SUMMARY DOCUMENT
APACMED INDIA ROUNDTABLE

14 DECEMBER 2021

'HEALTH TECHNOLOGY ASSESSMENT OF MEDICAL DEVICES IN INDIA'

This document provides a brief summary of the deliberations and key takeaways from the closed-door policy roundtable organized by APACMed India to review the current HTA landscape, look at some of the regional best practices and the role that the medical device industry can play in its implementation.

APACMED INDIA ROUNDTABLE

'HEALTH TECHNOLOGY ASSESSMENT OF MEDICAL DEVICES IN INDIA'

PARTICIPANTS

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- **Mr Indranil Mukherjee**, Managing Director, BBraun Medical India, ExCo Sponsor, HTA Task Force, APACMed
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- **Mr Nilesh Maheshwari**, Senior Principal & Head - Public Health, South Asia, IQVIA
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- **Mr. Arif Fahim**, Regional Director - Asia Pacific, Global Health Economics & Reimbursement, Abbott
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INTRODUCTION

India has taken up the task of achieving universal health coverage (UHC) by 2030 with upmost priority. To achieve this goal, it is paramount to have efficient health systems, trained healthcare workers, and easy access to medicines and technologies while ensuring affordability of treatment options. To adopt the practice of evidence-based decision making in India, the government has created an institutional arrangement known as the Health Technology Assessment in India (HTAIn) under the Department of Health Research (DHR).

HTAIn is responsible to carry out research related to clinical effectiveness, cost-effectiveness, and safety of drugs, devices and health programs using the Health Technology Assessment approach. The government is trying to create an infrastructure in which all the major stakeholders can work in a well-framed manner. These include not-for-profit bodies such as Public Health Foundation of India, publicly financed independent institutions such as Post Graduate Institute of Medical Education and Research (PGIMER), Make-in-India initiatives such as Kalam Institute of Health Technology (KIHT), and agencies such as World Health Organization, Federation of Indian Chambers of Commerce and Industry (FICCI), Indian Medical Association (IMA) and Patient Advocacy Groups.

HTAIn has already conducted a few landmark studies to help decision making. For instance, till date, eleven studies have been completed, of which ten are focused on medical devices with applications ranging from diagnostic screening and therapeutic care to surgical use. The primary role of HTAIn will be to evaluate available technologies and to promote innovation in medical technologies which will ultimately ensure quality healthcare at minimum cost. This will also help ensure the best health outcomes from the allocated health budget. This board will work on the pattern of National Institute for Health and Care Excellence (NICE) and will be instrumental in facilitating evidence-based policy making in India.

The COVID-19 pandemic has again shifted focus on some of the basic yet most significant factors in fastest developing economies such as India. The pandemic created a huge pressure on healthcare systems and highlighted the importance of making technologies accessible to public on fast track. Current public health needs demand accelerated approvals of new technologies. To achieve this, policy makers can leverage appropriate and timely HTA advice for faster, effective, evidence-based decisions. Private sector, with its expertise in the field can play a supportive role in achieving this. It is pertinent to initiate discussions and dialogues for greater awareness and exploration of opportunities, challenges, and possibilities around contribution from private players for wider implementation of HTA in India.

OBJECTIVE

As a regional trade association, The Asia Pacific Medical Technology Association (APACMed) has been actively working in the area of HTA in Asia Pacific. It has been contributing towards developing a robust, transparent, inclusive and value-based HTA for medical devices and diagnostics that facilitates transparent and evidence-based decision making and meets the core objectives of appreciating value of medical technology in public health. Recently APACMed India published a White Paper "Health Technology Assessment of Medical Devices (HTA) in India", in collaboration with IQVIA with an aim to review the current HTA landscape in India, share regional best practices, and explore the role of the medical devices industry along with providing recommendations for the way forward.

APACMed envisions an HTA system that makes the value assessment to help inform the appropriate use of technology which in turn improves patient quality of care in India. For accommodating the needs of a huge & diverse population like India, we need an effective tool to help prioritize interventions for improving the quality of healthcare. Therefore, HTA in India should act as such a systematic tool for prioritizing and identifying unmet health needs to inform policy and funding decisions. In line with its objective of promoting a value-based healthcare system, APACMed India organized a roundtable on 'Health Technology Assessment of Medical Devices in India'. The roundtable was intended to -

- Present the findings of the APACMed – IQVIA White Paper on HTA
- Drive greater awareness of HTA and its intended use in the MedTech context.
- Have a dialogue and deepen collaboration between governments, providers, payors and MedTech industry to institutionalize HTA and demonstrate its true value.

KEY TAKEAWAYS FROM THE ROUNDTABLE

- The panel agreed upon the need of wider implementation of the HTA program in India and acknowledged the current challenges in accomplishment of this objective.

- Capacity building remains a key challenge for implementation of HTA in India. Developing capabilities for robust health economic analyses without long term specialized courses and training programs in universities remains a challenge.

- Creating databases and registries to make quality data available for robust HTA is a resource intensive exercise. Availability of uniform and quality data for epidemiology, cost, and resource utilization is one of the key challenges to perform robust analyses. However, several initiatives have been taken by the government to develop quality databases (For e.g., National cost database). Industry stakeholders expressed their interest to contribute through global resources and expertise available with their team.

- Medical device HTA decision-making may be more complex compared to that of pharmaceuticals due to inherent differences in use and outcomes. These need to be considered while implementing HTA for medical devices.

- All agreed that patients must be kept at the center of all healthcare decision making. Patients' voice should be included in HTA decision making.

- HTA can be a solution for disruptive technologies that require both clinical and cost effectiveness evaluations to be established in the local setting. There is no health system that actually performs HTA for every product. So, priority determination is important while implementing HTA.

- Focusing on making decisions that help improve access for patients that need treatment; and the technologies should be developed for these patients

- While the importance of value-based procurement was acknowledged, however, the concerns around availability of reliable cost data, cost effectiveness analysis, wise deployment of limited resources need to be addressed.

KEY DISCUSSION POINTS

Policy Makers' Perspective

- There is a lack of specialized courses in health economics in the country, leading to limited skilled capacity for HTA. To address this, DHR will be introducing an MSc. programme on 'Health Economics and Technology Assessment' after due approval from the board. This programme is targeted to reach several universities for further dissemination. In the coming year, DHR will be working towards conducting capacity building workshops for stakeholders including industry, researchers and academicians.

- To overcome the challenges in obtaining robust cost & resource utilization data to feed cost-effectiveness models for India, DHR has built and published a costing database. The database is developed by Department of Community Medicine & School of Public Health, PGIMER, Chandigarh with technical support from International Decision Support Initiative (iDSI). It is a tool for health policy makers and analysts who need information on the unit costs of health services. The database provides information on economic costs of outpatient visits and inpatient stays at different levels of the health system. This database can be accessed by industry partners on request for their use and for providing comments and feedback.

- Apart from cost-effectiveness analysis, clinical effectiveness of the medical device needs to be established via various clinical studies, specifically RCTs and meta-analyses. However, there is a scarcity of local clinical data specially for medical devices, which can be utilized for HTA assessments. Research in this space needs to be boosted to make this data available in public domain, along with peer reviewed publications where industry and academia both can play an important role.
  There is also a need to bridge the gap between research and real-world data.

- Majority of the medical devices don't require an HTA because their need is well-established over the years. Only a miniscule proportion comprising of novel technologies in healthcare require a local HTA which should focus on a holistic approach keeping patients, payors, and society into consideration.

Medical Device Industry Perspective

- Industry has currently very limited involvement in the HTA process but is keen to support HTAin and advocates for a deeper involvement.
- Industry highlighted the challenges around current methodology, modelling, sample size, costing analysis and geographical coverage of published HTA reports.
- The implications that HTA have for clinicians and all other stakeholders in the healthcare delivery system is still an area demanding exploration.
- Globally, HTA and cost effectiveness analysis are well established areas of research in health economics. These tools are well grounded and practiced both from theoretical and practical perspective to make coverage decisions.

- It was highlighted that Value-based healthcare differs from the traditional HTA and cost effectiveness analysis. It is more about the patient perspective whereas traditional HTA and cost effectiveness analysis is more about the societal and payor perspective. Also, there are countries which have adopted both – where traditional HTA has been used to make coverage decisions and value-based healthcare is being used for incentivizing hospitals to improve outcomes.
- In India also, these principles of Value Based Healthcare can co-exist within the existing HTA framework and cost-effectiveness analysis where coverage decisions can still be made with these approaches.
- The industry acknowledged the use of HTA in context of disruptive innovation products. This can act as a pragmatic solution to the capacity allocation issue. Additionally, there is a need to put the patient at the fore front of whatever is done: whether it is at the level of physician treating the patient, a payor who is paying for care or a manufacturer that is developing the technology.

Payor's Perspective

- The payer acknowledged the rising demand for medical technologies, specifically newer technologies being introduced in the market owing to an increased disease burden in India. HTA as a tool can act as a fundamental pillar for effective healthcare decision making to ensure equitable access to the patients in need. From a healthcare funder's perspective, this ensures a balance between the provision of care, equitable access and sustainable healthcare.
- Payers also acknowledged the need for strategic collaborations between key stakeholders in industry, building tripartite alliance between the providers, payors and patients. The critical role of patient advocacy was also highlighted, especially in the context of chronic illnesses and rare diseases.

TESTIMONIALS

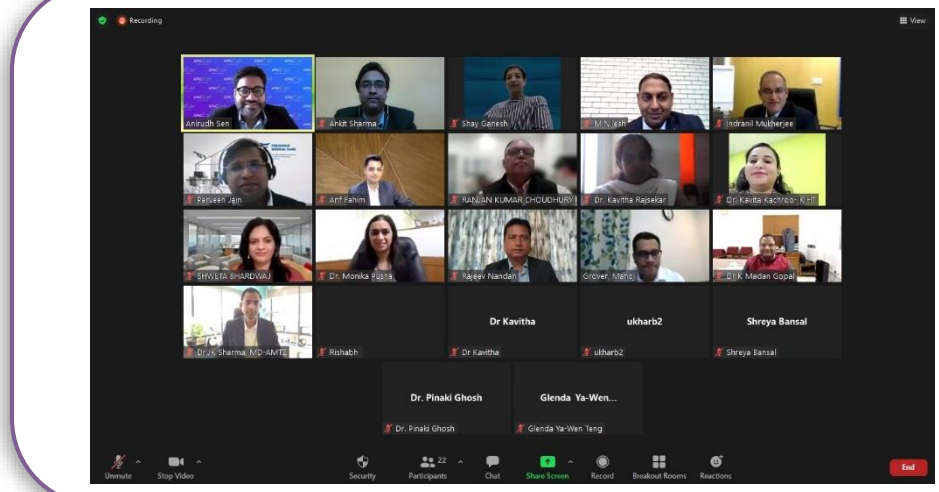
"APACMed Roundtable on 'Health Technology Assessment of Medical Devices in India' provided a forum for Government stakeholders, MedTech industry players, and payors in India to share viewpoints, promote awareness and initiate discussions on HTA ecosystem in India. It was indeed an interesting experience to be a member of a diverse and esteemed panel."

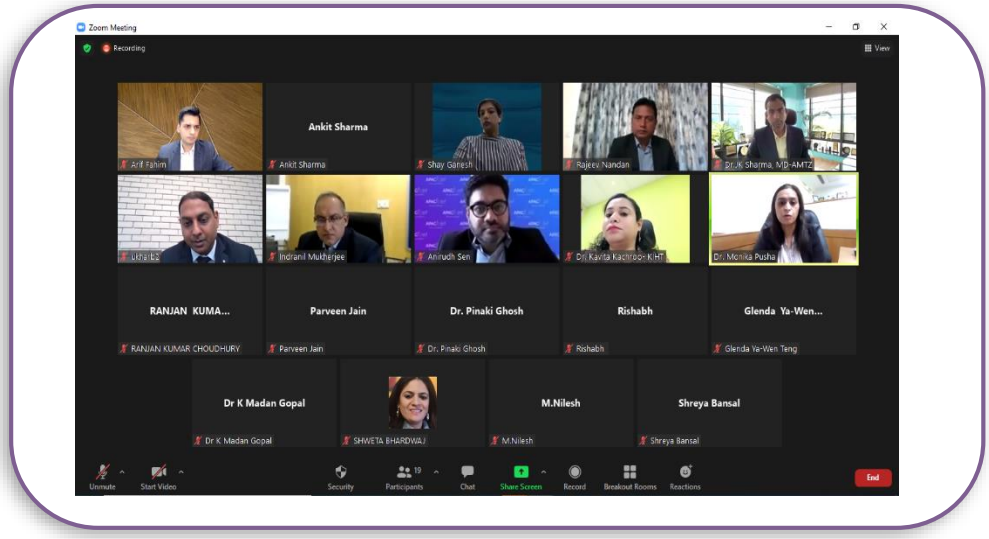
Dr. K. Madan Gopal, Senior Consultant, NITI Aayog

"Evidence based health technology assessment needs to become a standard instrument for social dialogue and administrative decision making in healthcare."

Dr. Jitendra Sharma, Managing Director & CEO, AMTZ and Executive Director- Kalam Institute of Health Technology

GLIMPSES FROM THE ROUNDTABLE





ABOUT ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION (APACMED)

Founded in 2014 and headquartered in Singapore, 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 Asia Pacific.

Providing a unified voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, with an active presence in India as well, APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of medical technology and promote regulatory harmonization. We strive to promote digital health innovation and impact policy that advances healthcare access for patients by engaging with medical device associations and companies in Asia Pacific.

APACMED CORPORATE MEMBERS

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