN NATIONAL MEDICINES POLICY

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INTRODUCTION

- Malaysian National Medicines Policy (MNMP) was endorsed in 2006 following a consultative process involving numerous stakeholders. MNMP has been implemented through a systematic consultation process and has been subjected to consistent review and monitoring.

- MNMP was responsible to improve people's health outcomes by increasing equitable access to and rational use of high-quality essential drugs. (DUNas 2007; DUNas 2012)

- A clear and official government statement that **defines and prioritizes 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.

INTRODUCTION

WHY WE NEED NATIONAL MEDICINES POLICY?

- Like many other countries in the world, the pharmaceutical sector is in undated with many players and therefore all the stakeholders need to come under one unifying framework.

- The experience of other countries has shown that complicated and interdependent problems are best addressed within a common framework.

- NMP defines a framework for setting and monitoring medium to long term objectives in the public and private pharmaceutical sectors – common framework to solve problems in pharmaceuticals. (WHO 2001)

LITERATURE REVIEW

MALAYSIA NATIONAL MEDICINES POLICY

◦ A national medicines policy is a comprehensive framework that identifies and clarifies medicines issues. It establishes standards for the pharmaceutical industry's critical sectors, including the public and private sectors (Almarsdóttir et al., 2019).

◦ The medicines policy establishes goals for the government and all healthcare sectors, including the pharmaceutical industry, and identifies broad and specific strategies for achieving those goals (Hoebert JM et al., 2019).

◦ Monitoring and evaluation are part of national medicines policy – important elements that should be set up in order to determine the country's capacity to implement the various elements in the policies or measure the policy progress. (Brudon P. et al. 1999)

LITERATURE REVIEW

MALAYSIA NATIONAL MEDICINES POLICY

◦ DUNas have been in effect for 16 years, during which time our country has seen significant changes in politics, the economy, social issues, and technology, in addition to legislative changes. Hence, it is necessary to review the National Medicines Policy to ensure that the rationale for its development remains relevant. As a result, it is deemed timely and appropriate to conduct research to identify methods for documenting MNMP's performance.

◦ Based on the review done, (quote org lain) there are limited number of studies relating to MNMP, most notably on the implementation or assessment of MNMP in its entirety.

LITERATURE REVIEW

LEVELS OF KNOWLEDGE AND AWARENESS OF POLICYMAKERS ON NMP GOALS & CONCEPTS

- Involving researchers in the policy process and policymaking in the conceptualisation and conduct of research has been advocated as the best solution in reducing the gap in policy formulation (Black, 2001). This also allows for an integrated policy process, where agenda setting, policy formulation, implementation and feedback are closely related.

- To put this into practice, it is important to know about the decision-makers' awareness of the policy and their attitudes about the use of the research evidence and communicated research findings to implement the policy (Hanney et al., 2003).

- Little is known about the correlation between knowledge and awareness and policy formulation by decision-makers, especially in the context of MNMP. Thus, it is necessary to determine policymakers' level of understanding as so that a good national plan can be developed.

RATIONAL OF STUDY

◦ It has been 16 years since the endorsement of MNMP in 2006. This study is one of the first documented study done on the overall performance of MNMP since its inception. Although various aspects of the MNMP implementation have been discussed formally through meeting, subcommittee meetings, proceedings and reports but still there is no such study has been attempted to date.

RESEARCH QUESTIONS & RESEARCH OBJECTIVES

NO.	RESEARCH QUESTIONS	RESEARCH OBJECTIVES (RO)
1.	What are the historical development of Malaysia National Medicines Policy and and how have they changed over time?	To provide an overview of the historical development of Malaysia National Medicine Policy **(Phase 1)**
2.	What are the challenges in implementing the NMP NMP and recommendations for further improvement?	To identify challenges in implementing the NMP and provide recommendations for further improvement. **(Phase 2)**
3.	What are the level of knowledge and awareness of pharmacy managers on the objectives and concepts of the National Medicines Policy of the Malaysia?	To determine the degree of knowledge and awareness of pharmacy managers on the Malaysia National Medicines Policy and the general status of pharmaceutical sector. **(Phase 3)**

METHODOLOGY

RO1 : To identify strengths and weaknesses of the Malaysia's pharmaceutical policy formation and implementation based on the status of NMP's key components.
(Phase 1)

❑ **STUDY DESIGN:**
- Descriptive and explanatory study design

❑ **DATA COLLECTION TOOLS**
- The sets of indicators in the **"Indicators for Monitoring National Drug Policies: A Practical Manual" (Brudon P et al, 1999)** will be used as the data collection format for this study.
- The indicators serve **2 purposes in this research:**
  - assessment of the implementation of NMP by measuring progress in key components **(structural & process indicators)**
  - Evaluation of the outcomes of NMP **(outcome indicators)**

❑DATA COLLECTION TOOLS

This sets of questionnaires contains 4 categories of drug policy indicators:

a) **Background information**

b) **Structural Indicators**
   - qualitative info to assess the pharmaceutical system's capacity to achieve policy objectives.

c) **Process Indicators**
   - quantitative info on the process by which a NMP is implemented. To assess the degree to which activities are being effectively implemented & the progress over time.

d) **Outcome Indicators**
   - quantitative info on the process by which a NMP is implemented. To assess the degree to which activities are being effectively implemented & the progress over time.

At this point of time, these data are readily available at the central level.

Table 1: WHO standardized NDP indicators

Background information
Population data
Economic data
Health status data
Health system data
Human resources
Drug sector organization

Structural and process indicators (quantitative and qualitative)
Legislation and regulation
Essential drugs selection and drug registration
Drug allocation in the health budget/public sector financing policy
Public sector procurement procedures
Public sector distribution and logistics
Pricing policy
Information and continuing education on drug use

Outcome indicators
Availability of essential drugs
Accessibility of essential drugs
Quality of drugs
Rational use of drugs

Reference: Brudon–Jakobowicz P, Rainhorn JD, Reich MR: *Indicators for monitoring national drug policies, a practical manual 2ⁿᵈ ed.* Geneva: World Health Organization; 1999.

❑ DATA ANALYSIS

○ No statistical method will be used to evaluate the data collected for the **Background Indicator**. Each data will be analysed relative to the previous year's trend, established theories, and/or comparison to the other findings of related studies.

○ Descriptive statistics will be used to describe the status of existence of the structural elements of NMP in Malaysia.

○ As the indicators are answered in the 'Yes' or 'No' format (based on the availability of data), negative response 'No' would suggest improvements needed to make significant progress towards achieving the overall policy objectives (Brudon et. al., 1999)

METHODOLOGY

○ **RO2 : To determine the level of knowledge and awareness of pharmacy managers on the Malaysian National Medicines Policy and the general status of pharmaceutical sector. (Phase 2)**

❑ **STUDY DESIGN:**
  ○ Cross-sectional study design
  ○ Respondents will be selected based on the criteria defined – "Pharmacy Managers":
    ➢ All the pharmacists attended the Malaysian National Medicines Policy Review Workshop.
    ➢ All Deputy Directors in the Pharmaceutical Services Programme and Sectional Head
    ➢ All States Deputy Director of Health (Pharmacy) and State Sectional Head
    ➢ Sectoral Head / Head of Pharmacy Department of the National Institute.

❏ DATA COLLECTION TOOLS

◦ Questionnaire - Adopt and adapt the WHO Structural Indicators as a survey questions and existing information of Malaysian National Medicines Policy.

◦ Pilot study suggested to be done to test on the reliability of the survey questionnaire.

◦ Questionnaire consists of 2 parts:

➢ General background information & characteristics of the respondents

➢ Assessment of understanding on the country's pharmaceutical sector (based on structural & process indicators and current Malaysian NMP).

◦ For the purpose to assess respondents' level of awareness, they need to answer either "Yes", "No" or "Not sure" based on their understanding of the situation.

❑ **DATA ANALYSIS**

◦ Descriptive and inferential statistics will be used to analyses data obtained in this study – to describe the characteristics of the respondents and level of understanding on Malaysian NMP.

◦ Non-parametric test for categorical variables – Chi-Square Test (X^2)

◦ Probability will be used to identify the significance of the difference between observed level of awareness of each group of pharmacy managers.

GANTT CHART

2023	Jan	Feb	March	Apr	May	June	July	Aug	Sept	Oct	Nov	Dec
Introduction	■	■	■									
Literature Review	■	■	■									
Methodology	■	■	■									
Data Collection - Phase 1			■									
Data Analysis - Phase 1			■									
Questionnaire development – Phase 2				■								
Pilot Study - Phase 2					■							
Discussion and Conclusion						■	■	■				

SIGNIFICANCE OF STUDY

○ This study will shed light on the current state of Malaysia's pharmaceutical sector in light of the country's National Medicines Policy. This data may aid policymakers in determining the specific strengths and weaknesses of existing policies.

○ Demonstrate the breadth of knowledge about the national pharmaceutical situation and its future directions among pharmacy managers at various levels in the public sector. This effort may improve the quality of policy formulation and the pharmaceutical sector's efficiency.

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