APACMed
The voice of MedTech

Asia Pacific Medical Technology Association

Annual Report

2019

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About the 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.

APACMed Strategic Pillars

Access

We strive to improve access to high quality healthcare for patients, by working in close collaboration with regulators, policy makers, 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.

Harmonisation

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.

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Harnessing the Dynamism of Healthcare in Asia Pacific

It is predicted that over 60% of the world's population will be living in Asia in ten yeas' time, and a large proportion of its citizens will be in the consuming class. Looking to the future, the United Nations Economic and Social Commission for Asia and the Pacific estimates that by 2050 more than a quarter of the population in Asia Pacific will be over the age of 60. This ever-changing landscape has created a wealth of opportunities for healthcare companies, who are increasingly shifting their focus to Asia, with innovations made possible thanks to technological advancements and the rapid digitalisation of health.

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Driven by higher healthcare costs, a rise in chronic diseases, a growing population of middle class citizens and a shift in the age demographic, the healthcare market in Asia Pacific is on track to achieve unprecedented growth at a rate of 19.9%, outperforming the 10% registered by the US and Europe.

Indeed, Asia Pacific is entrenching its position as a key region of unparalleled opportunities for growth, and this will only continue to accelerate:

In 2020, Asia Pacific will surpass Europe to become the second-largest market for MedTech, as a result of these shifting demographic trends. In parallel, we are witnessing the growth of smart hospitals and greater demand by consumers to own their health data through home-and self-care products, such as Fitbit and Apple's HealthKit. This has, in turn, sparked a health tech boom.

The accelerated adoption of digital health will have a significant impact on the delivery of healthcare across the region, with benefits including improvements in the quality and efficacy of drugs and medical devices, access to information and the automation of operational, clinical and administrative workflows. Analysts forecast that the electronic health records (EHR) market in this region is likely grow exponentially, at a compound annual growth rate of 5.7% until 2023.

Healthcare and the Fourth Industrial Revolution

The concept of "going digital" has now become ubiquitous in healthcare. New technologies are emerging at an unprecedented pace and impacting our lives in ways that could not have been imagined just a generation ago.

The so-called "Fourth Industrial Revolution" is profoundly impacting the entire field of medicine, and critical advances in biotechnology, immunotherapy, surgery or neonatal care are testament to this. All ecosystem actors are being forced to re-imagine and re-invent healthcare: the democratisation of genome scans and testing will continue to fuel the debate around ethics in science and medicine; AI trained applications - from health records to devices, and AI powered imaging and radiology, may soon be more accurate and reliable than humans. Remote surgery, robot physicians and 3D printed organs could soon become the norm.

The Internet of Medical Things

When viewed through the lens of improved patient outcomes and quality of care, the role that medical devices play is undeniably a vital one. While there are connected medical devices already available in the market, the lack of a shared omnichannel environment for these devices to "speak" with each other prevents physicians, diagnosticians and other healthcare professionals from fully optimising the potential benefits that a digitised ecosystem can offer.

Better known as the Internet of Medical Things (IoMT), this connected ecosystem of care presents manifold benefits for the future of healthcare (see fig. 1). For example, the introduction of AI into the spectrum of care can help shore up any potential gaps identified – be it a clinician's efficiency and accuracy making a clinical diagnosis, or to respond to labour shortage woes by performing nurses' routine administrative tasks.

The infrastructure necessary to create this connected ecosystem currently exists, but what restricts its deployment is the absence of a standardised shared network between devices and IT systems. This missing mode of communication needs to be built collaboratively, according to standards agreed upon and implemented as such, for personalised care to be delivered and improvements in patient outcomes to ensue.

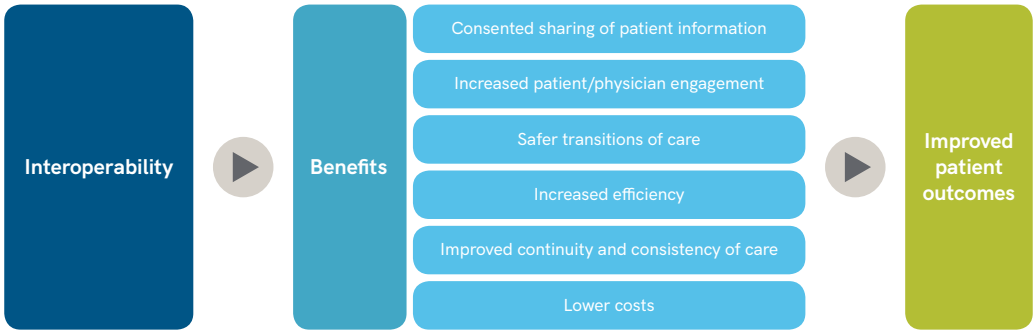

Fig 1: Benefits of Interoperability Source: Deloitte LLP (2018). MedTech and the Internet of Medical Things.

2019 has been a watershed year for transformative growth across the healthcare industry, with patient communication, access to care and satisfaction headlining conversations and playing a critical role in business decisions. Bolstered by an increasingly consumer-centric approach to health (and Google, Apple and other tech giants making moves into the healthcare space stand as testament to this), as well as the increased adoption of value-based care pay models, 2020 is likely to see a boom in patient engagement technologies, with new and innovative tools being developed to aid physicians and healthcare professionals in sharpening their clinical decision making to ultimately delivery better outcomes for their patients.

Many of the 48 countries within the Asia Pacific region continue to have under-served markets, which provide healthcare vendors numerous opportunities to offer innovative products and services targeting existing needs. Capitalising on these needs however will require medical device manufacturers, pharmaceutical companies and digital health providers to be able to successfully pre-empt market trends, navigate regulatory environments and better understand diverse demographics unique to each market.

Welcome Message

By APACMed Chairman, Andrew Frye

Dear APACMed Members,

2020 is set to be a milestone for our industry, as the Asia Pacific market is expected to surpass the European Union to become the second largest market for MedTech globally, behind the United States.

Our region accounts for nearly two-thirds of the global disease burden. With more than a billion people aged over 50 by 2025, and Asian countries contributing to around half of the global growth in higher income households by 2030, the demand for better access to quality and affordable healthcare is likely to increase exponentially.

Despite slowing economic growth across much of the world, health spending in Asia is expected to continuously rise at a steady 7.1 % CAGR between 2019 to 2023.

But that is not to say our industry will not face any challenges in addressing the growing demand for healthcare in a fragmented region with disparate regulatory regimes, complex reimbursement systems, and conflicting policy priorities.

Paradoxically, whilst our region has seen an increasing share of global innovation in health care and medtech, the needs of a vastly underserved population show no sign of slowing down. It is now more important than ever that, as an industry, we come together as a collective voice united by a single mission: to advance the standards of care and ensure high quality, accessible and affordable healthcare for all patients across Asia Pacific.

I have had the distinct pleasure and honour to serve as the Chairman on APACMed's Board of Directors since my appointment in February 2019, working hand in hand with my fellow board members and the APACMed Secretariat team.

2019 was a year of great growth for our Association, sharpening our focus on capability building, knowledge sharing, and driving in-country agendas with partner associations, which has boosted our membership to hit double-digit growth.

With the appointment of our new CEO Harjit Gill last February, we also strengthened the capabilities

of the Secretariat team and engaged in multiple new initiatives, the most prominent of which was the advocacy work across both mature and emerging markets in the region, creating a clearer framework to lead and partner across these different markets and associations is just beginning.

Through our Functional Committees, and their dedicated Centres of Excellence and Working Groups, we successfully engaged with regulatory and policy decision makers, ensuring our members play a key role in shaping the healthcare future beyond South East Asia by leveraging policy insights and connections between Japan, Korea and China to India and Australia.

Finally, APACMed continued to maintain its relevance by continuing the work on the revisions to its Code of Ethical Conduct, reflecting the highest standards of compliance across our industry.

The coming year will see us sharpen our focus on digital, innovation and advanced technologies – not only through the creation of APACMed's first Digital Health Functional Committee and our commitment to innovation via our partnership with the MedTech Innovator Asia Pacific, but also through our annual flagship event: the Asia Pacific MedTech Forum. Building on our 2019 theme of "Connecting Leaders, Connecting Care", we will be putting patients front and centre stage as we seek to better understand how the rise of empowered patient is set to transform the entire healthcare ecosystem as we know it. In addition to our annual flagship event, our 2020 calendar for 2020 will comprise many events catering to our different membership categories, giving members unrivalled opportunities to share and learn.

As we near the election of several new Board Directors at our February 2020 AGM, I would like to take the opportunity to thank some of our outgoing Board members for their contributions to the Association: Harvinder Singh, Divisional Vice President, Asia Pacific and Japan, Abbott Vascular; Rajkumar Narayanan, Region President, Asia, Alcon; and Warren Wang, Senior Vice President and President, Asia-Pacific, Boston Scientific. I wish them all the best of luck in their future endeavours and look forward to working with my new colleagues and the APACMed Secretariat team this year to better serve you.

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In Conversation with Harjit Gill, CEO

What has been the most exciting part of your role since your appointment as CEO in February 2019?

It has been incredibly insightful to embed myself into such a diverse and vibrant MedTech community and understand the industry through the many lenses of our members. I've been fortunate that my role has allowed me to gain a solid understanding of how various products and technologies, spanning surgical sutures to imaging machines, to AI powered data platforms, are being deployed to address a plethora of patient needs. Connecting with so many different people across the companies we represent, from the regulatory to the government affairs functions, to cyber security experts and chief medical officers has been immensely enriching.

Spending time in the markets we represent across the region – from China to India, as well as Korea, Malaysia and Indonesia, has been invaluable. Allowing us to better understand the nuances of the development of healthcare across the region, it has also enabled is to assess how we can better work with governments to move the needle when it comes to giving patients access to innovative medical technologies.

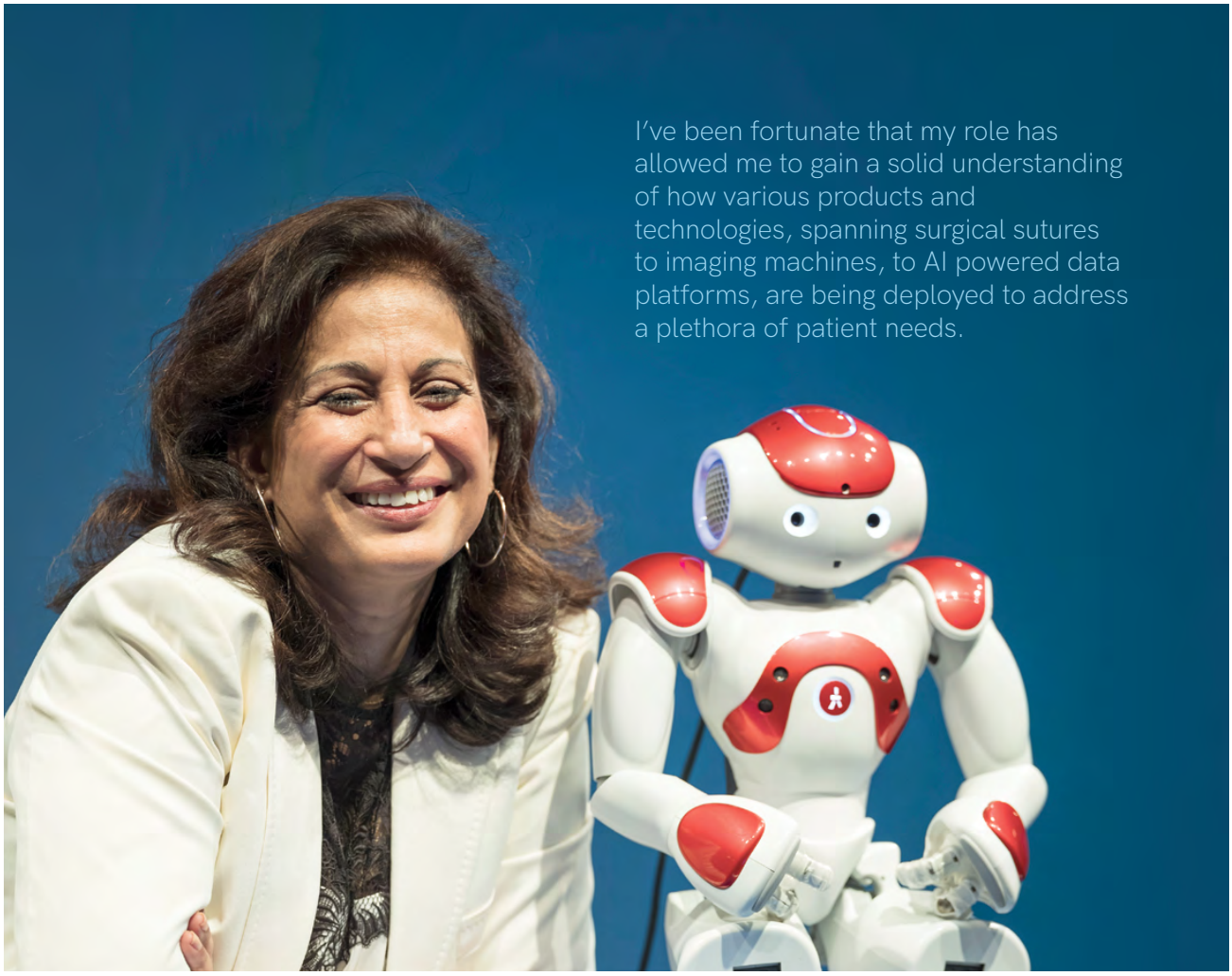
Finally, being involved in the fifth edition of the Asia Pacific MedTech Forum was a fantastic experience! APACMed was able to showcase real thought leadership in certain areas, be it scaling healthcare innovations with Professor Krishna Udayakumar from Duke University; leveraging technologies to scale surgical training with Professor Shafi Ahmed; or better understanding how other industries are successfully harnessing the potential of data and analytics to make data-informed improvements, as demonstrated by the CTO of Health Catalyst. As the regional voice of the industry, we wanted to provide our members with unique, original insights from world class speakers, and I think we achieved that.

What were the Association's key wins and achievements in 2019?

2019 was a great year for APACMed! We welcomed more members into our fold, increasing our membership base by more than 10% as compared to the previous year. On top of this, we had an overwhelmingly successful MedTech Forum with more than 1,000 delegates from over 30 countries in attendance. We were proud to launch the first-of-its-kind Connected Care showcase, featuring products and innovations from leading industry brands as well as start-ups and disruptors. And let's not forget the launch of the inaugural MedTech Innovator Asia Pacific competition, which saw more than 170 applicants from 35 countries compete across the region.

Our Functional Committees also made significant advances in driving collaborations to support our industry's growth – white papers developed with both Deloitte and IQVIA gave our Regulatory Affairs and Government Affairs Committees the opportunities to respectively build up regulatory capability across the region and bring the topic of Health Technology Assessments to the forefront. In addition, APACMed launched the Industry Footprint Study, in collaboration with our partners KPMG, which, for the first time, aggregated high-level data on the economic contribution of the MedTech industry in the region.

Our Legal, Ethics and Compliance Committee supported in the development of Deloitte's MedGrantTM platform supporting the continued education of healthcare professionals. Finally, our start-up and SME



Committee continued to mature, and we look forward to unveiling a series of bespoke programmes for this group in 2020.

How is APACMed seeking to make an impact in 2020?

As a regional organisation, we advocate access to safe and affordable medical technologies, and promote the value of innovation to address Asia Pacific's pressing healthcare needs.

In a context of heightened competition from the region's start-ups, as well as new tech players entering this space, traditional companies are having to constantly re-adjust as they navigate this rapidly evolving environment. MedTechs have traditionally focused on the premium segment, but now need to focus on a much broader group of patients and engage more transparently with healthcare providers if they want to remain relevant.

Our role is to help our members better understand those needs across very heterogenous markets; adapt or rethink current business models and solutions, and, increasingly, successfully demonstrate the value of their products. We do this by forging strong relationships with the entire healthcare ecosystem. This ranges from governments to regulatory authorities; provider groups and many others. There are markets where we lead the efforts, like ASEAN where we have been driving capability efforts, in the area of regulatory training. In mature markets like Japan and Korea, we partner and collaborate with our sister organisations. In 2020, we will reinforce our presence in the regions' two key markets of India and China by opening local offices.

At the end of 2019, we launched our new Digital Health Functional Committee, which we foresee to be a major workstream for us in the coming year, as we seek to better understand the deep transformations across the healthcare landscape, driven by big tech and digital, and powered by data. Valued at 144.2billion USD in 2018 and predicted to grow to 206 billion USD by the end of 2020, the digital health market can be perplexing. Our role as an Association is to help our members better understand the multiple facets of this digital transformation: from shifting business models, to the impact on healthcare providers and payers; as well as the multiple ramifications for patients, who are both more empowered, and potentially more at risk of data breaches, through the hacking of connected devices, for example.

Finally, in 2020, members can expect more targeted, tailored programmes as well as a full Calendar of Events. To better serve our start up members, for example, we will be launching the APACMed Founders' Circle with the involvement from Board Members and Corporate Member CEOs.

We will also be hosting a series of exclusive closed-door sessions with key game changers and thought leaders in healthcare for our senior leaders, as we did earlier this year with David Koh, CEO of Singapore's Cyber Security Agency. Members can also expect more webinars and networking events, as we continue to foster the industry's regulatory, public policy and compliance communities across the region.

Finally, we are already in the midst of planning our Annual Flagship event – the Asia Pacific MedTech Forum – and in 2020 our focus will be on the multidimensional aspects of patient empowerment. The Forum will explore the roles citizens can play in the proactive management of their health, from having the freedom to choose a doctor or specialist; to active participation in clinical decision-making, and feeling a sense of control over one's medical condition; to full access and ownership of medical and health data. I look forward to telling you more in due course!

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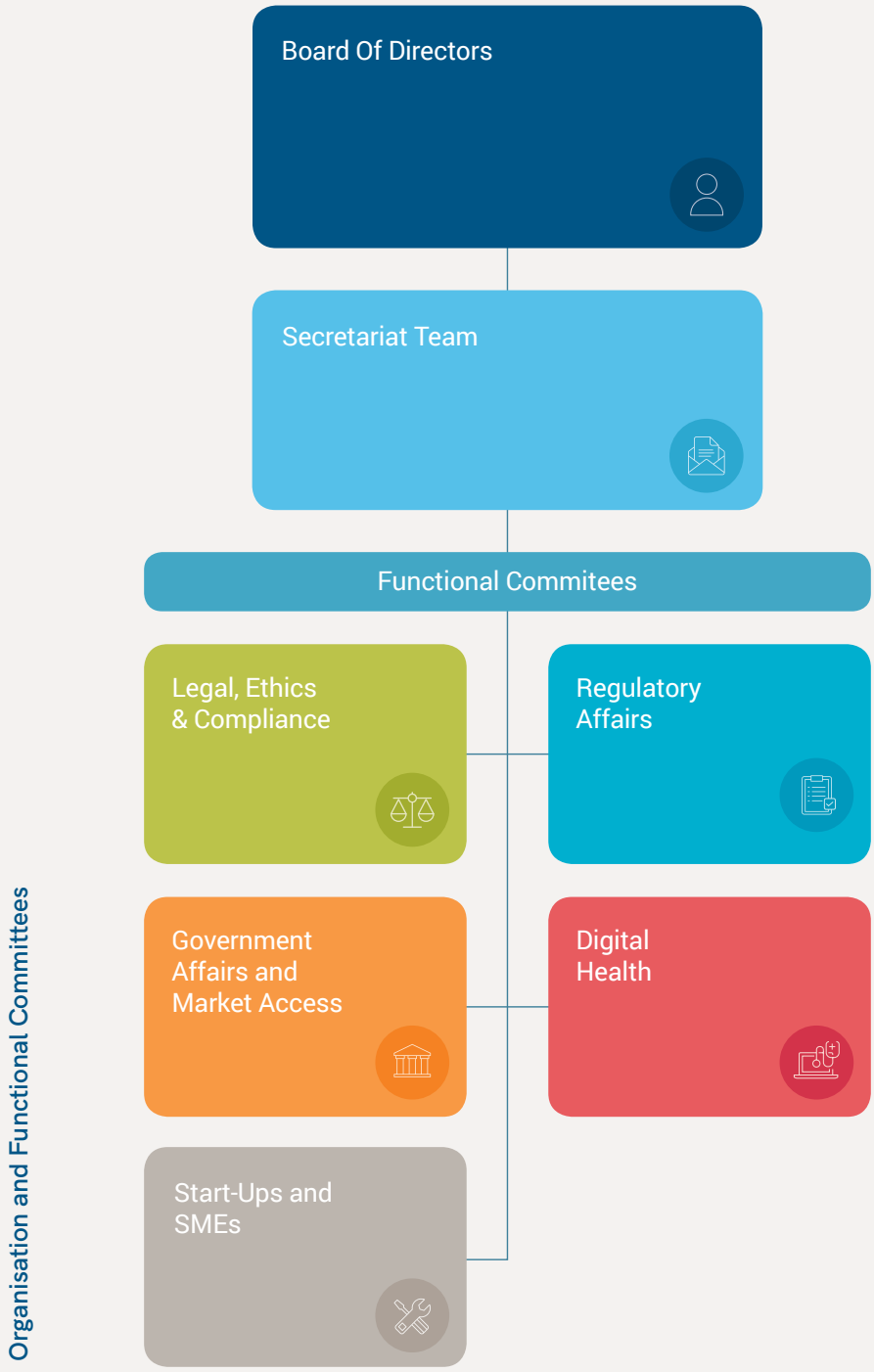
APACMed Structure & Governance



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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 Dickinson & Co.

Ian Burgess
Chief Executive Officer, Medical Technology Association of Australia

Chee Hong Lam
President, B.Braun, Asia Pacific

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

Rajkumar Narayanan
Region President, Asia, Alcon

Sanjay Prabhakaran
President, Asia Pacific, Hologic

Yukishige Sanada
Managing Director, Terumo Asia Holdings

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

Harvinder Singh
Divisional Vice President, Asia Pacific and Japan Abbott Vascular

Elisabeth Staudinger
President, Asia Pacific, Siemens Healthineers

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

Warren Wang
Senior Vice President and President, Asia Pacific, Boston Scientific

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APACMed Secretariat Team

Harjit Gill
Chief Executive Officer

Alex Chen
Manager,
Communications

Yasha Huang
Director,
Regulatory Affairs

Nishan Pillai
Finance and
Operations Manager

Emilie Rapley
Director,
Communications

Roberta Sarno
Manager,
Digital Health

Gabriel Sim
Director,
Strategic Partnerships

Georgia Swan
Manager, Government Affairs
and Market Access
Manager, Legal, Ethics and
Compliance

Sajin Varghese
Senior Advisor

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APACMed Functional Committees

Regulatory Affairs

Chair

Miang Tanakasemsub
Regional Regulatory Affairs and Government Affairs Head, APAC. Alcon

Vice Chair

Jason Guo
Director Regulatory Affairs, Quality & Compliance Abbott

Adelheid Schneider
Head of Quality and Regulatory Affairs, APAC, Roche

We would like to use this opportunity to recognise our Outgoing Chairs and Vice Chairs and thank them for their contributions, support and guidance helping to steer our Functional Committees:

Dominik Reterski
Vice President, Corporate Quality Medtronic

Government Affairs and Market Access

Chair

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

Vice Chair

Hitendra Joshi
Head of Government Affairs & Market Access B. Braun Medical Industries

Lars Jandt
Vice President, Emerging Asia & Vice President Public Affairs, APAC, Fresenius Medical Care

Rajeev Nandan
Head, Market Access and Government Affairs Alcon

Legal, Ethics & Compliance

Chair

Campbell Clark
Vice President, Legal and Compliance APAC, Medtronic

Vice Chair

David Rosenzweig
Ethics & Compliance Officer, APAC, Abbott

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

Paul Sumilas
Vice President, Compliance Officer, and Senior Legal Counsel, APAC, Zimmer Biomet

Start-Ups and SMEs

Chair

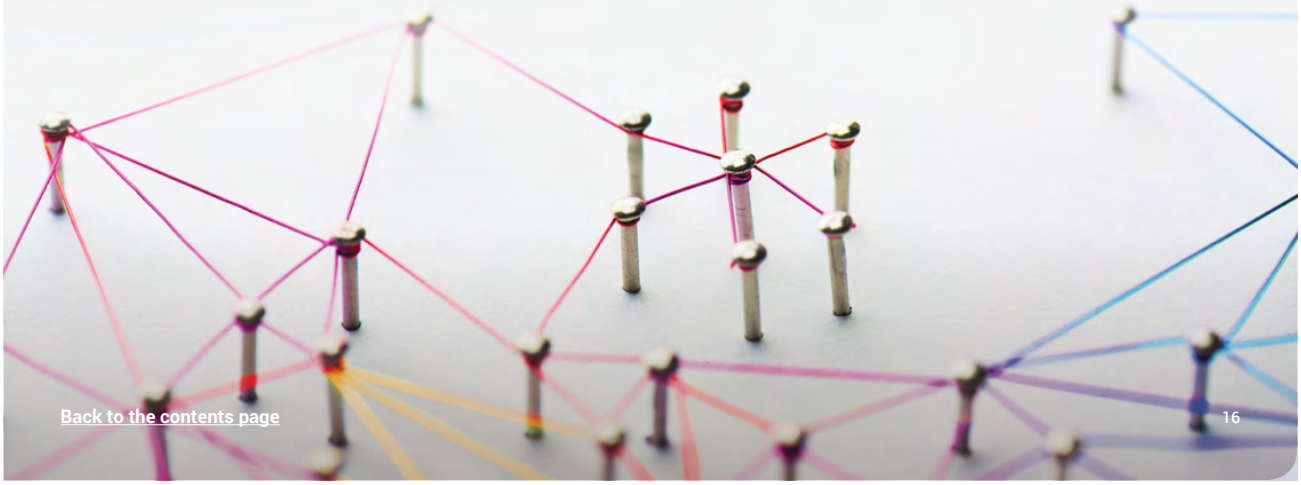
Benjamin Hong
CEO, iota medtech

Vice Chair

Jane Wang
Co-founder & CEO
Roceso Technologies

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
- Participate in the annual Asia Pacific MedTech Forum, the industry's most impactful gathering of people and ideas in the region
- Demonstrate your commitment to the highest standards of ethics by signing and adhering to the APACMed Code of Ethical Conduct
- Receive special rates on registration and join APACMed-organised events, including but not limited to regular workshops, seminars, CEO roundtables and networking events
- Participate in Functional Committees and Working Groups with senior-level executives from the largest companies in the industry
- Stay informed – Receive the APACMed members-only alerts and newsletters
- Receive timely information providing early warning about regulatory and policy developments in the region and guidance on how to address them
- Leverage the APACMed network to explore business development opportunities with other MedTech companies, both big and small
- Benefit from exclusive market insights and analysis from APACMed knowledge partners



APACMed Members

Corporate Members

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SME Members

Associate Members

Industry Members

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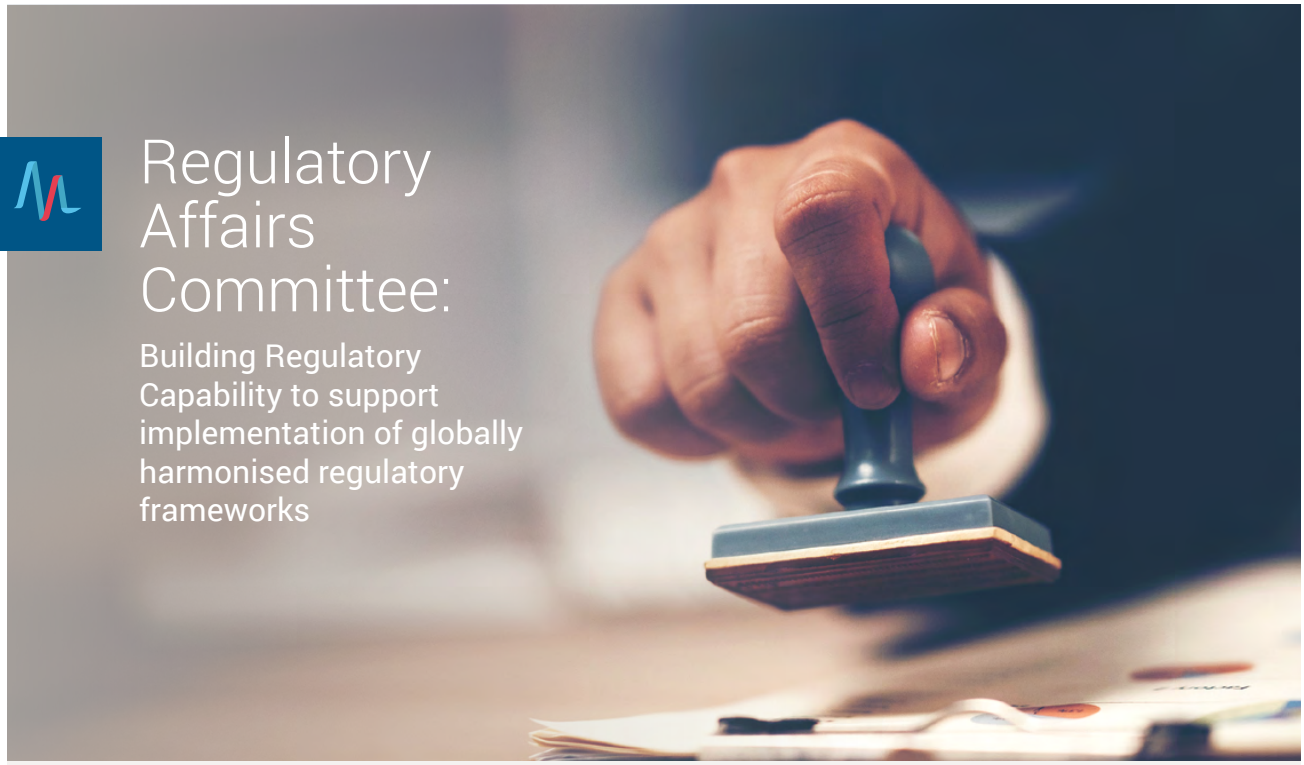

Regulatory Affairs Committee:

Building Regulatory Capability to support implementation of globally harmonised regulatory frameworks

Promoting Regulatory Convergence: APACMed Regulatory Work Across the Region

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:

01

Promote **regulatory convergence** in collaboration with government agencies, industry associations, academia and other stakeholders.

02

Build and support a strong regulatory workforce for MedTech industry and regulators, and drive **capacity building** initiatives in partnership with various stakeholders.

03

Advocate for policies that promote patient access to innovative technologies that advance patient outcomes.

For more details and information, please contact Yasha Huang, Director, Regulatory Affairs: **yhuang@apacmed.org**

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Promoting Regulatory Convergence

International Medical Device Regulators Forum

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), and to accelerate international medical device regulatory harmonisation and convergence. The current members are Australia, Brazil, Canada, China, Europe, Japan, Russia, Singapore, South Korea, and the United States of America. In 2020, APACMed will be the preferred partner supporting IMDRF conferences hosted in Singapore.

Asian Harmonization Working Party

In 2016, APACMed became 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 2019, AHWP member economies endorsed a white paper on regulators competency framework co-developed by AHWP and APACMed. In 2020, the two parties will move to the next step and look at developing training curriculum framework for MedTech regulators.

APACMed's Regulatory Convergence Initiatives

Regulatory Harmonization Steering Committee
Life Science Innovation Forum

In 2015, APACMed became Industry Coalition Lead of the Asia Pacific Economic Cooperation Regulatory Harmonisation Steering Committee (APEC RHSC). APEC RHSC represents 21 Member Economies and is tasked by APEC Ministers to achieve convergence on regulatory approval procedures for medical products by 2020.

ASEAN Medical Device Committee (AMDC)

APACMed is actively engaged with the ASEAN Medical Device Committee (AMDC), which serves as a platform to bring together ASEAN regulators and industry stakeholders to harmonise and shape the future of medical device regulations across Southeast Asia.

Capability Building and Thought Leadership

In August, APACMed co-organised the 8th ASEAN Medical Device Committee (AMDC) industry training and public private forum in Manila, Philippines to discuss AMDD implementation and challenges with regulators from 10 ASEAN countries, together with AMDC, Philippines Food and Drug Administration (FDA), and the Philippine Association of Medical Device Regulatory Affairs Professionals (PAMDRAP).

In August, APACMed finalised a position paper "Acceptance of Overseas Clinical Performance Evaluation". The paper includes a global comparison analysis of clinical performance evaluation requirements for IVD medical devices in IMDRF economies, ASEAN economies and other markets. It provides government stakeholders with a comprehensive overview of international best practice, and highlights specific challenges across several markets, as well as the scientific and socioeconomic justifications for adopting internationally harmonised practices.

In September, APACMed joined the International Medical Device Regulatory Forum (IMDRF) conference in Yekaterinburg, Russia, in preparation for co-organizing the IMDRF 2020 events in Singapore together with host Health Sciences Authorities.As the most important regulatory forum in MedTech, IMDRF provides the high-level platform for regulators and industry experts from the World Health Organization and 10 key markets to formulate and share common regulatory guidance, procedures and standards for the ease of reference and adoption by regulatory agencies across the world.

In October, APACMed supported the hands-on evaluation training in Singapore for 20 regulators from 10 ASEAN member states. The training was conducted in the Health Authority Sciences (HSA) office, with case studies using real dossiers for breast implant products. This hands-on training was well received by regulators and reviewers from ASEAN countries as many of them are attempting to equip themselves team with hands-on experiences on the way to implement AMDD in their own jurisdictions.

In collaboration with the Asian Harmonization Working Group (AHWP) and Deloitte, APACMed this year published a White Paper: "Competency Framework for Medical Technology Regulators".

MedTech regulatory agencies from the 13 AHWP economies participated in the self-assessment survey, the results of which provided the foundation to this competency framework.

Additionally, APACMed member companies participated in an industry survey to validate the findings from the first survey. This paper will be valuable for regulators as they develop actionable plans to address the competency development challenges faced across APAC, and ultimately deliver high-quality services to all stakeholders they collaborate with.

In November, this paper was endorsed by 32 AHWP member economies during the 24th Asian Harmonization Working Party (AHWP) Annual Meeting in Muscat, Oman. APACMed CEO Harjit Gill and Regulatory Affairs Director Yasha Huang were invited to the conference as plenary speaker and moderator for the digital health regulation panel respectively.

In December, APACMed supported the Asia Pacific Economic Cooperation Regulatory Harmonization Steering Committee (APEC-RHSC) Medical Device Priority Working Areas (PWA) pilot workshop hosted by China in Chengdu, as the industry coalition member. APACMed Regulatory Affairs Director Yasha Huang and Regulatory Affairs Committee Chair Miang Tanakasemsub attended this closed-door workshop together with 100+ regulators from 17 countries. APEC RHSC Medical Device PWA positions itself as the training arm of IMDRF and endeavours to provide trainings for regulators across the globe by coordinating resources from three parties: government, academia and industry.

Advancing Regulatory Advocacy

In 2019, APACMed Regulatory Affairs committee had 22 meetings with key government agencies in China, India, Indonesia, Malaysia, Philippines, Singapore, Thailand, and Vietnam to advocate for better

harmonized and more efficient regulatory schemes that protect patient access and business continuity.

China

In February, APACMed was invited by the National Medical Products Administration (NMPA) to attend the Expert Consultation meeting on post-marketing surveillance guidance documents as one of the very few selected industry associations.

In July, Harjit Gill and Yasha Huang visited government and industry stakeholders as well as think tanks in Beijing to discuss the Association's engagement and advocacy strategy for China, including: China Center for Food and Drug International Exchange (CCFDIE) of NMPA, China Association for Medical Device Industry (CAMDI), China Chamber of Commerce for Import & Export of Medicines & Health Products (CCCHMPIE), European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) China office, R&D-based Pharmaceutical Association Committee (RDPAC), Chinese Academy of Social Sciences, and University of International Business and Economics.

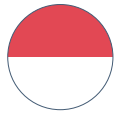
In September, APACMed co-organised the 10th China International Medical Device Regulatory Forum (CIMDR) alongside other peer associations in Suzhou, where Harjit Gill gave a keynote speech. Yasha Huang moderated the break-out session for Medical device innovative products and technologies and had a side meeting with the Director of Lecheng International Medical Tourism Pilot Zone Administration on accelerating market access in China.

India

In April, CEO Harjit Gill visited New Delhi to meet with industry stakeholders to discuss the Association's engagement and advocacy strategy for India, including AdvaMed India office, AmCham, and Mtai.

In July, APACMed organised a training for regulatory professionals with BSI on EU MDR impact for Indian market, materiovigilance and post-approval changes.

In November, Regulatory Affairs Director Yasha Huang was invited as a panellist to discuss India's National Digital Health Blueprint, together with the National Health Authority (NHA), healthcare providers, payers, and other industry partners, during the 6th Annual NATHealth Summit in India.



Indonesia

In December, APACMed led a delegation of 12 member companies to visit Indonesian Ministry of Health to discuss future collaboration in capability building as well as key issues related to IFU/eIFU, EU MDR/IVDR impact, change management, and post market surveillance. Both parties agreed to continue the dialogue and capability building activities to jointly improve access for patients in Indonesia.

Malaysia

In August, APACMed visited the Medical Device Authority in Malaysia to discuss collaboration in capacity building for regulators.

In October, Regulatory Affairs Director Yasha Huang and Government Affairs Manager Georgia Swan were invited to speak about healthcare innovation and capacity building at the International Medical Device Conference 2019 in Kuala Lumpur, Malaysia, officiated by the Honourable Prime Minister, Yab Tun Dr Mahathir Bin Mohamad.

Philippines

In May, APACMed led a delegation of 12 member companies to visit Philippines Food and Drug Administration (FDA) officials in Manila, to discuss the acceptance of overseas clinical evidence for IVD medical devices as well as phased-in implementation of the Medical Device Administrative Order (AO) to better harmonize with other ASEAN countries in classification and grouping. APACMed also had alignment meetings with two local associations on the same issues.

In August, APACMed had meetings with multiple stakeholders in Manila, including Philippines FDA, US International trade administration, AdvaMed, and other local industry associations. APACMed also summited the position paper on Acceptance of Overseas Clinical Performance Evaluation to Philippines FDA, attempting to protect the IVD industry from mandatory testing for all products in Philippines.

Singapore

In January and March, APACMed met with the Health Science Authority, Singapore (HSA) to discuss about new technology regulation, capacity building for ASEAN regulators, and collaboration for the International Medical Device Regulators Forum (IMDRF) 2020 events.

Thailand

In June, October, November, and December, APACMed had multiple meetings with Thailand Food & Drug Administration (FDA) to discuss about capacity building program and Thailand - Singapore Regulatory Reliance Project. With APACMed as its sole industry partner, the Thailand-Singapore regulatory reliance pilot project was successfully kicked off, with the aim of accelerating access to lifesaving and life sustaining medical technologies for patients in Thailand. 4 Thailand FDA officers completed the 2-week fellowship program within Singapore HSA; the first batch of 19 product categories was included into this pilot project. Building on the initial success, we plan to support the expansion of this regulatory reliance pilot project to another ASEAN country in 2020.

Vietnam

In July, APACMed led a delegation of 13 member companies to visit the Department of Medical Equipment and Construction (DMEC), Ministry of Health, Vietnam to discuss the current challenges in implementation of Decree 169/2018/ND-CP and proposed detailed recommendations to tackle the key issues for the benefits of patients in Vietnam.

In November, APACMed submitted a position letter to the Prime Minister Office on Industry Proposals to Avoid Interruption of Critical Medical Supply in Vietnam, providing recommendations on product registration under Decree 36/169 as well as advocating an additional 2-year extension until 1 January 2022 to ensure smooth transition and minimize medical supply disruption for the healthcare system in Vietnam.

In 2019, APACMed Regulatory Affairs Committee launched the monthly MedTech Regulatory Intelligence Watch, in partnership with IQVIA/Tarius, to provide members with actionable insights for markets across Asia Pacific.

Government Affairs and Market Access Committee:

Shaping healthcare ecosystems to facilitate increased access and affordability of medical technologies for patients across APAC

In 2019, the Committee grew to 66 members across 16 companies. Sincere thanks to our Committee leadership team and key members of our working groups for driving this increased engagement.

The Market Access Centre of Excellence (CoE) was initiated this year, with the mission of fostering collaboration in the space of pricing and reimbursement, HEOR and analytics and real-world evidence across the Asia Pacific region. The group facilitated the successful delivery of a number of key projects, establishing a sound knowledge base in the field of Health Technology Assessment and value-based decision making. This year also saw the establishment of four country-specific CoEs, based in India, China, Vietnam and Indonesia. These CoEs have played an instrumental role in driving key advocacy activities in these economies.

Advocacy and High Level Engagements

Indonesia: Halal Standards

In July, Georgia Swan, APACMed's Government Affairs and Market Access Manager, and a group of APACMed members met with Professor Sukoso, Head of BPJPH, in Singapore to discuss the Halal Standards implementation process in Indonesia. Key discussion points centred around implementation timings, trainings for industry, and clarifications on technical elements of the application scope. APACMed continued to engage with the Indonesian government throughout the year to seek clarification on key points around this standard as it applies to medical devices and in-vitro diagnostics.

Ministry of Health, Jakarta, Indonesia

In November, Georgia Swan, APACMed's Manager of Government Affairs and Market Access, together with members from APACMed's Indonesia CoE, met with key stakeholders from the Ministry of Health in Jakarta, Indonesia[[to discuss mutual objectives of achieving Universal Health Care sustainability and growing a robust and sustainable ecosystem that encourages investment and economic growth. Member participants from Medtronic, Boston Scientific, Abbott, B Braun, Fresenius Medical Care, Becton Dickinson and Varian were in attendance.

Malaysia: Halal Standards

APACMed undertook continuous advocacy efforts, in collaboration with industry association member Association of Malaysian Medical Industries (AMMI) and other local and global associations, regarding the Halal Standard for medical devices in Malaysia, which was approved in July. General requirements were made available thereafter however specific detail on scope, timelines and implementation process remained uncertain. APACMed submitted a position paper on this subject to the Prime Minister's Office and JAKIM in November 2019, which addressed key points around its implementation. APACMed continues to engage with Malaysian authorities, sister associations, and members on the ground in Malaysia to closely monitor and respond to updates on this issue

New Zealand: PHARMAC Consultation

In July APACMed, in alignment with the Medical Technology Association of New Zealand, responded to a public consultation by PHARMAC on Managing Fairer Access to Hospital Medical Devices. APACMed's response highlighted the differences between medicines and medical devices, the need for transparency in this new process, and the importance of incorporating appropriate expertise in the decision-making process. PHARMAC has since advised that they will engage further on the operational details and announce an implementation timetable for their management of medical devices in the first half of 2020. They have also confirmed, in response to this consultation, that the fairer access process will not commence until 2021 at the earliest.

Government stakeholders, New Delhi, India

In July, CEO Harjit Gill, and Manager of Government Affairs and Market Access, Georgia Swan, met with governmental stakeholders to discuss potential areas of collaboration. Together with members from Baxter, Alcon and Abbott, APACMed met with representatives from the National Health Authority (NHA), NITI Aayog, Bureau of Indian Standards (BIS) and Central Drugs Standard Control Organisation (CDSCO) as well as fellow Associations on the ground including NATHealth and the Medical Technology Association of India (MTaI).

Thought Leadership

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:

This white paper was completed in collaboration with IQVIA in December 2019 and will be formally launched in Q1 2020. Members from APACMed's Market Access CoE significantly contributed to the content. The paper sheds light on the evolving HTA environment of 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, and encouraging a multi-stakeholder system design and implementation process for Governments looking to adopt HTA across the region

"Reimbursement Price Revision System of Medical Devices in Japan" explanatory paper:

This paper, written by members from the Market Access CoE, provides a robust and easy-to-understand overview of the intricacies of the Japanese price revision reimbursement system for members, including potential future changes for the industry to be aware of.

Bi-monthly HTA update reports:

This year, the Market Access Centre of Excellence began creating and disseminating Health Technology Assessment (HTA) reports

to APACMed members. These reports provided regular updates on the HTA landscape in four key markets across the region: Australia, Japan, South Korea and Taiwan. This resource provided members with important updates on the application of HTA and its potential impact to businesses across APAC.

Webinars

Throughout the first half of 2019, a number of post-election webinars were hosted by the Committee, in collaboration with expert knowledge partners, to provide members with relevant insights into election outcomes and exploring the potential impacts to the healthcare ecosystem and relevant policy environment.

- Indonesia, Philippianes and Thailand elections (in partnership with Vriens & Partners)
- India election (in partnership with SKP group)
- Australian election (in partnership with the Medical Technology Association of Australia)

Legal, Ethics & Compliance Committee:

Raising business ethics standards across the region and supporting ethical interactions between HCPs and industry

In 2019, the Legal, Ethics & Compliance Committee grew to 50 members from more than 20 member companies, bolstered by the amount of work the Chair and Co-Chairs had put in this year.

MedGrant™

In July, Deloitte's MedGrant™ platform – designed with substantive input from APACMed's Legal, Ethics and Compliance community – went live. The web-based solution aims to effectively match grants provided by the MedTech industry to institutions and healthcare professionals in Singapore and is aligned with APACMed's Code of Conduct. Additional markets will be scoped for rollout in 2020.

APACMed Code Revision

In September, a working group formed to undertake the first code revision of APACMed's Code of Conduct since its implementation in 2015. Sincere thanks to the group driving the code revision, comprised of 13 members from 11 member companies: Medtronic, Abbott, Johnson and Johnson, Zimmer Biomet, Alcon, Siemens, Fresenius, Stryker, Geeta Thakerar Consulting, Baxter and Align. The group has commenced drafting the code revision, for completion in the first half of 2020.

Start-up and SME Committee:

Supporting and building APAC's Start-up ecosystem; facilitating collaboration between start-ups and established companies and supporting go to-market acceleration

Events and Workshops

This year, APACMed organised a series of workshops for the start up community. The Association will build on this work in 2020, and will be hosting virtual bootcamps for start-ups as well as more exclusive 'Founders Circle' events to connect founders to corporates. More information will follow in 2020.

In April, APACMed, in collaboration with Deloitte, organised a "Pitch Perfect" Workshop for start ups in the medical device and health tech space. This interactive workshop was a unique opportunity for start-ups to gain insights into how to make a start-up pitch stand out. Participants were given exclusive access to mentors across the medtech and healthcare fields.

"Today's Discoveries,Tomorrow's Innovations", was APACMed 5th SME Workshop. Held in August, and attended by over 100 members, the objective was to help early-stage startups have a better grasp of the regional landscape, and equip them with knowledge to better navigate reimbursement frameworks and regulatory hurdles.

MedTech Innovator Asia Pacific

The Asia Pacific MedTech Forum in October saw the launch of the MedTech Innovator Asia Pacific competition, which saw more than 170 applicants from 35 countries compete across the region.

Finally, in November, APACMed and MedTech Innovator marked their one year partnership, with a networking event, sharing key milestones, and inviting participants from the 2019 cohort to share their experience.

MEDTECH FORUM ASIA PACIFIC 2019

CONNECTING LEADERS• CONNECTING CARE

The annual Asia Pacific MedTech Forum is a mainstay in APACMed's calendar of events and one which the Secretariat team plans its entire year around. Since its inception, the MedTech Forum has consistently grown from strength to strength with each new edition, and has evolved from being an industry networking event into a gathering of gamechangers, all aligned in the belief and promise of what MedTech brings to the table.

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Held at Suntec Singapore International Convention and Exhibition Center from 7 to 9 October, the 2019 MedTech Forum sparked many lively debates and discussions amongst the 1,000+ delegates in attendance, as they broadened their perspectives and gained a deeper understanding of the digital technologies and solutions of today which will impact the future of healthcare in APAC.

Centered around the theme of "Connecting Leaders, Connecting Care", our exceptional line up of guest speakers and panelists explored how technologies like artificial intelligence (AI), computer-aided surgery, wireless communications as well as mobile apps and wearables will transform the way in which physicians and other healthcare professionals will deliver treatment and care.

Since its inception, the MedTech Forum has consistently grown from strength to strength with each new edition, and has evolved from being an industry networking event into a gathering of gamechangers, all aligned in the belief and promise of what MedTech brings to the table.

Dr. Anushka Patchava
United Nations
(CEFACT), Healthcare

Prof. Shafi Ahmed
Royal London
Hospital

Dr. Krishna Udayakumar
Duke Global Health
Innovation Center

Joseph M. Hogan
Align Technology

The provision of healthcare across the region's 48 countries remains highly fragmented; while this can at times be felt like an uphill battle, the Asia Pacific region is not burdened with as many legacy issues affecting for example, both the US and UK healthcare systems, and thus there is huge potential to leapfrog innovations.

Innovations such as AI and other healthcare technologies can spur rapid periods of growth, and it is in the MedTech community's best interest to act as both an accelerator and facilitator of such technologies, paving the way to a more connected world.

Once again, we'd like to reiterate our sincere appreciation to all our sponsors, exhibitors, and partners, who played such a pivotal role in making this years' edition of the MedTech Forum the biggest to date!

Special thanks to Chirag Amin, regional marketing director for Johnson & Johnson Asia Pacific, our charismatic, engaging and inspiring MC this year!

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Asia Pacific Medical Device Regulatory Summit, October 2019, Singapore

For the 4th year running, APACMed organised the only Asia Pacific MedTech Regulatory Summit for Regulators and the regulatory community. Attended by nearly 300 delegates, the meeting saw an exceptional line up of 18 speakers and guests from the WHO, regional harmonization initiatives, industry, academia, as well as 30 regulators from 15 economies.

The AHWP/APACMed/Deloitte white paper "Competency Framework for Medical Technology Regulators" was launched, followed by a panel discussion with Duke-NUS Medical School Centre of Regulatory Excellence (CoRE), the World Health Organization, Medical Device Authority of Malaysia, Health Sciences Authority of Singapore.

Regulatory Convergence best practices were shared by four regional conference platforms, i.e. ASEAN Medical Device Committee, AHWP, APEC – Life Sciences Innovation Forum, and South East Asia Regulatory Network.

Eminent speakers from government, industry associations, and industry shared their insights on digital health regulation trends in Japan, Korea, Europe, and US.

Asia Pacific MedTech Public Policy and Market Access Summit

For the first time at this year's MedTech Forum, APACMed held a Public Policy and Market Access Summit. The purpose of the summit, titled Moving Towards a Value-Driving Medical Technology Assessment: A Multi-Stakeholder Perspective, was to: understand value from a multi-stakeholder perspective; discuss the role of value in informing policy, pricing and reimbursement decision-making; and identify and discuss unmet needs, challenges and opportunities to address collaboratively moving forward. This summit was attended by over 130 people, with nine expert speakers from six countries, representing patients, research and academia, and industry.

The summit concluded with a panel discussion, during which panellists highlighted the importance of aligning the definition of value across different stakeholders in the HTA process so as to effectively capture the true value of a medical technology to the health system. The panellists agreed that there needs to be a holistic view of value, including preventive benefits, and highlighted the need to converge the eligibility criteria and willingness-to-pay for medical technologies and pharmaceuticals.

Asia Pacific MedTech Business Ethics & Compliance Summit

This year's annual Business Ethics & Compliance Summit brought together over 85 participants from the regional MedTech legal and compliance community. Organised by APACMed's Legal, Ethics & Compliance Functional Committee Leadership Team, programme highlights included an interview with Serge Bernasconi, CEO of MedTech Europe; updates on regional legal and compliance developments from law firms Sidley Austin and Covington; and an overview of Korea Medical Devices Industry Association's (KMDIA) implementation of its Fair Competition Code by Jooyup Chae, the Vice-Chair of its Ethics Committee.

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Annual Report 2019

APACMed

The voice of MedTech

Founded in 2014, the Asia Pacific Medical Technology Association (APACMed 亚太医疗技术协会) 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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