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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, 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, by working in close collaboration with regulators, policymakers, healthcare providers, payers and patients to develop policies and put forward recommendations which ensure optimal care pathways for patients, from diagnosis to treatment.



#### INNOVATION

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



HARMONIZATION

We drive common approaches aligned with international best practices promoting speed to access via common regulatory standards; security and efficiency to adapt new digital technologies; and ethical interactions with healthcare professionals through the adherence of the Code of Conduct.



### WELCOME MESSAGE

APACMed Chairman, Andrew Frye

Dear APACMed Members,

The world has undergone a metamorphosis, and with it, our industry, and indeed, the entire healthcare ecosystem has been radically transformed. APACMed's mission to advance the standards of care and ensure high quality, accessible and affordable healthcare for patients across the Asia Pacific region, has never resonated so powerfully.

Despite the uncertainty thrown upon us by Covid-19 and the unprecedented, drastic changes to the industry during this past year, APACMed continues to grow and strive. APACMed has expanded its reach, growing from 140 member companies in 2019 to 194 member companies by the end of 2020. Our Functional Committees have also seen tremendous growth, now being populated by over 800 active committee members across five committees: Government Affairs & Market Access; Legal, Ethics & Compliance; Regulatory Affairs; Startups & SMEs; and Digital Health.

Covid-19 is by no means behind us yet, but reflecting on these last 8 months, I am both immensely proud and humbled, to have witnessed how we – as an industry at the forefront of the pandemic – responded to the challenges brought about by this global crisis, and collectively stepped up in these unprecedented times.

As an industry, we demonstrated high levels of agility, and played a critical role responding to the pressing demands and challenges of our overworked, overstretched and under resourced health care providers. We worked tirelessly to develop new products and innovative solutions to respond to emerging health challenges. We ramped up production, and worked our way around global supply chain issues, to ensure patients could still get access to life enhancing and life saving devices.

But what unified us all, across the MedTech Industry was our sense of purpose – and this is really exemplified in the paper APACMed recently published with Deloitte "Improving Health & Transforming Lives".

Today, there is no doubt that telehealth, virtual, and home care are the future of healthcare; therefore, APACMed has and will continue to emphasize the power and need for digital health via the Digital Health Functional Committee, established in 2020. Moreover, APACMed continues to grow as an association and expand its reach across the region by creating a local team on the ground in India.

Moving into 2021, APACMed will continue to expand its reach by activating local teams across the region to collaborate and further illustrate the value of the MedTech industry – quite literally, through the 'Value of MedTech' project which stems from APACMed's recent work with Deloitte.

I would like to thank all of those who helped to contribute to the success of APACMed in 2020, including my fellow Board Members, our CoE Leadership Teams, our Functional Committee Members, all our APACMed Members, and most importantly, the Team at APACMed. I look forward to all we will accomplish in 2021.

# In Conversation with Harjit Gill, CEO



2020 has been a transformative year for the world and for our industry. We collectively led the fight against the Covid-19 pandemic, our people at the frontline, our products and services urgently needed and coming together to collaborate in the race for the vaccine. All of us had to pivot our ways of working and in some cases our business modes, embracing all things digital.

Like everybody else, at APACMed we made a concerted effort to engage digitally with as many of you as was possible, whether it be via the remote committee sessions, the educational webinars or indeed the Virtual MedTech Forum which was a first for us.

Some highlights of the year;

- A 40% increase in membership compared to the previous year,
- 23,000 visitors to our revamped website, giving you access to over 60 position papers, newsletters, and reports,
- 35 webinars attracting close to 4000 participants, discussing and debating a variety of issues and opportunities in healthcare,
- The first virtual MedTech forum where over 1400 delegates attended the four tracks covering topics from country insights to digital health,
- We established the Regional Trade Association network where we were able to share and collaborate on a number of issues affecting all countries in the fight against the pandemic,
- We launched a Digital Health committee that produced some critical pieces of work to help understand and accelerate digital health solutions,
- Our Functional Committees, steered by our Board produced 12 papers from Harnessing the power of interoperability within Medical Devices to Regulatory Reliance,
- Established our office in India where we are partnering with a number of local trade associations to build our advocacy work,
- We saw our members step up in phenomenal ways in response to COVID-19. Their contribution
  was brought to life in our report MedTech in APAC: Improving Health & Transforming Lives –
  with case studies from 35 member companies speaking to the dedication of MedTech's people,
  our product development and innovation, and the partnerships we forged across industries and
  economies to fight the pandemic.

As we continue our work in advocating for access to safe and affordable medical technologies, and promote the value of innovation, which is critical to address Asia Pacific's pressing healthcare needs, I want to thank our Board and all our Committee Members who continue to selflessly support and steer our efforts.





## **APACMed Board of Directors**



Andrew Frye Chairman, APACMed

Senior Vice President and President APAC, Baxter Healthcare



Graham McLean

Vice-Chairman, APACMed

President, Asia Pacific, Stryker

#### James Lim Treasurer, APACMed

Executive Vice President and President, Greater Asia, Becton Dickinsor



Art Butcher Executive Vice President & President, Asia Pacific,



**Ian Burgess** Chief Executive Officer, Medical Technology Association of Australia



Lam Chee Hong President, Asia Pacific, B. Braun



**Chris Lee** Senior Vice President and President, Asia Pacific, Medtronic



**Boston Scientific** 

**Probir Das** Chairman & Managing Director, Terumo Asia Holdings



**Sanjay Prabhakaran** Regional President, Asia Pacific, Hologic



Lance Little Managing Director, Region Asia Pacific, Roche Diagnostics Asia Pacific



Paul Tan Minjie Divisional Vice President, APAC, Abbott



**Elisabeth Staudinger** President, Asia Pacific, Siemens Healthineers



Julie Tay Senior Vice President and Managing Director, Asia Pacific, Align Technology



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



Sunil Vasanth Vice President, Surgical, Asia Pacific, Alcon



# APACMed Secretariat Team



Harjit Gill Chief Executive Officer



**Maryline Marquet** Vice President, Operations



Nishan Pillai Manager, Finance and Operations



**Roberta Sarno** Manager, Digital Health



Anirudh Sen Country Lead, India



Gabriel Sim

Director, Strategic Partnerships



**Georgia Swan** Manager, Government Affairs and Market Access Manager,

Legal, Ethics & Compliance



**Yu Liang** Director, Regulatory Affairs

# **APACMed Functional Committees**

Regulatory Affairs

Chair



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#### Miang Tanakasemsub

Regional Regulatory Affairs and Government Affairs Head, Alcon

Vice Chairs



Adelheid Scheider Regional Head for Regulatory and Quality, Roche Diagnostics



#### **Nishith Desai** Director of Regulatory Affairs, Medtronic



Jason Guo

APAC Director, Regulatory Affairs, Quality and Compliance, Abbott



**Alex Budiman** Vice President of Regulatory Affairs, BD

#### Government Affairs



### Shakilla Shahjihan

Chair

Divisional Vice President, Government Affairs, Asia Pacific & Japan, Abbott

Vice Chairs



#### Hitendra Joshi

Head of Government Affairs and Market Access, Asia Pacific, B. Braun



#### Christoph Liesche

Head of Public and Government Affairs, Asia Pacific, Fresenius Medical Care



**Rajeev Nandan** Head of Market Access and Government Affairs, Alcon



# **APACMed Functional Committees**

Market Access



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> Dr. Sang-Soo Lee Chair

Senior Healthcare Economics & Government Affairs Director, North Asia, Medtronic

#### Vice Chairs



#### Virginia Priest

Director, Health Economics and Market Access, Asia- Pacific, Boston Scientific



#### **Caitlin Asjes**

Senior Director, Government and Public Affairs, Greater Asia, BD

#### Startups & SMEs



### Alan Goh

Chair Co-Founder & CEO, NDR Medical Technology

Vice Chairs



Arun Sethuraman Founder & CEO, Crely Healthcare



**Simranjit Singh** CEO, Guardant Health Amea



**Aileen Lai** CEO, Healthbeats



**Dr. Nayanabhiram Kalnad** CEO, Avegen



**Dr. Goh Yi Xiong** Founder & CEO, Beacohealth



James Mendoza Co-Founder, Healthblocks



# **APACMed Functional Committees**

#### රී Legal, Ethics, & Compliance



#### Ana Garcia Bello Chair

Vice President, Law, Medical Devices Group, APAC, Johnson & Johnson

#### Vice Chairs



#### **Campbell Clark** Vice President, Legal & Compliance,



#### Christian Fitsch

APAC, Medtronic

Vice President, Chief Legal Counsel, Asia-Pacific, Stryker



#### **David Rosenzweig** Ethics & Compliance Officer, Asia-Pacific, Abbott

### Digital Health



#### Shamini Nair Interoperability Working Group Chair

Asia Pacific Director of Marketing, Abbott



#### Jim Sarka

#### Cybersecurity Working Group Chair

Vice President & CIO, Business Technology, Asia Pacific, Johnson & Johnson



#### Varun Veigas Regulatory Working Group Chair

Regional Manager, Regulatory Affairs, Asia Pacific, Roche Diagnostics Asia Pacific



#### Anh Bourcet Reimbursement Working Group Chair

Director, ASPAC Health Economics & Market Access, Health Outcomes, Global Orthopaedics & Biosurgery, Johnson & Johnson



# **APACMed Board Sponsors**



# APACMED IN NUMBERS

# 80%

GROWTH OF SOCIAL MEDIA FOLLOWERS

Number of social media followers increased from 5000+ in 2019 to 9000+ in 2020.

804

**COMMITTEE MEMBERS** 

Total number of members from 5 committees in 2020.

39%

#### GROWTH OF MEMBER COMPANIES

Number of member companies increased from 140 in 2019 to 194 in 2020.









# APACMED IN NUMBERS



**Corporate Members** 



### **SME Members**

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AKUOS	Analytica	P	AUTOYOS	avegen
AXIO	🕂 BeacoHealth	Beat my	BIORITHM	) Blazar
Surgical Systems	CareTech	CARTOSENSE	CREATZ	
daftaro	dhanush Healthcare Awerly Cer + Indexing Connection	C docquity	eko.ai	evitalz
ewoosoft	Forus Health Technology delivering care	~gaur		<b>GUARDANT</b>
налоок		healthblocks	HEALTHBEATS	HINRICH ERTYR
UNGPASS	MDoc	icliniq	ImmunoHeat	inochi care
iota medtech	iXensor.	JD Sammed	joye	Juvota
		Soft Implants for Soft Bones	<b>เ</b> บตามเก <sup>ะ</sup>	** mClinica pharmacy solutions
Logy.Al	LiveMore			MS1 MedSubOne Ltd
medifi	medios technologies	//// Medi Whale	MEDAI	MINOFI

### **SME** Members





### **Associate Members**



# GOVERNMENT AFFAIRS & MARKET ACCESS COMMITTEE

Shaping policies and processes to support increased access to medical technologies for patients in the APAC region.

In 2020, the Government Affairs & Market Access (GAMA) Committee grew to 140 members across 28 member companies.

Thank you to the GAMA leadership team for all of their support: Shakilla Shahjihan (Abbott), Hitendra Joshi (B Braun), Rajeev Nandan (Alcon), Christoph Liesche (Fresenius), Dr Sang-Soo Lee (Medtronic), Caitlin Asjes (BD), and Virginia Priest (Boston Scientific). Welcome and congratulations to the newly appointed Country Centres of Excellence Leadership teams:

- India: Vibhav Garg (Boston Scientific); Shivkumar Hurdale (Stryker); Rishi Sharma (Abbott)
- Indonesia: Reswita Gisriani (Medtronic); Wulan Putri Sunuwati (Siemens Healthineers)
- Vietnam: Julia Tran (Abbott); Kieu Anh Ngo (B Braun)

Participation in the GAMA working groups and country CoEs increased significantly this year. A new working group was also established this year – the Government Affairs & Market Access In-Vitro Diagnostics Working Group.



#### **Strategic Initiatives**

In 2020, APACMed's Government Affairs & Market Access Committee worked on a number of strategic initiatives to build understanding of key policy and market access topics.

#### White Paper

The Evolving Health Technology Assessment (HTA) for Medical Devices and Diagnostics in the Asia Pacific (APAC) Region and Key Considerations for Value Assessment Frameworks white paper

In January 2020, a white paper was published, titled The Evolving Health Technology Assessment (HTA) for Medical Devices and Diagnostics in the Asia Pacific (APAC) Region and Key Considerations for Value Assessment Frameworks. This paper was published in collaboration with IQVIA, with significant contributions from members of APACMed's Market Access Working Group. The paper sheds light on the evolving HTA landscape for medical devices and diagnostics across the APAC region, growing the knowledge base for agencies looking to incorporate these methodologies in their policy and reimbursement decision-making. APACMed and its members will use this tool to engage and work with governments to build capability in this space and support robust and sustainable HTA systems throughout the region. The paper was also translated into Mandarin and Vietnamese.

#### Indonesia Value-Based Assessment Report

In October 2020, APACMed completed a report on Indonesia's value-based decisionmaking mechanisms to inform work in collaboratively shaping this landscape with key stakeholders in Indonesia moving forward. This paper was published in collaboration with Vriens & Partners, with significant contribution from APACMed's Market Access Working Group and Indonesia CoE.

#### **Quarterly HTA Landscape Reports**

This year, the Market Access Working Group continued the production of quarterly Health Technology Assessment (HTA) reports providing regular updates on the HTA landscape in four key markets across the region: Australia, Japan, South Korea and Taiwan. This resource provides members with important updates on the application of HTA and potential impact to businesses in these markets across APAC.

#### APACMed Public Policy & Market Access Summit, MedTech Virtual Forum 2020

The Government Affairs & Market Access Committee organised a Public Policy & Market Access Summit at this year's APACMed Virtual Forum. In this summit, we heard from regional and global thought-leaders on key topics including consumer-driven policy shaping; value-based decision making for medical technologies; and navigating the changing geopolitical climate and shifts in supply chains.

#### Webinars

Throughout 2020, the Government Affairs & Market Access committee held a number of webinars on topics critical to this function, including:

- US-China Trade Relations Phase 1 Agreement (with Frontier View)
- The Future of Medical Device Reimbursement in Australia (with the Medical Technology Association of Australia)
- COVID-19 South-East Asia Policy Impact (with Vriens & Partners)
- HTA white paper launch (with IQVIA)
- Policies & personnel: Changes to Vietnam's government affairs context for the medical device sector (with Vriens & Partners)
- Impact of COVID-19 on regional healthcare budgets (with Frontier View)

#### Advocacy

In 2020, APACMed's Government Affairs and Market Access function undertook advocacy efforts on key matters critical to medical technology access across the region, including:

- India: COVID-19
- Indonesia: Procurement
- South Korea: Pricing, COVID-19
- Malaysia: Advertising & promotion, COVID-19
- Philippines: Pricing, procurement, HTA
- Singapore: COVID-19
- Vietnam: Pricing, procurement, COVID-19

#### High Level Meetings

#### Commission IX DPR RI, Panja Alkes Meeting, Indonesia

In November, APACMed's Government Affairs & Market Access Indonesia CoE was honoured to be invited to Indonesia's Commission IX DPI RI Medical Device Working Group session to present on building resilient MedTech systems in Indonesia. We look forward to growing this collaboration in 2021.



# LEGAL, ETHICS & COMPLIANCE COMMITTEE

Supporting APACMed's objective to raise ethics and compliance standards in our industry.

The Legal, Ethics & Compliance Committee grew to 75 members from over 25 member companies in 2020.

Thank you to our re-elected leadership team for all of their work this year: Ana Garcia Bello (Johnson and Johnson), Campbell Clark (Medtronic), David Rosenzweig (Abbott), and Christian Fitsch (Stryker).

A new working group, the Virtual Environment Working Group, was formed this year.

#### Key Activities 2020

#### APACMed Internal Compliance Guidance on Emergency Support

In April, the Legal, Ethics and Compliance Committee, led by the Leadership Team, published the APACMed COVID-19 Internal Compliance Guidance on Emergency Support. The document aimed to support APACMed members' legal and compliance teams to address deserving requests related to COVID-19, whilst attempting to limit inherent compliance risks.

#### Code of Ethical Conduct & FAQs Revision

In July, the Legal, Ethics and Compliance Committee, led by the Code Revision Working Group, completed and published APACMed's Code of Ethical Conduct and FAQs Revision. This is the second revision of the Code of Ethical Conduct since its implementation in 2016. The Code was revised to:

- Address member feedback and questions arising from previous iterations
- Introduce new sections based on new/heightened risks identified in the Asia Pacific region
- Make the Code easier to use through the introduction of a glossary
- Better align with the Codes of global sister Associations

Revisions were made to sections on Satellite Symposia and Third Party Procedural Training and new sections were added covering Technical Support in the Clinical Setting and Third Party Sales and Marketing Intermediaries.

#### Guidance on the Application of the APACMed Code of Conduct to Virtual Events

In November, the Legal, Ethics and Compliance Committee, led by the Virtual Environment Working Group, published the Guidance on the Application of the APACMed Code of Ethical Conduct to Virtual Events. The guidance is intended to assist members in ensuring that these virtual interactions comply with the letter and spirit of the APACMed Code of Ethical Conduct, with due consideration for other local codes and regulations, and highlights issues that members should consider in applying the Code to these online activities.

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**Events** 

#### Legal, Ethics, & Compliance Virtual Summit

This year, the Legal, Ethics and Compliance community held a virtual summit, which brought together over 130 participants from the regional MedTech legal and compliance community.

Participants heard from industry thoughtleaders on business critical compliance topics including:

- Stryker's 2018 US Securities and Exchange Commission Settlement – Christian Fitsch, Stryker and Ryan Rohlfsen, Ropes & Gray
- "Summer Reading" from Washington for Foreign Corrupt Practices Act (FCPA) – Nate Bush, DLA Piper

#### Physician Training & Employment Considerations During COVID-19

In October, the team from Bird & Bird presented to the Legal, Ethics and Compliance community on the topic of physician training and employment considerations during COVID-19.





### **DIGITAL HEALTH COMMITTEE**

The committee works closely with members to ensure their needs and priorities are met, while also prioritizing areas of work from the regional, stakeholder, and technology perspectives.

In January 2020, APACMed created a Digital Health Committee to meet global public health and industry needs. Operating in four key areas – cybersecurity, interoperability, regulatory and reimbursement polices - the committee has grown to more than 120 members from over 45 MedTech companies.

"Digitalization is a huge opportunity for organizing and delivering healthcare to people in Asia. I am deeply convinced that digitalization not only helps with providing access to care but also helps to create care with the patient at the centre,"

— Elisabeth Staudinger, President of APAC at Siemens Healthineers and Board Sponsor for the Digital Health Committee

The committee agreed to focus on two objectives for the first year: increasing the readiness of APACMed members in digital health by facilitating knowledge sharing; and promoting digital health for the benefit of patients and healthcare systems. The group is committed to advocate for policies that ease digital health innovation: data security, privacy, governance, harmonized standards, regulatory frameworks and value-based reimbursement.

#### **Knowledge Sharing**

Throughout the year the committee hosted 7 webinars on various topics, inviting leaders from the industry, government, hospitals, patient associations, regulatory bodies and policy makers to share knowledge, opinions and visions.

The topics addressed include:

- Empower patients with data
- Reimbursing and monetizing digital health in APAC
- India's national digital health blueprint: from paper to practice
- Regulating AI-based medical devices
- Accelerate digital innovation and saving R&D cost with digital twins and simulation
- Navigating cybersecurity policies and its intricacies
- The COVID-19 patient journey through digital solutions

The committee also organized APACMed's first virtual design thinking workshop, featuring experts from McKinsey Design. During this workshop, 28 MedTech leaders designed innovative digital health strategies to meet new needs of diabetic patients in the APAC countries during COVID-19 and lockdown. As part of its mission, the committee raises awareness on healthcare cybersecurity and advocates for harmonised standards to ease the implementation of a cyber secure healthcare ecosystem. The cybersecurity awareness month took place in October: in this occasion the committee partnered with MedSec, a cybersecurity organization that exclusively serves the healthcare industry, in a campaign to increase awareness.

The committee's quarterly newsletter has seen its second release in October. With the participation of the secretariat and committee members, it provides a selection of articles, videos and other resources in digital health.

#### **Cybersmart Infographic**



Healthcare data may be valued at up to **\$250 per record** on the black market. Healthcare organizations leverage specialized hospital information systems such as:

EHR systems

- e-prescribing systems
   practice management support systems
   clinical decision support systems
- clinical decision support systems
   radiology information systems and
- computerized physician order entry systems.

#### Additionally, thousands of devices that comprise the Internet of Things provide an increased quality of patient care:

- smart elevators
- smart heating
  ventilation and air
- conditioning (HVAC) systems
- infusion pumps
- remote patient monitoring devices



The global healthcare A.I. market is projected to reach over **\$28 billion in 2025.** 



A rise in compromised healthcare records, amounted to over **41 million** patient record breaches in 2019.

To meet patients' growing expectations and needs, healthcare organizations must empower care teams, optimize clinical effectiveness, and reinvent the care continuum, all while balancing cybersecurity.

The Digital Health Committee's mission is to support the Asia Pacific MedTech industry in addressing challenges and conquering digital health though building digital health ecosystems, creating knowledge, and advocating for optimal policies.

#### **Publications**

This year the committee focused on building the foundations by creating content on some of the most urgent digital health matters. As a next step, this content is being leveraged to engage with external stakeholders and shape the policy across APAC countries. The content published this year is illustrated below.

#### Cybersecurity

The committee works to raise awareness for the need of harmonized policy frameworks for cybersecurity. Currently, the policy landscape is quite fragmented and the group worked to map the approaches taken in each country, highlighting trends and gaps.

The project was conducted in collaboration with Accenture:

• Landscape of cybersecurity policies in APAC – Database and White paper

#### Interoperability

One of the benefits of digital health technologies is that they allow the communication and data sharing of connected medical devices, health solutions, electronic medical records, making healthcare interoperable. For that to happen, unique sets of standards adopted by all manufacturers in different healthcare settings and across geographies are needed.

The APACMed Digital Health Committee is working to explain the impact of interoperability on patient journey and raise awareness on the need for standard harmonization and publish a paper in collaboration with Unity:

• Harnessing the Power of Interoperability Within Medical Devices – Position Paper



#### **Digital Health Regulatory Frameworks**

It is important to develop regulatory measures that support digital health, so that more lifesaving technologies can be registered and brought to patients. These measures must be fit for purpose, targeting the unique features of digital health solutions. Policies designed on classical medical devices and readapted to include digital technologies are no longer suitable. Moreover, these measures should be consistent across countries to favour patient access everywhere.

The committee has built the first regional database referencing the existing policies regulating digital health. The database is quarterly updated by the members.

To answer the need for a fit-for-purpose regulatory framework for digital health technologies, the committee also worked on a Position Paper with recommendations and guidelines, addressed to regulators:

- Digital Health Regulatory Database
- Digital Health Regulation in APAC: Overview and Best Practices – Position Paper

#### **Digital Reimbursement**

If the final objective of the APACMed Digital Health Committee is to ensure more digital solutions get to patients to improve healthcare outcomes, who pays for these solutions is one of the fundamental questions to address. Especially in the APAC region, where universal healthcare is still a challenge and health systems are heterogeneous.

This year, the committee has published the first regional database referencing the reimbursement policies in APAC. It reveals high policy fragmentation, poor efforts on value assessment guidelines, and a considerable acceleration due to the pandemic. In such a young and fragmented environment, it is interesting to observe the approaches the industry is taking to get their digital health solutions reimbursed or, more broadly, paid.

Looking at the policy landscape on the one side, and learning from real examples from the industry on the other, the committee generated the first best practices framework for reimbursing and monetizing digital health. The framework is being used as a reference by the manufacturers while defining their market access strategy.

The project was conducted in collaboration with L.E.K. consulting:

- Landscape of Digital health reimbursement policies in APAC
- Navigating the Digital Health Rembursement Landscape in Asia Pacific

Finally, the committee published a position paper to provide recommendations to policymakers:

 Harnessing the Potential of Digital Health Technologies – Policy Pathways for Value Assessment & Reimbursement



## **REGULATORY AFFAIRS COMMITTEE**

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Building Regulatory Capability to support implementation of globally harmonized regulatory frameworks.

APACMed has been helping the MedTech industry navigate an increasingly complex and fragmented regulatory landscape across our region. APACMed's Regulatory Affairs Committee is the Association's largest committee, counting over 250 dynamic and engaged senior regulatory professionals.

Much of the regulatory advocacy efforts across the region coalesce around four interdisciplinary Centres of Excellence, covering China, Southeast Asia, the Indian Sub-Continent, and the exciting new addition of South Korea. Separate Working Groups across the region are dedicated to Regulatory Intelligence (RI), Capacity Building, and In-Vitro Diagnostics (IVD).

Through its Centres of Excellence and Working Groups, APACMed has successfully engaged members and fostered its networks at the local level across the region.



# Our work is underpinned by three strategic imperatives:

Promote <u>regulatory</u> <u>convergence</u> in collaboration with government agencies, industry associations, academia and other stakeholders

Build and support a strong regulatory workforce for MedTech industry and regulators, and drive <u>capacity</u> <u>building</u> initiatives in partnership with various stakeholders

<u>Advocate</u> for policies that promote patient access to innovative technologies that advance patient outcomes APACMed is actively involved in the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force on Medical Devices (GHTF). IMDRF works to accelerate international medical device regulatory harmonization and convergence. The current members are Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, and the United States of America.

In 2021, APACMed will continue to work closely to support IMDRF in promoting global regulatory convergence.

#### AHWP/GHWP

In 2016, APACMed became an Official Liaison Member of the Asian Harmonization Working Party (AHWP), a voluntary group of regulatory authorities and industry experts, representing 32 Member Economies across Asia and beyond. In 2020, AHWP announced its transformation from AHWP to Global Harmonization Working Party (GHWP) to better present its global perspective and vision. In 2021, the two parties will work closely to finalize the training curriculum for industry professionals.

# Capability Building IMDRF Meeting

In September, APACMed joined the IMDRF web conference hosted by Singapore. We were joined by regulators and industry experts from the World Health Organization and 10 other key markets. APACMed had the opportunity to touch on the importance of regulatory reliance in APAC to accelerate patient access to critical health products, especially in the context of a global pandemic.

In September, Regulatory Affairs Director <u>Yu</u> <u>Liang</u> gave a presentation in collaboration with Duke-NUS Centre of Regulatory Excellence (CoRE) on the latest trends of digital health regulations for the graduate certificate in Health Products Regulation. This presentation was very well received by attendees including industry professionals and regulators based on the survey conducted by CoRE.

In October, further to <u>AHWP, TGA of Australia</u> also accepted APACMed's invitation to participate as a contributor in the capability building initiative under the strong leadership of the Capability Building Working Group <u>Sharad Shukla</u> of J&J, <u>Adelheid Scheiner</u> of Roche and <u>Miang Tanakasemsub</u> of Alcon. TGA alongside AHWP and industry members provided valuable input on the white paper to identify key areas of training for industry professionals in APAC.

In November, APACMed, with the support of its Vice Chair of the Regulatory Affairs committee, <u>Adelheid Schneider</u> of Roche, presented updates on the latest regulatory updates and sharing some of the major challenges on IVDs in the APAC region to MedTech Europe. The presentation was hugely appreciated by members of MedTech Europe.

In December, APACMed initiated conversations with Strategic Engagement from the Centre of Regulatory Excellence of Duke-NUS to further explore opportunities for collaboration between the two organizations in terms of capability building. The efforts will continue into 2021 for fleshing out the details of potential partnership. In May, APACMed and our In Vitro Diagnostics Working Group published a position paper on Building Regulatory Agility for Adequate Access to Quality SARSCoV- 2 Test Kits During the Global Pandemic. The paper explored several emergency regulatory mechanisms for the access of test kits and proposed some recommendations moving forward.

Special thanks to the following contributors to the Chair and Vice Chairs of the IVDWG <u>Jacqueline Monteiro</u> of Abbott, <u>Rose Yu</u> of Hologic, <u>Pai Lin Lai</u> of Siemens and <u>Yasha</u> <u>Huang</u> of Roche as well as the Sponsor <u>Adelheid Scheiner</u> of Roche.

#### Regulatory Advocacy Singapore

In January, APACMed met with Singapore's Health Science Authority (HSA) for the annual dialogue to discuss about APACMed's key achievements in 2019 and further collaboration in 2020 to support HSA in hosting IMDRF events, enhance the quality of the MedTech forum and expand regulatory reliance.

#### China

In November, APACMed along with the support of the Chairs and Vice Chairs of the China Centre of Excellence Echo Liu, Victoria Qu, Crystal Nie and Fan Bu coorganized the 11th China International Medical Device Regulatory Forum (CIMDR) alongside other peer associations, industry players and regulators in Fuzhou where Regulatory Affairs Director Yu Liang gave a presentation advocating for regulatory reliance, capability building and digital health.

#### Thailand

APACMed, and under the leadership of our Chair of the RA committee Miang Tanakasemsub of Alcon, had multiple meetings with Thai Food & Drug Administration (FDA) to discuss about the capability building program and Thailand-Singapore Regulatory Reliance Project in 2020. Building on its success in 2019, phase one of pilot submissions for regulatory reliance was launched in September where Thai FDA accepted 12 new applications for Class C or D products that were registered with Singapore's Health Science Authority (HSA). Our Chair of the South East Asia Centre of Excellence Priscilla Koh of J&J played an important role in agreeing with HSA on its capacity to support regulatory reliance. In 2021, we plan to expand the project to include additional pilot submissions.

In addition to submitting a position letter, APACMed is also working closely with the local association Thai Med to ensure that our voice is heard by regulators and government representatives to minimize the impact of the proposed new regulation on the supply of medical device technologies in the market.

#### South Korea

APACMed has been actively involved with the proposed renewal process pertaining to the medical devices act enforcement rule in Korea to ensure that it will be aligned to the best practices globally and that it will not result in unnecessary regulatory burden for both regulators and the medical device technology industry. Based on feedback from our Center of Excellence in South Korea, our position paper contributed to the improvement of the latest version of the regulation that has been released by MFDS in December where several critical terms such as performance data were removed. MFDS also has the intention to include the details of the requirements in a lower level of the regulation to ensure that it can be easily revised in the future. Lisa Park of Alcon and Renee Cotta of BSCI contributed to such success.

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# STARTUP AND SME COMMITTEE

Supporting and building APAC's Startup Ecosystem; facilitating collaboration between start-ups and established companies and supporting go to-market acceleration.

#### **APACMed Startup Membership**

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The APACMed startup community has expanded to over 100 members spanning medical device technologies, diagnostics and digital health and covering a diverse range of therapeutic areas from cardiology, diabetic care, nephrology, orthodontics, orthopaedics, ophthalmics, oncology, women's health, respiratory, neurology, urology to wound management. We are also proud to have representation from countries such as Singapore, India, Australia, South Korea, Indonesia and Malaysia and plan to add more members along with our expanding geographic presence.

#### **APACMed Founders Series**

In 2020, we launched the Founder's Series to bring valuable support and resources to our startup community. The program included topical webinars with top tier consultants and resources from our member community (i.e. Founders Campus). We also have organized more than 20 mentors who provide valuable expertise and assistance to our startup members (i.e. Founders Circle). We are grateful everyone's generosity sharing their time and expertise.

#### APACMed-MedTech Innovator Showcase

Our shared goal is to accelerate innovation and success for our members. An example is the APACMed partnership with MedTech Innovator in the Asia Pacific Accelerator competition where we have supported 20 companies with mentorship in areas such as product commercialization.

#### What's Next?

We believe there is a tremendous source of innovation and value within our member community of innovators, corporates and investors. Building on this ecosystem, we will be expanding potential collaborations with large multinationals, public sector agencies and likeminded organizations (i.e. Founders Collaborate).



# COUNTRY INSIGHTS: APACMED IN INDIA

Working cross-functionally across government affairs, market access, regulatory affairs and digital health through dedicated Centre's of Excellence to help strengthen healthcare systems, drive access and affordability, and promote a robust and sustainable ecosystem that encourages investment, trade and innovation in India.

In May of 2020, APACMed opened its first country office in India, with an objective to work on the ground with local governments, industry, healthcare professionals, patient groups and academia to help strengthen systems, drive access and affordability, and promoting a robust and sustainable ecosystem that encourages investment, trade and innovation in India. With Anirudh joining as Country Lead, we envision to enhance APACMed footprint and engagement in the country, and realize our vision of becoming a credible voice and knowledge partner in shaping policies in India through high-level engagement and visibility.

India-specific priorities were identified and Task Forces were formed on mid to long-term strategic projects with leads and co-leads providing leadership and direction to the groups:

- GAMA Health Technology Assessment, Value of Technology in Universal Healthcare, Make in India for Medical Devices
- RA Regulatory Capacity Building, MDD Standards, Unique Device Identification

Elections were held and India's CoE leadership teams for GAMA and RA were appointed:

- GAMA India: Vibhav Garg (Boston Scientific); Shivkumar Hurdale (Stryker); Rishi Sharma (Abbott)
- RA India: Kirti Arora (Boston Scientific), Gaurav Verma (BD), Prashant Prabhakar (Teleflex)

#### Collaborations and Engagement with Local Trade Associations

In 2020, APACMed India established strategic partnerships with key local trade associations to work jointly in shaping strategic healthcare ecosystem initiatives in India.

#### NATHEALTH

- Signed MoU & formed joint working group on 'Value of Technology in Universal Healthcare'
- President NATHEALTH delivered Keynote Address on at the APACMed Virtual Forum 2020
- Leadership Team participated as a Speaker in Exclusive India Leaders Session at APACMed Virtual Forum 2020





# Medical Technology Association of India (MTal)

- Collaborated to develop India Profile of Value of MedTech Study
- Leadership Team Participated as a Speaker in Exclusive India Leaders Session at APACMed Virtual Forum 2020

## Data Security Council of India (DSCI – A NASSCOM Initiative)

• Organized joint webinars on Digital Health topics such as Cybersecurity and Personal Data Protection Bill

#### **INVEST INDIA**

- Developing joint White Paper on Make in India for Medical Devices & Diagnostics
- Partnered with Invest India to organize a Webinar Series on PLI Scheme for Medical Devices

#### Confederation of Indian Industry (CII)

• Leadership Team participated as a Speaker20

#### Federation of Indian Chamber of Commerce & Industry (FICCI)

 Leadership Team participated as a Speaker in Exclusive India Leaders Session at APACMed Virtual Forum 2020

### **Engagement with Government**

#### **Bureau of Indian Standards (BIS)**

- Member of BIS Sectional Committees MHD 5, 6, 7, 12, 15, 17 & 19
- Invitee at Bureau of Indian Standards (BIS) Trade Association Meetings

## Ministry of Health & Family Welfare (MoHFW)

 Submitted Position Paper on Unique Device Identification (UDI) for Medical Devices in India to MoHFW

- Introductory Meeting and Presentation on Regional HTA White Paper to Department of Health Research (DHR), Ministry of Health & Family Welfare, Gol
- DHR representative joined as Speaker at India HTA Webinar
- Invited by <u>CDSCO</u> (Device & Drug Regulator) to submit inputs on Classification of Non- Notified Medical Devices

# Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers

- Submitted comments on Form VI to National Pharmaceuticals Pricing Authority (NPPA)
- Submitted comments on draft Uniform Code for Medical Device Marketing Practices (UCMDMP) to Department of Pharmaceuticals

#### **Capability Building Initiatives**

APACMed India office organized a number of webinars and training programs in 2020 on topics critical to the sector, including:

- Make in India for Medical Devices
- Cybersecurity Threats & Best Practices in an Age of Tele-Health
- PDP Bill: Lessons Learnt from Global Privacy Regimes and Impact on MedTech Industry
- Anatomy of a successful UDI Program for MedTech Industry (Module 1,2 & 3)
- Increasing Access to Innovative Medical Technologies: Global Best Practices on HTA Policy and Assessment Frameworks
- Software as a Medical Device (SaMD): Demystifying Connected Health Regulations

#### **Strategic Projects**

In 2020, APACMed India Government Affairs & Market Access Centre of Excellence worked on a number of strategic initiatives through the three taskforces formed to build understanding of key policies and market access topics.

#### Health Technology Assessment (HTA)

A task force has been formed with industry experts who are working on several initiatives in the areas of HTA with an objective to become a credible industry partner to the government and other stakeholders, in the pursuit of developing a robust, transparent, inclusive and value-based assessment of health technology for MDDs; and one which is in line with an ideal HTA system, that meets the core objective of appreciating the value of medical technology with the scope to assess innovative technologies as well as that which provides access to unmet patient needs.

#### Value Based Healthcare

A task force has been formed with industry experts who are working on several initiatives in the areas of Value based Healthcare with an objective of promoting value-based healthcare principles and concepts in India with special focus on procurement reforms, and advocate the long term benefits including accelerating innovations, improving patient outcomes and reducing the total cost of care.

## Make in India for Medical Devices & Diagnostics

A task force has been formed with industry experts who are working on several initiatives with an objective to create and deliver a narrative through interventions that supports government to realize the goals of Make in India for the MedTech industry. The narrative will focus on developing streamlined regulations, predictable evidence-based policy environment, and support for investment and competition, with the goal of boosting the capabilities of local industry.

#### India Leadership Team

In 2020, APACMed India Government Affairs & Market Access Centre of Excellence worked on a number of strategic initiatives through the three taskforces formed to build an understanding of key policies and market access topics.



#### Vibhav Garg Chair, GAMA

Director, Government Affairs Strategy, India Hub & ASEAN, Boston Scientific

#### Vice Chairs, GAMA

**Rishi Sharma** Head, Government Affairs, Abbott Healthcare

#### Shivkumar Hurdale

Director, GA/RA/QA India; RA Advocacy Stryker



#### **Kirti Arora** Chair, RA

Associate Director, Regulatory Affairs & Quality Assurance SA (India Hub), Boston Scientific

#### Vice Chairs, RA

**Gaurav Verma** Director, Regulatory & Government Affairs, BD

#### Prashanth Prabhakar

Senior Manager, Regulatory Affairs, Teleflex Medical





### The voice of MedTech

While this year was the 6th edition of the APACMed MedTech Forum, it was the first Virtual Conference APACMed has conducted. As a result of COVID-19, companies across the world had to act with agility when adapting to new work environments. This was reflected in this year's theme

### NUMBER OF DELEGATES ATTENDING EVENTS



– Redefining Healthcare Agility



On September 24, 2020, the Asia Pacific Medical Technology Association (APACMed) hosted our first ever Virtual Forum. We were joined by 1,450 attendees to hear from over 130 speakers from around the world on the theme of "Redefining Healthcare Agility". With the switch to a virtual event, we were able to expand the size of the conference, leading to a greater range of speakers and discussion topics. Our forum featured everything from innovative technological advancements in the MedTech industry, to the impact of China-US relations on the medical supply chain.



APACMed had the honour of having Andrew Frye, Senior Vice President & President, Asia Pacific, Baxter Healthcare, & Chairman of the Board, APACMed, kick off our very first virtual forum. In his opening address, Andrew talks about the acceleration of virtual and home care as a result of COVID-19, and stated that telehealth is the future of healthcare.

"The pandemic drove an acceleration of virtual and home care, as hospitals sought to reduce in-patient admissions, making connected care or connecting with patients a standard to strive for and improve upon."

Andrew shared his pride for the way the MedTech industry has collaborated and assisted in the fight against the coronavirus, stating that we've all "collectively stepped up in this time". Like he mentioned, as the industry has had to be agile in the response to COVID-19, this year's forum theme, Redefining Healthcare Agility, is perfectly fitting.



APACINE APACMED VIRTUAL 2020 REDEFINING HEALTH CARE AGILITY35 24 September 2020



Innovation Agility



This year we hosted 5 Global CEOs as our featured keynote speakers: Ashley McEvoy (Johnson & Johnson), Dr. Bernd Montag (Siemens Healthineers), Jose (Joe) Almeida (Baxter), Kevin Lobo (Stryker), and John Groetelaars (Hillrom). Each keynote discussion was focused around the theme of Innovation Agility. All of our Global CEOs were interviewed by partners at McKinsey & Company.

### Leadership Agility in the Time of COVID-19





"Don't be afraid to bring a bit of yourself to the table - flaws and all!" Lance Little, Managing Director, Asia Pacific, Roche Diagnostics

The Meet the CEO Series featured the APACMed board of directors, and gave each board member the opportunity to talk about their own career journeys and how they've tackled the challenges of COVID-19 with agility and resilience. Our board also shared what each of their respective companies are doing to both maintain employee safety and wellbeing during the time of a pandemic and how they are engaging in the fight against the coronavirus.

### Regional Insights





The Regional Insights Track of the Forum kicked-off with the release of the APACMed – McKinsey: Business Sentiment Survey, which gave insights from over 180 senior MedTech executives surveyed from a range of different product sectors, business scales and geographies on the current market trends and overall business sentiment post COVID-19.

This was followed by exclusive regional and country specific roundtables including Korea, Japan, China, ASEAN, & India where healthcare leaders including Chairs of various local associations like KMDIA, AMDD, CCCMHPIE, MTaI, CII, FICCI etc. shared insights on how their respective countries have dealt with COVID-19 and their key learnings. As well as how they were able to create opportunities for themselves through this crisis.



Activating the Healthcare Ecosystem





We explored how different stakeholders from across the healthcare ecosystem came together to address the new and rapidly changing COVID-19 catalysed environment; companies are working together to treat patients in this 'new normal'. Regional thought leaders shared their perspectives on the hospital of the future; the digitalisation of healthcare and its impact on the critical areas of patient access and strengthening systems; and challenges and opportunities in the use of data in optimising operations and adding value in healthcare.

### The Acceleration of Digital Care





Andrew Frye, Senior Vice President & President, APAC, Baxter Healthcare, Joe Di Vivo, President, Hospitals & Health Systems, Teladoc, Amkidit Afable, Vice President, Strategy & Innovation, Zuellig Pharma, & Glenn Snyder, Medical Technology Segment Leader, Deloitte The Digital Health Solutions track was a virtual road trip on the digital innovations we saw rolled out in 2020, and what we will continue to see moving forward, be it; Augmented Reality, 3D, Digital Therapeutics, Remote Monitoring, or telehealth. This track exemplified the importance of digitalising healthcare, and demonstrated that the progress has already begun. Digitalisation is inevitable.

### Regulatory Agility & Reliance





The Regulatory Committee track had the honor of welcoming esteemed speakers from around the world: the Therapeutic Goods of Australia, Health Canada, Thai FDA, the Health Sciences Authority of Singapore, the Bill and Melinda Gates Foundation, Roche Diagnostics APAC, the Centre of Regulatory Excellence at the Dule-National University of Singapore Medical School, BrandwoodCKC, the Pharmaceuticals and Medical Device Agency of Japan. The panels discussed the importance of regulatory agility and reliance. Such importance has been further highlighted by the current pandemic, where regulators are required to be more flexible in their approval processes and potentially rely on the decisions made by other regulators to expedite the availability of the muchneeded health products to contain the pandemic. 37



Public Policy & Market Access





The Public Policy & Market Access track brought together thought-leaders from consumer bodies, government, industry and research to discuss areas critical to policy preparedness for healthcare sustainability. Expert insights were shared on consumer driven policy shaping; valuebased healthcare decision making in the MedTech sector; and navigating the changing geo-political climate and upcoming shifts in in the supply chain landscape for the MedTech Industry.

### Activating Digital Health





Within the Digital Health Committee track, speakers from all around the globe discussed how to approve and reimburse digital health solutions that are cyber secure and interoperable. Today more than ever the healthcare ecosystem must come together to bring the best solutions to patients. Optimal regulatory and reimbursement frameworks are urgently needed. They should be specific to digital health, which is intrinsically different from the classical medical devices, and harmonized across countries. The role of APACMed will be critical to foster the dialogue among patients in the near future.

APACMed-MedTech Innovator Showcase







The Startup Committee track provided perspective on the startup ecosystem in Asia Pacific, with insights from MedTech startups and investors. One of the highlights of the startup session was the APACMed-MedTech Innovator Showcase, where 20 of the best and brightest MedTech startups across Asia Pacific were featured.

The winners of the APACMed-MedTech Innovator Showcase are Healthy Networks, Cartosense, and Autoyos.

# APACMed 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.





#### **WEBINARS**

Join exclusive complimentary webinars on hot-button topics.

### RESOURCES

Access resources on the membersonly section on APACMed website.

### NETWORK

Leverage the APACMed network to explore business development opportunities with other MedTech companies, both big and small.

03

### ETHICS

Demonstrate your commitment to the highest standards of ethics by signing and adhering to the APACMed Code of Ethical Conduct.

# 04

### MEMBERS COMMITTEES

Participate in Functional Committees and Working Groups with senior-level executives from the largest companies in the industry. 06

05

### MARKET INSIGHTS

Benefit from exclusive market insights and analysis from APACMed knowledge partners.

07

### APAC MEDTECH FORUM

Participate in the annual Asia Pacific MedTech Forum, the industry's most impactful gathering of people and ideas in the region.

08

### MARKET INTELLIGENCE

Receive timely information providing early warning about regulatory and policy developments in the region and guidance on how to address them.

### Annual Report 2020

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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