APACMed 10TH ANNIVERSARY

A Decade of Progress

ANNIVERSARY

ANNUAL REPORT 2023

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Asia Pacific Medical Technology Association *(APACMed)*

Addressing the growing demand for healthcare in Asia Pacific requires a different kind of innovative thinking from all stakeholders in our economies. This means that patients, policymakers, payers, healthcare workers, hospital administrators, medical technology and pharmaceutical industries need to collaborate differently to solve the region's common healthcare challenges.

By providing a unifying voice for the medical devices and in-vitro diagnostics industry in Asia Pacific, the Asia Pacific Medical Technology Association (APACMed) works to promote innovation and impact policy that advances healthcare access for patients.

APACMed's mission is patient-centric and calls for new creative partnerships within the healthcare and medical technology ecosystem, amongst key stakeholders including clinicians, governments, regulators, payers, healthcare providers, patient advocacy groups and academia.

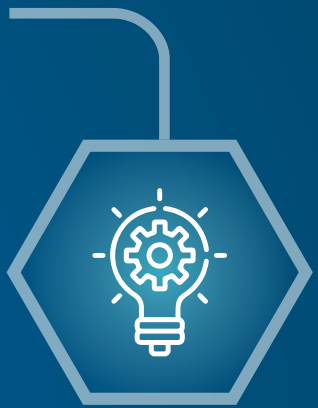
Our Mission

APACMed strives to continuously improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in the Asia Pacific.

APACMed Strategic Pillars

ACCESS

We strive to improve access to high quality healthcare for patients through close collaborations with our members and the wider ecosystem stakeholders to help shape policies that truly impact the lives of patients.



INNOVATION

We support innovative new technologies and start-ups that improve quality of care and healthcare outcomes.

HARMONISATION

We drive common approaches aligned with international best practices and standards to promote speed to access in a safe, secure and ethical manner through the adherence to the Code of Conduct.

Patient Story

Life-Changing Innovation that Cures and Cares

Melissa Lim
Patient and President of the Brain Tumour Society (Singapore)

Lighting struck twice for me.

I was a brain tumour patient in 2004 and prior to that, a caregiver to my mother who had brain cancer.

Yet thanks to MedTech, the doctors who used MedTech so skilfully and the regulators behind the scenes who had encouraged and cleared the way for MedTech that were used to save me, I am still here today.

One day in 2003, I was so dizzy and ill at the end of the workday that I could not drive myself home. I had to sit at a bench at the broadcasting station, where I worked, and could only call my team to help me. I was soon in the A&E, thinking that I could die that night. The doctors tried to stabilise my condition with a medicated drip, and suggested that I consult an ENT specialist. The ENT specialist said that it was likely a single episode as he had assessed that I was in good health. Since I was covered by medical insurance, he suggested that I do an MRI just to be on the safe side. Neither of us expected any surprises - I even arranged a lunch appointment right after my MRI appointment.

On MRI day, I was in total shock when I was told that I had a fairly large brain tumour of 3.5cm in diameter. I was in such a shock that I left the radiologist abruptly for lunch as I could not accept the news. Memories of my late mom and how she died came rushing back to me. I was overwhelmed by the possibility that I could die sooner than I expected and worse of all, go through what my late mom did – I did not think that I would have the strength to endure it.

Good sense kicked in later when I remembered that there are many kinds of brain tumours and maybe mine was not as bad as hers. When I went back to the radiologist, he explained to me that with good neurosurgery, I would be able to survive and still lead a full life.

A 16 hours craniotomy or brain surgery ensued. I am grateful that technology has progressed and it is not an ancient 16-minute procedure where doctors knock a hole into one's skull and use their fingers to dig out the tumours. The doctors told me that my nerves were carefully wired so that they can be detected during the surgery and a brain mapping device, amongst other sophisticated equipment, was used to successfully excise 98% of the brain tumour in a very delicate area of my brain.

I woke up to discover outcomes I had expected – a huge surgical scar, facial palsy and deafness. The most distressing unexpected outcome was the 3 large sticky crusts on my scalp that were wounds caused by the 3 pins that held my head during surgery. I was devasted when my hair fell out after the scabs dried up. I hoped against hope but my hair never grew back in those spots.

15 years later, I met a young patient who experienced the same hair loss and emotional trauma. In June 2023, I chanced upon the distributor of these pins in an exhibition at a Healthcare conference and I told them that these pins gave me 3 large scars. Hair loss due to the use of the pins was not something they had heard of before. It set me thinking - could the scarring for hundreds of patients after me be prevented if the manufacturer had known about this back when I had this sad experience and found a way to redesign pins?

With AI and digital advances, we can expect exciting innovations in MedTech. However, according to studies related to patient safety, although there are significant advances in medical technology over the last 4 decades, patient safety issues have not improved. We must not let the thrill of chasing product development innovation distract attention from what really matters – the patient's experience.

The MedTech industry saves countless lives and has a great impact on human beings. However, it can make a transformative difference when it strengthens its engagement and collaboration with patients in order to improve product designs for better treatment outcomes.

This article was adapted from Melissa Lim's keynote session at MedTech Forum 2023. To watch a full replay of her recording, please scan the QR code.

Welcome Message

John Collings, APACMed Chairman

"I remain so proud of our collective efforts to impact patient lives in the Asia Pacific over the last 10 years. The MedTech industry has increasingly stepped up to the challenge of delivering improved health outcomes and patient experiences. That said, the job is not done; we must continue to scale and innovate our collective impact into the next decade ahead."

Dear APACMed Members,

It's hard to believe I'm wrapping up my second year as Board Chairman. A challenging year, to be sure, getting back into the full swing of activities following the pandemic while also dealing with our many internal and external pressures in the industry.

Yet, I remain incredibly excited of our collective impact on the quality of healthcare delivered across the Asia Pacific. We all have great stories about our products and services making a real difference to patients, caregivers and healthcare providers. Which is why this year's MedTech Forum focussed on innovation and human potential resonated so strongly for me. Our industry thrives on innovation, we are known for it.

There are many great examples of our collective impact in 2023. To highlight a few efforts from the hard work by the APACMed Committees, we continued to drive regulatory harmonisation and reduce time-to-market by strengthening regulatory bodies in China, India, and ASEAN. In market access, our value-based healthcare efforts led to direct dialogues with the Singapore government on the Implant Subsidy List implementation. We also released a "Value-based Pricing for MedTech" white paper with recommendations to chart a path for closer collaboration between the industry and government. In Digital Health, we organised a closed-door Policy Forum in collaboration with our partner associations to review the current landscape and potential policy developments in digital health reimbursement in Australia, Korea, Japan and Singapore with an aim to influence policy conversations regionally. In ESG, we released resources such as a landmark white paper and an online dashboard, helping companies to navigate the changing landscape of environmental regulations across 6 markets in APAC. We also continued to advocate for collaboration between stakeholders to strike a balance between environmental goals and the imperative to uphold the availability of essential medical devices for patients.

We also mustn't overlook our impact through country-level activation. Our relationships with AMDD (Japan), KMDIA (Korea), and MTAA (Australia) are going from strength-to-strength as we witness these local partners now proactively reaching out to us to collaborate on emerging policies and regulations. Certainly, we will continue to build on these relationships into 2024.

While these are just a few examples, I am so very proud of our APACMed community and impact, in our role as the only MedTech association representing the unique needs across a very diversified region. I would also like to extend my thanks to the APACMed Secretariat for their tireless efforts in making these various working groups and engagements possible.

So, let us celebrate the successes of 2023 while remaining eager for even greater ambitions in 2024. Coming into the 10th year of APACMed, it is a time to reflect on a new era. I look forward to working with all of you to advance our collective vision further.

Sincerely,
John Collings
Chief Executive Officer
APACMed

In Conversation with

Harjit Gill, APACMed CEO

"The MedTech industry has become a critical enabler of health systems around the Asia Pacific, with the awareness and impact of APACMed reaching an all-time high. Now, as we complete our first decade and move into the next one, we look forward to achieving even bigger and bolder impact for patient access around the region."

The year 2023 has no doubt been a tough one. While on one hand we rebounded just about back to normalcy following the pandemic period, we also face an environment and industry undergoing many pressures, placing even greater emphasis on the work we do at APACMed.

Which is why our 2023 theme of innovation and human potential, selected by key stakeholders at the end of 2022, resonated so strongly. Innovation is the lifeblood of the MedTech industry. Coming out of COVID-19, we observed shifts in both innovation and the MedTech industry – the need to embrace a disruptive culture and to make a real human impact in our efforts. Governments, similarly, are positioning significant resources behind MedTech and talent. Throughout the year, we emphasised innovation across patient empowerment, healthcare workforce enablement, as well as reflecting on the industry's own capability needs ahead. Our role at APACMed in bringing safe, affordable access to innovative medical technologies for those in need, therefore, remains more important than ever.

It's been a busy year for APACMed in that sense. A few of the highlights for me include:

Our largest membership to date – 350 member companies.

The Environmental, Social and Governance Working Group was established to support members in navigating issues. We launched a policy intelligence dashboard and published the "Why ESG Matters for MedTech in the Asia Pacific" Paper to inform ongoing advocacy for fit-for-purpose policies.

Regulatory Affairs Committee's initiatives harmonised regulatory understanding, spurred innovation, strengthened regulatory bodies' capabilities, and promoted vital industry-regulator collaboration across the Asia Pacific.

In-Vitro Diagnostics Working Group continued to advocate for sustainable funding and availability of diagnostics by engaging key policymakers, payors and clinicians from Australia and Thailand with a specific focus on cardiovascular diseases.

Start-up Committee launched a first-of-its kind APACMed Innovation Community and matchmaking database to bring our corporate and start-up innovators closer together.

Digital Health Committee focused on increasing awareness and influencing policy conversations towards development and implementation of frameworks, pathways and policies for reimbursement of digital health technologies in the Asia Pacific.

Over 24 events throughout the year, attended by 1,700 members.

A very successful MedTech Forum 2023 where we connected with over 1,450 delegates.

I would like to thank our APACMed members and stakeholders, who represent a diverse cohort of large and small organisations, from the public and private sector, across a wide range of geographies in the Asia Pacific. Your spirit of innovation inspires APACMed's mission, and the contributions and energy are critical for our capability and capacity building. I would also like to thank the APACMed Secretariat for executing on the vision with utmost quality, including by staying on top of the live issues along the way. With 2023 coming to a close, I look forward to setting an even higher bar in 2024, a landmark year for APACMed as we complete a decade of progress while also planning ahead for the next decade of impact.

Sincerely,
Harjit Gill
Chief Executive Officer
APACMed

Patient Story

Empowering Patients to Battle Disease

When Manju Katyal was 55, she was diagnosed with stage-four breast cancer. At the time, she remembers feeling as though she had two options for how to react: She could grieve and feel self-pity, or she could look at her diagnosis as a challenge and be ready for her fight against cancer with a positive mind.

Manju chose option number two.

This mindset carried her through the 16 chemotherapy sessions and the 33 radiation sessions that would follow. Manju never let her extensive treatment impact her strong spirit.

One day, during the first of her radiation sessions, Manju felt a little bit scared. But when she stepped up to the machine that would help her fight her cancer, she gave it a warm smile and decided that the machine was in fact her friend. She remembers saying: "Look, you have to see my face for the next 33 days, and I have to see yours. Best is if we become friends. We're in this together!"

From that day onward, Manju's journey got easier and easier. She didn't experience a single side effect due to the radiation. She has now been cancer-free for two years and says that life is even better now than it was before her diagnosis. As Manju puts it, "Cancer taught me to live better, love better, and enjoy every day to the fullest!"

When asked what her advice would be to other cancer patients, she had this to say: "If I could do this at 55, so can you. All you need is a positive outlook and compassion in your heart. But I also understand that this positive attitude needs to come from your family and friends too! And that's why I advise doctors to encourage counselling for family members of cancer patients. We all need to shower each other with love and pure compassion."

This article was contributed by Varian.

Organisation & Committees

Board of Directors

Secretariat Team

Committees

Government Affairs & Market Access

240+ Committee Members

Digital Health

300+ Committee Members

Regulatory Affairs

400+ Committee Members

Legal, Ethics & Compliance

130+ Committee Members

Start-Up & SME

200+ Committee Members

John Collings
Chairman, APACMed
President, Asia Pacific
Stryker

Probir Das
Vice Chairman, APACMed
Group Executive Officer
Terumo Corporation
Chairman, Terumo Asia Holdings
Chairman & Regional Representative
Asia Pacific & India

Lam Chee Hong
Treasurer, APACMed
President, Asia Pacific
B.Braun

Farhana Nakhooda
General Manager &
Senior Vice President, Asia Pacific
Health Catalyst

Steven Flynn
President, Asia Pacific
Baxter Healthcare

Vy Tran
Head, Asia Pacific Japan
Siemens Healthineers

Alex Gu
Senior Vice President & President
Greater China Region
Medtronic

Justin Leong
President, Asia & Latin America
Resmed Asia

Lance Little
Managing Director
Roche Diagnostics Asia Pacific

Stephen Morse
Senior Vice President & President
Asia Pacific
Boston Scientific

Marc Radatt
Chief Executive Officer
Olympus Asia Pacific

Tim Schmid
Executive Vice President, Worldwide
Chairman, MedTech
Johnson & Johnson

Paul Tan Minjie
Divisional Vice President
Asia Pacific
Abbott

Pavan Mocherla
Executive Vice President & President
Greater Asia
Becton Dickinson

Committee Board Sponsors

Government Affairs & Market Access

Paul Tan Minjie
Divisional Vice President, Asia Pacific
Abbott

Digital Health

Farhana Nakhooda
General Manager &
Senior Vice President, Asia Pacific
Health Catalyst

Regulatory Affairs

Lance Little
Managing Director
Roche Diagnostics Asia Pacific

Legal, Ethics & Compliance

Tim Schmid
Executive Vice President, Worldwide
Chairman, MedTech
Johnson & Johnson

Start-up & SME

Justin Leong
President, Asia & Latin America
Resmed Asia

Country Board Sponsors

ASEAN

Vy Tran
Head, Asia Pacific Japan
Siemens Healthineers

CHINA

Alex Gu
Senior Vice President & President
Greater China Region
Medtronic

INDIA

Pavan Mocherla
Executive Vice President & President
Greater Asia
Becton Dickinson

JAPAN

Stephen Morse
Senior Vice President & President
Asia Pacific
Boston Scientific

KOREA

Marc Radatt
Chief Executive Officer
Olympus Asia Pacific

AUSTRALIA

Steven Flynn
President, Asia Pacific
Baxter Healthcare

Harjit Gill
Chief Executive Officer

Gabriel Sim
Director, Strategic Partnerships

Christine Tan
Director, Country Activation

Anirudh Sen
Director, Digital Health

Glenda Teng
Director, Government Affairs & Market Access

Nishan Pillai
Manager, Finance & Operations

Alicia Chang (Zhang Li)
Country Lead, APACMed China

Adip Puri
Country Lead, APACMed India

Benish Aslam
Manager, Government Affairs & Market Access
Country Lead, Indonesia

Su Fen Ong
Manager, Government Affairs & Market Access

Cindy Pelou
Manager, Regulatory Affairs & Legal, Ethics & Compliance
Country Lead, South Korea

Ankit Sharma
Manager, APACMed India

Shreya Bansal
Research Associate, APACMed India & Regulatory Affairs

Candice Ng
Manager, Events

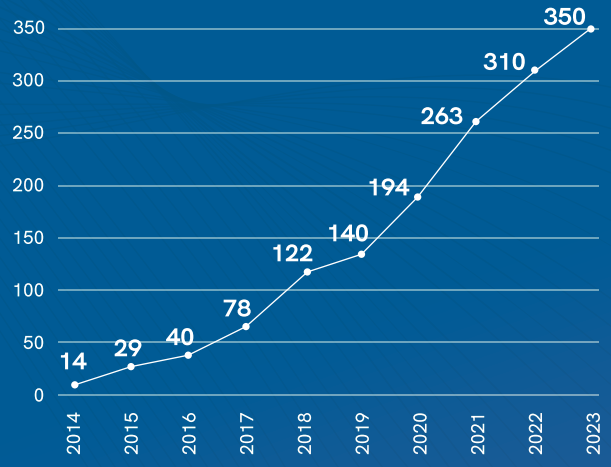
Devya Bharati
Associate, Regulatory Affairs

Birgitta Riani
Assistant Manager, Digital Health

Zoey Ma
Assistant Project Manager, China

13 % GROWTH OF MEMBER COMPANIES

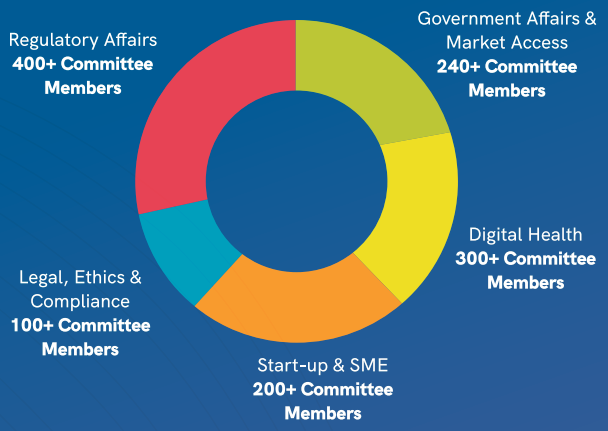
Number of member companies grew from **310 in 2022 to 350 in 2023**



Number of Member Companies

OVER 1,240+ COMMITTEE MEMBERS

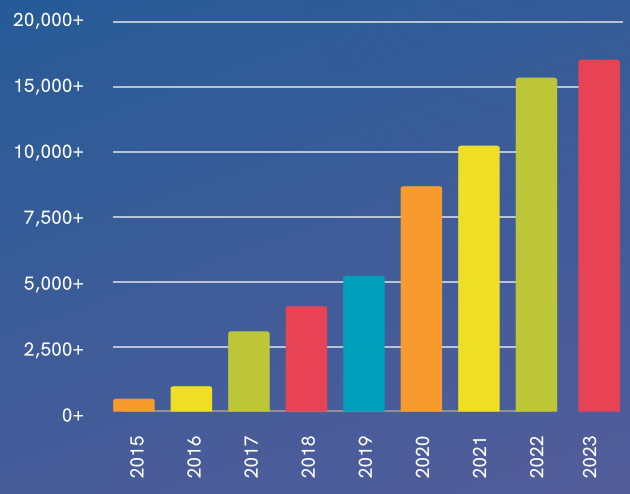
from **5 committees in 2023**



Number of Committee Members

10 % GROWTH OF SOCIAL MEDIA FOLLOWERS

Number of social media followers increased from **16,000+ in 2022 to 17,681 in 2023**



Number of Social Media Followers

MedTech Forum Delegates

1,350 in 2022 VS **1,458** in 2023

Networking Opportunities

Hosted **1,692 members in 2023** to get together as an industry to collaborate and share best practices

- CEO Dinner
- Start-up Connect
- APACMed Innovation Community
- APACMed Outreach
- APACMed Breakfast Conversations
- Committee Townhall
- HR Meet & Greet
- Marcomm Group Meeting

3,150 DELEGATES

Events, Workshops and Conferences

10 POSITION PAPERS

Published across 4 committees

Corporate Members

Start-up & SME Members

Start-up & SME Members

Industry Association Members

Associate Members

Government Affairs & Market Access Committee

The Government Affairs & Market Access (GAMA) Committee has been going from strength to strength with over 240 members from 50 companies actively contributing to various strategic initiatives related to policy shaping, live issue advocacy and best practices sharing.

Core Leadership

Shakilla Shahjihan
Government Affairs Chairperson
Divisional Vice President,
Government Affairs,
Asia Pacific & Japan
Abbott

Jane Mcmillan
Government Affairs Vice-Chairperson
Head, Government Affairs & Policy
MedTech Asia Pacific
Johnson & Johnson

Dr Sang-Soo Lee
GAMA Committee Co-Chairperson & Market Access Chairperson
Senior Healthcare Economics &
Government Affairs Director
Medtronic North Asia
(Korea & Japan)

Pinaki Ghosh
Market Access Vice-Chairperson
Senior Manager HEOR and
Market Acess Asia Pacific
B. Braun

Hui Sin Teo
Government Affairs Vice-Chairperson
Market Access & Government
Relations Leader, Greater Asia
Becton, Dickinson and Company

Rajeev Nandan
Government Affairs Vice-Chairperson
Head, Market Access & Government
Affairs, India & SEA Region
Alcon

Alice Chu
Market Access Vice-Chairperson
Senior Director, Market Access &
Medical Affairs, Asia Pacific
Glaukos Corporation

Country Centres of Excellence

CHINA

Anita Song
Chairperson
Director, Health Economics,
Policy and Reimbursement
Medtronic Greater China

Ning Yue
Vice-Chairperson
Strategic Access Director
Becton Dickinson China

Jenny Jin
Vice-Chairperson
Senior Director, GA & QREM
Fresenius Medical Care China

INDIA

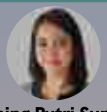
Vibhav Garg
Chairperson
Director, Government Affairs
Strategy, India Hub & ASEAN
Boston Scientific

Ravi Valia
Vice-Chairperson
Director, Government Affairs India
Medtronic Pvt. Ltd.

Vineet Gupta
Vice-Chairperson
Head of Government Affairs
Siemens Healthineers

INDONESIA

Wanda Harahap
Chairperson
Government Affairs Director
Abbott Indonesia



Wulaning Putri Sunuwati
Vice-Chairperson
Head of Government Affairs &
Business Development,
Head of Quality Regulatory
Siemens Healthineers Indonesia

Lenny Santida Tarigan
Vice-Chairperson
Country Market Access
Government Affairs &
Partnership Leader
Medtronic Indonesia

SOUTH KOREA

Jongbae (JB) Kim
Chairperson
Head of Health Economics &
Market Access (Hema)
Johnson & Johnson Medical Korea

Nicole Kim (Se-A)
Vice-Chairperson
Senior Manager, Quality,
Illumina, South Korea

Monica Jin
Vice-Chairperson
Senior Manager, Global Access
Value & Economics,
Intuitive Surgical Korea

VIETNAM

Julia Tran
Chairperson
Regional Director, Government Affairs of
Vietnam, Thailand, Cambodia, Laos & Myanmar
Abbott

Thuy Pham
Vice-Chairperson
Market Access Lead
Boston Scientific Vietnam

Strategic Initiatives

In 2023, GAMA's key market shaping initiatives are as follows:

Value-Based Market Access

To support the government in implementing the Implant Subsidy List in Singapore, APACMed, together with our knowledge partner Vista Health, co-developed a white paper titled "**Value-based pricing for MedTech: A Collaborative way Forward for Singapore**". Launched in September 2023, the paper delved into the value-added services provided by MedTech firms and recommended closer collaboration between the industry and governments to manage healthcare costs while supporting innovation.

Environmental, Social and Governance (ESG)

ESG-related policies are evolving quickly across the globe and the Asia Pacific region, making it difficult for MedTech companies to track these developments and respond to policy changes. Recognising this gap, APACMed co-developed an environmental regulatory dashboard for 6 strategic markets and a white paper with our knowledge partner, Bain & Co. titled "**Why ESG matters for MedTech in the Asia-Pacific**". The dashboard and white paper were launched respectively in July 2023 during a APACMed Breakfast Conversation and in October 2023 during the Medical Technology Association of Australia (MTAA) Conference.

Striking the Balance Between Domestic Resilience, Innovation, and Quality Healthcare

"Buy Local /Make in X" policies have emerged in public procurement policies to protect local manufacturers. Localisation policies have unintended negative consequences such as limited macroeconomics gains and reduced patient access and lower quality outcomes. Fair procurement is vital to ensure resilient supply chains and access to quality care. Healthy competition is necessary to foster high quality innovation and help local businesses in terms of capacity building and knowledge transfer. Leveraging our policy communications toolkit "**Striking the Balance Between Domestic Resilience, Innovation, and Quality Healthcare**" developed in 2021 to help our members engage government stakeholders to promote fair procurement for innovation and growth in the Asia Pacific region, GAMA activated key messages in several markets such as China, Indonesia and Singapore.

Advocating for fair procurement for medical devices in Indonesia: Policy Dialogue and Policy Brief on Building Healthcare Resilience

In response to local content requirements imposed on medical devices, APACMed partnered with local knowledge partner-Indonesian Health Economics Association (inaHEA) to hold a series of closed-door discussions with policy-makers which culminated with a policy forum on " **Building Healthcare Resilience**" held in Jakarta, Indonesia on 30th May. The keynote address for the forum was delivered by the General Secretary of Ministry of Health of Republic of Indonesia. The forum was well attended by senior government officials, clinical associations including the Indonesian Cancer Association, Indonesian Anesthesiology, and Intensive Therapy Specialists Association (PERDATIN), Indonesian Digestive Surgeon Association (IKABDI), West Java Pediatric Nurse Association (IPANI) and the industry. A series of discussions were held on how the government and healthcare stakeholders can collaborate towards the common goal of striking the right balance between innovation, domestic resilience, and quality healthcare for Indonesia.

The proceedings from the forum was incorporated into the policy brief document that was officially launched at the 8th Biennial Scientific Meeting (BSM) held on 27th October at at Depok City, Indonesia. The launch was held as a part of the three-day 8th Biannual Scientific Meeting of Indonesian Health Economics Association attended by over 350 attendees including Vice Minister of Finance, senior officials from Ministry of Health, House of Representatives and Social Security Agency of the Republic of Indonesia.

The launch was followed by a multistakeholder panel discussion including speakers from the Ministry of Health, Clinical Association, Patient Association and industry. The discussion emphasised the need for collaboration between the government, industry and other healthcare stakeholders in developing The Pharmaceutical and Medical Device Dictionary as an instrument for fair procurement.

Health Services Transformation

APACMed partnered the Singapore Ministry of Health Office for Healthcare TransformationMOHT for their MOC@Home pilot to conduct landscape scanning on chronic disease monitoring and post discharge monitoring in Singapore and provided a catalogue of solutions matched to the requirements of MOHT. This culminated in a policy discussion with Singapore and China policymakers in February 2023.

Policy Intelligence Bulletin

Arising from members' feedback to receive timely policy updates, APACMed worked with our knowledge partner, Ipsos on a quarterly policy intelligence bulletin. The inaugural edition released in October 2023 covered South Korea, Japan and Australia. From 2024, APACMed will expand coverage to include China, India and Thailand.

Country Activation

Country Activation in Malaysia and Vietnam

APACMed held the Value Based Market Access Symposium in Malaysia and Vietnam in February and October 2023 respectively. Partnering local associations like AmCham Malaysia, EuroCham Vietnam and US-ASEAN Business Council, the symposiums delved into live issues such as Vietnam's Amended Law on Tender and shared regional market access best practices with policymakers and industry members.

Events and Membership Engagement

Public Policy & Market Access (PPMA) Expert Summit at the MedTech Forum 2023

GAMA came up with the individualised theme around strengthening the ecosystem for Evidence-based Policymaking for our Public Policy & Market Access (PPMA) Expert Summit which was held on 6th December 2023. The summit was filled with a series of enriching discussions such as ESG related initiatives in the APAC region, case study on collaboration with the government to create a New Service Fee for IVD in South Korea, advocacy for adoption of Value-Based Pricing for MedTech in Singapore, evidence-based decision making for healthcare in APAC, presentation on roadmap for promoting R&D in India's Medical Device Sector and discussion on promotion of quality innovation in the Asia-Pacific Region. Due to the diverse nature of the summit, there was something for everyone who attended the summit and the fruitful discussions and presentations uncovered new grounds for collaboration among the attendees.

GAMA Strategy Retreat

In November 2023, the GAMA Secretariat conducted its Annual Strategy Retreat where members came together to celebrate achievements in 2023, gain insights from healthcare mega trends via a presentation by the Boston Consulting Group and prioritised key initiatives and countries for activation in 2024.

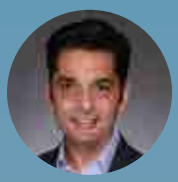
Live Issue Advocacy

Engagement with Ministry of Health Agency for Care Effectiveness for Implant Subsidy List (Singapore)
Engagement with Ministry of Health and Gakeslab on local content (Indonesia)
Amended Law on Tender (Vietnam)
Value-based Market Access Presentation at MedLab Asia 2023 (Thailand)
Engagement with Chine Investment Promotion Agency on local content requirements (China)
Value-based healthcare (Malaysia)
Honebuto policy and pricing revision (Japan)
Engagement with National Environment Agency on exemption for certain hazardous substances used in medical devices (Singapore)

Digital Health Committee

Established at the height of the COVID-19 pandemic in 2020, the Digital Health Committee was formed with the primary objectives of knowledge sharing and advocating for policies that facilitate innovation across the entire digital health product journey, spanning regulatory approval, market access, reimbursement, and utilisation. Since its inception, the Committee has witnessed substantial growth, comprising over 320 individual members hailing from 85+ companies. Notably, the Committee's expansion strategy involved the establishment of six country Centres of Excellence (COEs) across the region. These COEs, strategically positioned in ASEAN, Australia, China, India, Japan, and South Korea, serve as focal points to localise the Committee's regional initiatives and foster enhanced engagement with local stakeholders.

Core Leadership



Arif Fahim
Reimbursement Chairperson
Regional Director, Health Economics & Reimbursement
Abbott

Jamie Kebely
Reimbursement Vice-Chairperson
Vice President, Government Affairs, Asia-Pacific & Japan
Siemens Healthineers

Josephine Hong
Reimbursement Vice-Chairperson
Head of Marketing, APAC
Philips

Dr. Julian Sham
Reimbursement Vice-Chairperson
APAC Clinical Digital Transformation Lead, Roche Information Solutiuons (RIS)
Roche

Jim Sarka
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Strategic Initiatives

Advancing Reimbursement Capabilities in Korea, Japan, Singapore and Australia

In 2022, the Committee initiated the Digital Health Reimbursement Alliance, expanding its outreach to a broader spectrum of stakeholders beyond APACMed's traditional network. This expansion encompassed diverse geographical regions outside the Asia Pacific and included industries beyond MedTech. The primary objectives of establishing the Reimbursement Alliance were:

- Facilitating a platform for stakeholders to exchange insights, advocate for policies, and collaboratively work towards enhancing accessibility to digital health solutions.
- Offering learning opportunities to stakeholders across both private and public sectors, aiming to foster knowledge exchange and expertise in the realm of digital health.
- Providing valuable support to policymakers in crafting and implementing frameworks for value assessment, funding strategies, and reimbursement models specifically tailored for digital health initiatives.

This year, among several initiatives, the alliance organised the first Digital Health Reimbursement Policy Forum in partnership with Eversana in May, which brought together policymakers, experts, and academics from Singapore, Japan, South Korea, Australia, Germany, France, and the United Kingdom, with an aim to create a baseline understanding of the current state of digital health reimbursement in key Asia Pacific, European and US markets.

The digital readiness of the chosen Asia Pacific markets was compared against several of the advanced markets such as the US, Germany, France and the UK, who have made considerable advancements, not only in reimbursing various digital health technologies but also in establishing reimbursement frameworks suited to their country requirements.

Policymakers from the four Asia Pacific markets were brought to the table to discuss the progress made in deciphering the complex reimbursement pathway for digital health and the outstanding challenges which make it difficult to bring new innovation earlier into the market and increase access to patients via reimbursement.

Cybersecurity Labelling Scheme for Medical Devices in Singapore

Announced at the Singapore International Cyber Week 2022, the Cybersecurity Labelling Scheme for Medical Devices [CLS(MD)] is part of the efforts by the Ministry of Health (MOH), Cyber Security Agency (CSA), Health Sciences Authority (HSA), and Synapxe to better secure Singapore's cyberspace and to raise cyber hygiene levels in medical devices.

Under the voluntary CLS(MD), medical devices are rated according to 4 levels of cybersecurity provisions and assessments, and the cybersecurity label for medical devices would provide an indication of the level of security in medical devices. The label aims to improve security awareness by making the cybersecurity provisions of medical devices more transparent to healthcare users and empowers them to make informed purchasing decisions.

The APACMed Cybersecurity working group, collaborated with Singapore's Cybersecurity Agency (CSA), Health Sciences Authority (HSA), Ministry of Health (MOH), and Synapxe, to support the development of the pioneering cybersecurity labelling scheme tailored for connected medical devices. This initiative saw the launch of its sandbox phase last year, marking a significant milestone.

Throughout the year, the working group facilitated multiple consultation sessions with the Singaporean government that aimed to provide invaluable industry insights, feedback, and inputs crucial for refining and enhancing the scheme. The collaborative efforts between the working group and government entities were instrumental in fostering an environment of collaboration and ensuring the scheme's alignment with industry needs and cybersecurity standards within the medical device domain.

Advancing Digital Health Maturity in ASEAN

Under our Health Data and Interoperability working group we hosted an exclusive closed-door policy roundtable (in collaboration with KPMG) aimed at fostering a dialogue between ASEAN Ministries of Health and data experts. This roundtable aimed to facilitate discussions that drive interoperability, implementation of international health data standards, and provide crucial support for nationwide health information exchange projects across the ASEAN region.
The primary objective of this closed-door roundtable is to share invaluable experiences, fostering collective awareness through a strategic 2-step approach:

Phase 1: Interoperability and International Health Data Standards for Nationwide Electronic Health Records

Phase 2: Regional Standards and Governance for Cross-Border Health Data Exchange

Attendees included representatives from Ministries of Health from Singapore, Indonesia, Malaysia, Vietnam and Thailand as well as experts from Europe who shared use cases and global best practices (Austria ELGA Nationwide Electronic Health Record, IHE, EU Data Space); focusing on lessons learned, key enablers and constraints.

Publications

The Power and Promise of Health Data: Value for Innovation, Quality & Care Efficiency

The future of healthcare will be underpinned by insights and outcomes derived from data, and the benefits of an interconnected healthcare ecosystem cannot be understated. Health data is in a position to help to achieve a more sustainable, efficient, and equitable ecosystem, which is a top priority for governments in the Asia Pacific region.

With this imperative the APACMed Digital Health Committee's working group on Health Data & Interoperability commissioned a White Paper with the title, 'The Power and Promise of Health Data: Value for Innovation, Quality and Care Efficiency'. The paper delves into the immense value that health data brings throughout the product lifecycle for the MedTech industry, patients, policymakers, and all stakeholders within the broader healthcare ecosystem.

It would also provide the reader with insights and key findings which lays out the opportunity for health data in the region, as a case for policy intervention along with industry examples and recommendations for regulators and policymakers to consider acting upon, including by right-sizing resource allocation to the topic.

The Paper is available on the APACMed website and can be downloaded here.

Building Resilient Health Systems in a Digital Era: Cybersecurity in Remote Care Management

With the growing prominence of remote healthcare management, concerns about the safety and utilisation of associated technology have become increasingly prevalent, both within and beyond the healthcare sector.

As a proactive step, our Cybersecurity Working Group partnered with L.E.K to embark on an in-depth exploration of this domain culminating into a Position Paper. Our collaborative efforts entail comprehensive research, engaging discussions with pertinent subject matter experts, and dialogues with policymakers. Through these endeavours, we aim to gain nuanced insights into the current landscape of remote care solutions, prevailing cybersecurity frameworks, and pinpoint gaps, especially from an Asia Pacific perspective.

This paper serves as a pivotal platform to underscore the critical significance of cybersecurity, robust health data management, and the assurance of patient safety, particularly within the realm of Remote Healthcare Management. Our primary objective is to present recommendations and actionable steps that advocate for the secure utilisation of remote care management solutions across all stakeholders.

The Paper is available on the APACMed website and can be downloaded here.

Digital Health Reimbursement Policy Newsletter

The Digital Health Reimbursement Alliance also launched the 'Digital Health Reimbursement Policy Newsletter' a quarterly publication that disseminates updates, insights, and information related to reimbursement policies concerning digital health technologies in the Asia Pacific region and beyond. The newsletter covers:

- Policy Updates: Information about updates, or new policies related to reimbursement for digital health solutions, including insights into regulatory developments and guidelines.
- Event Announcements: Notifications about upcoming webinars, conferences, or events related to digital health reimbursement

Events

Digital Health Summit at the MedTech Forum (MTF) 2023

The Digital Health Summit titled, Enter the Next Healthcare Evolution—Digital! took centre stage on Day 2 of the MedTech Forum, uniting trailblazers and thought leaders from the MedTech, healthcare, government, and technology sectors. The objective was to forge a collective exploration at the intersection of digital advancements and healthcare solutions.

Our overarching goal was to uncover the profound transformative impact of digital health and AI on reshaping patient care, diagnostics, and the delivery of healthcare services. The Summit aimed to dissect the evolving landscape, uncover innovative strategies, and spotlight the potential synergies driving the convergence of technology and healthcare.

Therefore, the objectives for the event focuses on the 3 Es of Innovation:

Empowering Patients: The Digital NATIVE: Leading the Consumerisation of Healthcare: Examining innovation adoption from a patient journey lens: Latest innovations, adoption experiences, and the path forward for patient empowerment through innovation.

Enabling Healthcare: HEALTHCARE 4.0: Moving from Digital Health to…Health: Exploring innovation's impact on the healthcare workforce: success stories in innovation adoption and their impact on caregivers' lives. Unveiling valuable insights from challenges encountered and lessons learned thus far.

Elevating The Industry: Be Digital-Future Ready: Unlock Success for INDUSTRY in the Digital Era: Looking inward for MedTech: Navigating innovation adoption and talent. Strategies for staying ahead and transforming workforces to embrace innovation in the industry.

Deep Dive on the National Health Insurance Reimbursement Guidelines for Digital Therapeutics in Korea

The APACMed Digital Health Reimbursement Alliance has been actively advocating for fit-for-purpose Digital Health reimbursement and striving for equitable access to Digital Health technologies for patients within the Asia Pacific region.

Last August, the Korean Health Insurance Review and Assessment Service (HIRA) introduced ground-breaking updates to their national health insurance reimbursement guidelines, specifically tailored to accommodate digital therapeutics (DTx) and artificial intelligence (AI)-embedded technologies. These revised guidelines are designed to facilitate the rapid adoption of cutting-edge medical technologies, emphasising evidence generation through a comprehensive evaluation of innovative medical devices. APACMed organised a webinar under the aegis of the alliance to brief our members on this important development.

CyberStorm - Cybersecurity TableTop Exercise

The Cybersecurity Working Group orchestrated a dynamic 1-day cybersecurity tabletop exercise (TTX) known as "CyberStorm," bringing together key players in the MedTech sector. The event simulated a series of realistic cyber incidents, providing participants with practical experience in responding to emergent cyber threats. The exercise allowed participants to immerse themselves in real-time scenarios, prompting discussions on pivotal leadership decisions crucial in the event of a major cyber incident, such as a ransomware attack. The interactive exercise provided a practical platform for members to strategize, test response protocols, and exchange valuable insights on effective crisis management in the face of cyber threats. This initiative stands as a testament to the Cybersecurity Working Group's commitment to proactively prepare the MedTech industry against cyber vulnerabilities, fostering a culture of readiness and resilience in today's evolving digital landscape.

Regulatory Affairs Committee

The Regulatory Affairs (RA) Committee counts over 400 regulatory professionals from over more than 50 corporate member companies, based across the Asia-Pacific region as members. Much of the regulatory advocacy efforts coalesce around market-based Centres of Excellence (CoEs), covering: China, South Korea, Southeast Asia, and India. Separate Regional Working Groups (WGs) are dedicated to: Digital Health Regulatory, Regulatory Intelligence (RI), Capacity and Capability Building (CB), and In-Vitro Diagnostics (IVD).

Core Leadership

Miang Tanakasemsub
Chairperson
Head of Regulatory Affairs (RA), Asia Pacific (AP)
Johnson & Johnson Vision

James Chan
Vice-Chairperson
Regulatory Affairs Director, APAC
Varian Medical System
(A Siemens Healthineers Company)

Jason Guo
Vice-Chairperson
APAC Director, Regulatory Affairs, Quality & Compliance
Abbott

Marianne Yap
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Vice President, Quality Regulatory & Government Affairs Asia Pacific,China & Japan
Alcon

Yasha Huang
Vice-Chairperson
Head of Regulatory Policy Asia Pacific, Global Regulatory Policy & Intelligence
Roche Diagnostics

Country Centres of Excellence

CHINA

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Cook South East Asia

INDIA

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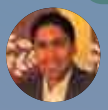

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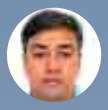

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QA & RA Lead, Indochina & Frontier Market Plus
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REGULATORY DIGITAL

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Sr. Manager, Regulatory Affairs, Software
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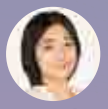

Soeun Park (Estella)
Vice-Chairperson
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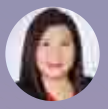


Dacia Su
Secretary
Regulatory Affairs Director, Asia
Embecta

Regulatory Affair Committee's vision, mission and tools

Pioneering regulatory excellence dedicated to optimizing patient access to medical devices, and aspiring to be the preferred partner of regulators and policymakers

REGULATORY CONVERGENCE	REGULATORY RELIANCE	REGULATORY AGILITY
Promote harmonization across various international markets	Leverage the work done elsewhere to be more effective and increasing speed to market	Advocate for flexibility to accommodate to emerging innovative technologies and advancement

PREDICTIVE REGULATORY INTELLIGENCE

STRATEGIC ADVOCACY

REGULATORY CAPACITY BUILDING

Key Strategic Initiatives

Engagements with international regulatory bodies and authorities

Global Harmonization Working Party (GHWP) Annual Meetings

26th GHWP Annual Meeting in Riyadh, Saudi Arabia

APACMed, as an Industry Liaison Member of the Global Harmonization Working Party (GHWP), participated in the 26th GHWP Annual Meeting in Riyadh, Saudi Arabia, in February 2023, and in the 27th GHWP Meeting in Shanghai, China, in November 2023. The events, prominent gathering for MedTech regulators, industry professionals, and associations, featured a two-day engagement for the APACMed delegation. The delegation, including the APACMed Secretariat, regional leaders from the Regulatory Affairs Committee, and Country Regulatory Affairs leaders from China and India, participated in meetings, panel discussions, and presentations.

Key highlights included a presentation on regulatory agility, focusing on the need for more innovative regulatory pathways, and on regulatory reliance, harmonization and convergence. Additionally, APACMed presented findings from the GHWP-APACMed Regulators Curriculum Paper, which was endorsed by GHWP, designating APACMed as one of GHWP's formal training partners. We would like to highlight the importance of collaborative regulatory platforms such as GHWP in building consensus and fostering industry development, this aligns with APACMed's dedication to enhancing regulatory capacity in the Asia-Pacific region.

International Medical Device Regulators Forum (IMDRF)

The 24th Management Committee meeting of the International Medical Device Regulators Forum (IMDRF) held in Berlin, Germany in September 2023 marked a significant milestone in the pursuit of regulatory harmonisation and convergence in the MedTech industry. The conference was a pivotal opportunity to address crucial themes and engage with stakeholders from across the globe. Key topics were explored during the conference, including devices for specific patient groups, innovative medical devices, regulatory tools for fostering innovation, digital labels, unique device identification, and amendments to the EU Medical Device Regulation.
The IMDRF 24th Management Committee meeting in Berlin served as a catalyst for advancing regulatory harmonisation and convergence in the MedTech sector. The insights gleaned from this conference are invaluable, providing a roadmap for the industry's future endeavours. By fostering collaboration, embracing innovation, and leveraging regulatory tools, the MedTech community stands poised to deliver safer, more effective, and accessible medical technologies to patients worldwide.

The annual ASEAN Medical Device Committee (AMDC) conference

After a 4-year hiatus due to the COVID-19 pandemic, the ASEAN Medical Device Committee (AMDC) conference resumed in 2023, taking place in Brunei Darussalam from September 11th to 14th. This annual gathering convenes ASEAN regulators to harmonize regulations and standards for medical devices across member countries, facilitating a consistent regulatory landscape in the region. APACMed collaborated with the AMDC Committee to host the Capacity-Building Program and Public-Private Forum (PPF) on September 14, 2023. The PPF provided a platform for industry stakeholders to engage with ASEAN regulators, fostering dialogue and addressing challenges in the Medical Device Sector. The Capacity-Building Program, featuring sessions by experts like Mr. Sharad Mi. Shukla and Dr. Ed Woo, covered topics such as Software as a Medical Device (SaMD), EU Medical Device Regulations, and effective change management processes. Ms. Yasha Huang introduced Regulatory Agility and Good Reliance Practice, emphasizing the importance of convergence and harmonization among regulatory authorities for evidence-based decisions that prioritize patient safety. APACMed's participation underscores its commitment to advancing regulatory capabilities and promoting collaboration within the ASEAN region.

Collaboration with the World Health Organization (WHO)

Meeting with the WHO during the 26th GHWP Annual Meeting

In ongoing discussions with the World Health Organization (WHO), APACMed has been exploring synergies in regulatory system strengthening, specifically focusing on Regulatory Reliance. The relationship was strengthened when WHO officials participated in the APACMed Regulatory Transformation Symposium in May 2022. During the symposium, WHO emphasized the importance of regulatory reliance in the Asia-Pacific region, based on the Good Reliance Practice (GReP) guidance document. Subsequent virtual discussions culminated in a face-to-face meeting on the sidelines of the GHWP Annual Meeting in Riyadh. GHWP provided a platform for both organizations to plan the way forward in promoting reliance in the region. APACMed has initiated the process of joining WHO's Coalition of Interested Parties (CIP), a significant step to accelerate the drive for reliance in the Asia-Pacific region. The meeting also resulted in tailored strategies for individual markets and marked a significant milestone towards the goal of regional harmonization in APAC. To close this year of close collaboration, the WHO participated in the APACMed MedTech Forum in December 2023, with a presentation on the significance of regulatory reliance, harmonization, and convergence.

Developing a Strong Regulatory Workforce Through Capacity and Capability Building

MoU between APACMed and the National University of Singapore (NUS)

Signing of the MOU between Ms. Harjit Gill, CEO of APACMed and Professor Teo Kie Leong, Acting Dean of the NUS College of Design and Engineering

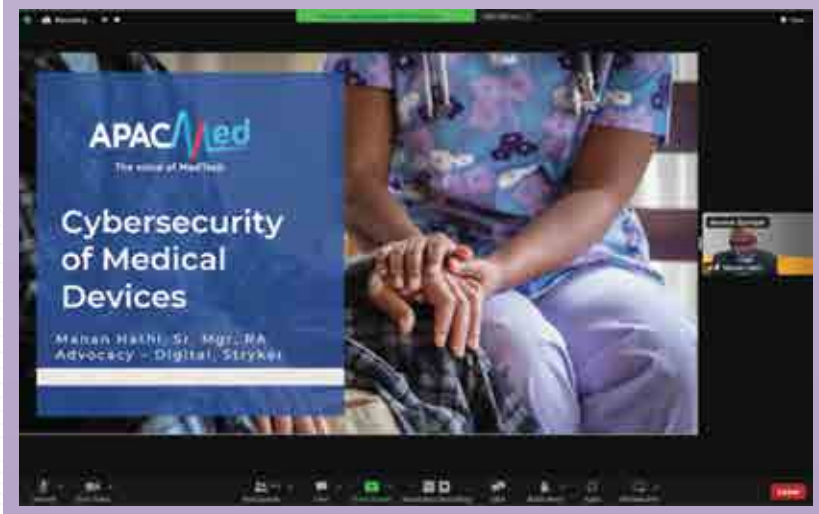
On July 27, 2023, a Memorandum of Understanding (MoU) was officially signed between APACMed and the National University of Singapore (NUS), marking a collaborative effort to develop enhanced professional development programs for Medical Device Regulatory Professionals. The partnership aims to leverage APACMed's resources, industry expertise, and awareness of emerging trends. During the signing event, Professor Teo Kie Leong, Acting Dean of the NUS College of Design and Engineering, emphasized the significance of the collaboration, recognizing APACMed's wealth of resources and expertise. The joint effort between academia and industry seeks to create a more relevant training program that stays current with the dynamic changes in the regulatory sector. Ms. Harjit Gill, CEO of APACMed, expressed delight at the opportunity to establish a learning platform connecting industry and academia, raising standards and skills in the medical technology regulatory profession. Following the MoU signing, an industry seminar featured presentations by industry experts, including Mr. Sharad Shukla from Johnson & Johnson, Mr. Sanjay S. Kumar from Invisalign Singapore, and Mr. Seet Wing Gang from Cook Medical. We look forward to future joint initiatives with NUS's Biomedical Engineering department.

Capacity and Capability Building Training for Regulators

Dedicated to our mission of fortifying the MedTech regulatory workforce, we joined forces with the Global Harmonization Working Party (GHWP) to craft the 'Training Curriculum for MedTech Regulatory Authorities.' This collaborative initiative aimed to establish a standardized and harmonized training curriculum, encompassing various core competencies. The primary focus was on shaping the future trajectory of regulatory training for all GHWP member jurisdictions, empowering them to navigate the complexities of an ever-evolving global regulatory landscape. In 2023, APACMed actively implemented numerous training programs for regulators, extending support to regulatory bodies in Sri Lanka, Malaysia, Indonesia, Vietnam, New-Zealand, and participating in the annual ASEAN Medical Device Committee (AMDC) meeting.

In executing these training programs, APACMed tailored the content to address region-specific concerns while concurrently tackling overarching themes crucial for regulatory advancement. The initiatives delved into locally pertinent topics, offering regulators in Sri Lanka, Malaysia, Indonesia, Vietnam, New-Zealand, and participants at the annual AMDC meeting targeted insights into their unique regulatory landscapes. Simultaneously, the programs explored broader strategic imperatives, emphasizing the critical aspects of driving regulatory agility and efficiency through reliance, promoting convergence and harmonization, and establishing platforms for meaningful dialogue and advocacy on key strategic topics. By championing these initiatives, APACMed reaffirms its unwavering commitment to fortifying regulatory capabilities, nurturing collaboration among diverse stakeholders, and ensuring that regulatory authorities are not only adept at navigating local intricacies but also well-prepared to navigate the ever-evolving global regulatory landscape. This commitment underscores APACMed's pivotal role in shaping a resilient and forward-looking regulatory ecosystem within the Asia-Pacific region and beyond.

Online Capacity and Capability Building Training



The RA Committee has been instrumental in creating content on competency frameworks, gap analysis, and training curriculums over the years. Evolving from this foundation, our aim has extended to assume the role of a training provider, leading to the inception of the APACMed e-Learning Hub (ELH). Launched in 2022, the ELH represents our latest member offering. Currently comprising 30 modules, the hub spans various courses strategically designed to align with different stages of a product lifecycle across diverse regulatory functional domains, including Pre-Market, Regulatory Knowledge and Application, Regulatory Strategy, Quality & Compliance, and Post Market. Excitingly, in 2023, the ELH is undergoing a comprehensive revamp to provide a fresh, modern feel and updated content, ensuring an enhanced learning experience for our users.

In a joint partnership with Clarivate, APACMed held a successful webinar on The Evolving Regulatory Landscape for In Vitro Diagnostics (IVD) in the Asia-Pacific (APAC) region. The webinar featured discussions led by Sam Kay and Raghav Thangri from Clarivate. Coupled with industry perspective and experiences provided by panel speakers Yasha Huang (Roche diagnostics) and Victor Tan (previously Ortho-Clinical-Diagnostics). The webinar covered the impact of changes in European regulations on the IVD industry in the APAC, EU-IVDR and its impact on APAC Markets and fruitful discussions on how to drive innovation and the role of AI in the IVD space.

Additionally, Sharad Mi Shukla (J&J), Yenny Aggaro (Stryker), and Yu Hosakai (Cook Medical) leads of the Southeast Asia COE team organised an online cybersecurity training workshop for APACMed members. There were over 140 APACMed participants in this session. Manan Hathi, Senior Manager of Regulatory Affairs at Stryker and Chairperson of the Regulatory Digital Working Group at APACMed, led the cybersecurity-focused training which received tremendous positive feedback and aided our members in understanding the new and emerging landscape. This workshop is an example of SEA COE's continuous efforts to improve members' proficiency in the field of digital health and keep them up to date on the most recent developments in the MedTech industry.

Advocacy On In-Country Live Issues

Halal Policy in Indonesia

In 2021, Indonesia introduced Government Regulation No. 39, a groundbreaking Halal Policy applicable to all products, including Medical Devices, with a specific focus on disclosure of Animal-Derived Materials (ADMs) in production. This policy posed challenges for MedTech companies due to unclear standards and potential risks to patient access to critical medical devices. Responding to this, APACMed published a Position Paper on Halal Policy in 2022, outlining industry challenges and recommendations for its smooth implementation. Following this, a Roundtable session was organized in Jakarta in September 2023, engaging key stakeholders from the Indonesian government, including BPJPH, IACC, Gakeslab, the Ministry of Health Indonesia, and MUI. Moderated by industry experts, the session facilitated a robust discussion on the implications of Halal Policy in the MedTech sector, allowing for the expression of challenges, clarification of queries, and exploration of collaborative solutions. The stakeholders demonstrated receptiveness to concerns, highlighting the importance of a comprehensive scope and showing a willingness to consider industry recommendations. The session was not only an opportunity to voice concerns but also a platform for seeking common ground and fostering collaboration among stakeholders, with APACMed members committed to continued cooperation on the discussed points.

Laos New Regulation

In the next year, Laos will begin to regulate medical devices. Through sharing recommendations and offering industry inputs when needed, APACMed has maintained close ties with Laos PDR Ministry of Health with the help of Ms Chloe Tan, QA & RA Lead, Indochina, and representative from Frontier Market Plus, Medtronic, SEA lead for Laos, to provide guidance on the optimal approach to take during the implementation phase. In order to facilitate implementation, give industry and regulators time to adjust to the new rules, and promote harmonization, we have also been advocating for Regulatory Reliance.

In other advocacy efforts, APACMed represented the APAC region in discussions related to New Zealand's Health Bill, articulating industry challenges and supporting MTANZ. The health bill has since been repealed. Additionally, Miang Tanakasemsub, our RA Committee Chairperson, led a capacity-building session at the MTANZ conference on Regulatory Harmonization.

Regulatory Intelligence

We are the first regional association to come up with a magazine-type monthly regulatory intelligence bulletin. The objective of this bulletin is to provide our members with up-to-date regulatory briefs and actionable insights, which can contribute to key regulatory decision- making processes for all markets across Asia Pacific. The bulletin will continue to publish thought leadership editorials, key country regulatory updates, regional regulatory trends and analysis, abstracts from important regulatory conferences, and expert interviews with regulators, KOLs and other subject matter experts. Our primary objective with Regulatory Intelligence is to monitor policies closely and respond proactively to emerging regulations and changes that could impact the industry. This approach enables APACMed to initiate advocacy efforts at an early stage, influencing changes before any significant impact occurs, thereby minimizing disruptions to our members' workforce.

RegConnect is a recent initiative by the RA committee aimed at fostering collaboration between government agencies and industry stakeholders. Through this platform, our esteemed members get the chance to engage in discussions with regulators, facilitating an exchange of key insights. It serves as an opportunity for regulators to shed light on their ongoing initiatives and provide a glimpse into what the industry can expect. RegConnect creates a unique space that fosters connections between both industry representatives and regulators.

In 2023, we were honored to have the participation of three regulators in RegConnect—Mariammah Krishnasamy from the Medical Device Authority, Malaysia; Pak Fikriansyah from the Ministry of Health, Indonesia; and Tracey Duffy from the Therapeutic Goods Administration, Australia. Each session proved to be a success, attracting over 120 participants each time, with engaging and insightful discussions.

Legal, Ethics & Compliance Committee

Composed of 130+ individual members from 30+ companies, the Legal, Ethics & Compliance Committee (LECC) works to raise standards of doing business across the Asia-Pacific region, including the facilitation of ethical interactions between industry and healthcare professionals, as well as industry adherence to APACMed's Code of Ethical Conduct.

Core Leadership

Christian Fitsch
Chairperson
VP, Chief Legal Counsel, Asia Pacific
Stryker

Bernd Dudel
Vice-Chairperson
Head of Legal and Compliance
Asia Pacific
Siemens Healthineers

Emma Press
Vice-Chairperson
VP, Legal Asia and ANZ/Japan
Medtronic

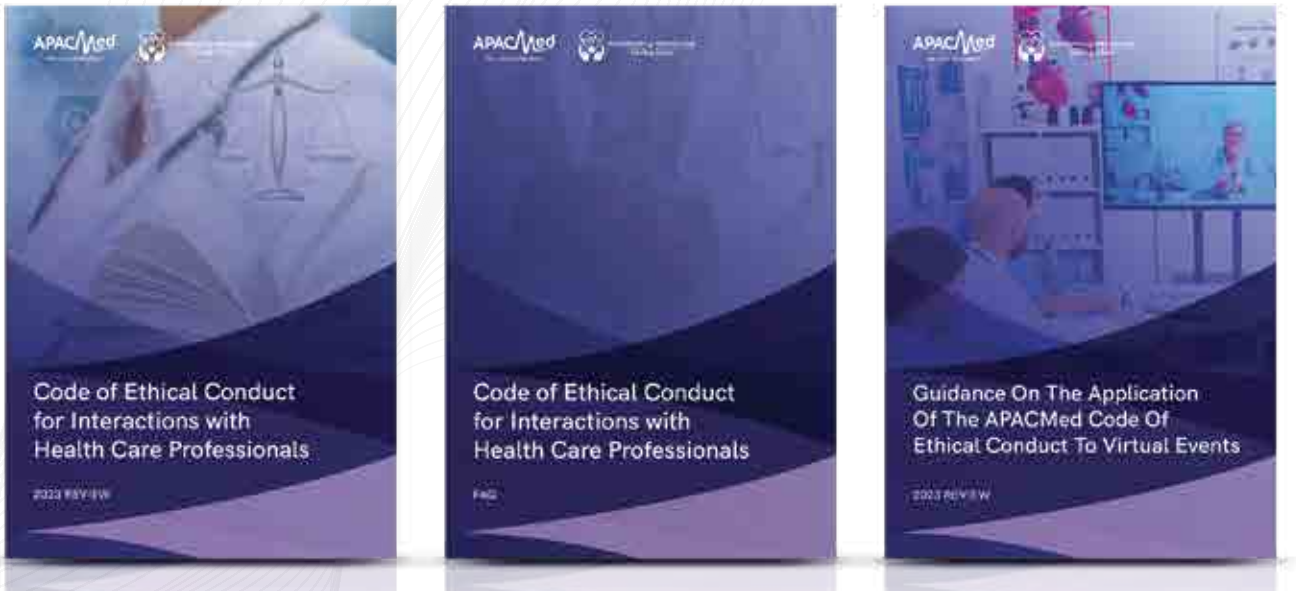
Jye Mei Wong
Vice-Chairperson
Regional Senior Legal &
Compliance Counsel, Asia Pacific
Boston Scientific

Strategic Initiative

The purpose of the Code is to facilitate ethical interactions between Members and HCOs and HCPs. Members commit to adhere to this standard by adopting and abiding by the ethical principles outlined in the Code.

The Code has been under regular review since the first version came into force on 1 January 2016. In February 2022, the Legal, Ethics and Compliance Committee reviewed the Code, especially its regulations on providing gifts and branded items to HCPs, an area which needed to be revised in order to comply with the Modernised KL Principles (published by APEC early 2022). The revisions will be effective on 1st Jan 2024 in order to provide Members sufficient to adapt and change internal policies and procedures.

The latest version of the Code of Ethical Conduct is available, together with the FAQ and Guidance on the application of the Code to virtual Events, onto the APACMed website.



Why were changes referred to the provision of gifts and other contributions made?

Adoption of APEC's KL Principles:

APACMed has aligned its gift policy with the standards defined by APEC (Asia-Pacific Economic Cooperation) in the KL Principles.

These principles serve as a regional benchmark for ethical practices in the healthcare industry.

Clarification of Ethical and Compliant Interaction with HCPs:

The revised gift policy aims to provide clearer and more specific guidance on ethical and compliant interactions with Healthcare Professionals (HCPs) regarding gifts and other contributions.

Clear guidelines help foster transparency, trust, and responsible engagement within the HCPs.

Alignment with other Medical Device Associations:

APACMed recognizes the importance of international harmonization and cooperation.

The updated policy ensures compatibility with international standards set by medical device associations such as AdvaMed and Medtech Europe.

In early 2023, the LECC has announced its newly elected leadership team. Leading the charge as the new Chair is Christian Fitsch, Vice President, and Chief Legal Counsel APAC for Stryker Corporation. New Vice-Chairs: Bernd Dudel: Head of Legal and Compliance Asia Pacific, Siemens Healthineers Emma Press: Vice President, Legal Asia and ANZ/Japan, Medtronic Jye Mei Wong: Regional Senior Legal & Compliance Counsel, Boston Scientific.

Their combined expertise and diverse perspectives promise a dynamic and effective leadership that will drive the committee's initiatives forward. Since their election, the new LT has been diligently working on updating the APACMed LECC charter, which has been officially revised after a workshop with the LECC members. The revisions aim to better align the committee's purpose and objectives, ensuring it remains at the forefront of promoting ethical conduct and compliance standards within the medical technology industry.

APACMed LECC's purpose is to support, advocate and elevate ethics & compliance standards in our industry:

Support

- Support other APACMed Committees and the Board
- Share Information and best practices within LECC
- Strengthen the LECC Community

Advocate

- Promote Code of Ethics & general guidance materials
- Highlight and address emerging legal, ethical or compliance issues
- Collaborate with other med-tech associations

Elevate

- Provide a forum to resolve potential issues before escalation
- Engage with industry stakeholders in the region
- Connect to and apply learnings from other industries to support our purpose

As the industry continues to evolve, the APACMed LECC leadership team stands poised to play a crucial role in navigating challenges, fostering collaboration, and elevating ethical and compliance standards across the Asia-Pacific region.

Knowledge Sharing Sessions

This year, the LEC Committee hosted a number of closed-door discussions and webinars with expert knowledge partners in order to provide members with relevant insights into critical compliance related matters. Some of the topics covered include:

- Recent Healthcare Sector Antitrust Cases in the APAC region
- Presentation on Enforcement Trends: current trends, best practices, and potential challenges in the ever-evolving legal landscape
- Legal Horizons in MedTech: Environmental, Social and Governance (ESG) Compliance and Artificial Intelligence (AI) Integration

In response to enthusiastic feedback and expressed interest from LECC members regarding increased involvement in specific areas, the committee is set to launch four working groups in 2024. These groups will focus on Environmental, Social, and Governance (ESG) Compliance, Artificial Intelligence, Interactions with Healthcare Professionals and Patient Organizations, and Collaboration with Pharma. For additional details about these groups, please reach out to our LECC lead.

In-Vitro Diagnostics Working Group

APACMed formed the In Vitro Diagnostics Working Group (IVD WG) during the COVID-19 pandemic to recognise the pivotal role diagnostic testing plays in containing the spread of the virus and facilitating the reopening of economies. Beyond the immediate response to the pandemic, the group has recognised and emphasised the broader role of diagnostic technologies across various disease states and the patient's journey.

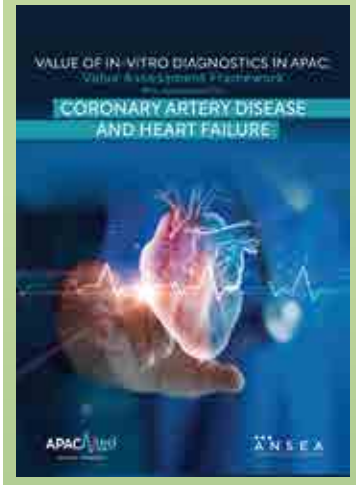
Despite diagnostics accounting for over 70% of clinical decision-making, there has been insufficient prioritisation in healthcare systems across the region[1].

The World Health Assembly Resolution on 'Strengthening Diagnostic Capacity' passed in May 2023 represents a significant milestone in recognising the critical value of diagnostics. APACMed aims to build on this momentum, continuing to advocate for improved patient access to diagnostic innovations in collaboration with various stakeholders in the healthcare ecosystem.

Strategic Initiatives

In 2023, the In-Vitro diagnostics working group's key strategic initiatives are as follows:

Value of In-Vitro Diagnostics in APAC: Value Assessment Framework with applications for Coronary Artery Disease (CAD) and Heart Failure (HF)



In 2023, APACMed, in partnership with and our knowledge partner Ansea Consulting developed a white paper to generate awareness on need for enhanced recognition of the substantial value that In-Vitro Diagnostics (with a specific focus on CAD and HF) provide to multiple stakeholders in the healthcare ecosystem. It advocates for IVDs to be backed by sustainable funding and their widespread availability at all levels of care to ensure patient access to high quality diagnostics. The paper also recommends a fit for purpose value assessment framework for diagnostics and inclusion of various types of evidence for full value assessment of IVDs.

Regional Roundtable on Value of In-Vitro Diagnostics in the Asia Pacific Region with applications for Coronary Artery Disease (CAD) and Heart Failure (HF): Deep Dive into Thailand and Australia

In November 2023, a closed-door roundtable was held with stakeholders from Australia and Thailand including government officials, payors, academicians, clinicians and local trade associations. The roundtable included a discussion on the implementation of the recommendations from the white paper in each of the two respective countries- highlighting the specific challenges and opportunities for adoption. It also provided a platform for cross-sharing and learning between the two markets -at different stages of journey- towards improved funding and accessibility to CAD and HF related diagnostics.

Unlocking the Value of Quality Next-Generation Sequencing in APAC

APACMed developed a white paper on 'Unlocking the Value of Quality Next-Generation Sequencing in APAC' in partnership with LEK Consulting. The paper articulates the need and benefits of quality NGS and provides guidance on setting quality standards across different resource settings in APAC for a diverse group of stakeholders. It recommends the need for different stakeholders to work together to establish more effective and market-appropriate national policy strategies for adoption of quality NGS. The paper is translated into Mandarin, Korean and Japanese.

[1]*Rohr, Ulrich Peter et al. "The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report." PLoS ONE. (2016); 11 (3):1-16*

Events and Membership Engagement

In-Vitro Diagnostics Expert Summit at the MedTech Forum 2023

An inaugural, standalone summit was held for In-Vitro Diagnostics as a part of the MedTech Forum on 6th December. A series of exciting and enriching sessions were organized around the theme of 'Addressing Access Barriers for Diagnostics'.

The first part of the summit focused on the implications of the landmark World Health Assembly Resolution on 'Strengthening Diagnostics Capacity' for the APAC region. Keynote presentations by the Lancet Commission and FIND set the foundation on the priority areas for the resolution. This spurred further discussions on its implementation roadmap highlighting the need for stakeholder collaboration for realizing the full value of diagnostics in bringing health for all.

The second part of the summit focused on unlocking the value of precision medicine through Next Generation Sequencing. The discussion started with a patient advocacy leader from Australia, sharing his perspectives on the need for quality standards for Next-Generation Sequencing technologies and barriers faced in accessing them. This was followed by a multi-stakeholder sharing of perspectives on the value of quality NGS, quality assurance, and standardization and how quality standards can enhance the clinical utility of NGS technologies.

The summit was warmly received by the attendees as meaningful connections were made and opportunities for future collaboration were uncovered.

IVD Strategy Retreat

In November 2023, the IVD working group secretariat conducted a hybrid annual strategy retreat. The retreat served as a platform for reflection, celebration, and forward-looking strategic planning. A thought-provoking presentation by Pathology Awareness Australia on a successful stakeholder engagement strategy for effective policy shaping kickstarted the discussions.

Apart from celebrating the wins of the past, the members helped to prioritize the specific initiatives and markets for the 2024 workplan. The involvement of Vista Health in facilitating discussions added a valuable external perspective to the working group's strategies.

Start-up & SMEs Committee

Consistent with the theme of innovation, more than 50% of APACMed members are now in the start-up category. APACMed welcomed 45 new start-up members in 2023, taking the total to 200 companies spanning across a range of solution types, disease themes, and geographies.

Core Leadership

Kris Liang
Strategy & BD
Stryker Asia Pacific

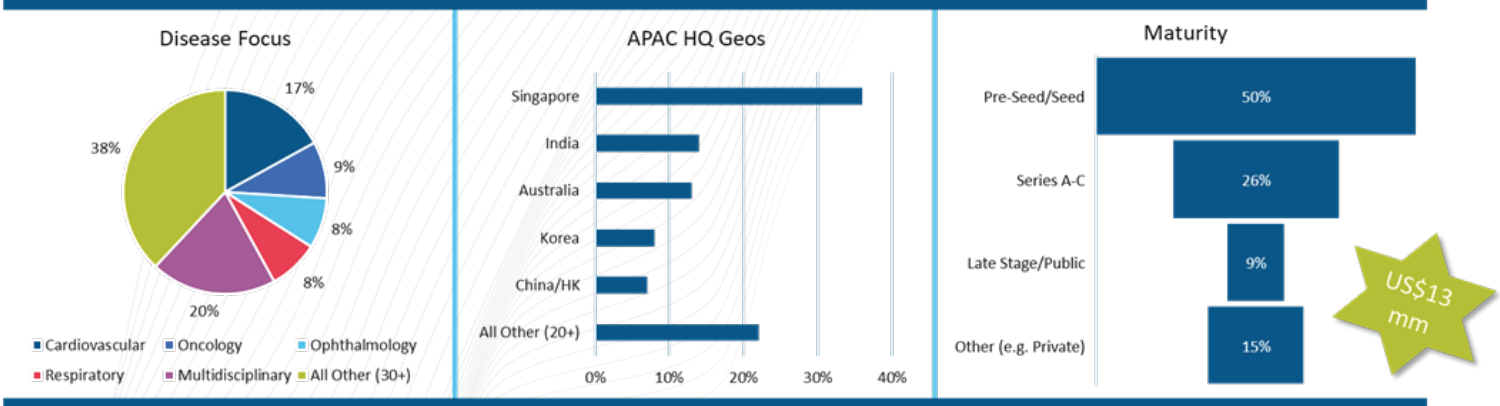
Ashley Wittorf
Head of BD
Johnson & Johnson Asia Pacific

Dr. Lynne Lim
Founder & CEO
NousQ

James Sung
CEO
MatrixLabs

Below is a snapshot of the APACMed start-up member portfolio, using proprietary analysis collected and analysed by our organisation:

APACMed start-up members cover the gamut of medical devices, digital health, and enabling services:



While clinical innovation is a common trend, there remain challenges in partnerships and financing for growth.

APACMed's goal for start-ups centres around the acceleration of innovation in the Asia Pacific region, supporting members with building out ecosystems, expanding collaborations (such as with corporates), and navigating regulatory and reimbursement pathways.

Accordingly, key outputs of APACMed start-up efforts this year included:

Start-up curriculum

We hosted multi-stakeholder events around in-demand topics such as Intellectual Property (IP), regulation, funding, and manufacturing for scale. The curated curriculum offered start-ups an opportunity to engage directly with key experts as well as to network with each other and wider industry leaders.

Corporate venturing

In order to better support start-ups with corporate matchmaking, we identified the "innovation" contact at our corporate members and created the APACMed Innovation Community (AIC). A kick-off in April found that 80% of corporates have or are building dedicated external innovation functions in the region, and that they are open to various stages of start-up growth, as well as financial and non-financial partnerships.

Matchmaking database

We launched a first-of-its-kind corporate-start-up MedTech database for the Asia Pacific, using self-reported and desktop research data. Stakeholders are able to filter by categories such as disease theme, geography, regulatory status, and commercialization status to find each other and to connect.

Financing of innovation

We continue our partnership with the MedTech Innovator program, the world's largest MedTech accelerator. More than USD 200,000 was awarded for innovators in the region to scale up their solutions, including through corporate partnerships. Congratulations once more to the winners!

Matchmaking events

Beyond the above, we continued matchmaking throughout the year. This came in the form of direct requests by corporates or start-ups, networking events, and an executive-level breakfast session to discuss innovation in the region. We also hosted Innovation Day at the MedTech Forum, featuring keynote talks, start-up pitching to corporate challenge statements (reverse pitching), and ample time for networking.

In 2024, we look forward to continuing to build up our start-up member portfolio and to hosting matchmaking opportunities, including with more focus in-country around the Asia region. We will also seek to engage in more policy and capability building activities, consistent with the broader APACMed innovation mission.

Global and Regional Partners

Our partnerships within the region with local trade associations are fortified and strengthened through robust collaborations in 2023.

Overview for ASEAN, Japan, Korea & Australia

Our partnerships within the region with local trade associations are fortified and strengthened through robust collaborations in 2023.

In Southeast Asia, we continue to lead actively with support and guidance to advocate for policy formulation alongside local partners and members to their governments and capability build by upskilling and reskilling regulatory teams.

Leveraging the comprehensive insights encapsulated in the Position Papers published by Committees, we partnered with similar associations in Australia, South Korea, Japan and Singapore in various strategic topics to engage policymakers, regulators and government officials to help shape policies. Through these processes, APACMed team was able to foster enhanced competencies through best practices sharing from subject matter experts and officials from United States, United Kingdom and European geographies with the overarching goal is to propel the advancement of MedTech solutions for the betterment of patients and societies across the entire region.

Our Partners

The alliance and growth of our local and global partners is integral as we bring our work into the countries being a regional voice as we endeavour to collectively advocate in diverse strategic domains to influence local governments, thereby shaping policies that positively impact patients, members, and the wider healthcare industry.

Apart from aligning our voices, APACMed is instrumental in aiding our partners in the areas of creation of Position Papers, submission letters on critical ongoing issues and capability building initiatives.

Globally as we experience similar and recurring challenges in the MedTech domain in Asia Pacific region, our collaborative efforts spans beyond local partners to global organizations such as World Health Organization, The Global MedTech Alliance, The International Medical Device Regulators Forum, MedTech Europe, Advamed, American and European chambers, business councils striving with similar interests for their members and countries.

Japan • American Medical Devices and Diagnostics Manufacturers' Association (AMDD)
• Japan Federation of Medical Devices Associations (JFMDA)

Korea • Korea Medical Devices Industry Association (KMDIA)

Australia • Medical Technology Association of Australia (MTAA)

New Zealand • Medical Technology Association of New Zealand (MTANZ)

Singapore • Medical Technology Industry Group of Singapore Manufacturers' Federation (SMF)
• Association of Medical Device Industry (AMDI)

Malaysia • Association of Malaysian Medical Industries (AMMI) and Malaysia Medical Device Association (MMDA)

Thailand • Thai Medical Device Technology Industry Association (ThaiMed)

Vietnam • European Chamber of Commerce in Vietnam (EuroCham VN)

Indonesia • The Association of Entrepreneurs for Laboratory and Health Equipment (GAKESLAB)

Philippines • Philippine Association of Medical Device Regulatory Affairs Professionals (PAMDRAP)
• Healthcare Technology Association of the Philippines (HTAP)

Myanmar • Myanmar Pharmaceutical and Medical Equipment Entrepreneurs' Association (MPMEEA)

Sri Lanka • Sri Lanka Chamber of Medical Devices Industry (SCLMDI)

US Asean Business Council

EU Asean Business Council

American & European Chambers of Commerce

Europe • MedTech Europe

US • Advamed

World Health Organization

International Medical Device Regulators Forum (IMDRF)

Global MedTech Alliance (GMTA)

Local Trade Association Partners

Other Regional & Global Association Partners

AdvaMed · MedTech Europe · US-ASEAN · EU-ASEAN · EuroCham · AmCham

Our Key Collaborations with Partners in 2023

Regulatory Affairs

Hala Policy for Medical Technologies (Indonesia)

In 2021, Indonesia implemented the Indonesia Government Regulation (PP) No.39 that impacted all medical device products to disclose the use of Animal-Derived Materials in the production of the final product.

This posed significant challenges to medical devices companies due to the limited clarity on standards, requirements and guidelines. It threatened the access of care to patients especially in critical and life-saving medical equipment. Being the first globally to implement such a regulation, it altered already stringent testing and assessments required to determine the safety and efficacy of medical devices and possibly pave the way for other countries to follow suit if left unaddressed.

APACMed published the Position Paper on Halal Policy in March 2022 to highlight the challenges faced medical devices companies, the risks of limited care to patients and recommendations for smooth implementation of Halal Policy respecting and upholding Islamic values.

A roundtable with key stakeholders of the Indonesian government (The Halal Product Assurance Organizing Body (BPJPH), he Indonesian Association for Clinical Chemistry (IACC), the Ministry of Health Indonesia and Majelis Ulama Indonesia (MUI)) took place in September 2023 where constructive discussions was held over the implications of halal policy for medical devices including the recommendations published in the Position Paper.

The session paved the way for ongoing dialogue with these stakeholders to seek common ground and explore collaboration avenues for seamless transition to changes in regulations.

Regulatory Capacity Building

Improving the industry and regulators capabilities stands as a fundamental pillar for APACMed in the region. Through ongoing upskilling and reskilling, MedTech will remain a core contributor of healthcare to bring faster access and new technologies to save lives and offer better quality of life to societies. Capability building took place is these countries in 2023 including some noteworthy highlights.

APACMed had the opportunity to collaborate with AMDC Committee to host the Capacity-Building Program and Public-Private Forum (PPF), held at the sidelines of the 12th AMDC Meeting on 14 September 2023, Thursday. The PPF provided APACMed the opportunity to connect industry stakeholders with ASEAN regulators and conduct Capacity-Building Program that covers a diverse range of topics designed to enhance the general and functional technical competencies of regulators and industry experts.

A regulatory training workshop was held in March for 20 officers from the Thai Food Drug Administration covering specific topics to enhance existing and new staffing needs including good regulatory practices, change management, software as a medical device and biocompatibility for medical devices.

Conducted training for 50 Ministry of Health officers from Indonesia in September encompassing topics related to harmonization for reliance and convergence, standards and testing requirements for regulatory compliance of medical devices and diagnostics.

Digital Health

Digital Health Reimbursement Policy Forum

This year APACMed together with our knowledge partner Eversana organized the inaugural event with the ambition to gather knowledge of the current landscape of reimbursement status for digital health technologies across four major APAC markets based on the level of digital readiness vs advanced western markets. These included Australia, Singapore, South Korea and Japan.

Policymakers from the four APAC markets were brought to the table to discuss the progress made in deciphering the complex reimbursement pathway for digital health and the challenges which makes it difficult to bring the new innovation earlier into the market to increase access to patients via reimbursement.

Most of the APAC markets believe that reimbursement for digital technology is at a novice or Intermediate stage but clearly showed that digital health technologies is certainly gaining momentum and the critical discussions regarding establishing reimbursement pathways remain unclear.

Learnings from Germany, France and UK, reinforced the pressing need for digital health reimbursement pathways to developed.
Policymakers are looking forward to recurring editions of the Forum for learnings that may possibly lead to eventual framework development.

Interoperability Round Table (ASEAN)

In June, the committee in partnership with KPMG organized a round table for ASEAN regulators with the objective to knowledge share and collaborate with global and local bodies on best practices for data sharing frameworks, governance and standards within the region to minimize data burden, leverage common data across the ecosystem for patient, provider and policy-maker insights and interventions.

The outcome of the roundtable that included the tech lead representatives from Ministries of Health in ASEAN are keen to establish a working group cross-regional should be formed to meet quarterly to discuss challenges, progress and plan ahead on ASEAN interoperability.

Value-Based Market Access

In emerging markets, policy makers are looking for value assessments to update important drugs and devices into essential national reimbursement lists for universal health coverage. However, the challenge remains in the lack of established and clear processes and guidelines for assessing these technologies. Collaboration and feedback from stakeholders across the health care ecosystem is needed, in order to successfully design and implement value-based pricing and reimbursement policy, aligning incentives to ensure good patient outcomes are delivered at appropriate costs.

Partnering local associations including AmCham Malaysia, EuroCham Vietnam and the US-ASEAN Business Council, APACMed engaged decision-makers in Malaysia and Vietnam through a series of Value-Based Market Access Workshops in Feb and Oct 2023 respectively. The workshops brought together payors, providers, physicians and policymakers, together with industry, to share best practices on value-based pricing and procurement based on patient outcomes, with realistic, implementable healthcare financing models.

Government Affairs & Market Access

Environmental, Social and Governance: What Lies Ahead for the MedTech Industry

In July 2023, the APACMed Breakfast Conversation delved into the critical theme of Environmental, Social, Governance (ESG) within the MedTech industry in collaboration with Bain & Co.

APACMed, is committed to assisting the MedTech sector in navigating the complexities and possibilities of the environmental landscape. Recognizing the growing significance of the environment for long-term success and sustainability, particularly in the Asia-Pacific region, companies face challenges such as evolving regulatory frameworks, changing consumer expectations, and a dynamic global economic context. Despite these hurdles, they also encounter unprecedented opportunities.

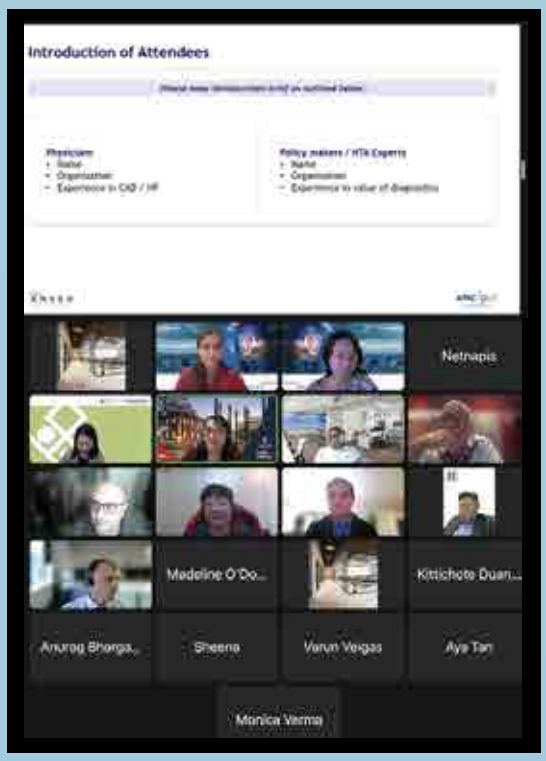
During this session, leaders from MedTech companies shared insights on striking a balance between competitiveness and strategic investments for the future, especially in the context of the price-sensitive APAC market. The identified areas where APACMed could play a pivotal role in supporting the industry included capability building and the development of an industry-specific narrative aimed at securing exemptions considering healthcare considerations.

This event coincided with the unveiling of an online environmental regulatory dashboard designed to enhance monitoring capabilities. Accessible on the APACMed website, this tool was developed through the collaborative efforts of APACMed and Bain & Company. Fifteen member companies joined forces to create a comprehensive dashboard focusing on environmental regulations specific to the MedTech value chain across six APAC markets. The initiative was further enriched by surveys involving 120 customers and over 800 employees, including various executives from MedTech companies. These surveys aimed to better comprehend how shifting stakeholder expectations reinforce the strategic priority of ESG for companies in the MedTech sector.

Looking ahead, APACMed is committed to sustaining support for its members, with a focus on the highlighted areas discussed during the event. The white paper resulting from the partnership between APACMed and Bain & Company serves as a foundation for ongoing efforts to address the challenges and seize the opportunities presented by the evolving environmental landscape in the MedTech industry.

In-Vitro Diagnostics (IVD)

Value of Diagnostics in APAC: Value Assessment Framework with Applications for Cardiovascular Disease



Diagnostics play a pivotal role in delivering quality healthcare; however, there exists a disparity between the value they provide and the funding they receive. This discrepancy is often attributed to the absence of a suitable value assessment framework that comprehensively captures the worth of diagnostic technologies. In turn, this incomplete evaluation leads to an underestimation of their value in funding and reimbursement decisions.

Published in September 2023, the white paper titled "Value of IVD in APAC: Value Assessment Framework with Applications for CAD and HF" utilized Coronary Artery Disease (CAD) and Heart Failure (HF) as concrete use cases. By demonstrating the substantial value of In Vitro Diagnostics (IVDs) to various stakeholders, the paper advocates for sustainable funding and widespread availability of IVDs across all levels of care.

In November 2023, a closed-door roundtable was held with stakeholders from Australia and Thailand including government officials, payors, academicians, clinicians and local trade associations. The roundtable included a discussion on the implementation of the recommendations from the white paper in each of the two respective countries- highlighting the specific challenges and opportunities for adoption. It also provided a platform for cross-sharing and learning between the two markets - at different stages of journey- towards improved funding and accessibility to CAD and HF related diagnostics.

In November 2023, a closed door roundtable took place as the initial step toward greater diagnostic access, addressing the pressing public health priorities in the region. The event focused on the need for value recognition, associated funding, and access for IVDs in CVDs, specifically in Thailand and Australia. Attendees included Lancet Commission, policymakers, clinicians, payors, academicians and local trade associations. The identified next steps for 2024 indicate a continued commitment to advancing this initiative and reinforcing the dialogue around IVDs in the local context. By enhancing the value recognition of diagnostic technologies, their integral role in universal healthcare delivery can flourish, aligning with the World Health Assembly's 76th resolution passed in May 2023.

Country Insights: APACMed in India

APACMed India is fully committed to collaborating with regulators and policymakers to achieve the goal of providing patients with access to high quality and affordable medical technology. APACMed India is working towards the creation of a robust and sustainable ecosystem that encourages investment and innovation. In India, APACMed is actively engaging with relevant government stakeholders, Key Opinion Leaders (KOLs) and subject matter experts in India through its various functional committees. APACMed in India is constantly working to identify key regulatory trends, shaping policies and working towards the growth of the medical device industry.

APACMed is a member of various government committees and forums, such as the Steering Committee of the National Medical Devices Promotion Council (NMDPC), the Standards Committee of the Bureau of Indian Standards (BIS), as well as industry consultations organized by the Department of Pharmaceuticals (DoP), the Central Drugs Standard Control Organisation (CDSCO), and the Department of Health Research (DHR).

Executive Committee in India

Shishir Agarwal
Chairperson
President & Managing Director
Terumo India

Tushar Sharma
ExCo Member
Managing Director & GM,
India & South Asia
Abbott Vascular India &
South Asia

Rishubh Gupta
ExCo Member
Managing Director
Roche Diagnostics India

Mandeep Singh Kumar
ExCo Member
Vice President & Country
General Manager
Intuitive India

Atul Grover
ExCo Member
Managing Director
Inda / South Asia
BD

Aditya Banerjee
ExCo Member
Managing Director
B.Braun India

India ExCo Meeting 2023

APACMed India held its Executive Committee (ExCo) meeting to evaluate the progress made on the identified agenda in 2023 and discuss potential projects to be undertaken in 2024. The discussions will help to solidify our multi-year vision, strategy, and objectives for APACMed in India.

Key Projects under our Centres of Excellence

Government Affairs & Market Access (GAMA) CoE

A: CEO Roundtable on Value Based Procurement (VBP)

APACMed India organized a CEO Roundtable in Gurgaon on the topic of 'Roadmap to Value-Based Procurement'. The objective of the roundtable was to gather insights from the healthcare industry on this important topic through a facilitated discussion by PwC India. The roundtable was attended by John Collings, Chairman, APACMed, and CEOs from various sectors of the healthcare industry such as MedTech, Diagnostics, and Hospitals. The aim was to formulate a roadmap that could be recommended to relevant authorities in the government for implementing a Value-Based Procurement framework for India.

B: State Outreach on VBP

In 2023, APACMed India launched state outreach programmes in Tamil Nadu, Andhra Pradesh, Kolkata, and Gujarat to promote and amplify the concept of Value-Based Procurement (VBP) in the country. The main objective of the outreach was to share the VBP paper with the officials and make them aware of the concept and its benefits, emphasizing the adoption of VBP for high-end medical devices.

C: Reimbursement Roundtable

APACMed India and Parexel hosted a closed-door roundtable discussion on the theme of "Advancing Collaboration & Inclusivity in Medtech Reimbursement for Better Health Outcomes". The roundtable was attended by representatives of the National Health Authority (NHA) and the National Health Systems Resource Centre (NHSRC). The discussions focused on India's medical device reimbursement framework, challenges faced by stakeholders, recommendations to make the process more inclusive, and enhancing industry participation in the evolving reimbursement landscape.

D: R&D Paper Launch

APACMed launched a report titled 'From Volume to Value: Fostering Research and Innovation in India's Medical Device Industry' in collaboration with KPMG in India. The event was attended by distinguished guests from various fields such as Dr Vinod Paul, Member, NITI Aayog, representatives from Indian Council of Medical Research (ICMR), Indian Institute of Technology (IIT) Delhi, Biotechnology Industry Research Assistance Council (BIRAC), academia and industry leaders. The focus of the session was on the collaboration between the government, private sector, and academia to foster innovation and work as partners. The participants also discussed best practices from global markets among other key topics.

E: Launch of Coffee Table Book

A Coffee Table Book titled 'Transforming Healthcare through Innovation- Our Impact and Footprint in India' has been published by GAMA CoE to showcase the journey of APACMed members and their contribution to the overall healthcare system in India. The member impact and footprint study was launched at the USIBC 'India Ideas Summit' in June 2023 at the U.S. Chamber of Commerce headquarters in Washington, D.C., USA. This coffee table book serves as a tool for APACMed to continue engaging with policymakers and other ecosystem stakeholders in order to create awareness about the role and impact of its member companies in the country.

A social media campaign is currently underway to promote and amplify our members contribution mentioned in the coffee table book.

Regulatory Affairs (RA) India CoE

A: Engagement with Regulator

The Regulatory Affairs India leadership met with Dr. Rajeev Singh Raghuvanshi, who is the Drug Controller General of India for the Central Drugs Standard Control Organization (CDSCO) - the national regulatory authority for medical devices in India. The purpose of the meeting was to provide an overview of the RA India strategic projects and seek guidance from Dr. Raghuvanshi. APACMed is actively working in collaboration with CDSCO to foster a favourable regulatory ecosystem for medical devices in India.

B: Capacity Building

The RA India CoE is dedicated to enhancing the capability and skill of the regulatory workforce in the Indian medical technology industry. In 2023, the leadership team of RA India CoE engaged in discussions with Dr. Eswara Reddy, Joint Drugs Controller of the Central Drugs Standard Control Organization (CDSCO), to explore the possibility of organizing capability building workshops for MedTech regulators in India in 2024. APACMed continues its discussion with CDSCO to help build and support a strong regulatory workforce in the country.

C: FAQ Document shared with CDSCO

The RA India CoE formulated a document that contains frequently asked questions (FAQs) related to Medical Devices and In Vitro Diagnostics. These FAQs provide answers to some of the common queries about medical equipment registration, retention, SaMD and refurbishment. The document was presented to Shri. Aseem Sahu, Deputy Drugs Controller (India), CDSCO. This document could serve as a useful resource for the regulators, port authorities, and other relevant stakeholders to resolve issues pertaining to the Medtech industry. It would also help in promoting ease of doing business for the medical device industry in India.

Digital Health (DH) India CoE

Digital Health Symposium

In September 2023, APACMed organized the Digital Health Symposium in New Delhi to raise awareness and share knowledge about Digital Health Regulations and Reimbursement in India. The symposium was themed as 'Transforming Healthcare through Digital Health'. It saw the participation of senior stakeholders including Government entities such as Central Drugs Standard Control Organisation (CDSCO), Indian Council of Medical Research (ICMR), Postgraduate Institute of Medical Education and Research (PGIMER), National Health Systems Resource Centre (NHSRC), The Centre for Development of Advanced Computing (CDAC), Subject Matter Experts, Payors and the MedTech industry. The discussions during the symposium focused on the current digital health and reimbursement landscape in the country, and suggested policy pathways that could lead to greater digital adoption in India.

Live Issues

Recognizing the dynamic policy landscape that impacts the industry, we intend to continue to monitor and support on current matters. Few of the crucial issues that we took up this year:

- Request for inclusion of other "High End High Value Equipment" & issuance of No Objection Certificate to Import for business continuity
- Request for exemption to continue import/ manufacture of Class C or Class D Medical Devices for further 6 months. Also, request was placed to allow adequate time to make required changes in the label.

National Medicines Regulatory Authority (NMRA) Workshop in Sri Lanka

APACMed India RA CoE visited Sri Lanka to further amplify their efforts in streamlining the medical device registration process and introduce the regulatory reliance concept in the country. The delegation, consisting of APACMed members and Secretariat, included eight members. The symposium was attended by over 30 NMRA officers, including the CEO and Head of Medical Device Regulatory Division. The CoE remains committed to working with NMRA officials to simplify regulatory processes in Sri Lanka.

Country Insights: APACMed in China

APACMed China seeks to continue presenting the unique value of the MedTech industry in one of Asia's most important markets, and to share the voice from the industry to improve patient access to medical technologies and solutions.

Core Leadership

COE MEMBERS : REGULATORY AFFAIRS

Annie (Qiman) Yin
Chairperson
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Strategic projects for market access in China

In 2023, APACMed China office continued policy shaping on strategic topics including reimbursement for digital solutions, exploring pathways of innovations under DRG reform, and out-of-hospital care concept.

DH Reimbursement

On May 9, APACMed China held the China Digital Health Reimbursement Forum in collaboration with our association member CCCMHPIE. More than 70 representatives from the government, academic institutions, industry, and international organizations attended the event.

Policy forum on DRG-based Innovation pathway

On June 9th, APACMed China organized the China DRG policy forum, and invited national DRG payment technical group lead, national renowned HTA expert and leading physicians and decision-makers of pilot cities to discuss the current policies, next steps, and technical considerations of DRG implementation in China. The event was opened by Alex, China Board sponsor, Senior Vice President of Medtronic Global, and President of Medtronic Greater China. Over 100 representatives and experts from around 30 corporate members in China attended the forum. APACMed China also released the paper, DRG-based Value Assessment of Innovative Medical Technology.

Policy shaping on out-of-hospital care

Building on the results of China expert dialogue on out-of-hospital care in August 2022, APACMed China organized the "Out-of-hospital Care Forum- 'Internet + Healthcare' New Settings and Technology Application in China" as a regular activity of Zhongguancun Forum, on August 25, 2023, in Beijing. This forum was co-hosted by the Tsinghua University Institute for Global Industry, CAICT, drawing over 100 attendees from the government, academic institutions, hospitals, and industry. It shared case studies in China and models applied in Singapore and Belgium, and explored viable solutions tailored for Chinese patients. We published the report "Medical Technologies in Out-of- hospital Care of China" in both Mandarin and English, with the goal of helping to translate global experiences into local practice.

Success in SaMD classification advocacy

To seek clarity on SaMD classification, APACMed China developed the China SaMD policy recommendation and successfully convinced China regulator to consider re-classification of some type of SaMD products. In the group visit led by APACMed China to NMPA, APACMed China SaMD WG exchanged views with NMPA experts and some products were successfully re-classified as non-medical devices.

Events

APACMed China organized 10 events in China with diversified partners, attracting a total number of around 1000 attendees, including the strategic projects related forums, webinars for innovation and the first-ever China-ASEAN MedTech cooperative session on the 9th MedTech Forum. We have developed a series of Go-ASEAN webinars including:

Webinar with CCCMHPIE on capability building for Chinese-companies

More than 100 attendees from over 60 Chinese medical innovation enterprises participated in the meeting. From a global health perspective, the webinar shared analysis about the demand for medical diagnostic products and discussed the regulatory trends and registration pathways for medical devices in the ASEAN market, providing valuable references and recommendations for enterprises seeking to enter into the ASEAN market.

Webinar with CAICT on Digital Health International Development

Bringing together 36 representatives and speakers to analyze the trends and international cooperation directions of digital health technology and how to unlock opportunities in APAC/ASEAN market.

China-ASEAN cooperative session, The Asia Pacific MedTech Forum 2023

The China-ASEAN cooperative session on MTF focused on pathways into ASEAN and new opportunities for innovation in China's medical reform and review green pathway. Professors, government officials and regulators from Peking University, Tongji Medical School of HUST, Hainan Boao Lecheng International Medical Tourism Polit Zone, Hainan International Economy and Development Bureau, Malaysia Medical Device Authority and Indonesia MoH presented a multi-dimensional discussion to share their profound insights.

Consolidated strategic Relationships in China and internationally

APACMed China is gradually building up a more comprehensive network in China, including NMPA, NHC, MIIT, MOFCOM, NHSA, academia including PKU and Tsinghua University, key local associations to ensure our members' voices are heard and together we shape an more enabling environment for our members' business.

Strengthening substantial cooperation during APACMed CEO Ms. Harjit Gill's visit to China

During her 2 day visit to Beijing in September 20 to 22, 2023, APACMed China team further explored opportunities with NHC, NMPA and various other academic partners in China.

APACMed CEO Mrs. Harjit Gill's meeting with DDG Mr. He Zhaohua of China National Health Commission in Beijing.

APACMed CEO Mrs. Harjit Gill's meeting with China NMPA Deputy Commissioner Xu Jinghe.

2023 marked the first anniversary of the APACMed China office. On the evening of September 21, APACMed held a social evening and invited key strategic partners in China and some member representatives to discuss and navigate future cooperation with us.

Key cooperation partners of APACMed in China, including the CCMHPIE, the Institute for Global Industry of Tsinghua University, the China Academy of Information and Communications Technology, the Australian Trade and Investment Commission, Scottish Development International, Medtronic, Abbott, ResMed, Fresenius Medical Care, and Roche Diagnostics, participated in this event.

Coordinated the APACMed close-door meeting with NMPA as GHWP Chair on the 26th and 27th GHPW conference

More vibrant and diversified member retreat

Active engagement among members

APACMed China office has kept connecting with more than 150 representatives from over 30 member companies. Regular online and offline meetings have been organized to review the past work of APACMed and hear from our members. With supports and instant feedbacks from our members, APACMed China could make great progress during the last year.

Member group visits to stakeholders

APACMed China has been actively designing member group visits to key stakeholders, including Shanghai Health Development Research Center, China Investment Promotion Agency for live issues and policy interpretation.

APACMed China will continue to serve as a platform with expertise and industrial resources to help foreign companies better understand Chinese policies.

In a nutshell, APACMed China will continue to serve as a platform to connect the industry with different stakeholders based on our existing promising strategic projects, popular event series, and powerful network. Sincere thanks to all members who gave us strong support in 2023! Let's make joint efforts and do something great in 2024!

Flagship Events: MedTech Forum 2023 & APACMed Breakfast Conversations

In terms of flagship events, APACMed added a new concept in 2023 known as the APACMed Breakfast Conversations (ABCs). Held approximately every quarter, the idea was to offer an executive-level platform for discussion and debate of key trending, impactful topics. The opportunity to collaborate around common industry challenges is well in line with APACMed's role of driving policy advocacy and patient access priorities for innovative medical solutions.

ABCs conducted in 2023 included:

Geopolitics, with FrontierView, Vriens & Partners, Vista Health;
Talent, with Russell Reynolds Associates, Becton Dickinson, Workforce Singapore, LinkedIn;
Artificial Intelligence, with IQVIA, Microsoft, Roche, Health Catalyst, Aicadium;
ESG, with Bain, Stryker, Johnson & Johnson, Medtronic; and
Innovation, with LEK, Boston Scientific, Philips, HealthBeats, LifeSpans, MTPConnect.

We will continue (and scale up) the ABC format in 2024. Stay tuned for further details!

With the ABCs concluding by Q3, APACMed then shifted focus towards the annual MedTech Forum (MTF). Back for its ninth year, the MTF featured more than 1000 delegates from 30+ countries, including hundreds of speakers, hours of content, and networking opportunities. Beyond industry representatives (corporates as well as start-ups), delegates included governments, healthcare providers, trade associations, and more. Further details about current and prior Forums can be found at: https://apacmed.org/medtech-forum/past-medtech-forums/

The theme for the 2023 MTF centred around innovation. In part, because this was the #1 voted on topic coming out of the 2022 MTF, of course core to the impact and future of the MedTech industry. And yet, we put a twist on the 2023 theme by attending to the "human potential" element as well. We observed MedTech and innovation on a similar journey post COVID-19 – the need to embrace a disruptive culture and to make a real human impact. Governments, similarly, are positioning significant resources behind tech and talent.

We defined innovation and human potential for the MTF 2023 around three main areas:

Empowering patients;

Enabling the healthcare workforce; and

Elevating the MedTech industry

These "Three E's" were displayed and debated across the two days of the conference:

Key takeaways from the discussion included:

For patients, they see great merit in MedTech in terms of life-saving diagnostics and treatments. Yet, patients seek more involvement in industry topics like design-with-empathy and sustainable access. Patient representatives at MTF called on APACMed to collaborate together on innovation ahead.

For the healthcare workforce, tremendous progress has been made in the digital/data era (with various use cases shared), pushed in large part by the COVID-19 pandemic. Generally, the healthcare workforce's perception of the MedTech industry is positive from the perspective of driving the innovation agenda, yet the healthcare workforce reminded us that they are under stress too and thus a focus on their well-being is important to be mindful of.

For the MedTech industry itself, stakeholders commented on the decades of innovation and human potential investments which are coming to fruition, and expressed excitement for the Asia-Pacific region. That said, the industry must remember that the region is highly diverse and local cultural considerations require a tailored approach. There remains much more work to be done around both internal and external capability development.

Ultimately, when discussing challenges, all stakeholders agreed that usually the issues are more related to the people and process rather than the technology itself. Therefore, stakeholders discussed the need for inclusive, co-created, Asia-Pacific centric design for products and solutions. While only about 50% of delegates surveyed initially felt that healthcare innovation is delivering on its promise in the region, nearly 80% felt this way by the end of the sessions due to the recognition of issues while framing out clear progress and collaboration plans to take forward. All-in-all, MTF 2023 and the innovation + human potential theme left delegates with a sense of optimism and inspiration for the future.

Beyond the plenary discussions, the MTF also held break-out tracks for multi-stakeholder groups to deep dive into relevant areas of interest. These break-out tracks included topics such as evidence-based decision-making (for market access), AI/ML frameworks for regulatory pathways, access barriers for IVD technologies, among other tracks such as digital health, ethics & compliance, and China-ASEAN collaborations.

Lastly, and perhaps most importantly, the MedTech Forum provided plenty of opportunities for delegates to network with one another. Platforms for networking included a networking app, exhibition spaces, a social reception, and an Innovation Day with corporate-start-up matchmaking.

We look forward to seeing everyone next September for MTF 2024 and the celebration of 10 years of APACMed's impact in the region.

APACMed Membership

APACMed grew our membership from 310 in 2022 to 350 in 2023, representing a 13% increase in total membership number. In 2023, we added 69 new members, including 3 corporate members and 16 associate members.

New Corporate Members

APACMed welcomed 3 new Corporate Members in 2023.

New Associate Members

APACMed welcomed 16 new Corporate Members in 2023.

Membership Category

Corporate

Corporations manufacturing and conducting R&D in medical equipment, devices, in vitro diagnostics or digital health solutions with global annual sales above USD 50 million.

Associate

Service Providers including consultants, contract manufacturers, CROs, investors, distributors, recruiters, lawyers and etc.

Industry Association

National Associations representing the interests of the medical technology industry in any country in Asia Pacific.

Start-ups & SMEs

Start-ups or SMEs manufacturing and /or conducting R&D in medical technology with annual sales less than USD 50 million.

Membership Category	2022	2023	Growth
Corporate Members	65	57	-13%
Associate Members	68	74	8%
Start-up & SME Members	163	201	23%
Industry Association Members	14	18	29%
Total	310	350	13%

Membership Benefits

- Be part of a collective voice focused on improving the standards of care, driving access and collaboration, and shaping the future of healthcare in the Asia Pacific.
- Participate in Functional Committees and Working Groups with senior-level executives from the largest companies in the industry.

- Join regular workshops, seminars, CEO Roundtables and other networking events.
- Participate in the annual Asia Pacific MedTech Forum, the industry's most impactful gathering of people and ideas in the region.

- Benefit from exclusive market insights and analysis from APACMed Knowledge Partners.
- Receive timely information providing early warning about regulatory and policy developments in the region and guidance on how to deal with them.
- Access extensive resources on our Members-only section on the website.

APACMed

The voice of MedTech

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed 亚洲太医技术协会) is the only regional association to provide a unified voice for the medical technology industry in Asia Pacific.

APACMed works proactively with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory convergence.

To access a digital copy of this report, visit
www.apacmed.org/annualreport2023

Learn more about the association at
www.apacmed.org

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