



Policy Memo on WHA Resolution 76.5 on Strengthening Diagnostics Capacity

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The Asia Pacific Medical Technology Association (APACMed) represents over 200 members from across the Asia Pacific region. Together, we are committed to working with governments and other stakeholders to facilitate patient access to innovative and life-saving medical technologies, supporting strong and thriving healthcare systems across the region, and promoting a robust and sustainable regional ecosystem that encourages investment, trade and innovation.

APACMed supports our members in the medical technology industry as they seek opportunities to participate in economic and industrial strategy discussions, and healthcare policy formulation supporting sustainable healthcare systems.

This memo details APACMed's position in response to the resolutionⁱ.

A APACMed recognizes and acknowledges the following priorities:

1. That effective and quality assured diagnostics requires a comprehensive health-systems approach where labs function as part of organized and integrated diagnostic networks that enable the optimum selection and use of diagnostics, and a skilled and licensed workforce operates in safe facilities supported with the appropriate infrastructure and adequate financing.
2. The need for policymakers to prioritize the management of diagnostics more broadly in the aspects of procurement, supply chain, maintenance, safe use and decommissioning. That the above is particularly relevant for the extended logistics of Point-of-Care testing (POCT) at the primary care and community care level in underserved and remote communities. That dedicating resources towards enabling the delivery of diagnostics in these settings will contribute towards expanding provision of care.
3. The critical role of rapid and accurate diagnostics in combating future pandemics and growing antimicrobial resistance, and hence improving diagnostics capacity at national and subnational levels is essential.
4. That building such capacity necessitates testing at the primary care and community level, that complement investments in national and regional laboratory systems. Having programs tailored to the needs of affected populations in different settings, including centralized testing and treatment in urban and peri-urban settings and decentralized testing and treatment in rural and remote areas.

B The medical device industry is supportive of:

1. The right of countries to promote healthcare access for all - in a way that upholds intellectual property protection vital to the development of health products and eschews anti-competitive practices.
2. The development of national diagnostics strategies that include regulation and the assessment and management of diagnostics, to accelerate adoption and use of diagnostics. This will involve adapting existing resources such as the WHO Model List of Essential In Vitro Diagnostics and the WHO lists of priority medical devices to local contexts, prioritizing the need to increase access in underserved populations. Additionally, the industry supports the resolution's call for the list to be updated to include innovative diagnostics.

3. Increased prioritization of diagnostics as a vital component in support of Universal Healthcare (UHC) objectives. The value of diagnostics in preventing premature deathsⁱⁱ is often under-recognised in healthcare spending decisions and reimbursement policies, with diagnostics accounting for only 1-2% of healthcare expenditure despite influencing approximately 66% of treatment decisionsⁱⁱⁱ.
4. Harmonization and twinning practices and reliance mechanisms for the regulation, manufacturing and supply of quality assured diagnostics.

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In line with the medical technology industry's effort to support the development of resilient and sustainable healthcare systems, APACMed would like to propose further collaboration and dialogue on the following:

1. Building supply chain resilience to ensure continuous access to care

Improving equitable access to safe, effective and quality assured diagnostics – as called for in WHA Resolution 76.5 – is a critical objective of all countries. While the industry is supportive of governments' efforts to build the capacity of local health systems and achieve their goals of healthcare transformation, the future supply of diagnostics for patients relies on a resilient, global supply chain to support and augment patient needs in the Asia Pacific region.

Resilient supply chains are designed to weather a myriad of disruptive forces; global interdependence within supply chains can help enhance resiliency and flexibility and reduce over-reliance on any one market for aspects of manufacturing or supply. The global nature of medical technology supply chains requires a holistic, blended approach with appropriate incentives in a facilitative trade environment, to compliment advances in domestic capacity and industrial base.

The critical role of medical technology in both peacetime and during health crises also necessitates continuous partnerships between global stakeholders – governments, industry players and healthcare providers. Public private partnerships were critical in supporting the COVID-19 pandemic response and addressing global supply chain challenges, enabling better visibility across the supply chain for essential medical commodities. Maintaining consistent collaboration between the public and private sectors across borders will further build supply chain resilience and a country's ability to mobilize in times of crises.

2. Ensuring continued quality and access for optimal patient outcomes

Medical technology industries in advanced economies thrive on a robust resource base that relies on both domestic and imported components. In turn, they serve patients around the world, becoming key contributors to the economy.

LMICs that aim to build up their domestic capabilities need approaches that counteract potential risks to quality and affordability resulting from lower yields in new processes or reduced economies of scale. Rather than high-level sector-wide targets, policymakers could benefit from adopting a more granular, phased approach to building domestic resilience – focusing on developing capabilities in realistically achievable categories or production phases first, before moving up the value chain to more complex processes and products. This allows opportunities for various players in the value chain to contribute based on their relative strengths and ensures quality is maintained.

Therefore, while APACMed recognises the benefits of building domestic resilience, we propose that the strengthening of domestic resilience of a country be accompanied by a thorough assessment of each country's unique domestic development capabilities, production capacity, and limitations in order to maintain high quality affordable devices for patients while minimizing disruptions to the supply chain. The medical technology industry is committed to playing a constructive role in partnering countries to identify, build and invest in the capabilities that contribute to this outcome.

ⁱ World Health Assembly. (2023, May 30). Strengthening Diagnostics Capacity. WHA Resolution on Strengthening Diagnostics Capacity. https://apps.who.int/gb/ebwha/pdf_files/WHA76/A76_R5-en.pdf

ⁱⁱ Fleming, K. A, et al. (2021). The Lancet Commission on diagnostics: Transforming access to diagnostics. The Lancet Commissions, 398 (Nov 2021).

ⁱⁱⁱ Rohr UP, Binder C, Dieterle T, Giusti F, Messina CGM, Toerien E, et al. The value of in vitro diagnostic testing in medical practice: A status report. PLoS One. 2016;11(3):1-16.



This memo was produced by APACMed in consultation with its member organizations.

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The **Asia Pacific Medical Technology Association (APACMed)** represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific.