APACMed

The voice of MedTech

Asia Pacific Medical Technology Association

ANNUAL REPORT 2021

CONTENT

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, 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

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

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 of the Code of Conduct.

APACMed Strategic Pillars

Welcome Message

Andrew Frye, APACMed Chairman

Dear APACMed Members,

In my 2020 welcome message, I talked about the "metamorphosis" of our world and industry, as a result of the COVID-19 pandemic. The pandemic remains omnipresent and the need for high-quality, accessible, affordable healthcare greater than ever. So, firstly, I would like to thank everyone across the industry ecosystem for your efforts. The war is not yet over, but the battles are being won, in large part due to the contributions of the advancements in MedTech innovations.

Secondly, I would like to take an opportunity to reflect on how the last few years have shaped our future, potentially in some cases for the better. In my MedTech Forum speech, "Emerging Stronger Together", I discussed the incredible commitment and collaboration of our APACMed members in rising to the challenge. Asia-Pacific is home to 60% of the world's population, and on a trajectory toward half a billion people who are over the age of 65; yet across all age groups 700 million people still lack even the most basic healthcare support. I believe COVID-19 is forcing all of us to rethink our legacies in the region, to do more to drive out the inequities, and to ensure, by working together, we deliver on our promise of equipping health-for-all through the use of modern medical technologies.

The above sentiments translate directly into our priorities for APACMed. In 2021, we launched the Digital Health Committee during the pandemic, given the great uplift on all-things digital, through which we progressed tactical discussions on regulation and reimbursement of these novel technologies, digging deeply into areas such as Remote Care Management (RCM). As well, we held value-based market access discussions with key government bodies, focused on themes such as diagnostics during COVID-19 and evolving cost-effectiveness analysis via outcomes-oriented contracting. We also continued our focus on compliance matters, offering sharing forums amongst members to unify around legal frameworks, like the Global Distributor Compliance (GDC) toolkit. I feel our relevance and focus was confirmed as our overall APACMed member base expanded by 36% year-on-year, dominated by the small-to-medium size companies of which now total 140. Perhaps most importantly, I'm excited by our country-level activation focus, as APACMed build out localised partnerships and Centres of Excellence (COEs) beyond Southeast Asia to transform our visions into a reality on the ground.

We all look forward to return to some state of normalcy soon; in the meantime, we must continue the effort together and to learn from each other. I'm confident we will come out the other side of this journey an improved MedTech Industry. Over the coming pages, you can learn more about the details of the APACMed achievements I've mentioned, and beyond.

Thank you, and I look forward to seeing you (hopefully in person) in 2022!

In Conversation with

Harjit Gill, CEO : *How was 2021 for APACMed?*

First let me say, how proud I am that our members and partners continue to come together in the fight against the pandemic. We have strengthened our efforts to remain at the forefront of this evolving coronavirus fight, be it in the hospital or the home. As tough as it is, it has also been an inspiring time to be in the healthcare industry as we forge new collaborations and fast track innovation for the future. In fact in my 2021 MedTech Forum speech, I talked about the new care models and patient empowerment that have emerged as we shift into an endemic mentality, reshaping healthcare around new innovations and capabilities through collaboration. We look forward to facilitating more discussions around these important topics in 2022 as well.

For now, let me focus on some of the highlights and progress we made together in 2021:

- Our member base grew by 36% year-on-year, totalling 263. We added a new member category for players specialising in the Digital Health space, as we expect greater ecosystem collaboration here. Start-up members grew the fastest in 2021, representing the largest cohort now at 140 companies!
- Nearly 3,000 attendees to more than 40 webinars run throughout the year, a necessity during the pandemic times. Topics and geographies ranged across the APACMed efforts, further covered in this report.
- After 2020's fully virtual MedTech Forum (our flagship event), 2021 gathering saw a return to the hybrid format under the theme of "Health Futures By 2025". More than 1,700 participants representing 33 countries gathered for interactive discussions, networking, virtual showcases, innovation competition voting, and more. Nearly 100% of respondents said they will be back at the Forum again in 2022, which is a fantastic telling point.
- At the Committee level, I'm proud of our output in the form of continued expansion of our Digital Health efforts in the areas of regulation and reimbursement, as well as deep dives into Remote Care Management (RCM) and country-level activities. On the Government Affairs & Market Access side, beyond continued ground support for COVID-19 matters, we formally launched the exciting Health Services initiative. For our Legal, Ethics & Compliance team, we produced the Global Distributor Compliance (GDC) toolkit as well as new competition guidelines for members. For the start-up members, we hosted "Meet the Corporate" programs for improved matchmaking, as well as, through our collaboration with MedTech Innovator, awarded more than USD200,000 in cash prizes.
- We added focus on country-level activation of the above. We now have dedicated teams, partners and in many cases, Centres of Excellence, in key markets like ASEAN, Japan, Korea, China, India and Australia. This infrastructure is instrumental in 2022 as we drive even greater cross-border sharing, harmonisation and policy formation for the MedTech industry.
- Finally an 80% increase with 43,595 visitors to our website compared to the previous year, giving them access to over 80 position papers, newsletters and reports.

On behalf of the entire APACMed team and Board, we thank you for your continued commitment and support. We have exciting plans in store for 2022, which I look forward to sharing with you in due course. Do feel free to reach out with your contributions along the way. Perhaps my most important takeaway from the COVID-19 experience, is that we all have something to teach and learn on this continued march toward high-quality, accessible, affordable healthcare for all.

Thank you!

APACMed
Structure & Governance

Organisation & Committees

Board of Directors

Secretariat Team

Committees

Government Affairs & Market Access
210 Committee Members

Digital Health
250 Committee Members

Regulatory Affairs
323 Committee Members

Legal, Ethics & Compliance
94 Committee Members

Start-Up & SME
280 Committee Members

APACMed
Board of Directors

Andrew Frye
Chairman, APACMed
Senior Vice President & President, APAC
Baxter Healthcare

Elisabeth Staudinger
Vice Chairman, APACMed
Managing Board Member &
Head of APAC
Siemens Healthineers

James Lim
Treasurer, APACMed
Executive Vice President &
President, Greater Asia
Becton Dickinson

Art Butcher
Executive Vice President
& President, Asia Pacific
Boston Scientific

John Collings
President, Asia Pacific
Stryker

Probir Das
Chairman
Terumo Asia Holdings

Lam Chee Hong
President, Asia Pacific
B. Braun

Chris Lee
President
Medtronic Asia Pacific

Lance Little
Managing Director
Roche Diagnostics Asia Pacific

Tim Schmid
Company Group Chairman,
Medical Devices, Asia Pacific
Johnson & Johnson

Paul Tan Minjie
Divisional Vice President, APAC
Abbott

Julie Tay
Senior Vice President,
Commercial Strategy
Align Technology

APACMed
Board Sponsors

Committee Board Sponsors

Government Affairs & Market Access

Paul Tan Minjie
Divisional Vice President, APAC
Abbott

Digital Health

Elisabeth Staudinger
Managing Board Member & Head of APAC
Siemens Healthineers

Regulatory Affairs

Lance Little
Managing Director
Roche Diagnostics Asia Pacific

Legal, Ethics & Compliance

Tim Schmid
Company Group Chairman,
Medical Devices, Asia Pacific
Johnson & Johnson

Start-up & SME

Julie Tay
Senior Vice President,
Commercial Strategy
Align Technology

Country Board Sponsors

ASEAN

Lam Chee Hong
President, Asia Pacific
B. Braun

CHINA

James Lim
Executive Vice President &
President, Greater Asia
Becton Dickinson

INDIA

Probir Das
Chairman
Terumo Asia Holdings

JAPAN

Art Butcher
Executive Vice President &
President, Asia Pacific
Boston Scientific

KOREA

Chris Lee
President
Medtronic Asia Pacific

AUSTRALIA

John Collings
President, Asia Pacific
Stryker

APACMed *Secretariat Team*

Harjit Gill
Chief Executive Officer

Nishan Pillai
Finance &
Operations Manager

Gabriel Sim
Director, Strategic Partnership
& Start-up Program

Christine Tan
Director, Country Activation &
Marketing

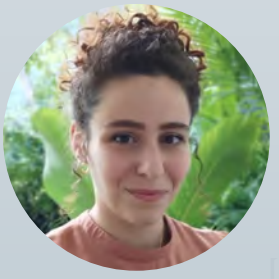
Anirudh Sen
Country Lead, APACMed India & Director,
Regulatory Affairs, APAC

Alicia Chang
Country Lead,
APACMed China

Glenda Teng
Manager, Government Affairs &
Market Access

Roberta Sarno
Manager, Digital Health

Gideon Praveen Kumar
Manager, Regulatory Affairs



Cindy Pelou
Manager, Legal,
Ethics & Compliance

Ankit Sharma
Manager, APACMed India

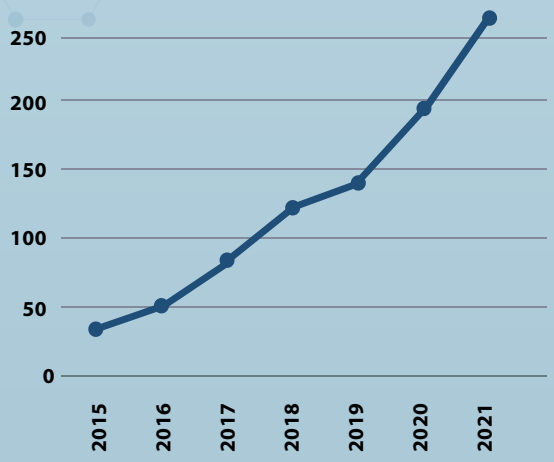
Benish Aslam
Assistant Manager,
Government Affairs &
Market Access

Shreya Bansal
Research Associate,
APACMed India &
Regulatory Affairs

APACMed *in Numbers*

36 % GROWTH OF MEMBER COMPANIES

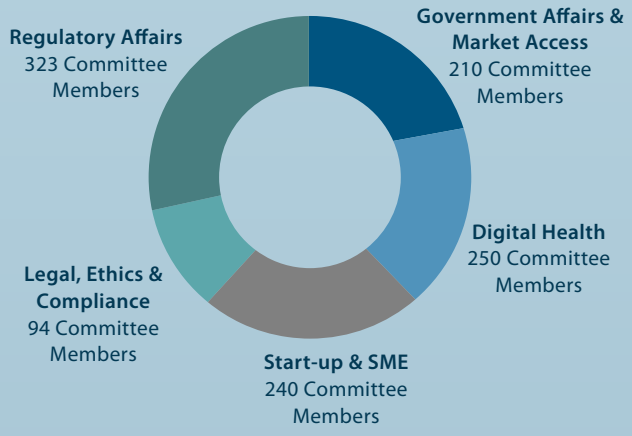
Number of member companies increased from **194 in 2020** to **263 in 2021**



Number of Member Companies

1,177 COMMITTEE MEMBERS

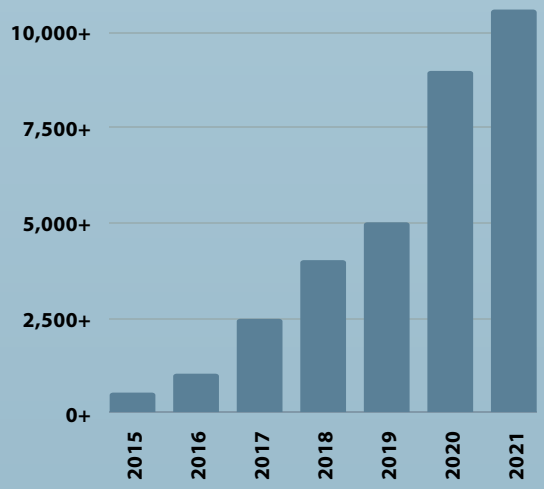
Total number of members from **5 committees in 2021**



Number of Committee Members

24 % GROWTH OF SOCIAL MEDIA FOLLOWERS

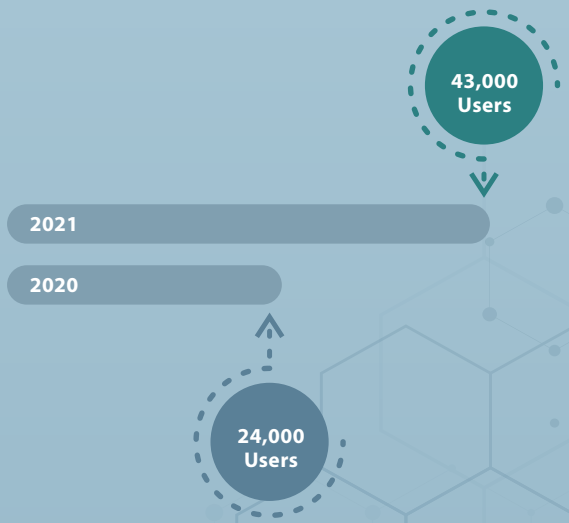
Number of social media followers increased from **9,000+ in 2020** to **11,000+ in 2021**



Number of Social Media Followers

80 % GROWTH OF WEBSITE USERS

Number of website users increased from **24,000+ in 2020** to **43,000+ in 2021**



Number of Website Users

7,800+ DELEGATES

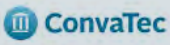
Events, Workshops and Conferences

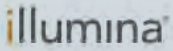
17 POSITION PAPERS

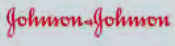
Published across 4 committees

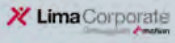
APACMed *Members*

Corporate Members









APACMed *Members*

Digital Health Members

aws · AVERY DENNISON · NOVARTIS

Associate Members

accenture · Alchemy Advisors · AliraHealth · amcor · ARROWFAST · AURIGA · Baker McKenzie Wong & Leow. · Biomed Global · CATCHER · Clarivate Analytics · Cisema · C&M INTERNATIONAL LLC · Deloitte. · DEMCON · DKSH · DN & ASSOCIATES · DTG MEDICAL · ENTERPRISE IRELAND · EVERSANA · FESTO · Geeta Thakerar · Getz Healthcare · Graham Engineering · HiMed · indegene · IQVIA · K&L GATES · KINGFISHER · KOCH UHLMANN GROUP · KORN FERRY · KPMG · L.E.K. · MEDLINE · MEDTECH ACTUATOR · Messe Düsseldorf · NAMSA · NHIC National Health Innovation Centre · Ogilvy · PHARMALEX · qtec eurep · ROBERT WALTERS · SIEMENS Ingenuity for life · SINGAPORE BIODESIGN · SPAG · TEGRA MEDICAL · transmedic · trendlines medical · agtech · labs · Tuyacoz Solutions Pte Ltd. · UPS Healthcare · VRIENS & PARTNERS · WHITE ROOK ADVISORY · WILDDESIGN · ZUELLIG PHARMA

Start-up & SME Members

23strands · 5C Network · Aarca Research · abm RESPIRATORY CARE · ACCREDIFY · ADIUVO DIAGNOSTICS · Advante Medica Pte Ltd · ADVENTA · Aktivolabs. · ALPHA INNOMED · ANALYTICA · AROGYA.ai · AUTOYOS · AXIO · Beato SMART DIABETES MANAGEMENT · BIORITHM · Caltech · careMonitor · CareTech · CARTOSENSE · cogni.dx · CONNECT 2 MY DOCTOR · CrelioHealth · CRELY · daftaro · Denti.AI · docquity · DOXIVA · eko.ai · epillo · EREMEDIUM · evitalz · fitterfly · Forus Health · GenesisMedTech · GUARDANT · HANDOK · Healint · Healkee Medical · HEALTHBEATS · HEALTH BETA · HealthCare Scientific · Healthians · helios BIOELECTRONICS

APACMed *Members*

Start-up & SME Members

APACMed *Members*

Industry Association Members

Government Affairs & Market Access Committee

Working with policy makers and other stakeholders across the healthcare ecosystem, in order to shape policies and processes that facilitate increased access and affordability of medical technologies for patients in the Asia-Pacific region.

Core Leadership

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

Christoph Liesche
Government Affairs Vice-Chairperson
Head of Public & Government Affairs, Asia Pacific
Fresenius Medical Care

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

Virginia Priest
Market Access Vice-Chairperson
Director, Health Economics & Market Access, Asia-Pacific
Boston Scientific

Shivkumar Hurdale
Government Affairs Vice-Chairperson
Director – GA/RA/QA
India & RA Advocacy (ASPAC)
Stryker

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

Alice Chu
Market Access Vice-Chairperson
Director, Market Access & Medical Marketing, APAC
Glaukos

Country Centres of Excellence

INDIA

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

Parveen Jain
Vice-Chairperson
Head, Regulatory Affairs, Quality & Government Affairs
Fresenius Medical Care

Vineet Gupta
Vice-Chairperson
Director - Government Affairs (South Asia)
Varian Medical Systems

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

VIETNAM

Julia Tran
Chairperson
Director of Government Affairs
Abbott Laboratories GMBH Vietnam

Nguyen Thi Li Minh
Vice-Chairperson
Market Access Lead
Baxter Vietnam

This year, over 200 industry professionals representing 40+ companies (corporate members) participated in live advocacy activities, capability building, and sharing of best practices – as members of the APACMed Government Affairs & Market Access (GAMA) Committee.

Strategic Initiatives

The GAMA Committee worked on a number of strategic initiatives to build understanding of key policy and market access topics.

COVID-19 Diagnostics Project (Paper Launch, Industry Awareness Session and Media Initiatives)

In February 2021, a whitepaper "Critical Role of Diagnostics in COVID-19 Management" was co-produced by APACMed and L.E.K. Consulting's Life Science Centre of Excellence, outlining recommendations for the integration of COVID-19 testing strategies. This was followed by an association awareness session held in March, to share perspectives with medical associations and professional societies, so that the recommendations can be incorporated in discussions with governments across the Asia-Pacific region. Given the ever-evolving COVID-19 pandemic-related updates on measures with respect to public health and surveillance, reopening of economy, resumption of travel and vaccine rollout, an addendum to the whitepaper was added in July.

Relatedly, the following two media articles were published this year to raise awareness about the critical role of diagnostics in COVID-19 management:

- "Testing our way to COVID-19 recovery", Devpolicy Blog, September 2021
- "Adding antibody tests to the arsenal", Southeast Asia Globe, October 2021

South Korea Webinar Series on Market Access for Innovative Technologies: Digital Health Solutions and Surgical Robots

South Korea is a regional leader for developing advanced medical innovations such as digital health technologies, surgical robots and more. This two-part webinar series on Digital Health Solutions and Surgical Robots, held in July and November 2021, respectively, dove into South Korea's digital health landscape and recent policy developments, including challenges and opportunities of market authorisation, Health Technology Assessment (HTA)/reimbursement, and key legal and regulatory considerations.

Remote Care Management Policy Dialogue: Japan, Australia, India, South Korea and ASEAN

In partnership with the APACMed Digital Health Committee, the GAMA Committee organised a series of Digital Health Policy Dialogues on Remote Care Management (RCM), from July to September 2021. The multi-stakeholder dialogues culminated in proposed initiatives for expediting patient access to RCM solutions in seven countries in the Asia-Pacific. Attendees of these open-door sessions witnessed how governments, industry and other key stakeholders could work proactively and productively together to shape policies and pathways, supporting increased and affordable access to RCM solutions. The findings and learnings from all the stages of the series were consolidated in the form of a whitepaper that was launched at the MedTech Forum 2021.

Market Access Database

APACMed's Market Access Working Group (MAWG) released a capability building toolkit in August 2021 in the form of a Market Access Database. The comprehensive database details the end-to-end market access process, pathways and stakeholders in 17 countries across the region and globally. The toolkit was compiled through interviews with experts from APACMed's regional and global membership, desktop research, and reviewed and validated by NUS Saw Swee Hock School of Public Health's Health Intervention and Policy Evaluation Research (HIPER) Centre, Singapore.

Policy Watch

Quarterly HTA Landscape Reports

The MAWG produced quarterly HTA reports, providing regular updates on the HTA landscape in four key markets across the region: Australia, Japan, South Korea and Taiwan. Members were updated on the application of HTA and potential impact to business in these four markets.

External Speakers for Committee Meetings

At the quarterly GAMA Committee meetings, the policy horizon was scanned for salient geopolitical issues which impact the MedTech industry, and experts then invited to share their views on the identified topics. This year, the following topics were discussed:

- Regional Comprehensive Economic Partnership (RCEP): Impact & Opportunities for the Healthcare Industry (Presentation by White Rook Advisory, March 2021)
- The Biden Administration's Healthcare Policy Agenda & Implications for MedTech Industry in APAC (Discussion with Chad Norberg, Economic Unit Chief, US Embassy Singapore, June 2021)
- Evolving Policy Landscape in Countries Undergoing Elections in APAC: Implications for Healthcare & the Economy (Presentation by Bower Group Asia, September 2021)
- Living with Localisation: Opportunities & Challenges (Presentation by White Rook Advisory, December 2021)

Communications

Members also benefited from connecting with other industry colleagues through a range of GAMA hybrid engagement platforms (in-person and virtually):

Public Policy & Market Access Expert Summit at the MedTech Forum 2021

At the virtual Summit, members heard from regional and global industry leaders as well as policy and academia leaders on the theme of "Driving Access to Value & Innovation: Now and in a Post-Pandemic Future". Key topics included lessons from the pandemic for continuity of access to care, the importance of a global/local balance to ensure ongoing patient access to new and innovative medical technologies, patients' perspectives in reimbursement decision-making, shifting from price-based to value-based access pathways, and the new frontier for MedTech industry: Health Service delivery and its opportunities and challenges for adoption in the Asia-Pacific region.

Highly Engaged Leadership Team, WG and Centre of Excellence (COE) Meetings

Members gathered as a whole Committee every quarter. In addition, and where there was an interest fit, members initiated, led and/or served in advocacy and capability building initiatives, alongside fellow GAMA professionals. The platforms included locally-based COE teams and project-based WGs. At the apex, the GAMA Leadership Team convened every month to discuss insights from market intelligence, and to provide guidance to the Secretariat on the evolving policy landscape.

Advocacy

In 2021, the GAMA Committee undertook advocacy efforts on key matters relevant to medical technology access across the region, including:

1. **Australia**: Prosthesis List
2. **Indonesia**: Local Content
3. **Vietnam**: Medical Device Registration & Medical Equipment Placement
4. **Philippines**: Pricing & Procurement
5. **Regional**: Vaccine Prioritisation

Digital Health Committee

Shares the voice of the industry with the public and private digital health decision-makers and provides a neutral platform for public-private collaborations on regulatory, cybersecurity, reimbursement, health data and interoperability matters.

Core Leadership

Alex Lee
Interoperability Chairperson
APAC Strategic Planning & Partnerships Director
Abbott Diabetes Care

Jim Sarka
Cybersecurity Chairperson
Vice President & CIO, Business Technology, Asia Pacific
Johnson & Johnson

Varun Veigas
Regulatory Chairperson
Policy & Strategic Partnerships Lead
Roche Diagnostics Asia Pacific

Anh Bourcet
Reimbursement Chairperson
Director, Market Access APAC, Rapid Diagnostics
Abbott

Country Centres of Excellence

ASEAN

Anwar Rafique
Chairperson
CEO & Co-Founder
SSIVIX Lab

AUSTRALIA

Michael Nobes
Chairperson
Market Access Director, Asia Pacific
Abbott Diabetes Care

Gregg Boalch
Vice-Chairperson
Managing Director
Caretech Services

CHINA

Varun Veigas
Chairperson
Policy & Strategic Partnerships Lead
Roche Diagnostics Asia Pacific

Tony Liu
Vice-Chairperson
General Manager
ResMed China

Manan Hathi
Vice-Chairperson
Senior Manager, Regulatory Affairs, Software
Stryker Corporation

INDIA

Shweta Bhardwaj
Chairperson
Associate Director, Global Policy
Johnson & Johnson

Seema Arora
Vice-Chairperson
National Marketing Head, Asia & Latin America
ResMed

Sushant Jaiswal
Vice-Chairperson
Manager - Regulatory Affairs
Roche Diagnostics India

JAPAN

Jun Sekiguchi
Chairperson
Director, Japan Government Affairs
Baxter Ltd

KOREA

Gordon Danton
Chairperson
President, Japan & Korea
ResMed

The Digital Health Committee was introduced in January 2020 in order to share knowledge and to advocate for policies that ease innovation across the whole digital health product journey, from regulatory approval to market access, reimbursement and use.

In two years, the committee has grown to 250 individual members from more than 75+ companies, and now has six Centres of Excellence (COEs) across ASEAN, Australia, China, India, Japan and South Korea. The COEs work to bring the regional efforts of the committee into the countries and to engage with local stakeholders.

Strategic Initiatives

Advancing Regulatory Capabilities

Fit-for-purpose regulatory frameworks for digital health are strongly needed in the Asia-Pacific, as they can enable the delivery of life-saving solutions to patients in a safe, effective and timely manner. After publishing the first industry position paper in early 2021, the committee conducted roundtables with Health Sciences Authority (HSA) in Singapore and Therapeutic Goods Administration (TGA) in Australia. As a result, the new digital health regulatory guidelines in Singapore, for example, take into consideration of the APACMed position and recommendations.

Building Reimbursement Capabilities in Australia and India

In early 2021, the Committee published an industry position paper on the implementation of value assessment, funding and reimbursement of clinical-grade digital health technologies. APACMed and its members then shared the position with key stakeholders in India and Australia, as part of advocacy and policy-shaping efforts.

Policy Recommendations on the Use of Health Data for Regulatory, Funding and Reimbursement Decision-Making

In 2021, the Committee initiated its work on health data with a project on the use of Real-World Evidence (RWE) for regulatory and reimbursement decision-making. The Committee has collected and published examples of RWE utilisation in the Asia-Pacific and beyond, and further more organised a roundtable with international and regional experts from private and public sector in order to discuss perspectives for a better use of RWE in the region. A policy paper will be released in 2022.

Cybersecurity Labelling Scheme for Medical Devices

The Committee collaborated with Singapore's Cybersecurity Agency (CSA), Health Sciences Authority (HSA), Ministry of Health (MOH) and Integrated Health Information Systems (IHiS), on developing a cybersecurity labelling scheme for connected medical devices. The pilot will be launched in 2022.

Publications

Digital Health Regulation in the Asia-Pacific

In early 2021, the Committee published the position paper "Digital Health Regulation in Asia-Pacific: Overview and Best Practices", calling for the development of fit-for-purpose frameworks for digital health across countries in the region. In the paper, the committee assesses the digital health regulatory strategies in Australia, Japan and Singapore, identifying best practices and gaps based on international recommendations. The paper concludes with recommendations to regulators, in order to support them with implementation of frameworks specific to digital health. Following the first paper, the committee published two spin-off papers on South Korea/China and India.

Pathways to Innovation - Advancing Remote Healthcare During & Post COVID-19

Remote Care Management (RCM) solutions enable patient care outside of conventional clinical settings and bring it to where the patient resides, such as at home, in remote areas or on the go. In 2021, APACMed organised dialogues with private sector stakeholders and policymakers from the region, focusing on remote care and market access strategies. The key learnings from these sessions, together with perspectives and next steps, are summarised in the paper "Advancing Remote Healthcare During & Post COVID-19".

Digital Health Ecosystem in China

Providing a holistic view of the ecosystem of digital health and digital transformation in the medical devices industry in China, the paper aims to provide use cases on typical practices and hurdles faced by the industry when developing digital health solutions.

Events

Digital Health Summit at the MedTech Forum (MTF) 2021

Over 675 attendees joined the Summit during MTF where three hours of content were presented and 13 speakers to guide through the following topics:

- The Digital Health Patient's Journey
- **Cybersecurity**: Hacking Healthcare
- **Interoperability**: Harnessing the Power of Data
- **Regulatory**: The Future of the Regulatory Paradigm for Digital Health
- **Reimbursement**: Building Patient Access to Digital Health

The Future of Healthcare is at Home: A Dialogue with Healthcare Practitioners

The expansion of care beyond traditional settings, enabled by digital solutions, represents an important component in the continuum of care. Health Care Practitioners (HCPs) are at the forefront of the application of the new technologies for remote care. It is important to not only understand the landscape of digital health solutions available, but also the barriers that the HCPs face in using them. In 2021, APACMed organised dialogues with private and public sectors to address remote care delivery and financing challenges, in order to provide greater access and affordability to patients. This dialogue provided insights into current practices and challenges faced by ASEAN HCPs, to better understand the needs of the practitioners and the patients in the region.

Getting Closer to Patients: Patient Engagement and Activation for MedTech

Given the increased emphasis on patient-centric care, there is a trend among MedTech companies to think about how they can directly engage with patients along the care pathway, often through digital platforms and tools. At the same time, industry players often find challenges in transforming themselves from a B2B commercial approach towards B2C engagement, where new business models and capabilities are needed. In this webinar, the Committee delved into why MedTech companies should think about patient engagement, as well as experience sharing from peer companies that have made progress in this area.

Adopting Digital Identifications in Healthcare

Digital identification offers a number of benefits in the healthcare system. Particularly in the COVID-19 context, digital identification brings value on elements including vaccines and COVID-19 test kits, ventilators and etc. A Unique Device Identification (UDI) system standardises and adequately identifies medical devices through their distribution and use, yet has different regulatory frameworks for implementation globally. Although digital identification brings clear benefits to the healthcare industry, there are several barriers that impede the optimal implementation of this technology. During this webinar, speakers discussed the benefits of digital identification in healthcare and other sectors, illustrated its use, and provided an overview of UDI regulatory context globally, with a focus on the management of the pandemic.

Digital Twins across Product Design, Validation and Virtual Patients

When the pandemic began, the global medical industry rapidly tried to grapple with supply shortages alongside the mitigation of business risks. One of the many outcomes is the accelerated move towards a digital ecosystem. As a result, the future of clinical trials is evolving and aiding for cheaper and faster go-to-market models by combining lab experiments, in-vivo trials, and computational modelling (called in silico trials). Speakers shared case studies of how Digital Twins accelerated complex product development to regulatory approval, while seamlessly integrating into the manufacturing process.

Regulatory Affairs Committee

Building capability to support implementation of globally harmonised regulatory frameworks.

Core Leadership

Miang Tanakasemsub
Chairperson
Head of QA Commercial & Regulatory Affairs, APAC
Cardinal Health

Adelheid Schneider
Vice-Chairperson
Regional Head for Regulatory & Quality
Roche Diagnostics

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

Nishith Desai
Vice-Chairperson
Director of Regulatory Affairs
Medtronic

Alex Budiman
Vice-Chairperson
Vice President of Regulatory Affairs
BD

Country Centres of Excellence

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Chairperson
Regulatory Affairs Director, Baxter

Crystal (Nie Jing)
Vice-Chairperson
RA Director, APAC Johnson & Johnson

Victoria Qu
Vice-Chairperson
Director of Regulatory Affairs, Abbott

Zhou Lipan
Secretary
Roche

ASEAN

Priscilla Koh
Chairperson
Lead-Director, Regulatory Affairs Johnson & Johnson

Yenny Anggoro
Vice-Chairperson
Director – RA & QA Stryker ASEAN

Yu Hosokai
Vice-Chairperson
Regulatory Affairs Manager - SEA Cook South East Asia

Kenneth Cheong
Secretary
RA & QA Manager
Convatec

INDIA

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Chairperson
Director, Regulatory & Government Affairs, BD

Prashanth Prabhakar
Vice-Chairperson
Head - Regulatory Affairs Boston Scientific India

Jaya Sunil Lande
Vice-Chairperson
Manager - Regulatory Affairs Abbott Healthcare

KOREA

Leslie Kim
Chairperson
RAQA Director Stryker East Asia

Justin Yea
Vice-Chairperson
Senior QRA Program Manager Medtronic

Lena Kim
Secretary
RA Director
Cook Medical

Working Groups

IN-VITRO DIAGNOSTICS

Yasha Huang
Chairperson
Regional Regulatory Affairs & Policy Lead Roche Diagnostics Asia Pacific

Jacqueline Monteiro
Vice-Chairperson
Assiociate Director, Regulatory Affairs Abbott

Qi Li
Vice-Chairperson
Head of Quality & Regulatory Affairs, EAO Beckman Coulter

Nashata Isa
Secretary
Senior Regulatory Affairs Specialist Qiagen

REGULATORY INTELLIGENCE

James Chan
Chairperson
Manager – RA & QA, Southeast Asia + South Korea Varian Medical

Shivkumar Hurdale
Vice-Chairperson
Senior Director RA & QA, APAC Stryker Asia Pacific

Jane Lin
Vice-Chairperson
Head of ASPAC Regulatory Affairs Johnson & Johnson Medical

Muhammad Sohail
Secretary
Manager – RA & Pharmacovigilance QREM Fresenius Medical Care Pakistan

CAPACITY BUILDING

Sharad Shukla
Vice-Chairperson
Head, Regulatory Affairs Johnson & Johnson

Kazuhiro Iwasaki
Vice-Chairperson
Chief
Terumo

Marianne Yap
Vice-Chairperson
Head, Regulatory & Government Affairs, APAC, Alcon

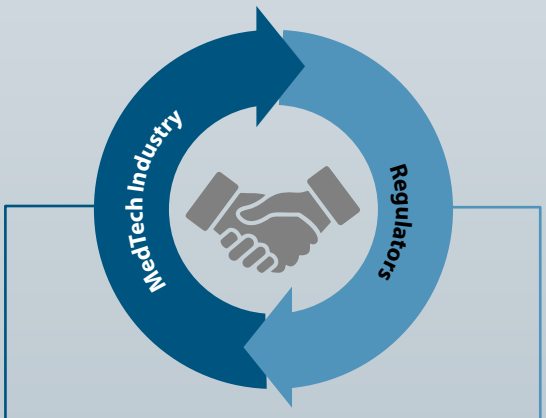
Tanushree Ghatak
Secretary
QRA Manager, India Cardinal Health Medical Products India Pvt. Ltd.

APACMed's Regulatory Affairs (RA) Committee has been helping the MedTech industry navigate an increasingly complex and fragmented regulatory landscape across the region. The Committee is the association's largest, counting over 320 dynamic and engaged senior regulatory professionals.

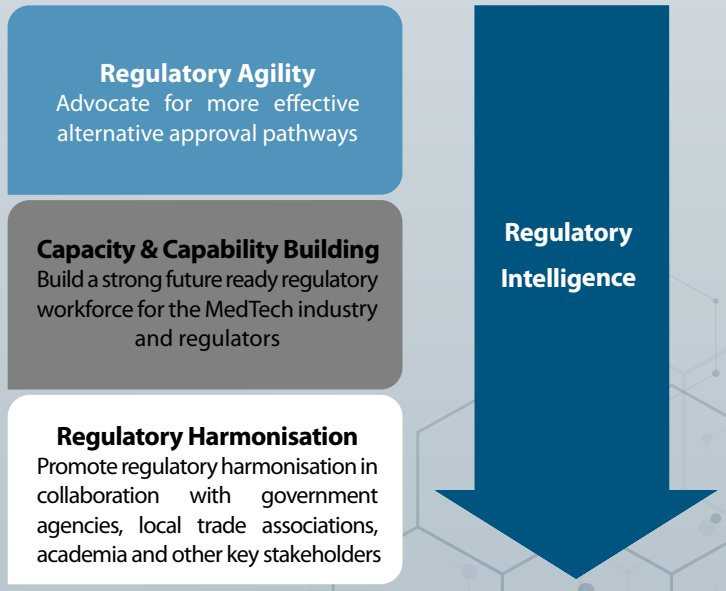
Much of the regulatory advocacy efforts across the region revolve around four interdisciplinary market-specific Centres of Excellence (COEs), covering China, Southeast Asia, the Indian Sub-Continent and South Korea. Separate regional Working Groups (WGs) are dedicated to Regulatory Intelligence, Capacity Building and In-Vitro Diagnostics (IVD). Through its COE and WG structures, the Committee has successfully engaged its members and fostered its networks at the local level.

RA Committee's footprint across the region

The Committee's work also involves building collaboration and partnerships with the broader ecosystem, in order to enhance reach and to amplify messaging. Some existing collaborations include:



Motto of the RA Committee



The work done by the RA Committee falls under three strategic pillars.

Driving Regulatory Agility and Efficiency through Reliance

In 2021, APACMed held multiple meetings with Thai Food & Drug Administration (FDA) to discuss the Thailand-Singapore Regulatory Reliance Project, under which a regulatory reliance pilot was being conducted with Singapore Health Sciences Authority (HSA) as the reference agency. The idea of regulatory reliance is an expedited medical device registration program that the manufacturer or importer can request as permission for faster approval (applicable to Class 4 medical devices). After successfully running the pilot, through APACMed's consistent and continuous efforts, this program has become a permanent offering by Thai FDA. In this program, the Thai FDA Medical Control Division will assess the performance and safety of the medical device, based on the results of the safety assessment and performance of the same medical device from the HSA in Singapore.

The Committee leadership team moreover held dialogues with the Philippines FDA last year to sensitise and create awareness of the benefits of reliance, which resulted in the Philippines FDA announcing their regulatory reliance abridged pathway for processing of Class B, C and D applications that were approved in any ASEAN country using CSDT documents.

Developing a Strong Regulatory Workforce through Capability Building

Industry Curriculum White Paper

In February 2021, the Capacity Building WG, in collaboration with GHWP and Accenture, published the "Medical Device Regulatory Training Curriculum for Industry Professionals". The objective was to provide members with a holistic view of the current needs and future direction of regulatory trainings for RA industry professionals, keeping in mind the dynamic and ever evolving MedTech landscape which faces frequent new business and regulatory challenges. The most essential and relevant learning goals for MedTech regulatory industry professionals have been outlined in the training curriculum, focused on defining the future direction of regulatory capacity development for all AHWP/GHWP and APACMed member companies.

Regulators Curriculum Design Workshop

The Capacity Building WG, in collaboration with GHWP and Accenture, organised a Regulators Capacity Building Curriculum Design Workshop on 29 September 2021. Regulators from over 10 jurisdictions, including Taiwan, Malaysia, Thailand, South Korea, Indonesia, Mainland China, Hong Kong SAR, Kyrgyzstan, Saudi Arabia, State of Kuwait, Jordan and Pakistan, participated in the workshop. The workshop was well received and is expected to play a catalyst role in creating research-based curriculums and training modules for regulators, which would eventually help upscale the knowledge base of these colleagues across region and thereby lead to faster approvals and more efficient systems. APACMed is currently developing a whitepaper on Training Curriculum for Regulators in the Asia-Pacific.

Capacity Building for Regulators

The Capacity Building WG organised a series of capacity building workshops on functional competencies for the Ministry of Health of the Republic of Indonesia on 14 September 2021. 144 officials participated in the workshop and the sessions were very well received. The feedback provided by the regulators was a testament of the need to upskill and modernise the existing frameworks, as well as create awareness of new, emerging and futuristic technologies. APACMed understands that efforts like this would help support implementation of globally harmonised regulatory frameworks across the region.

Promoting Regulatory Convergence and Harmonisation

Regional Initiatives

The RA Committee, under the aegis of its IVD WG, published the EU-IVDR position paper highlighting the impact of changes to Asia-Pacific markets under the In Vitro Diagnostic Medical Devices Regulation in Europe, with an aim to promote best regulatory practices and to propose recommendations to ease the transition. The change is expected to bring a significant impact across entire Asia-Pacific region in coming years, due to reliance of many local countries on European approval of the common medical device products.

In June 2021, the IVD WG published a position paper entitled "Risk-based Regulatory Oversight of Research Use Only (RUO) Products". In this paper, APACMed highlights that some regulatory authorities, for various reasons, have created highly burdensome regulatory measures for RUO products that are disproportionate to the risks of such products, without addressing the root cause of key concerns, such as off-label use, with the appropriate stakeholders. Through this paper, the WG attempts to illustrate key stakeholder responsibilities throughout the RUO lifecycle, highlight RUO oversight divergences in key markets, as well as propose recommendations on a risk-based RUO oversight mechanism that is consistent with global good practices.

Market Specific Initiatives

Thailand

In June 2021, the Southeast Asia COE submitted a Position Letter on New Medical Device Regulations in Thailand. In addition to submitting the position letter, APACMed is also working closely with the local association, ThaiMed, to ensure that APACMed member voices are heard by regulators and government representatives in order to minimise the impact of the proposed new regulation on the supply of medical device technologies in the market. A position paper is under discussion with ThaiMed.

Indonesia

In September 2021, the Southeast Asia COE submitted a Recommendation Letter in response to the July 2021 Draft Decree of The Ministry of Religious Affairs of Indonesia, regarding Types of Products and Consumer Goods Products Mandatory to be Halal Certified notified to WTO. The draft decree stipulates the scope of products subject to mandatory halal certification, including a very large number of medical devices. According to APACMed, the scope of coverage in the draft is overly broad. While the draft includes 17 categories and 68 sub-categories, it covers nearly 3,000 types of products based on Indonesian Ministry of Health data.

Malaysia

In May 2021, APACMed submitted a Position Paper with Recommendations to Facilitate Adoption of the Requirements for Labelling of Medical Devices in Malaysia. APACMed recognises that the topic on the implementation of the medical device labelling requirements is not new to MDA nor industry and would like to acknowledge the impact of the collaboration MDA has demonstrated with the local industry association, MMDA. The previously implemented three-year transition has been extremely welcomed. APACMed, together with MMDA, wishes to further partner with MDA and continue the dialogue, with the aim of reducing regulatory burden on industry and ensuring business continuity for healthcare facilities and patients through the ongoing supply of safe and efficacious technologies to the Malaysian market.

In November 2021, APACMed conducted a survey on the re-registration process in Malaysia, after being made aware of the challenges faced by the industry in obtaining the medical device approvals in a timely manner. Based on the survey, APACMed submitted a recommendation letter to highlight that a delay in the re-registration of medical devices acts as a barrier to continuous supply of medical devices into the Malaysian market. This could in turn significantly impede and impact patients' access to quality healthcare services.

South Korea

In October 2021, APACMed conducted a survey among its members on the challenges faced by members due to the Korean Good Manufacturing Practices (KGMP) renewal. APACMed, in partnership with AdvaMed, then wrote a position letter to Medical Device Safety Bureau, Ministry of Food, and Drug Safety (MDFS) to address issues created by KGMP renewal and to ensure that the new KGMP process does not result in supply interruptions to Korea.

Sri Lanka

In June 2021, under the aegis of its Indian RACOE, APACMed, through a Position Letter, requested NRMA to revise or reconsider 'Clause 46(3)' of the Proposed New Medical Devices Regulations (according to NMRA Act No. 05 of 2015) in the current draft. The clause may cause substantial damage to the present foreign investment, may deter future foreign investments and create disruptions in supply for critical products.

India

In September 2021, the India RA COE issued a recommendation letter on the ICMED Plus Scheme launched by Quality Council of India, which aims to be an end-to-end quality assurance scheme for the medical devices sector in India. The APACMed recommendations were aimed at discouraging a parallel certification scheme, which could potentially pose the risk of multiple quality benchmarks being set for the same product category, thereby causing a disruption in the market and potentially leading to suboptimal clinical outcomes.

Regulatory Intelligence

APACMed provides members with timely regulatory updates and actionable insights from the Asia-Pacific markets through a monthly newsletter for a rapidly changing regulatory landscape, as a means to support members with strategic decisions. The Regulatory Intelligence WG moreover developed an interactive digital platform that provides a dynamic, user-friendly experience for our members to share important regulatory updates. The WG is also in the process of rebranding and repackaging the newsletter into a monthly bulletin format, which will include additional information such as trends, analysis and forecasts, editorials, and expert interviews with regulatory KOLs.

RA Expert Summit at the MedTech Forum (MTF) 2021

The MTF was a very important event for APACMed, as the entire pandemic-hit world slowly crawls back to normalcy despite intermittent hiccups. Centred around the central theme "Health Futures by 2025", the RA Expert Summit at the MTF brought together a diverse group of stakeholders from the healthcare and MedTech ecosystem, including government, regulators, industry and academia, who shared their vision of the future focussing on three key topics – Regulatory Agility, Regulatory Harmonisation and Regulatory Capability Building. The event was graced by the presence of prestigious regulators and experts from Indonesia Ministry of Health, Malaysia Medical Device Authority (MDA), Singapore HSA, Australia Therapeutic Goods Administration (TGA), MedTech Europe and Centre of Regulatory Excellence (CoRE) among others. Panelists all agreed that it would be critical for authorities in the Asia-Pacific to have agile and risked-based mindset in dealing with changes triggered by dynamically changing new regulations, and also to actively explore various possible solutions together with industry partners, so as to ensure supply continuity for our patients during the pandemic.

External Forums

The RA Committee actively participated in various government and industry forums in 2021. The Committee is regularly invited to share on APACMed's perspectives and views related to trends, best practices and recommendations. Some of the key events included:

- HSA Annual Industry Dialogue (Singapore)
- AHWP Annual Conference (Hong Kong)
- DIA-CoRE Singapore Annual Conference (Singapore)
- China International Medical Device Regulatory Forum (China)
- PPH Asia 2021 (Singapore)

Legal, Ethics & Compliance Committee

Supporting APACMed's objective to raise ethics and compliance standards in the MedTech industry

Core Leadership

Ana Garcia Bello
Chairperson
Vice President, Law, Medical Devices Group, APAC, Johnson & Johnson

Campbell Clark
Vice-Chairperson
Vice President, Legal & Compliance, APAC, Medtronic

David Rosenzweig
Vice-Chairperson
Ethics & Compliance Officer Asia Pacific, Abbott

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

Composed of 94 individual members from 37 companies, the Legal, Ethics & Compliance (LEC) Committee 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.

Strategic Initiatives

Global Distributor Compliance (GDC) Toolkit

At the beginning of the year, the LEC Committee, partnered with AdvaMed to launch the Global Distributor Compliance (GDC) Toolkit in the Asia-Pacific region. Offered in multiple languages, the GDC Toolkit comes with over 50 compliance assets including training slides, compliance forms, communication templates, infographics and more, across the six key areas of global compliance. Closed-door sharing sessions of the GDC Toolkit were organised with the Malaysia Medical Device Association (MMDA) and with the Medical Technology Association of Australia (MTAA)'s Code Authority Committee, providing an overview of the content of the toolkit and its application in order to support the objective of raising ethics and compliance standards across the region.

New APACMed Guidelines - Competition Guidelines

The Committee recently published the APACMed Competition Guidelines. These Competition Guidelines for APACMed activities are intended to remind members of key competition law principles when participating in trade associations activities and to minimise competition law risk. The Guidelines apply to all APACMed activities, including but not limited to: committees, task forces, and working groups. The policies and procedures described in these Guidelines have been established to avoid competition law liability for APACMed and its members, and to prevent the appearance of impropriety.

Knowledge Sharing Webinars

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. Working with peer committees such as Government Affairs & Market Access, the webinars covered topics such as COVID-19 vaccination rates and testing policies, government attitudes toward country reopening and transforming the compliance function through analytics. Given the nature of the go-to-market strategy for many of APACMed member companies, manufacturers have significant reliance on distributors across the Asia-Pacific region. However, this comes with significant risk, as manufacturers must then entrust distributors to have compliance at the heart of what they do and to be guided by the same principles and standards that manufacturers are. This is especially true given the direct interactions that distributors have, on the behalf of manufacturers, with government officials and healthcare providers; in addition, distributors have to manage their own compliance risk and programs. In December 2021, the LEC Committee invited its members to its second LEC Summit of the year entitled "Manufacturers and Distributors: Focusing on Ethics and Compliance". The meeting was kicked off with a roundtable that brought together representatives from Fresenius, Roche and Stryker to deep dive into the lifecycle of working with distributors. The second part of the summit comprised a dialogue with two APACMed member distributors, DKSH and Zuellig Pharma, who shared more about their compliance programs and their perspectives of the distributor-manufacturer relationship.

Start-up & SME Committee

APACMed's shared goal continues to be the acceleration of innovation and success for the members, building on this ecosystem, expanding potential collaborations amongst large and small companies, as well as broader public sector agencies and like-minded organisations.

Core Leadership

Alan Goh
Chairperson
Co-Founder & CEO
NDR Medical Technology

Arun Sethuraman
Vice-Chairperson
Founder & CEO
Crely Healthcare

Simranjit Singh
Vice-Chairperson
CEO, Guardant Health
AMEA

Aileen Lai
Vice-Chairperson
CEO
Healthbeats

The APACMed start-up family welcomed 69 new members last year, taking the total to 140 start-up companies spanning across medical devices, diagnostics and digital health, and covering a diverse range of therapeutic areas from cardiology, diabetic care, nephrology, orthodontics, orthopaedics, ophthalmology, oncology, women's health, respiratory, neurology urology, to wound management. APACMed is delighted to have earned stripes as an established regional association for the industry, as members now not only represent the Asia-Pacific region but moreover from as far as Europe, USA, Canada and the Middle East, who want to leverage APACMed's strategic position as a springboard to the region and rest of the world.

In 2021, the Committee organised its resources and events based on members' prior feedback; hence, curated themes of focus included: funding, regulatory, market access and talent acquisition and retention, as a means to foster collaborative opportunities with multinational corporations and other key ecosystem stakeholders.

Related to mentorship, start-up members were paired with senior industry business leaders, who lent their time and knowledge to guide start-ups in their journey and to find success in their business venture.

Furthermore, the Committee is in its third year running of partnership with MedTech Innovator Asia Pacific, under which the collaboration witnessed 20 companies vying for the winning spot, ultimately awarded to Hong Kong-based Opharmic Technology. The Committee also promoted Medtronic's APAC Open Innovation Challenge as an additional platform for start-ups to pitch their solution; the opportunity being to take part in Medtronic's MedTech Innovator Asia Pacific Accelerator Program, where start-ups compete to win and enjoy high-profile visibility, access to industry decision-makers, a customised curriculum including 1-1 corporate mentorship, cash prizes, and in-kind awards.

The Committee's collaboration sessions took on several forms. The Committee hosted meetings quarterly between multinational corporate and start-up companies, which was a key request from the member base. The final instalment of the "Meet the Corporate" initiative with Becton Dickinson in November 2021 resulted in six companies being selected to pitch their solutions for potential partnerships. While the process is ongoing for next round of meetings with the selected companies, these initiatives are instrumental in the Committee's strive to increase the MedTech innovations for the region through such strategic partnerships.

In 2022, APACMed aims to line up more collaborative opportunities and to generate new resources catered to evolving MedTech ecosystem trends in order to give start-ups a leg up.

Country Insights:
APACMed in ASEAN, Japan, Korea & ANZ

Build relationships with local trade associations to bring the work done by Committees into countries for implementation for members, thereby partnering local association voices on the ground, so as to strengthen APACMed's drive for policy shaping with local governments.

As a regional trade association, it is of strategic interest to form and partner with local associations on the ground to strengthen industry voices collectively in a bid to bring advocacy work to local governments, and to help shape policies of benefit to APACMed members. Apart from policy shaping, APACMed brings competency building of knowledge and skills as well as best practices sharing. Strategic partners in the region include:

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

South 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) and 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)

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

Key Collaborations with Partners

Government Affairs & Market Access

- **Role of Diagnostics in COVID-19 Management White Paper**

  The pandemic brought along many unprecedented events, including health and economic challenges to policymakers globally. While vaccines took the centre stage of most countries in order to decrease the mortality rates and to control the spread of disease, effective testing approaches remain essential to control transmission and to monitor vaccine efficacy. The role of diagnostics was elevated, especially as markets reopen gradually and safely for resumption of normalcy. APACMed's paper advocated for testing strategies that may be used to confront different pandemic scenarios across the region. Awareness sessions were held for trade associations, professional societies and KOLs to share the paper and to support local governments in reopening economies.

- **Cost Effectiveness Analysis**

  In Japan, APACMed, in collaboration with AMDD, Pharmaceutical Research and Manufacturers of America (PhRMA) and AdvaMed, came together to learn from the pharmaceutical industry about Japan's Cost-Effectiveness Analysis strategy, process, and impact, in view of possible impending similar regulations on the MedTech industry. The topic continues to be monitored for regulatory changes, and APACMed will then leverage pharma references in order to review and define the MedTech industry's advocacy approach.

Digital Health

- **Digital Health Regulation**

  The Digital Health Regulatory Overview and Best Practices paper was shared across the region with regulators in a bid to create a fit-for-purpose regulatory framework for Digital Health solutions, particularly Software as a Medical Device (SaMD), that is safe with speed and scale to market.

  Singapore is the first country to implement the APACMed recommendations into their regulations and efforts will continue in 2022 for other countries.

- **Remote Care Management Policy Dialogue Series**

  COVID-19 has catalysed patient care outside of conventional clinical settings. APACMed organised dialogues with private sector stakeholders and policy-makers from Australia, Japan, South Korea, Malaysia and Thailand, focusing on remote care and market access strategies, followed by the publication of a paper. In 2022, further engagement sessions are planned with similar audiences in order to cover reimbursement of these solutions.

Regulatory Affairs

- **European Union Medical Device Regulation and IVD Regulation Position Paper**

  The position paper promotes best regulatory practices and proposes recommendations to ease transition to the new regulation set by the EU. Discussions were held with local partners, edits on recommendations were made where needed, and submissions to governments (Malaysia, Vietnam, Indonesia and South Korea) were made, referencing the paper.

- **Regulatory Reliance**

  Regulators are increasingly facing challenges to provide prompt access to safe, effective, and quality medical technologies to those in need. While innovation is thriving, it has led to growing complexity of medical devices and technologies, making it difficult for regulatory authorities to assess them. Reliance presents a suitable solution to the challenges of the current dynamic regulatory ecosystem, reducing time and cost to market. In late 2021, the team found success with a pilot case between Singapore as a reference market for Thailand, followed by Philippines FDA giving clearance for similar reliance under the ASEAN Medical Device Directive. The idea being any medical devices approved by the Regulatory Authority of any ASEAN member country, will then be cleared for use in other countries in the bloc. Similar reliance projects will continue to roll out in 2022.

- **Regulatory Capacity Building**

  The Regulatory Affairs Committee conducted a capacity building workshop for the Ministry of Health Indonesia in September 2021 that included topics such as Unique Device Identification, regulations for software and Artificial Intelligence, robotics, regulatory agility in the post pandemic world, and digitisation for clinical decision support.

  Similar workshops of such can be customised by APACMed based on the needs of the members and markets, with an ambition to further build out regulatory capacity in 2022.

Legal, Ethics & Compliance

- **Global Distributor Toolkit**

  The Global Distributor Compliance Toolkit, created by AdvaMed and supported by APACMed, was launched to the region with translations for local associations to leverage with their members. The toolkit sets out to raise ethics and compliance standards for MedTech distributors. APACMed furthermore held sharing sessions and webinars for all partner associations.

Country Insights: *APACMed in India*

Partner and work closely with local stakeholders in order to help strengthen systems, build capabilities, and drive access and affordability by leveraging a regional presence that fosters harmonisation, convergence, and best practices promotion from the region.

As one of the key markets for member companies, APACMed set up an office in India in 2020. In line with our above objective (including further strengthening the APACMed footprint and drive of the strategic agenda in India), the year was kickstarted by setting up the '**India Executive Committee (ExCo)**' comprising of country CEOs. The ExCo acts as an overarching governing council and advisory board providing strategic direction and leadership to the Secretariat. The ExCo also supports the teams by sponsoring projects as well as leading the advocacy and external outreach efforts, guiding in defining areas of collaboration and formation of workplans, and engaging with the ecosystem as APACMed 'ambassadors' to represent the industry's views at relevant forums.

INDIA EXECUTIVE COMMITTEE

Pavan Mocherla
Chairperson
Managing Director, India
South Asia
Becton Dickinson

Meenakshi Nevatia
Vice-Chairperson
Managing Director, India
Stryker India

Narendra Varde
Vice-Chairperson
Managing Director, India &
Neighbouring Markets
Roche Diagnostics India

Madan Rohini Krishnan
ExCo Member
VP, India Subcontinent
Medtronic India

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

Vivek Kanade
ExCo Member
Managing Director
Siemens Healthineers
India

Rishubh Gupta
ExCo Member
Commercial Director
Baxter India Pvt. Ltd.

Manoj Madhavan
ExCo Member
Managing Director
Boston Scientific
India

Indranil Mukherjee
ExCo Member
Managing Director
B. Braun India

Shishir Agarwal
ExCo Member
Managing Director
Terumo India

In 2021, the APACMed India agenda was focused on four Strategic Pillars (ABCD):-

A - Accelerating Digital Health

B - Build the Regulatory Framework

C - Capacity and Knowledge Expansion

D - Driving Market Access

In 2021, the establishment of a third local Centre of Excellence (COE), the India Digital Health COE, was a testament to APACMed's commitment to leveraging opportunities and playing a key role in shaping the fast-evolving digital health environment in India.

APACMed India has also made significant progress in creating visibility and awareness about the association to the government, and through thought leadership initiatives, APACMed has been able to secure a seat at the table at the Department of Pharmaceuticals (DoP), Department of Health Research (DHR), Bureau of Indian Standards (BIS) and Central Drugs Standard Control Organisation (CDSCO), where APACMed members have been participating actively in industry consultations.

Going by a philosophy of 'Partnering' in India, APACMed have established partnerships and collaborations with local bodies, as well as other associations like NATHEALTH, MTAI, Invest India and DSCI, with whom APACMed is now working on specific projects. The objective of these partnerships is to leverage one another's strengths and to be a force multiplier, in order to amplify the work that the various parties are doing in India.

Key Projects

Government Affairs & Market Access

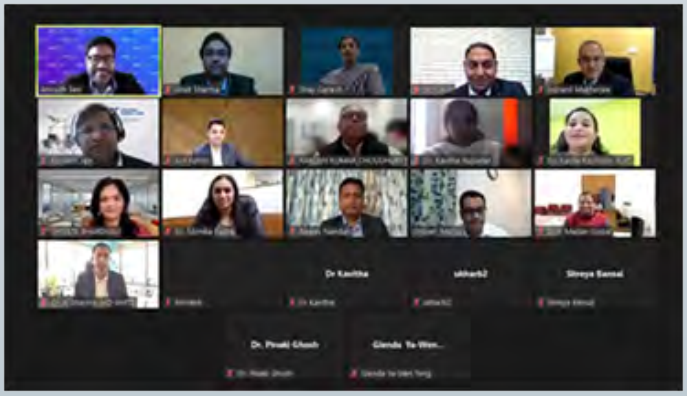
- **Health Technology Assessment (HTA)**

  - HTA India White Paper

  In 2021, the COE published the India HTA Paper, in collaboration with IQVIA. The paper is an extension of the regional HTA report and provides a review of the HTA landscape in India. The paper also provides recommendations and areas of consideration to ensure more informed decision-making, in order to promote an equitable, efficient, and high-quality health system in India.

  - HTA Policy Roundtable

  Following the development of the above paper, APACMed organised a closed-door virtual roundtable on "**Health Technology Assessment of Medical Devices in India**". The roundtable saw a diverse set of stakeholders from government bodies like NITI Aayog, DHR, NHSRC, AMTZ/KIT, along with payors from the MedTech industry. The roundtable aimed at presenting some of the key findings from the paper, as well as seek stakeholder views and perspectives around the adoption of HTA in India – roadblocks, opportunities, and way forward through collaborated efforts for this critical policy reform.



- **Value of MedTech**

  APACMed India collaborated with the Medical Technology Association of India (MTaI) to jointly develop a case study compendium entitled "Impact of MedTech in India during the COVID-19 Pandemic", featuring local examples of our member companies and highlighting the value of MedTech in contributing to stronger healthcare systems, healthy societies, and economic prosperity.

Regulatory Affairs

- **EU Regulations**

  - EU MDR IVDR Position Paper

  APACMed India's RA COE developed a position paper (an extension of the regional position paper) on EU-MDR IVDR to promote best regulatory practices and to propose recommendations to CDSCO, thereby ensuring minimum market disruption and allow a smooth transition from MDD to MDR and IVDD to IVDR. The paper was followed by an in-person meeting with the Drug Controller General of India to present the APACMed findings and recommendations.

  - Position Paper on Unique Device Identification (UDI)

  In 2021, the Government of India came with a ruling requiring manufacturers to comply with mandatory tagging of medical devices with a UDI, effective 2022. Since this is a new regulation, members felt necessary to create awareness and to sensitise regulators by developing a position paper on UDI, highlighting related laws and regulations across the globe as well as the need to make the Indian rulings globally harmonised, especially in the evolving scenario and given India's state of readiness.

Digital Health

- **Digital Health (DH) Reimbursement**

- DH Reimbursement Policy Roundtable

The India DH COE organised a closed-door virtual roundtable on the theme "**Harnessing the Potential of Digital Health Technologies Policy Pathways for Value Assessment & Reimbursement for India**". The objective of the roundtable was to share key findings and recommendations coming out of the APACMed's regional paper on digital health reimbursement, with government stakeholders, MedTech industry players, hospital groups, physicians, as well as multi-laterals, associations, and think tanks in India. The roundtable moreover aimed to promote awareness, to share best practices about funding and reimbursement for digital health tools and technologies, and to advance discussion on future policy pathways for digital health reimbursement in India.

- Remote Care Management (RCM) Policy Dialogue

In June 2021, a regional policy dialogue with a focus on RCM was conducted in order to explore the complex digital health ecosystem, how it is transforming the way healthcare is delivered, and the ways in which the industry can work together to promote greater access to, and affordability of RCM solutions in the Asia-Pacific region. India was one of the selected countries that participated, with attendees from Ministry of Electronics and Information Technology, Government of India, associations like MTal and NATHEALTH and leaders from the MedTech industry, who shared their perspectives and views on the way forward for India.

- **Digital Health Regulation**

- Digital Health Regulation Position Paper

A paper on Digital Health Regulation for India was published, which was a spin-off from the regional paper. The objective being to review India's regulatory approaches for software regulation alongside international best practices, reiterating the framework for fit-for-purpose regulation of Digital Health solutions. In addition, the paper aims to provide regulators with recommendations that enable the implementation of a harmonised framework supporting the introduction of safe and effective digital health solutions, at a pace that matches the speed of innovation and benefits regulators, software developers and most importantly, patients.

- SaMD Guidance Document

The Digital Health Regulation paper was followed by a "**Guidance Document on SaMD Regulations**", taking a lifecycle approach. This guidance is the recommendation from APACMed to CDSCO on the regulatory approach for software-based medical devices. CDSCO to continue to adapt its policy approach to Software as Medical Devices (SaMD) with emergence of new software-related technologies and evolving risks.

Advocacy on Live Issues

Remaining cognisant of the fact that on-the-ground, live issues are impacting the industry, APACMed India, while focusing on the 'Growth Agenda', has continued to engage with the policymakers on current matters. Some of the key topics that were taken up during the course of the year included:

- Position Paper on amended Public Procurement Order
- Position Paper on ICMED Plus
- Position Paper on Legal Metrology
- Position Paper on NMRA New Regulations
- Recommendations on Union Budget
- Position Paper on National Medical Device Policy
- Letter on Vaccine Prioritisation

Country Insights: *APACMed in China*

Envisions to continue to present the unique values 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.

APACMed China at a Glance

In April 2021, APACMed opened its country office in China, to work with the local government, healthcare professionals, industry associations, members based in China, in order to shape an enabling ecosystem and to create smoother policy pathways. Throughout the year, APACMed has achieved the following milestones in China:

- Engaged around 20 central and local partners in China
- Released four papers together with the Committees
- Organised various webinars/events to attract more than 700 viewers
- On-boarded five Chinese local companies to demonstrate the APACMed voice as a regional association

APACMed Value Propositions in China

As a regional MedTech association, APACMed focuses on being a regional, impartial, inclusive, and strategic partner for China, particularly from the following aspects:

- **Regional:** Sharing regional best practices in MedTech policy shaping to support the *Healthy China 2030 Strategy*
- **Impartial:** Speaking as an independent association on behalf of the MedTech Industry
- **Inclusive:** Collaborating with MNCs, SMEs, local Chinese trade associations, HCPs, and medical service providers in China and across the wider Asia-Pacific region
- **Strategic:** Focusing on long-term impactful and strategic issues that are relevant to China, such as digital health, value-based assessment, health services, and more

In a nutshell, APACMed is committed to the vision of "From regional to local, in China for the Asia-Pacific", and together, with members, APACMed strives to create a healthcare ecosystem that works for the benefit of the whole industry.

Collaboration & Engagement

In 2021, APACMed China engaged more than 20 central and local government stakeholders, academic institutions and government think tanks as a mechanism to support the main initiatives, including:

- **Engagement with Key Partners**

  - Institute of Global Industry (IGI) of Tsinghua University

  APACMed signed a MoU with IGI of Tsinghua University, with the long-term vision to support priority areas in *Healthy China 2030 Strategy*, including health services for key patient groups, medical reform policies, regulatory science, and digital health technology application.

  - Regulatory Science Research Institute, NMPA and Sichuan University

  Explored mechanism of regular exchanges and collaboration and Chinese government officials were invited to speak at the Regulatory Affairs Expert Summit at the MedTech Forum 2021.

  - China Investment Promotion Agency (CIPA), Ministry of Commerce

  APACMed were invited as a member of the Life Science and Health Committee of CIPA, to explore how to jointly shape a sound ecosystem in both the national and local level policy-making processes.

  - China Chamber of Commerce for Import & Export of Medicines and Health Products

  As one of the partner trade associations in China, APACMed worked closely with the Chamber to share regional best practices in regulatory agility and market access policies. Both parties then jointly submitted the APACMed IVDR paper to the Chinese government bodies, and subsequently the APACMed regulatory reliance article was included in the government's annual Bluebook on the Internationalisation of China's Pharmaceutical and Medical Industry 2021.

- **Engagement with Key Government Bodies**

  - National Medical Products Administration

  APACMed submitted the EU IVDR paper and the SaMD China & Korea paper to both National Medical Products Administration and CMDE, together with partners in China. APACMed was furthermore invited as the keynote speaker at the closing ceremony and four parallel sessions at the 12th China International Medical Device Regulatory Forum, organised by CCFDIE and hosted by NMPA.

  - National Health Commission

  APACMed was invited as a keynote speaker at the China-WHO joint conference, organised by China National Health Development Research Center, to share its Remote Care Management learnings in China and across the Asia-Pacific region.

Events & Webinars

In 2021, APACMed launched an array of events and webinars in order to better introduce major policies in China to the wider regional community, facilitating business development in China. These events/webinars have garnered more than 700 views since April.

China Health Dialogue Series

- **Case Study on Diagnosis-Related Group (DRG) to Support Innovation**

  The dialogue was intended to advance members' understanding of China's healthcare ecosystem. Panelists discussed their views on DRG implementation in Wuhan, including the multilayered medical security system as well as payment innovation.

- **Home Use Test Kits & their Role in COVID-19 Control**

  The webinar featured deep dives into the current practices of rapid self-testing for COVID in the USA, including approval status and usage scenarios. In addition, insights and observations on self-testing solutions and practices in the "new normal" were presented from both Asia-Pacific and China perspectives to 200 attendees.

- **MedTech Forum 2021 (MTF)**

  The China session at MTF focused on the application of digital solutions towards universal health coverage in China. The session presented multi-stakeholder perspectives on the theme, from the policymaking, international partnership, and primary-level angles. The session also had deep dives into use cases that might be applied in China's leading hospitals, and the pioneering underway in Zhejiang province. Representative speakers included government, academic and KOL executives.

Strategic Projects in China

China Remote Care Management

As an integral part of the APACMed Remote Care Management (RCM) initiative, the China RCM Dialogue, held by APACMed in partnership with Tsinghua University, dove into the status and future development of remote care models in China. 18 speakers, including China's most respected medical policy experts from government, academia, and the WHO, shared their insights at the dialogue. This first-ever APACMed event in China attracted more than 110 online attendees from APACMed corporate members in China, government bodies, HCPs and partners. Insights provided from China were also included in the committee paper: "Advancing Remote Healthcare During & Post COVID-19".

Digital Health Ecosystem in China

This year, APACMed China worked with members and partners to present a comprehensive overview of the digital health landscape in China and had deep-dives into three types of categories; namely: hospital-facing, physician-facing and patient-facing solutions. "Digitalization of China Medical Device Industry" has been released in both English and Chinese languages.

Digital Regulation in China

In 2021, APACMed reviewed Korea and China's regulatory approaches for software regulation alongside international best practices, reiterating the framework for fit-for-purpose regulation of digital health solutions. APACMed released and submitted the paper entitled "Digital Health Regulation in Asia-Pacific: China and Korea" in both English and Chinese languages, and will continue to conduct policy shaping activities in China in 2022.

MEDTECH FORUM ASIA PACIFIC 2021

HEALTH FUTURES BY 2025

Following the 6th edition's pivot into fully virtual format, the 7th edition of APACMed's MedTech Forum (MTF) saw a return to the hybrid world in 2021. The idea was to really consider the industry's bets in this new normal, under a theme of "Health Futures By 2025". Conversations oriented around patient power, care models, capacity building, reimbursement pathways and innovative collaborations, all underpinned by increasing levels of digitalisation. Dig into the following pages to learn more!

Number of Delegates Attending MTF

2017	From 22 countries	622
2018	From 25 countries	758
2019	From 31 countries	1,092
2020	From 34 countries	1,450
2021	From 33 countries	1,707

In October 2021, more than 1,700 attendees representing 33 countries convened for the APACMed's annual MedTech Forum (MTF). After 2020's MTF that took place in an entirely virtual context due to the COVID-19 pandemic, this year's 7th edition saw a return to a hybrid format. And given that innovation was a key factor in the MedTech industry's role during the pandemic, APACMed members selected a theme of "Health Futures By 2025", in order to align around key innovation bets that are most likely to deliver on health system equities in the Asia-Pacific region over the coming years. Over two days, MTF featured live and broadcasted talks from a wide array of healthcare ecosystem leaders, as well as break-out tracks and discussions so as to maximise the interaction opportunities. The MTF web platform, moreover, allowed attendees to network, learn more about APACMed and event sponsoring organisations, take virtual tours of care pathway technologies and compete for quiz competition prizes. Overall, attendee survey feedback about MTF 2021 was very positive, showing appreciation for diversity of the content and with nearly 100% of respondents indicating that they will join MTF again in 2022!

17 Sponsors

56 Sessions

15 Hours of Content

145 Speakers

1,707 Attendees

33 Countries

"Our industry is undergoing a major transformation, and we need to be ready to drive it. The Asia- Pacific represents 60% of the world's population, an ageing population where chronic disease is on the rise; so it's critical we come together as industry leaders. It's great to see our APACMed community continuing to grow, including at a local country level across the region."

Harjit Gill, APACMed CEO, in her opening remarks for MTF 2021

"The strong multistakeholder presence at MTF 2021 demonstrates the commitment of our community to come together to tackle global health challenges, especially as we rewrite the playbook following the COVID-19 pandemic. The pandemic has proved what we can achieve through collaboration, across organisations of all sizes and geographies. Delivering on the promise of innovation will require such a coalition, particularly along emerging trends such as digitalisation. As industry leaders, let us pave the way and emerge stronger together."

Andrew Frye, Baxter Asia-Pacific President & APACMed Chairman of the Board, in his opening MTF 2021 remarks titled: "Emerging Stronger Together"

MEDTECH FORUM ASIA PACIFIC 2021
HEALTH FUTURES BY 2025

CEO Summit

Asia Pacific CEO Summit

Industry executives convened live to reflect on recent learnings, as well as to rally around innovation and collaboration opportunities ahead. Ongoing digital transformation proved a consistent theme, under which new care models and health equities were discussed across a range of stakeholders. Focus was also given toward ensuring we continue to humanise the bets placed on the futures of this sector.

Expert Summit: Public Policy & Market Access

This track focused on the themes of public policy and market access, with a specific discussion line along the value of innovation in a post-pandemic world. Interactive segments therein included pandemic learnings, localisation, value-based contracting, and the patient's role in reimbursement decision-making.

Expert Summit: Digital Health

The Digital Health Committee was formed in 2020 and has been a key driver of APACMed activities in the recent period. This track looked at the journey of the digital health patient, across discussion topics such as cybersecurity, interoperability, regulation and reimbursement. Sharings across the Asia-Pacific and beyond proved insightful in this fast-moving space.

Expert Summit: Regulatory Affairs

This track continued to drive its efforts at enabling regulators to be more agile and harmonised in the Asia-Pacific, with a view to equip a future-ready workforce. Discussion topics included regulatory trends observed during the pandemic, the new EU Medical Device Regulation (MDR) protocols and capacity development activities at localised levels across the region.

Rise of Digital Innovation

It's hard to consider 2025 futures without the strong role of all-things digital. Discussions across a range of stakeholders and geographies featured topics such as new sector entrants, East-West learnings, data empowerment and organisational preparedness for the transformation. APACMed member companies presented on their respective tech advancements and APACMed also released its new whitepaper looking at a deep dive into Remote Care Management (RCM).

Health Futures Core Focus Discussions

MTF 2021, under the umbrella of Health Futures, was oriented around the curated pillars of: patient empowerment, new care models, capability building, reimbursement pathways and innovative collaborations. Ecosystem leaders discussed their role in bringing trustworthy MedTech interventions for equity, across physical as well as mental health. The content pontificated what life may look like over the foreseeable future, and how stakeholders can continue to work together to achieve the vision. "Patient Centricity" remained at the core of the innovation concepts (a teaser for what's in store at MTF 2022!).

Country Insights

In addition to the above content, participants had the opportunity to break into country-level deep dive discussions. It is important for APACMed initiatives to be cultivated in partnership at the field level. Track geography coverage included Japan, India, China, South Korea and ASEAN, across a range of topics such as business sentiments, UHC, policy-shaping, regulatory harmonisation and of course, digital transformation.

MedTech Innovator (MTI)

Keeping in line with MTF's overall theme, the event once again featured the MTI initiative. Following a month's long submission review process, MTF attendees were able to vote real-time on their favourite concepts. In addition, breakout tracks were held to discuss the views from founders and investors. Congratulations to Opharmic Technology (Hong Kong) on taking home the grand prize, inclusive of USD175,000 and a one-year APACMed membership. Runners up, Biorithm (Singapore), Miraqules (India) and VPIX Medical (South Korea) also received cash prizes. Nayam Innovations (India) was awarded a one year of residency at JLABS in Shanghai and Adiuvo Diagnostics (India) won a cash prize for best pitch video. These are indeed the future bets!

MEDTECH INNOVATOR ASIA PACIFIC

APACMed Membership

APACMed grew our membership from 194 in the year 2020 to 263 in 2021, representing a 36% increase in total membership number. In the year 2021, we added a record 69 new members, including 12 new Corporate Members. Also recorded was membership growth across all five membership categories – Corporate, Digital Health, Associate, Start-up & SME and Industry Association.

In 2021, APACMed launched a new membership category for Digital Health. This category is meant for global tech and digital technology companies that do not have medical device sales, including mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalised medicine. APACMed welcomed three new members, including Amazon Web Services, Avery Dennison and Novartis Biome. We also expanded our start-up members to 140, accounting for 53% of our total membership base.

New Corporate Members

APACMed welcomed 12 new Corporate Members in 2021:

3M

Ansell

ASP Advanced Sterilization Products

Beckman Coulter

BIOMÉRIEUX

Cepheid A better way.

dexcom

GLAUKOS

illumina

straumanngroup

Vazyme

Wondfo 万孚

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 USD50 million.

Digital Health

Tech and Digital Technology Companies that do not have device sales, including mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalised medicine.

Start-up & SME

Start-ups or SMEs manufacturing and/or conducting R&D in medical technology with annual sales less than USD50 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.

Membership Category	2020	2021	Growth
Corporate Members	44	54	23%
Digital Health Members	0	3	N.A.
Associate Members	38	53	39%
Start-up & SME Members	100	140	40%
Industry Association Members	12	13	8%
Total	194	263	36%

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 Asia-Pacific.
- Participate in Functional Committees and Working Groups with senior-level executives from the largest companies in the industry.

- Join regular webinars, workshops, seminars and roundtables.
- Participate in the annual MedTech Forum, the industry's most impactful gathering of people and ideas in the region.
- Join networking events.

- Benefit from exclusive market insights and analysis from APACMed Knowledge Partners.
- Receive timely information providing early warnings 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.

Annual Report 2021

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.

Learn more about the association at **www.apacmed.org**

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