

IMPROVING ACCESS TO HIGH QUALITY
HEALTHCARE ACROSS ASIA PACIFIC



ANNUAL REPORT 2017

www.apacmed.org



OUR MISSION

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

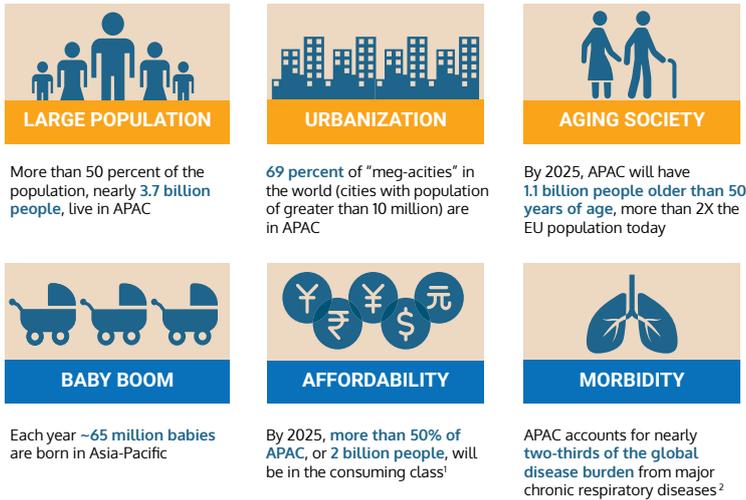
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Transforming Healthcare across Asia Pacific: How the MedTech Industry is striving to meet unmet needs

The scope of patient needs in Asia-Pacific is unprecedented. More than 3.7 billion people live in Asia-Pacific, and by 2025, about a quarter of the region's population will be elderly. Each year around 65 million babies are born in Asia-Pacific. More than two-thirds of the world's cities with more than 10 million people are in Asia-Pacific, and by 2025, more than 50% of the region, or 2 billion people, will be in the consuming class.

Significant needs and growing demand for healthcare in APAC



¹With income greater than \$3,600.
²Measured as disability-adjusted life years (DALYs) lost to COPD, asthma, and lung cancer. SOURCE: IHS Economics (2015); World Bank; McKinsey Insights

But the story goes well beyond demographic trends. For more than a decade, the global economic center of gravity has been sliding away from the developed Western economies and toward Asia-Pacific. The shift has been led mostly by China's rapid economic growth, but not exclusively. The region could account for 35 percent of the world's total GDP by 2020, from 25 percent in 2000, and be home to four of the world's top ten national economies.

The region's healthcare needs reflect its size. In 2015, for example, Asia-Pacific accounted for nearly two-thirds of the world's overall burden for chronic respiratory diseases, according to measures of disease-adjusted life years (DALY), and nearly half the world's burden of all critical and chronic diseases. By 2025, more than a billion people in the region will be older than 50, entering a life stage where medical needs increase sharply.

A number of trends underpin the demand for improved healthcare in Asia-Pacific. Among these, many governments are thinking about instituting universal healthcare. Some private hospital chains are expanding rapidly, while new funding channels, such as private equity, are opening. Brisk innovation in healthcare delivery models also suggests a vibrant sector. The market for MedTech in Asia-Pacific is estimated to reach \$133 billion by 2020. This is undoubtedly a demanding region for business leaders, particularly compared with more developed and homogeneous markets, such as North America, where many business models were created and have evolved.

Although highly regulated, the MedTech industry shows significant room for growth, if companies manage to successfully overcome the specific challenges of the region. Indeed, the MedTech industry has traditionally focused on the premium segment and not yet penetrated Asia-Pacific as fully as many other industries have. Along with a generally cautious approach to the region, MedTech companies have been hindered by specific barriers such as: limited financial resources and a frugal attitude toward spending on healthcare; multiple customer segments that are difficult to serve efficiently;

underdeveloped medical infrastructure and workforce, which inhibits the adoption and use of new technology; a fragmented and inconsistent set of regulatory and reimbursement regimes that serve as a deterrent to introducing new technology; intense competition from regional start-ups, as well as increasingly from global leaders in adjacent industries, such as high tech and consumer electronics.

Thus, it is more important than ever for actors of the MedTech industry to come together to address these challenges, and collectively address the vast unmet healthcare needs of our region.

APAC realities for MedTech industry



Source: MedTech in Asia, Committing at scale to raise standards of care for patients, McKinsey & Company, 2015

Improving standards of care for patients in Asia Pacific: APACMed's patient centric mission

The APACMed mission is patient centric and calls for new creative partnerships among key stakeholders in the healthcare and medical technology ecosystem. Our key stakeholders include but are not limited to clinicians, governments, regulators, payers, healthcare providers, patient advocacy associations and academia.

We aim to achieve our mission through focused initiatives and activities addressing the needs of the diverse healthcare markets in the region relating to access, innovation and collaboration.



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 promote a cost-effective, value-based approach to healthcare in Asia Pacific by demonstrating the value of innovative medical technologies in improving quality of care, and healthcare outcomes.



COLLABORATION

We provide a platform for knowledge exchange and engage with all stakeholders to raise awareness of, and develop new and unified solutions that meet the demands of diverse and complex healthcare markets in Asia Pacific.

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 health care challenges.

The Association partners with all key stakeholders to meet the growing health care needs and expectations of stakeholders and improve healthcare outcomes in Asia Pacific.

APACMed Board of Directors 2017



VLADIMIR MAKATSARIA

Chairman, APACMed

Company Group Chairman, Asia Pacific, Johnson & Johnson Medical Devices Companies and Chairman Johnson & Johnson China



ANNA MARIA BRAUN

Vice-Chairman, APACMed

President, B. Braun Asia Pacific and Member of the Management Board, B. Braun Melsungen AG.



JAMES LIM

Treasurer, APACMed

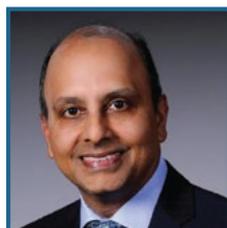
Executive Vice President and President, Greater Asia, Becton Dickinson & Co.



HARVINDER SINGH

Divisional Vice President, Asia Pacific and Japan

Abbott Vascular



RAJKUMAR NARAYANAN

President Asia

Alcon

Raj replaced Eric Van Oppens during the course of 2017



SUPRATIM BOSE

Executive Vice President and President, Asia-Pacific Middle East & Africa

Boston Scientific



BOB WHITE

Senior Vice President and President, Asia Pacific

Medtronic



MASSIMILIANO (MAX) COLELLA

Senior Vice President Asia Pacific

Smith & Nephew



GRAHAM McLEAN

President, Asia Pacific

Stryker



HIDEO ARASE

Managing Director

Terumo Asia Holdings

Director & Senior Executive Officer

Terumo Corporation



IAN BURGESS

Chief Executive Officer

Medical Technology Association of Australia (MTAA)

Chairman Foreword

Vladimir Makatsaria



“Profound changes are already reshaping the entire healthcare value chain, on an unprecedented scale.”

VLADIMIR MAKATSARIA
Chairman

In 2017, APACMed continued to grow and mature. The association now represents 84 members, has strengthened the capabilities of the Secretariat and engaged in multiple new initiatives, including revisions to the new Code of Conduct that align the Association with global best practice. This is a testament to the efforts of our Association and the importance of concerted action across our industry.

The accomplishments of our Association are the combined result of the work of Fredrik Nyberg, CEO of APACMed and the Secretariat team, as well as each and every member of our Functional Committees and my fellow Board Members. My sincere thanks to them all.

I also want to acknowledge someone who has had a profound and long-lasting impact on our industry at large and APACMed in particular: Supratim Bose. For me, as well as many of us within the Association, he has been a guiding force and mentor. He has worked tirelessly on behalf of patients throughout Asia Pacific. He was a driving force of the creation of APACMed, and has served on its board since we founded the organisation. As he is now set to retire from his role of President of Asia Pacific, Boston Scientific I would like to thank him as he moves onto the next exciting next chapter in his life.

This year's Asia Pacific MedTech Forum, under the theme [“Transforming Healthcare through Innovation”](#) allowed us to reflect on the impact of innovation in driving more efficient care delivery.

Profound changes are already reshaping the entire healthcare value chain, on an unprecedented scale. From the use of augmented reality in medical training, to the growing adoption of robotics in surgery; from the application artificial intelligence in clinical decision making, to patient centered mobile apps for health monitoring and disease management.

By 2020, Asia Pacific will have surpassed the EU as the second biggest market for medical technology behind the US; yet, an overwhelming majority of the population across region, still does not have access to affordable healthcare.

It is often said that we are on the cusp of a '4th Industrial revolution', and as an industry, it is clear that we are only just beginning to see the potential of these exponential technologies in reducing costs, increasing access and improving care. We have a collective responsibility to address these inequalities and must continue to nurture our relationships with both existing actors and emerging, nontraditional players, with whom we share the same patient centric vision.

CEO Report

Fredrik Nyberg



“APACMed will continue to promote shared action to drive innovation that improves standards of care in Asia.”

FREDRIK NYBERG
CEO

This year was pivotal for our Association. We significantly grew our membership base with a particularly impressive growth within the SME/ Start up category, and as we marked our third anniversary, we were proud to reach an important milestone ahead of our forecast financial projections and report a surplus at the end of 2017.

I am also proud to report back on the significant achievements of the past year, and I am confident that 2018 will see us taking the Association to new heights

Advocacy, in the broadest sense, is, and will remain a cornerstone of the Association’s work, as we strive to ensure our members are given a voice in critical public policy and regulatory discussions across the region. This year, thanks to the tireless efforts of both our Government Affairs and Regulatory Affairs Committees, we strengthened our efforts to help address broad healthcare challenges, by putting forward evidence-based recommendations which highlight the value of innovation whilst ensuring patient access to high quality, affordable medical technology.

By engaging in a wide range of discussions, from new device regulations in Vietnam and Malaysia to the divisive issue of price controls in India, to China’s complex clinical evaluation guidance, we were able to enhance our collaboration with key policy makers and regulators across the region and play an important role in shaping the region’s healthcare policy agenda.

In 2018, we aim to strengthen the Secretariat’s core functions further, which will enable us to build deeper and stronger engagement locally, and, with the support of our local Industry Association members, will allow APACMed to meaningfully address the region’s unmet healthcare needs.

One of our priorities in 2017 was the revision of APACMed’s Code of Ethical Conduct for Interactions with Health Care Professionals. In order to preserve and enhance the independence of Health Care Professionals’ (HCPs) decision-making, the Board of APACMed revised the Code in 2016 with a view to eliminate Direct Sponsorship of HCPs by APACMed Members to attend or speak at Third Party Educational Events as of 1 January 2018. This is an important step to align our Code with other international industry codes and guidelines, and regulations, serving to further enhance ethical standards in Asia Pacific.



Our efforts were focused on communicating the Code revision and explaining the impact of the change to both members and external stakeholders such as medical societies, professional associations, and conference organisers

Finally, we continued to raise the profile of the Association and engage our members, through numerous events and networking opportunities during the year. Our third Asia Pacific MedTech Forum was our most successful to date, with over 600 delegates gathering in Singapore to explore the multiple facets of disruptive innovation in healthcare. Importantly, the Forum also forced us to reflect on areas where, as an industry, can do more.

As the first and only Association representing the diverse voices of companies across the MedTech ecosystem, APACMed will continue to promote shared action to drive innovation that improves standards of care in Asia. I hope that our important mission will resonate with many more companies, associations and startups across the region in the coming years.

As always, I would like to extend my heartfelt thanks to all APACMed members for their ongoing support and involvement in spearheading the work of our Functional Committees, and in actively sponsoring our events.

Our work this year would not have been possible without the steadfast support of our Chairman Vladimir Makatsaria and our Board of Directors – thank you for your unwavering enthusiasm and support across our strategic areas of focus.

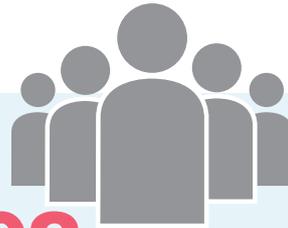
And lastly, I would like to thank the APACMed Secretariat team, for their energy and commitment. As we continue to grow the team, it is essential to remember the need to always stay relevant and serve our members.

APACMed Highlights and Activities

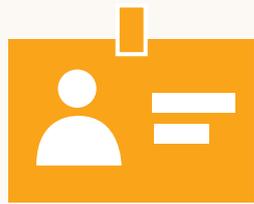
32

events, networking & learning opportunities attended by

1,893 participants

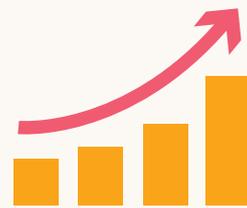


84



Members:
Corporate, Associate,
SME & Industry Associations

33



New Member Organisations

192

Active member representatives across

5

Functional Committees



2,450+



Followers across social media channels

USA
San Jose

KOREA
Seoul

JAPAN
Tokyo

INDIA
New Delhi

CHINA
Hangzhou
Beijing
Hong Kong

South East Asia
Singapore
Kuala Lumpur
Penang
Ho Chi Minh City
Hanoi
Surabaya
Japan

APACMed
local engagements

APACMed Functional Committees

LEGAL/ETHICS & COMPLIANCE COMMITTEE



Chair:

Campbell Clark, Chief Ethics & Compliance Officer, Asia Pacific, Medtronic

Vice Chairs:

Benji Kwak, VP, Compliance Officer & Senior Legal Counsel, Zimmer Biomet

Richard Hamilton, Chief Legal Counsel, Stryker

Ana Garcia Bello, Vice President Law, Medical Devices Asia Pacific, Johnson & Johnson

REGULATORY AFFAIRS COMMITTEE



Co-Chair:

Carol Yuan, VP, Regulatory Affairs Johnson & Johnson Medical Asia Pacific



Co-Chair:

Miang Tanakasemsub, APACMed RA Co-Chair Regional Regulatory Affairs Head, Asia Pacific & Russia Alcon

Vice Chair:

Jason Guo, Regulatory Affairs & Quality Compliance, Asia Pacific Abbott Vascular

GOVERNMENT POLICY COMMITTEE



Chair:

Chris Colwell, Senior Director, Public Affairs, Greater Asia, Becton Dickinson

Vice Chairs:

Shakilla Shahjihan, Regional Director, Government Affairs, Asia Pacific, Abbott

Hitendra Joshi, Head of Government Affairs & Market Access, Asia Pacific, B.Braun

COMMUNICATIONS COMMITTEE



Chair:

Dr Hsien-Hsien Lei Hsien-Hsien Lei, Vice President Communications and Value-Based Healthcare, Asia Pacific Medtronic

Vice Chairs:

Richard Sumich, Head of Communications & Public Affairs, Johnson & Johnson Medical Devices, Asia Pacific

Joanna Ng, Regional Head, Corporate Communications, Asia Pacific, B. Braun Group

MEDICAL & CLINICAL AFFAIRS COMMITTEE



Chair:

Dr Amit J. Shanker, Chief Medical Officer, Asia/Australia/Middle East/Africa, Boston Scientific

Vice Chair:

Dr Laurent Metz, HEMA Lead Asia Pacific - Medical Devices Sector Johnson & Johnson Medical Asia Pacific

Advancing Business Ethics in MedTech: APACMed Compliance Activities

Revision of the APACMed Code of Ethical Conduct to eliminate direct sponsorship of Health Care Professionals' (HCPs) to attend or speak at Third Party Educational Events

2017 was a pivotal year for our Association on the compliance front. Following on from the Board's decision in September 2016 to eliminate direct sponsorship of HCPs, as of 1 January 2018, the Legal/ Ethics and Compliance Committee revised [APACMed Code of Ethical Conduct](#).

Selected members of the Legal/ Ethics and Compliance Committee, the Communications Committee and APACMed Secretariat formed a Steering Committee to develop a Communication Plan targeting both internal audiences (members) and external stakeholders.

Internal communications

- A series of webinars, hosted by the Committee were held for members, to explore the implications of the code revisions, and going through a series of scenarios.
- In addition, a comprehensive Communications Toolkit was developed for members, including Q&A, communication guidelines and creative assets for use on social media. Finally, a dedicated email helpline was established for members (code@apacmed.org).
- In September 2017, APACMed held the first Compliance Dialogue, brought together 50 commercial and compliance leaders of our corporate members to openly discuss challenges associated with the elimination of direct sponsorship. A total of 51 representatives attended the event.

External Communications

- In our efforts to raise awareness of the Code across the region, the revised Code has been translated into: Chinese (traditional & simplified), Vietnamese, Thai, Bahasa Melayu and Bahasa Indonesia. A brochure designed to provide further guidance on the Code revisions to Healthcare Professionals, Healthcare Institutions, Professional Associations and Conference Organisers was developed; a digital version, which can be used by commercial teams, is also available for APACMed members.
- In terms of outreach, letters on behalf of APACMed CEO were sent to more than 400 external stakeholders across the region, and a number of meetings with both national industry associations, such as AMMI, TAMTA, ThaiMED, and medical societies, including Academy of Medicine Singapore, took place over the course of 2017; these will continue in 2018.



In September, APACMed was well represented at the 2017 APEC Business Ethics for SMEs Forum in Hanoi, which was attended by many members of the Legal/ Ethics & Compliance Committee. The initiative monitors code of ethics development and implementation by 29 medical device sector industry associations across the APEC region, collectively representing over 13,000 member enterprises. When this initiative's capacity-building program was launched in 2012 to support implementation of the APEC Kuala Lumpur Principles, 12 of these monitored medical device sector industry associations had a code of ethics. In 2017, 26 of these associations have a code of ethics or formalized commitment.



November 2017: Joint AdvaMed/ APACMed/ MTAA/ MTANZAsia Regional MedTech Compliance Meeting

The annual joint Compliance Meeting, was attended by 60 delegates, including many representatives of the APACMed Legal/ Ethics & Compliance Functional Committee. Session highlights led by invited speakers included:

- Legal Updates and Developments in Korea: Kyle Choi and Hwa-Soo Chung, both from Korea's premier law firm [Kim & Chang](#)
- Update on India Physician Code: Dr. Milind Antani, Nishith Desai Associates



◀ **Left to right:** Fiona Goh, Zimmer Biomet ; Gareth Lee, Cardinal Health; Jessie Yap, Abbott ; Han Pin Toh, Arthrex; Campbell Clark, Medtronic.

In January 2018, APACMed issued a [joint statement](#) with AdvaMed, MedTech Europe and Mecomed announcing the revision to the respective Code of Ethics, thereby demonstrating strong industry commitment to eliminating direct sponsorship across the globe. The statement also reiterates global industry support for the advancement of HCP training and education, for the development of life-saving medical technology, and for the improvement of patient care.

All relevant documents are hosted on the dedicated portal of the [Members Only section](#) of the APACMed Website.

Promoting Regulatory Convergence: APACMed Regulatory Work

Speed to market is a priority for many of our members, as they navigate a multitude of increasingly complex regulatory frameworks across the region. APACMed's work on this front is broadly focused on advocating the convergence of regulatory systems for medical products and devices, in order to improve public safety and patient access to high quality, innovative, life enhancing technologies and products. In 2017, the Association continued to build visibility within international platforms, successfully gaining traction, and establishing itself as a leading, credible industry voice.

APACMed's regulatory work is underpinned by three strategic imperatives:

Establish APACMed as a key partner for fruitful dialogue with Governments across the region

- Over the last two years, APACMed has established itself as a key player on the international scene. APACMed is Industry Coalition Lead, at 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. Thanks to the active engagement of several industry associations, including APACMed, for the first time, APEC RHSC established a new PWA (Priority Work Area) specifically for medical devices; these PWAs had until now be focused almost exclusively on pharmaceuticals.
- At the end of 2016, APACMed also became [Official Liaison Member](#) of the [Asian Harmonization Working Party \(AHWP\)](#), a voluntary group of regulators and industry members, representing 30 Member Economies. Quan Tran continues to hold the position of Vice-Chair (Industry), and the RA Committee Co-Chairs, Carol Yang and Miang Tanakasensum both serve on the Technical Committee . In December 2017, APACMed supported and spoke at the 22nd AHWP Meeting in New Dehli, India.
- APACMed supported and participated in the International Medical Device Conference (IMDC) in August, hosted by MDA in Penang, Malaysia, and had continued to collaborate closely with the ASEAN Medical Device Committee (AMDC) throughout the year.



Left to right: Anju Vaishnav, Roche; Latika Vats, Medtronic; Sushmita Choudary, B Braun, Kirti Arora, Boston Scientific; Carol Yan J&J; Asok Kumar, J&J, Jason Guo, Abbott.

Engage regulators and drive advocacy efforts in key local markets across the region

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

China Centre of Excellence

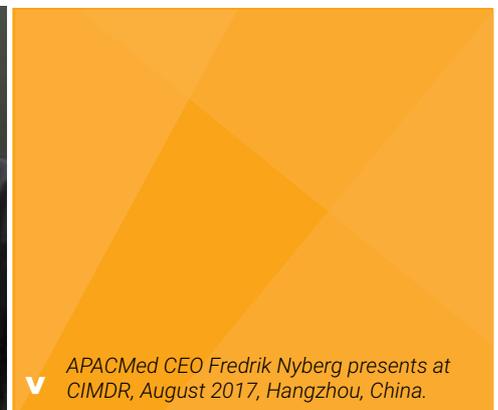
The China CoE is led by Carol Yan, Johnson & Johnson; Ye Guo, BD; Shi Pan, B. Braun, and Victoria Qu, Abbott.

- In 2017, the APACMed China CoE continued its ongoing dialogue with [China Food and Drug Administration \(CFDA\)](#), providing timely feedback to the regulator, as well as its affiliate organisations, on both pre- market and post- market activities; an MoU is expected to be signed in 2018.

- APACMed provided input on the CFDA's overseas medical device inspection, including detailed feedback to the CFDA inspection centre to further improve and standardize inspection processes and requirements. The CFDA issued a Provision for Medical Device Overseas Inspection (Draft for Comments) in December 2017 for comment, which incorporated the feedback from both APACMed and other industry groups. APACMed raised concerns and provided on China's clinical evaluation guidance, most notably for IVD product which are lacking guidance for clinical evaluation pathway. In response to concerns raised by the industry, the CFDA issued, in November 2017, the "Notice on the clinical evaluation document requirement for IVDs exempt from Clinical Trials".
- The group further cemented its relationship with CFDA by engaging the [China Center for Food and Drug International Exchange](#). The former Director General CCFDIE spoke at the Asia Pacific MedTech Forum and the RA Summit in November 2017.
- APACMed supported and spoke at the [8th China International Medical Device Regulatory Forum \(CIMDR\)](#).
- In 2018, the China CoE will be spearheading many new initiatives, including taking part in the annual [International Medical Device Regulators Forum \(IMDRF\)](#), due to take place in March in Shanghai. The CoE's preparatory work for this critical meeting will involve liaising with [Global Medical Technology Alliance \(GMTA\)](#) as well as local industry associations, in order to convey the industry position to the world's medical device regulators.



▲ Right to left: Yongheng CHANG, former Deputy Director of CCFDIE; Bin XUE, Director General of CCFDIE; Fredrik Nyberg, CEO of APACMed; Quan TRAN, RA VP APACMed; Victoria QU (Abbott)



India Centre of Excellence

The India CoE is led by Latika Vats, Medtronic and Asok Kumar, Johnson & Johnson

In collaboration with other industry associations, APACMed continued to foster close ties with the [Central Drugs Standard Control Organization \(CDSCO\)](#) in India, and made significant inroads and advocacy wins in this market.

- After an ongoing advocacy campaign led by APACMed, in October 2017, CDSCO published an office memorandum seeking to provide clarification on importing consignments of Medical Devices & IVD held at Port Offices. APACMed submitted a position paper on the Classification of medical devices and in vitro diagnostic medical devices under the provisions of the Medical Devices Rules, 2017. As a result of this ongoing dialogue, CDSCO have verbally agreed to review proposals, with a view to minimize business impact on the industry.

ASEAN Centre of Excellence

The ASEAN CoE is led by Nishith Desai, Medtronic, and Terry Song, Boston Scientific.

- **Vietnam: Ministry of Health granted a one-year extension on the implementation of Decree 36 for class B, C and D medical devices.**

APACMed led an industry delegation in dialogue with Vietnam Department of Medical Equipment and Construction (DMEC) with regards to the issue of review and approval of applications before the 1st January deadline. The group shared best practices of regulation and transition times from other markets (such as Malaysia, Thailand, Indonesia, Singapore, Korea, EU, and India). DMEC then partnered with APACMed to prepare the documentation for submission to the country's law makers to request for extension on implementation. APACMed closely coordinated its response with EuroCham and other trade associations to ensure that a strong industry voice was heard on this issue.

- **Malaysia: Regulators Extend Moratorium for Medical Device Registrations**

In December 2017, the [Medical Device Authority \(MDA\)](#), made public its decision to grant an extension of an additional 6 months until 30 June 2018, for Full Enforcement on Registration Requirement for Medical Devices under Section 5 of Medical Device Act 2012 (Act 737). APACMed ASEAN COE, in collaboration with AMMI (Association of Malaysian Medical Industries) joined forces and launched an advocacy campaign in order to raise awareness with MDA of the challenges, as well as request an extension. Regulators subsequently invited industry representatives to formally present their concerns at the MDA Board Meeting mid-December, which, ultimately, resulted in the moratorium.

Build capacity across the ecosystem, from regulatory authorities to regulatory functions within medical device companies

Regulatory Strengthening & Capacity Building

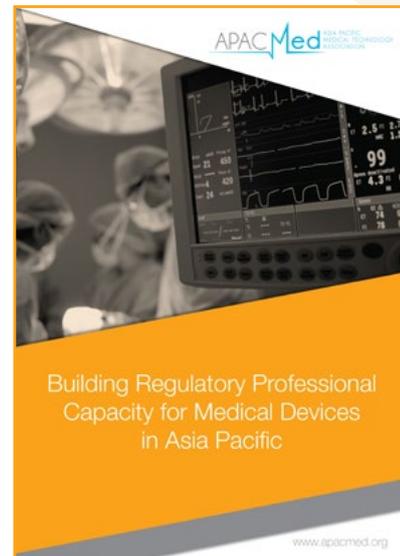
- In October 2017, a joint regulatory training programme was held by APACMed in partnership with the Indonesian Association of [Medical & Laboratory Appliance Enterprises \(Gakeslab Indonesia\)](#) in conjunction with the [5th ASEAN Medical Device Committee Meeting](#), Surabaya, Indonesia. This was attended by 200 participants.
- In November 2017, the 2nd APACMed Regulatory Affairs Summit closed the Asia Pacific MedTech Forum in Singapore, and was attended by 78 participants. The morning session included a number of interactive sessions and panel discussions, whilst a joint APACMed/ CoRE at Duke - NUS round table (by invitation only) was held in the afternoon, bringing together regional regulators including representatives from the China Food and Drug Administration (CFDA), [Korea's Ministry of Food and Drug Safety \(MFDS\)](#), and [Singapore's Health Sciences Authority \(HSA\)](#) and senior members of APACMed.



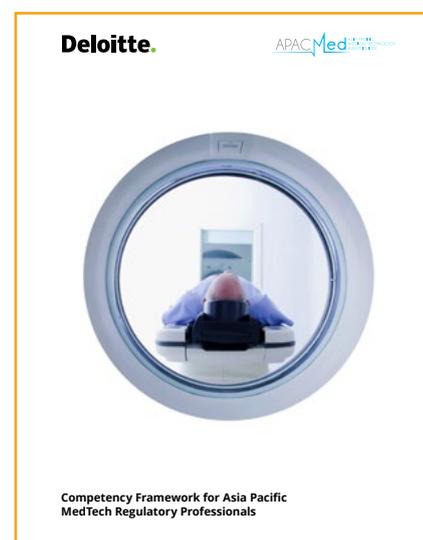
Building Regulatory Capacity for Professionals in the MedTech Industry



- In February 2017, APECMed launched the white paper [“Building Regulatory Professional Capacity for Medical Devices in Asia Pacific”](#). The paper includes a summary of discussions held at the 2016 RA Summit. The report puts forth the steps to progress along the path of regulatory capacity building.
- In July APACMed announced its partnership with Duke-NUS Medical School’s [Centre of Regulatory Excellence \(CoRE\)](#), pledging joint commitment to promote regulatory convergence and capacity building across the region. To this effect, CoRE and APACMed signed a memorandum of understanding (MoU) to foster links and explore opportunities of co-operation in medical technology, with a focus in the areas of capacity building, policy innovation and sustainability.



- The Second RA Summit in November was also an opportunity to launch the joint APACMed/ Deloitte white paper [“Competency Framework for Asia Pacific MedTech Regulatory Professionals”](#). APACMed and Deloitte Consulting jointly conducted surveys on RA capacity building in August 2017 with an aim to define the future direction of regulatory training and development, technology, with a focus in the areas of capacity building, policy innovation and sustainability.



Shaping the Healthcare Policy Agenda: APACMed Advocacy

APACMed's Government Affairs Functional Committee made considerable inroads in key markets this year, and spearheaded a number of successful advocacy initiatives, under the joint leadership of Chris Colwell (BD), Hitendra Yoshi (B.Braun), and Shakilla Shahjihan (Abbott).

India: Price Controls

In 2017, the developments in India galvanised our Government Affairs Committee. Following the decision of the [National Pharmaceutical Pricing Authority \(NPPA\)](#) to adopt a blanket approach to price controls on coronary stents, APACMed sent an official letter to the Chairman, highlighting importance of rewarding innovation and fostering a healthy investment environment to promote access to technologies that improve outcomes, and pointing to the potential adverse consequences of such measures.

- APACMed Trade Mission to India

In May, a delegation of APACMed representatives held a series of high level meetings with a number of GOI officials. In August, further letters were sent to NPPA, following the decision to extend the price control measures to knee implants. APACMed called for the GOI to reconsider its decision to implement price controls on both knee implants and coronary stents, as imposed earlier in the year, and urged the authorities continue the dialogue with the industry to develop sustainable solutions, before initiating any further price control measures.

APACMed also worked closely with Medical Technology of India (MTI) and other industry associations to align and coordinate submissions.



Left to right: Prabhat Jain, Abbott; Hideo Arase, Terumo; Vladimir Makatsaria, J&J; Chris Colwell, Becton Dickinson; Fredrik Nyberg, APACMed; Eric Rugo, Stryker; Dr. Shrvan Subramanyam, Roche; Anand Apte, B.Braun

Malaysia: Halal Certification of Medical Devices

In August, APACMed submitted a formal response to the Malaysian Standards Authority on the proposed draft standard for halal certification of medical devices, expressing its concern on the practicalities of implementation given the complexities of the global supply chain for medical devices, as well as the potential impact on public tendering. APACMed continued its ongoing dialogue with the relevant authorities throughout the year, who seem favourable to reviewing the scope of the standard, which currently extends across the manufacturing process.

China: National Price Negotiations

In coordination with AdvaMed, APACMed reached out to the [Singapore Economic Development Board \(EDB\)](#) and the Ministry of Trade and Industry (MTI), to raise awareness of the notice published by [National Health and Family Planning Commission \(NHFPCC\)](#) in September 2017 regarding the national price negotiations. In this notice, industry was given eleven days to comply with a series of requirements, including providing clinical pricing information which is not readily available, as well as information on production which is considered to be proprietary. Failure to provide the information required in the dedicated timeframe would result in companies being shut out of the Chinese market until further notice.

The Singapore Ministry of Trade agreed to write a formal letter directly to their Chinese counterparts defending the medtech industry, requesting a formal meeting and extended timelines.

Following this joint concerted action, the NHFPCC announced it would be extending the submission deadline to 9 October.

All relevant documents can be found on the [Government Affairs Committee](#) portal of the APACMed website.



APACMed Events

Flagship Events

APACMed Second Annual General Meeting February 2017, Singapore

The 2017 APACMed Board of Directors was elected at our second Annual General Meeting in Singapore. Vladimir Makatsaria, Company Group Chairman, Asia Pacific, Johnson & Johnson Medical Devices Companies, Chairman Johnson & Johnson China, and Anna Maria Braun, President, Asia Pacific & Member of the Management Board, B. Braun Melsungen, B. Braun Medical Industries, will continue to serve in their respective roles as Chairman and Vice-Chairman of APACMed. James Lim, Executive Vice President and President, Greater Asia at Becton Dickinson, is appointed Treasurer.

We welcome three [new Directors](#) elected to the Board; full details are available on the APACMed Website.

- **Graham McLean**, President, Stryker Asia Pacific
- **Massimiliano (Max) Colella**, Senior Vice President Asia Pacific, Smith & Nephew
- **Ian Burgess**, CEO, Medical Technology Association of Australia (MTAA)



Left to right: Max Colella, Smith & Nephew; James Lim, BD; Supratim Bose, Boston Scientific; Vladimir Makatsaria, J&J; Harvinder Singh, Abbott; Bob White, Medtronic; Hideo Arase, Terumo; Graham McLean, Stryker. McLean, Stryker.

Absent: Anna Maria Braun, B. Braun; Eric Van Oppens, Alcon; Ian Burgess, MTAA.



2017 Asia Pacific MedTech HR Summit, June 2017, Singapore

The second Asia Pacific MedTech HR Summit, co-hosted by talent partner Korn Ferry brought together over 50 senior human resources leaders and other delegates, under the theme [“Rising to the MedTech Challenge: Building a Sustainable Talent Pool in Asia Pacific”](#).

The event, opened by Fredrik Nyberg, CEO, and Vladimir Makatsaria, Chairman, featured insightful presentations:

- **Value Based Healthcare: A Transformation from Providing Care to Managing Health**
 - Hocking Cheng, Managing Director, APAC, International Population Health, Aetna.
- **Facebook & Business Innovation**
 - Sandhya Devanathan, Country Director, Singapore; Regional Lead E-Commerce, Travel & Financial Services Facebook.

The [summary report](#) as well as selected presentation slides are available on the Member Resources section of the APACMed website.



KORN FERRY
Recruitment • Training • Retention

2017 Asia Pacific MedTech HR Summit
Event Highlights

Thank you for joining us at the second edition of the Asia Pacific MedTech HR Summit jointly organized by Asia Pacific Medical Technology Association (APACMed) and Korn Ferry.

Under the theme “Rising to the MedTech Challenge: Building a Sustainable Talent Pool in Asia Pacific”, the event brought together over 70 attendees comprising of business leaders and senior HR practitioners from 27 leading organizations.

Featuring 9 sessions and 14 speakers and panelists, the summit addressed critical areas such as value-based healthcare, innovation, capacity building, organizational agility, culture transformation and understanding the millennial workforce.

We hope you have enjoyed the discussions and had the chance to network among your peers and look forward to seeing you again soon!

Best Regards,
Fredrik Nyberg
CEO
APACMed

Gladly He
Senior Client Partner
Korn Ferry

APACMed
ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

EVENT DETAILS

- Date: Tue, 20 June 2017
- Venue: Pullman Hotel Singapore

Event Statistics

- 70 Attendees
- 27 Leading Organizations
- 14 Speakers & Panelists
- 9 Sessions

MedTech SME Workshop, September 2017, Singapore

APACMed's third annual MedTech SME Workshop, attended by over 100 delegates, specifically targeted medical device and IVD start-ups, digital health ventures, mid-sized MedTech R&D and manufacturing businesses, as well as research institutes, investors and service providers.

Programme highlights included:

- Developing a Strategic Marketing Plan for your Medical Device
- Manufacturing Challenges Facing Start-up Device Companies
- ASEAN Medical Device Directive Implementations and Singapore Update
- MedTech Product Design & Development – Enhancing Efficacy and Outcomes with Empathy and Technology
- IP Protection for Medical Devices in Asia Pacific
- Investment into MedTech & Digital Health in Asia
- Building Successful MedTech Distribution Channels

The full programme, list of [speakers and photos](#) are available on the APACMed website.



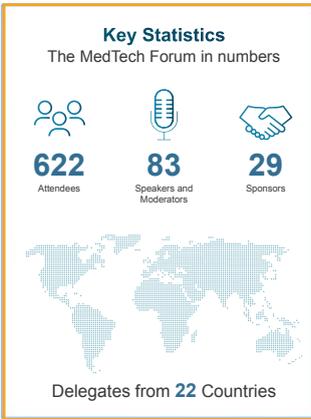
Investment into MedTech & Digital Health in Asia Panel

Left to right: Erwan Barre, Partner (Foreign Lawyer), RHTLaw Taylor Wessing, CJ Chen, Head of Strategic Initiatives, Emerging Asia, Baxter Healthcare; Philip Kowalczyk, Senior Director, New Business Development Johnson & Johnson Medical Asia Pacific; Ong Jeong Shing, Investment Director, Venturecraft; Colin Tan, Chief Operating Officer, EndoMaster



2017 Asia Pacific MedTech Forum, November 2017, Singapore

The third edition of the Asia Pacific MedTech Forum, under the theme [“Transforming Healthcare through Innovation”](#) was held from 9-11 November, at the Star Performing Arts Theatre in Singapore.



This year, we are proud to report that the Forum brought together record 622 attendees, from 22 countries including senior medical device executives, regulators, policy makers, healthcare providers, payers and governments representatives.

This year's theme allowed us to explore the multiple facets of innovation within the healthcare ecosystem in our region. Indeed, the accelerating pace of technological advancement, from artificial intelligence and augmented reality, to mobile health and big data, is profoundly transforming the global healthcare landscape. The scale and speed of change across the entire healthcare value chain is unprecedented. As disruptive technologies are emerging across the region, innovative models of care delivery are also challenging traditional practices, propelling MedTech players to rethink their business models, and forge new partnerships to deliver the best patient outcomes.

This year's programme counted 83 speakers including:

- Dr Yasuhiro Suzuki, Chief Medical & Global Health Officer and Vice-Minister for Health, Ministry of Health, Labour and Welfare (MHLW), Japan
- José (Joe) E. Almeida, Chairman, President & Chief Executive Officer, Baxter International
- Michael F. Mahoney, Chairman and Chief Executive Officer, Boston Scientific
- Scott Huennekens, CEO Verb Surgical
- Dr Simon Kos, Chief Medical Officer, Microsoft
- Rahul Khosla, Chairman Max Healthcare Hospital Group, India
- Runa Khan, Founder and Executive Director, Friendship (Bangladesh)
- Roberta Lipson, Founder & CEO of United Family Healthcare, China

The feedback from attendees was exceptional: 88% of post-event survey respondents rated the plenary sessions Good, Very Good or Excellent.

The Conference [Highlight Report](#) and the [Highlights video](#) are now available on the APACMed website.



Left: José (Joe) E. Almeida, Chairman, President & Chief Executive Officer, Baxter International

Right: Michael F. Mahoney, Chairman and Chief Executive Officer, Boston Scientific



Members Events & Networking

Members Breakfast co-hosted by Deloitte: “Technology Disruption in Global Healthcare: Implications for the MedTech Industry”, May 2017, Singapore

- Christopher Park, Partner and Life Science Sector Leader, Deloitte Consulting, U.S., provided an overview of the major trends shaping the industry.

Following this event, Deloitte and APACMed hosted the **1st APACMed CIO Round Table**, bringing together the Chief Information Officers and IT leaders from APACMed Corporate Members. The objectives were two-fold:

- Bring together Regional MedTech IT Leaders to reflect upon their critical role, and discuss challenges and opportunities resulting from unprecedented technological change impacting the industry
- Identify common interests with a view to creating an APACMed Working Group/ Functional Committee.



Members Networking event co-hosted by McKinsey, July 2017, Hong Kong

- Franck Le Deu, Head of China Healthcare Practice gave a presentation on “China Healthcare and MedTech Trends”. Over 40 members attended, including Board representatives of [Hong Kong Medical & Healthcare Device Industries Association Limited \(HKMHDA\)](#).

Members Breakfast Event, co-hosted by QuintilesIMS “Impact of Changes in Global Medical Device & Diagnostics Regulations”, August 2017, Singapore

- “FDA Insights: Update on Medical Device Approvals”, Christopher M. Sloan, Principal Consultant, QuintilesIMS (USA)
- “The new EU MDR: changes & Implications”, Caroline Freeman, Principal Consultant, QuintilesIMS (UK)

Digital Health Workshop, co-hosted by PWC, August 2017, Singapore

- This one-day workshop addressed global and regional trends in Digital Health, as well as engaged in discussions around the following themes
 - > Executing a Digital Strategy while Managing Regulatory and Cybersecurity Constraints
 - > The Impact of Cybersecurity on Growth and Commercial Strategy
 - > The hands-on workshop included a combination of panel discussions as well as interactive breakout sessions, facilitated by PwC’s South East Asia Healthcare and Cybersecurity Leads. The opening address was given by Dr Eugene Soh, CEO of Tan Tock Seng Hospital (TTSH) in Singapore.



Webinars



Date



Webinars



Attendees

Date	Webinars	Attendees
March 2017	<p>Hosted by the Medical/Clinical Affairs Committee: "Medical Device Registries across Asia Pacific: Introduction and Overview"</p> <p>Hosted by McKinsey/Ropes & Gray: "China's Two Invoice System: Overview and Impact on the MedTech Sector"</p> <p>Hosted by the RA Committee: "India's New Medical Device Rules: Impact and Outlook for the Medical Device Industry"</p>	34 64 58
April 2017	<p>Hosted by the Medical & Clinical Affairs Committee: "Medical Device Registries: Guidelines and Future Directions"</p>	46
July 2017	<p>Hosted by the APACMed RA Committee and Korean Ministry of Food and Drug Safety MFDS, including Director General Dr. HeeKyo Jeong, and other senior officials: "Korean Medical Device Regulatory System: Introduction and overview"</p>	103
August 2017	<p>Hosted by the Legal/ Ethics & Compliance Committee: "Implications of the Code Revisions for Members and HCPs"</p>	125

APACMed Engagements



January	Singapore	APACMed CEO speaks at Asia PCR – Innovators Day
February	Singapore	2nd APACMed Annual General Meeting
March	Kuala Lumpur, Malaysia	APACMed CEO speaks at Association of Malaysian Medical Industries (AMMI) Progress Meeting
	Seoul, South Korea	APACMed CEO attends KIMES Korea exhibition and conference Meetings held with the Chairman of Korean Medical Devices Industry Association (KMDIA), multiple prospective members, and senior executives from some APACMed Corporate Members
	Singapore	APACMed CEO joins the Project Evaluation Panel of experts for the Innovation to Commercialisation (I2C) Programme at the National Health Innovation Centre (NHIC), Singapore.
April	Singapore	APACMed holds first Virtual Townhall for members
	Singapore	APACMed CEO speaker at Asia Health 2017 Exhibition & Conference, on two topics: “The Future of Medical Technology” and “MedTech Distribution in Asia Pacific – Changing Commercial Models”.
	Tokyo, Japan	APACMed signs Memorandum of Understanding with Japan Federation of Medical Devices Association (JFMDA)
May	Singapore	Meeting at APACMed Office with delegation from Margolis Centre for Public Health Policy, Duke University
July	Singapore	APACMed co-hosts “MedTech Connect” networking event
	Singapore	APACMed CEO speaks at “Icons of Healthcare” conference
	Hong Kong	APACMed hosts first members’ networking event outside Singapore, in collaboration with McKinsey
August	Penang, Malaysia	APACMed supports and participates in the International Medical Device Regulatory Forum hosted by MDA
	Hangzhou, China	APACMed supports and presents at CIMDR (China International Medical Device Regulatory Forum)
	Ho Chi Minh City, Vietnam	APACMed VP RA represents APACMed and the medical device industry at APEC RHSC (Regulatory Harmonization Steering Committee).
	Singapore	APACMed CEO meets Malaysia Investment Development Authority (MIDA)
September	Singapore	APACMed presents at EU trade mission event to approximately 50 European medtech SMEs
	Hanoi, Vietnam	Strong representation from APACMed, including Legal/Compliance Committee, at the 4th APEC Business Ethics for SMEs Forum
	San Jose, USA	APACMed CEO attends the GMTA (Global Medical Technology Alliance) APACMed CEO speaks on EY Asia Pacific Panel at AdvaMed Conference
October	Surabaya, Indonesia	APACMed in partnership with the Indonesian Association of Medical & Laboratory Appliance Enterprises (Gakeslab Indonesia) holds joint regulatory training programme in conjunction with the 5th ASEAN Medical Device Committee Meeting
December	Sentosa, Singapore	McKinsey-facilitated Strategy Meeting for APACMed senior leaders of Corporate Members.

Membership Categories

	Description
Corporate Members	Companies manufacturing and conducting R&D in innovative medical equipment, devices or in vitro diagnostics.
Industry Association Members	National associations representing the interests of the medical technology industry in any country in Asia Pacific.
Associate Members (non-voting)	Service providers (e.g. consultants, CRO's, recruiters), investors, distributors, contract manufacturers.
Small & Medium Enterprise (SME) Members (non-voting)	Companies manufacturing and/or conducting R&D in medical technology with annual sales less than US\$ 50 million.

Benefits of Membership

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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.
- 

Join regular workshops, seminars, CEO Roundtables and other networking events.
- 

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

Demonstrate your commitment to the highest standards of ethics by signing on to our industry Code of Conduct that guides ethical interactions with healthcare professionals.
- 

Benefit from exclusive market insights and analysis from APACMed Knowledge Partners.
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Receive timely information providing early warning about regulatory and policy developments in the region and guidance on how to deal with them.
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Participate in the annual Asia Pacific MedTech Forum, the industry's most impactful gathering of people and ideas in the region.
- 

Stay informed – Receive the APACMed Members-only e- Newsletter.
- 

Access extensive resources on our Members-only section on the website.
- 

For SME's – Benefit from networking with your much larger industry peers. Join tailored workshops on IP protection, regulatory strategy, capital raising, commercialisation, market entry and more.
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Get special rates on registration for APACMed events, including the annual MedTech Forum conference.
- 

Join to shape the association, the industry and the future of healthcare in Asia Pacific.
- 

Display you organisation's logo on the APACMed web site.

APACMed Members

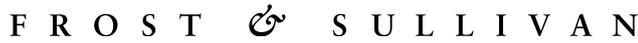
CORPORATE MEMBERS



SME MEMBERS



ASSOCIATE MEMBERS



INDUSTRY ASSOCIATIONS



APACMed Secretariat

Fredrik Nyberg, Chief Executive Officer

Quan Tran, VP Regulatory Affairs

Gabriel Sim, Business Development Director

Emilie Rapley Mills, Communications Manager

Clement Chung, Operations Manager

WenLi Cai, Executive Assistant

Partners

Knowledge partner: McKinsey & Co.

Talent Partner: Korn Ferry

Auditor: RSM Chio Lim LLP

Tax Advisor: Deloitte & Touche LLP

Corporate Secretary: Dentons Rodyk & Davidson LLP

Public Relations: Spurwing Communications

SAVE
THE
DATE

ASIA PACIFIC
MEDTECH
FORUM
2018

9 – 11 October 2018

Suntec Singapore International
Convention and Exhibition Centre

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