

Key points DUNas Mesyuarat Teknikal 2025 – Component 3 : Access to Medicines (7.2.25)

1. Chairwoman's Address

The Chairwoman, Pn Wan Noraimi, expressed her gratitude for the commitment of all stakeholders in supporting DUNas, particularly in the third component: Access to Medicines. DUNas continues to serve as a platform for ongoing communication to foster collaboration among multiple stakeholders. This meeting aims to review the implementation status of initiatives to ensure alignment with the country's healthcare needs and direction.

2. Meeting Minutes Feedback/ Maklum balas minit mesyuarat

a. Akses Kepada Ubat-Ubatan Malaysia Tahun 2022

- i. BAPF provided input to conduct a survey covering medications listed in the NEML. The survey will be conducted in both private and public healthcare facilities.
- ii. BAPF will assess the need for medications to be included in concession or central contracts to ensure their availability in KKM facilities.
- iii. BAPF is conducting another survey, *Kajian Pemantauan Harga Ubat (KPHU)*, which involves a basket of essential medicines from WHO and Health Action International, SDG baskets, and Single Product Registration Holders. Data collection will continue until mid-2025.

b. Healthy Competition

- i. MOPI: Local companies face challenges due to margin compression and the low pricing offered by innovator companies, which hinder their competitiveness.
- ii. MAPS: Price should not be the sole criterion for tenders. Other important factors include fulfillment capability, medicine quality, and stock availability.
- iii. PHAMA: Disagreed with MOPI's statement. PHAMA emphasized value-based medicines, focusing on patient outcomes rather than price competition, aligning with the direction of MNCs.
- iv. BPF: Acknowledged the margin compression issue raised by MOPI and the low pricing offered by innovator companies, which impact local companies' competitiveness. BPF encouraged MOPI to prepare relevant data for discussion with KKM.

- v. KKM's View: Price competition is unavoidable in an open tender approach. However, safety, efficacy, and quality remain the primary considerations. KKM prioritizes a comprehensive review from all aspects, not just price.
- c. Supply Contract to 2 Suppliers
 - i. MAPS: Suggested that KKM share more information, such as medication usage in KKM facilities, as many suppliers struggle to commit due to a lack of transparency in required quantities.
 - ii. PHAMA: Requested stakeholder engagement to clarify details, including the list of medicines, impact on patient outcomes, drug non-interchangeability, and fairness in the selection process.
 - iii. BPF:
 1. PHAMA may submit a formal request to BPPS for stakeholder engagement.
 2. The list of medicines follows the NEML.
 3. The primary objective is to ensure medication access for the population and reduce dependency on a single supplier.
 4. The policy was implemented at the end of 2024. Currently, one medication has been offered to two suppliers, while others are still pending approval from MOF.
 5. If two suppliers offer the same price, KKM will allocate distribution equally (50:50) , distribution by states.
 6. If two suppliers offer different prices, KKM will evaluate the products, and MOF will determine the distribution ratio. KKM/MOF may also renegotiate with suppliers to lower prices.
 7. For unregistered products, suppliers can contact NPRA for fast-track registration.
 - d. Mekanisme Penandaan Harga Ubat
 - i. Public Response: 74% of respondents supported the policy.
 - ii. MAPS: Raised concerns about patients' knowledge gaps in making informed decisions about medications.
 - iii. MOPI: Had no objection to displaying prices at the point of purchase but disagreed with displaying prices for B2B transactions.
 - iv. PHAMA: Emphasized that the mechanism should be simple and convenient.
 - v. BPF:

1. The policy has been approved by the Cabinet. It is expected to be gazetted in February 2025, with enforcement beginning after a three-month grace period.
 2. A stakeholder engagement session is scheduled for 27 February 2025 to provide briefings on the format, FAQs, and guidelines.
 3. All providers must display selling prices in physical or digital formats, such as printed labels, catalogs, whiteboards, TVs, PCs, or websites.
 4. The price display must include the generic name, brand name (without indication), price per unit, and price per package.
- e. Pembaharuan Tender Ubat sebagai Indikator DUNas
- i. Ratification of the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) has impacted the BAPF tender process.
 - ii. PHAMA: Disagreed with the inclusion of a second supplier for single-molecule medications, as it complicates the supply chain. Suggested a holistic approach to address drug shortages.
 - iii. BPF:
 - iv. The tender process takes approximately 6–11 months, depending on the product.
 - v. To ensure sufficient supply, BAPF has started the specification preparation process earlier.
 - vi. Appointing two suppliers is part of KKM’s reform agenda.

3. Pembentangan Pencapaian Pelan Tindakan Induk (PTI) DUNas Penggal Keempat bagi Komponen Akses kepada Ubat-ubatan

1.1 Enhancing the National Essential Medicines List (NEML) based on the country’s current need	The 7th NEML was endorsed and approved in December 2024.
1.2 Ensuring the availability of medicines listed under NEML by encouraging Product registration without compromising the elements of quality, safety and efficacy (QSE)	Number of unregistered medicines under NEML that have been granted priority review NCE: 1, Biologics: 0, Generic: 1 Number of unregistered medicines under NEML registered NCE: 4, Biologics: 0, Generic: 1
1.3 Developing guidelines on	Desk review findings highlighted several

<p>medicines that caters to consumer/ population needs & requirements where appropriate, i.e. religious considerations.</p>	<p>challenges, including limited alternatives, variations in religious interpretations, and ethical dilemmas.</p> <p>Recommendations</p> <ul style="list-style-type: none"> • Concerns related to religion, culture, and intolerance should be handled separately. • Healthcare professionals (HCPs) and patients should refer to NPRA for details regarding animal derived ingredients in medicines.
<p>1.4 Strengthening the use of local Pharmacoeconomics (PE) data in the selection of medicines</p>	<p>Surveys have been completed, and data analysis is in progress.</p>
<p>1.5 Developing MOH Traditional & Complementary Medicines (T&CM) Formulary</p>	<p>The draft formulary will be revised based on the latest feedback from the PHIS team and presented to higher management by Q2 2025.</p>
<p>2.1 Developing comprehensive National Medicines Stock Management System</p>	<p>Unified Public Consultation is scheduled in Q1 2025.</p> <p>A sub-module for drug shortage reporting will be developed in QUEST5.</p>
<p>2.2 Strengthening the procurement process for private and government Partnership through pooled procurement.</p>	<p>March 2024: The TKSUK initiative has been postponed until BPF can ensure that MOH and patients will benefit from this policy.</p> <p>March 2024: KPK has been informed of the decision to withhold this initiative. Currently, the initiative is on hold until further instructions from higher management.</p>
<p>2.3 Ensuring Continuous availability & self- sustainability of raw material of medicines under the NEML list</p>	<p>Discussions have been conducted with MOPI.</p>

3.1 Enhance mechanisms to Improve accessibility and affordability of medicines	The <i>Guideline on Medicines Access Schemes</i> has been revised and published. An evaluation of the economic impact will be conducted in 2025.
3.2 Developing medicines fees and Reimbursement framework	Involved in revision of reimbursements fees for medicines under Skim Perubatan Madani.
4.1 Initiating Medicines Price Transparency Mechanism 4.2 Engagement with all stakeholder involved in the pricing mechanism on the implementation of Medicine Price Transparency Mechanism 4.3 Monitoring the impact of Medicines Price Transparency Mechanism	Updates per above.
5.1 Development of the National Generic Medicines Framework	KPK and TKSU(K) have agreed with the proposed framework.
5.2 Generic Medicine Awareness Programme (GMAP)	Conducted stakeholder engagement.

Overall, achieved 10 out of 12 indicators.

4. Hal-hal lain

- a. MCPG proposed the establishment of a nationwide reporting platform for medicine shortages, similar to the system in Australia.
 - i. NPRA: NPRA is currently developing the framework and upgrading QUEST5. In the interim, they will begin with a Google Sheet for data collection.
 - ii. APHM: Private hospitals have experienced increased medication costs when sourcing certain medicines from local suppliers, compared to importing unregistered medicines via import permits. For shortage reporting, the government should have ready solutions—such as allowing alternative imports—to prevent panic hoarding.
 - iii. BPF: BPF encourages more suppliers to register medicines to enhance competition and reduce prices. It is understood that low volume can drive up prices. However, under existing regulations, providers are not

allowed to import unregistered products once a locally registered alternative is available.

- b. MCPG mentioned that not all medications pricing is listed in MYPRIME.
 - i. BPF: The MYPRIME portal is based on voluntary price declarations by suppliers and is not mandatory.

- c. PHAMA requested early notice regarding the implementation of pharmacoeconomic studies.
 - i. BPF will develop a plan and conduct stakeholder engagements on this matter.

- d. MAPS requested KKM to release historical sales and usage data from KKM facilities to assist in the tender process.
 - i. BPF: Suppliers may refer to external sources such as IQVIA or bumi agents for such data.

- e. PHAMA raised concerns that insurance companies have recently instructed private hospitals to prioritize generic medicines. This may discourage innovator companies from launching new products in Malaysia due to the smaller market size.
 - i. APHM: Insurance companies have formally communicated this request to all private hospitals, and hospitals are feeling pressured to comply.
 - ii. BPF: Since this involves multiple stakeholders, it falls outside the purview of this committee/BPF and requires engagement with other parties such as insurance companies and Bank Negara. KKM has also initiated several measures to address rising healthcare costs.