POLICY BRIEF

ON BUILDING HEALTHCARE RESILIENCE IN INDONESIA

A collaboration with healthcare stakeholders for Indonesia healthcare transformation journey-to strike a balance between domestic resilience, innovation and quality healthcare for better patient outcomes.

InaHEA
INDONESIAN HEALTH ECONOMICS ASSOCIATION

IKATAN EKONOM KESEHATAN INDONESIA

APACMed
The voice of MedTech

GLOSSARY OF TERM

TKDN (*Tingkat Komponen Dalam Negeri*)
Domestic Component Level, is a local content regulation to encourage domestic industries in increasing and diversifying various economic goods needed by both the government and private sectors.

KFA (*Kamus Farmasi dan Alat Kesehatan*)
The Pharmaceutical and Medical Device Dictionary, a dictionary containing unique codes for pharmaceutical and medical devices to be integrated into all relevant systems and used by health industry players.

Health System Resilience
Health system resilience is the ability of health systems not only to prepare for shocks, but also to minimise the negative consequences of such disruptions, recover as quickly as possible, and adapt by learning lessons from the experience to become better performing and more prepared.

AKD (*Alat Kesehatan Dalam Negeri*)
Local Medical Device, is a marketing authorization number of local medical device.

AKL (*Alat Kesehatan Luar Negeri*)
Imported Medical Device, is a marketing authorization number of imported medical device.

Adaptive HTA (Health Technology Assessment)
A pragmatic tool to rapidly scale up evidence informed decisions and help make the health benefit package more financially sustainable.

Value assessment framework
They are designed to measure and communicate the value of health technologies to inform healthcare decision making. Examining their development and characteristics, such as constituent value attributes (also known as value elements, criteria, or domains), scoring methods, and target users, can provide insight into understanding the impacts and influence of value assessment for health technology decision making.

Levels of care for – *Rumah Sakit Madya, Rumah Sakit Utama, dan Rumah Sakit Paripurna*
Levels of Care that are determined based on Indonesian Accreditation Assessment System.

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1. BACKGROUND

1.1 Based on the commitments of Indonesia's presidency at the G20 on "Strengthening the global health infrastructure", we endeavor to work together in this path of building resilience to promote balanced recovery for the region.

1.2 Through Indonesia's healthcare transformation roadmap 2030, the ambition of setting world-class centers of excellence for improving access & quality of care across the primary, secondary & tertiary hospitals in Indonesia are drawn and would require a strong partnership across the relevant stakeholders.

1.3 As part of this improvement, policymakers are seeking avenues for strengthening the medical device supply chain, building the capacity of the local health systems and healthcare manufacturing base and bolstering both the healthcare workforce and broader jobs case. Shortage of high medical devices in covid-19 era indicated the need of stable supply and well-managed medical device governance.

1.4 Implementation of industrial policy such as TKDN regulation[23] (indicating 45% as local) should be carefully planned to keep in mind types, quality and efficacy of locally available products to ensure continuity of health services.

1.5 The efforts of the Government of Indonesia for an inclusive & transparent healthcare market that invites the latest innovation to ensure the highest quality of care for its population is potentially supported through several approaches as proposed below.

2. FRAMEWORK FOR PRIORITIZATION AS PART OF STRENGTHENING MEDICAL DEVICE RESILIENCE

2.1 Issues

2.1.1 Currently, technologies with large value and volume are prioritized to enter a domestic production by considering the availability of raw materials in Indonesia.

2.1.2 In terms of the technology risks, low-and-medium risk technologies are currently developed locally but still lack of main reference to differentiate the specification of technologies and the mechanism to assess the quality standard.

2.1.3 Current freezing process does not account for whether these product categories have local alternatives of sufficient quantity and quality meeting patient needs. There is a need for a standardized process of quality assessment for all product categories.

2.1.4 Presented case studies (antibacterial surgical sutures and intravenous (IV) catheter) and the experts' opinions illustrated the impact of access restriction amid the clinical demands to improve the patients' quality of life. The use of high-

tech tools is an effort to reduce the risk of adverse events, especially in high- risk patient populations. The related adverse events put the cost increases to 3-4 times higher and the treatment becomes longer, resulting in an increase of overall workflow and maintenance costs. Access and continuity for innovative products should be prioritized for high-risk patients, as summarized below:

Case Study 1: Cancer- Majority of the Cancer patients in Indonesia (70%) access healthcare services in advanced stages of the disease (around stage 3 or 4). Higher technologies are needed to improve their quality of life at this stage of disease. Beside that, it is important to distribute quality services throughout the country which is also supported by comprehensive health education for the community to prevent cancer patients only come to healthcare services when they reach stage 3 and 4.

Case Study 2: Pediatric Patients- The medical devices needed for pediatric patients are different from those for the adults with specific requirements. Good quality and high level of technology is needed to meet the specific needs of this group of patients. The technological level of the device or implant has a direct impact on the lifetime of the device or implant. Even the use of devices that are of low- and medium-level of technology require the assistance of high technology.

Case Study 3: Post Surgical High-Risk Patients- Surgical site infections (SSIs) represent a substantial clinical and economic burden on patients and the healthcare system[1]. In Indonesia, SSI incidence from studies conducted in some hospitals ranged from 5.32–13.9% in the case of clean and clean-contaminated operations[2]. Numerous meta-analyses and international guidelines support that **Triclosan-Coated Sutures /** Antimicrobial triclosan sutures effectively reduces the risk for SSI[3,4,5,6,7,8,9,10,11,12,13,14]. Especially Patients with prolonged wound healing and high risk of Surgical Site Infection (e.g., older age, smoking, with comorbidities, diabetes, obesity)[15]. This evidence-supported medical technology innovation is aligned to the Indonesia government's efforts on healthcare resilience – optimizing healthcare resource utilization while providing quality healthcare to its citizens.

Case Study 4: Patients in hospital or at home care that needs IV Access/Fluid Therapy/IV Therapy- Patients in hospital or at home care that needs IV Access/Fluid Therapy/IV Therapy. CVC Catheters (Antimicrobial) can prevent bloodstream infections[16,17] and Peripheral IV Catheter with biomaterial cannula helps reducing the risk of peripheral IV therapy complications (such as phlebitis / thrombophlebitis)[18,19,20] with optimum indwelling time for IV Catheter that helps improve patient outcome and improves cost effectiveness for patients and hospitals. The use of biomaterial has reduced costs due to complications equivalent to a saving of USD 61, 200 per year with a prolonged indwelling time from 72 to 96 hours[21]. The use of antimicrobial catheters reduce cost by USD 196 per catheter by reducing microbial colonization[22].

2.2 Recommendations

2.2.1 **Balanced Approach to Localisation**: A more specific focus is needed in prioritizing medical equipment technology given the large variance. For example: focusing on high risk or low-risk technology. Differentiating between "low-tech" and "high-tech" products alongside patient demands for these products can lead to a more balanced approach to localization.

2.2.2 **Availability of local substitutes**: Consideration must be given to whether there is sufficient local capacity of appropriate quality to avoid gaps in supplies and ensure continuity of health services.

2.2.3 **Standardized Process of Quality Assessment**: Prior to obtaining the licenses in the form of AKD or AKL, each medical device should undergo a standardized process to ensure the quality meets the threshold. This process should be integrated with other medical devices registration process.

2.2.4 **Consultation and Collaboration**: Allowing a more frequent interactive discussion with the technology users (general practitioners, specialized clinicians, nurses, medical laboratory personnel, etc.) in both hospital, regional, and national level to mutually agreed on the prioritized technologies needed by vulnerable population as well as the eligibility criteria to utilize the high-risk technologies. The health stakeholders need to be supported as well to work as MDT (multidisciplinary teams) in order to achieve optimal results in medical services.

3. INSTRUMENTS & DATA PARAMETERS USED TO STRENGTHEN MEDICAL DEVICE RESILIENCE

3.1 Issues

3.1.1 On the product categories prioritized for substitution and TKDN regulation is enforced, 45% of total content must be local. However, the measurement/monitoring instrument from the government's perspective is still unclear.

3.1.2 TKDN should be applied with clearer detailed regulation and flexibility, as the primary should be on the focus on trying to do the best for patients, specifically to improve clinical outcomes.

3.1.3 Import substitution Decree (HK 01.07/Menkes/1258/2022)[24]: In line with President's instruction no 2 that instructs the MOH to update the policies in accelerating and increasing the use of locally manufactured medical devices, MOH issued the decree in 2022 for "Substitution of Imported Medical Devices with Domestic Medical Devices in the sectoral e-Catalogue". The implementation of substitution of imported medical devices with domestic medical devices in the e-Catalogue is carried out by the Freeze and Unfreeze mechanism. As per the decree, the implementation of the substitution of medical devices is reviewed by the Substitution Team once a week based on the National Medical Devices Production

Sufficiency Data Document prepared by the Directorate General of Pharmaceuticals and Medical Devices of the Ministry of Health. The Substitution Team issues freeze and unfreeze recommendations to the Bureau of Procurement of Goods and Services of Medical Devices. However, extended "freezing" periods with limited access to products that are needed for patient care (as highlighted in the case studies earlier) may impact continuity of care for patients.

3.1.4 Another instrument that is also being developed by the Ministry of Health to support health system resilience is the construction of a digital application called the Pharmaceutical Dictionary of Medical Devices (KFA) which will be a reference for all parties in the procurement, distribution, and use of drugs and medical devices. However, there are challenges in creating specific specifications for medical devices due to the complexity of the categories that will require large resources in identifying and analyzing the related information. Example: IV Catheter category of medical devices is represented as two subcategories in the current sectoral e-Catalogue but it has nine subcategories with different specifications that are not fully represented in the current classification system.

3.2 Recommendations

3.2.1 **Investment in information management systems**: Data systems that consider clinician and patient access, quality of care, availability of local substitutes of appropriate quality and differentiation between "low-tech" and "high-tech" products.

3.2.2 **KFA Development**:

a) We recommend enhancing the pharmaceutical and medical devices dictionary (KFA) as the central platform to show the distinction and specialties of all medical devices. KFA will serve as the single source of reference to assist government and relevant stakeholders to select and utilize the appropriate technology based on medical needs and with transparent and predictable governance (which to produce locally and keep the imported ones). Having objective data collected in the KFA and establishing standardized decision-making processes will support medical device resilience.

b) There is a need to build a special team that is dedicated to exploring the functions of medical devices and their application in hospitals. The authority to form this team rests with the Directorate of Medical Devices & Pharmaceutical Distribution (internal working group), where a team can be formed in charge of managing data and selecting data sources.

c) Industry, clinicians, patient groups, hospitals, and other relevant parties should be included in the process of KFA development to ensure that medical devices as a category are understood and represented appropriately.

d) Need to stratify the database based on clear specifications of all medical devices- on the basis of their unique materials, specified indication & clinical

outcomes to adequately represent the specifications of a particular subcategory in the database.

3.2.3 **Database for local availability of raw materials**: Need for a database on local availability of raw materials for all medical technologies along with cost effectiveness of producing locally vs importing.

3.2.4 **Need for transparent and harmonized systems**: The various instruments that are being used for specifications of medical devices should be harmonized to ensure that products can be reviewed and approved within reasonable timeframes.

4. OPPORTUNITIES FOR COLLABORATIVE COOPERATION TO SUPPORT THE DEVELOPMENT OF HEALTH RESILIENCE INSTRUMENT

4.1 Short & Mid Term

4.1.1 **Value of open dialogue**: Transparency, information sharing and open dialogue between the government and healthcare stakeholders can help support both economic and healthcare needs and development in Indonesia. It may also include the interactive discussions with the technology users (general practitioners, specialized clinicians, nurses, medical laboratory personnel, etc.) at both hospital, regional, and national level to mutually agree on the prioritized technologies needed by the vulnerable population as well as the eligibility criteria to utilize the high-risk technologies. Open and timely consultation on government policies that are enacted can allow for private sector to provide insights prior to launch.

4.1.2 **Value of public-private collaboration to enable innovation**: The public and private sector can collaborate to reach the right balance between domestic resilience, innovation, and ensuring patient access to world class medical products. Public-private approaches to develop KFA can be explored, specifically to form a dedicated team to provide and analyze relevant data that potentially build a clearer specification, function, and related indication of medical devices. Such **partnerships** between MNCs and local enterprises in the medical technology field can bring global innovation to Indonesia.

4.1.3 **Role of diversification**: To strengthen supply chain resilience of critical medical products, sourcing should be diversified to multiple reliable sources. Concentrating production in a single or few markets increases risk exposure and inhibits flexibility needed to respond to public health emergencies.

4.1.4 **Data Co-provision in supporting the value assessment frameworks such as Adaptive Health Technology Assessment (HTA) approaches to facilitate the prioritization**: Value assessment refers to not only lower health costs with better patient outcomes but makes healthcare by providers more efficient and targeted, increasing the overall efficiency of healthcare systems. Adaptive HTA enables the rapid assessment for promising technologies that potentially address significant

health needs for certain populations. Medical associations, hospital associations, industry associations, and other relevant parties are able to support this approach by providing required data from ongoing clinical trials, real-world studies, patient registries, or other supportive data. The collected evidence may also act as the rationale for technology prioritization at hospital level, specifically under technology procurement process.

4.2 Long Term

4.2.1 **Value of strengthening information management systems**: Investment on information management systems which drives improvement in availability and quality of data, leveraging data analytics for measurement or monitoring to drive efficiencies in the supply chain and provide early indications of disruptions.

4.2.2 **Value of healthy competition**: We envision that a level playing field can drive healthy competition – to enable strong local players that can also be competitive internationally.

4.2.3 **Establishing national centers of excellence**: In line with Indonesia's healthcare transformation pillar and a roadmap for 9 national priority disease areas; specialized centers of excellence such as tertiary care (*RS Utama*) or quaternary care (*RS Paripurna*) hospitals would be developed in Indonesia to ensure healthcare facilities are able to meet the specific needs of specialized populations. These centers of excellence would leverage the latest technologies suited to the needs of the specific populations that would improve the efficiency of the healthcare system in Indonesia through right siting to appropriate level of care for patient population.

4.2.4 **Role of Data to Support the Establishment of Evidence-based Policy**: To comprehend the dynamic information related to the medical device such as the specification, function and potential clinical outcomes, raw material availability, production and distribution costs, approved prices, and others; dedicated studies should be commenced in Indonesia. It may also include the involvement of public health experts knowing the role of medical devices to support the prevention program, data and insight from public health experts and health economists are needed to support the data generation. In the future, this data can be utilized as proxies for the assessment or the standardized registration process.

4.2.5 **Fit for purpose value assessment frameworks for Medical Devices in Indonesia**: Current HTA process have not fully accommodate the need to allocate the available resources to procure cost-effective medical devices. Practices used across countries can be used as benchmark to shape the HTA mechanism for medical devices and potential parties such as academicians, medical associations, and industry associations are able to support the provision of data and agreeable technical assistance such as training, benchmarking, or interactive dialogue to deep dive which approaches work best in Indonesia.

CALL TO ACTION

1. **Need for Industry representation at the MOH Substitution team that decides on "freezing" and "unfreezing" of medical devices.**
2. **Need for other voices to be included in the development of the national health data platform (KFA / pharmaceutical and medical devices dictionary). These voices include those of patients, industry, academia and healthcare professionals.**
3. **Need to partner with academia and think tanks (such as health economics association) to explore value assessment framework for medical devices as part of procurement decisions.**

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