**CURRENT SITUATION: WHERE DO THINGS STAND NOW?**

**BACKGROUND**

The Malaysian National Medicines Policy (MNMP) was approved in 2006 after a consultation process involving many stakeholders from the public and private sectors. It has been implemented through a systematic consultation process and has been subject to continuous review and monitoring. The MNMP aims to improve people's health by increasing equitable access to and rational use of quality essential medicines. The policy represents a clear and official government statement that defines and prioritises the government's medium to long-term goals for the pharmaceutical sector. It serves as a formal record of the aspirations, goals, decisions and commitments of the government and all stakeholders in the public and private sectors towards a common goal for the pharmaceutical sector.

The MNMP is an important framework to ensure that all Malaysians have access to safe, effective and affordable medicines. However, as the healthcare landscape is constantly evolving, the policy needs to be regularly reviewed and updated to ensure that it remains relevant and responsive to new health needs, regulatory changes and technological advances. The Pharmaceutical Services Programme had implementing MNMP 2017-2021 plan which expires in 2021. The plan was based on a medicines strategy formulated back in 2012. In the past two years, the pandemic has driven unprecedented impact to the nations especially to the pharmaceutical supply chain.

Conducting a situation analysis before revising the national pharmaceutical policy is important for several reasons:

* **To understand the current pharmaceutical situation in the health system**

A situational analysis helps to understand the country's health system, including infrastructure, health financing, health delivery mechanisms and health workforce. This understanding is crucial to ensure that the national pharmaceutical policy is in line with the overall health system and to identify any gaps or challenges.

* **Evaluation of current medicines policy**

Through proper analysis, we can identify gaps, challenges and limitations in current national medicines policy. By analysing current achievement in all the components of policy such as ‘Governance in Medicines’, ‘Quality, Safety and Efficacy of Medicines’, ‘Access to Medicines’, ‘Quality Use of Medicines’ and ‘Partnership and Collaboration for the Healthcare Industry’, it can support the process of revising or updating the national medicines policy.

* **Policy and action development**

Situation analysis is critical for developing effective strategies and action plans. The analysis helps identify areas where action is needed and what that action should look like.

Overall, a situation analysis is an important tool to support the revision or development of a national pharmaceutical policy. By providing an overview of the health system, health needs and the effectiveness of current policies, a situation analysis can help to address gaps in our current system and identify opportunities to improve overall health outcomes.

Referring to the review processes, in order

to ensure a comprehensive and meaningful review process of Malaysia's National Medicines Policy (NMP), it is important to take into account some important considerations such as:

* The review process **should be inclusive and involve stakeholders from across the health system,** including government agencies, healthcare providers, patient groups and the pharmaceutical industry. This helps to ensure that the review takes into account the different needs and perspectives of all stakeholders, leading to more effective and relevant policies.
* The review process **should be evidence-based,** i.e. it should draw on the latest research and data to make policy recommendations. When policy recommendations are based on sound science and best practise, the resulting policy is likely to be more effective and efficient.
* The review process **should be transparent, with clear communication and stakeholder involvement throughout the process**. This helps to build trust in the policy among stakeholders and the public.
* The review process **should include a thorough analysis of the current policy, including an assessment of its strengths and weaknesses and identification of areas where the policy could be improved**. By conducting a thorough analysis, the review can provide a more comprehensive understanding of the current policy landscape, leading to more effective policy recommendations
* The review should **consider the feasibility of policy recommendations**, including their cost-effectiveness, political feasibility and practicability. This helps to ensure that the resulting policy recommendations are actionable and can be implemented in the real world.

**GAP IN PERFORMANCE**

In these 15 years, our country has undergone significant changes politically, economically, socially, technologically and also legally. The health system and people's expectations of health services have also changed, in terms of the development of the health system and health-related information, the advancement of pharmaceutical technology such as biosimilars, biologics and precision medicine, the development of digital technology and also the pharmaceutical industry.

This picture shows the overall situation of the pharmaceutical ecosystem in Malaysia. Pharmaceutical Services Division, Ministry of Health Malaysia, manages the pharmaceuticals in Malaysia as early from the clinical research to consumer use.

**MALAYSIA PHARMACEUTICAL ECOSYSTEM**

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Based on our earlier analysis and the overall situation of the pharmaceutical ecosystem in Malaysia, there are few important focus points that need to be included to address the gaps, such as:

1. **Expansion of scope for Governance in Medicines**
   * Current scope – Law and Regulations Perspectives, Ethical Conduct.
   * Propose scope –to include elements of improvements in the selected guidelines.
2. **Expansion of scope for ‘Partnership & Collaboration for the Healthcare Industry’**

* Clear direction and explanation for ‘technical partnership / collaboration’

1. **Include human resource development (HRD) as one of the priority areas.**

* Not as priority pillar in DUNas 2nd term and 3rd term DUNas

1. **Clear governance and oversight structure for implementation of DUNas**
   * Roles of each divisions in the Pharmaceutical Services Programme in implementing DUNas.
   * Training of ‘process expert’ in each of the divisions
2. **Active Involvement from Private Sector and Industry Player**

Most initiatives in the DUNas focused on the government, but as we want to further improve our pharmaceutical sector, the private sector should be involved holistically to overcome and propose better initiatives for the rakyat.

Other than that, movement restrictions due to pandemic COVID-19 in 2021 until early 2022 make it difficult for us to organise a workshop to review the National Medicines Policy. Given the limited time and resources, the option to hold the workshop on a limited capacity may have an impact on the desired outcome of the workshop. As I have already shared, for a holistic and comprehensive input, it is very important that more stakeholders participate.

1. **Limited Capacity**

Limited number of participants that allowed during the *Fasa Peralihan Pandemik* in 2022 which is only 20 to 30 pax per session, make it difficult to plan for a holistic engagement.

1. **Limited Time and Resources**

More engagement sessions need to be held to ensure that all stakeholders have been included. A series of focus group discussions on a small-scale is one of the challenges since it involves the use of additional resources (budget allocation) and limited timeframe to complete the review process.