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White Paper

ACCELERATING MARKET ACCESS FOR A MATURING MEDTECH INDUSTRY IN APAC

Eliza Chong, Management Consultant, MedTech, Asia Pacific, IQVIA

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FOREWORD

As Asia Pacific continues to undergo unprecedented demographic changes, the need for a holistic approach to transform healthcare delivery has never been greater. Addressing the growing demand for healthcare in a fragmented region with disparate regulatory regimes, complex reimbursement systems, and conflicting policy priorities, requires a different kind of innovative thinking from all stakeholders across the MedTech ecosystem.

This paper, Accelerating Market Access for a Maturing Medtech Industry in APAC, published in collaboration with IQVIA, the Asia Pacific Medical Technology Association (APACMed), with significant contributions of key executives from the industry, aims to provide the context to this evolving environment, as governments continually strive to improve access to healthcare by fully leveraging the value of health technologies.

The paper shares rich insights into creating market access enabled organisations. Market access can no longer be understood through the narrow lens of pricing and reimbursement, without taking into consideration other elements such as regulatory, supply chain & channels, training & education, stakeholders & KOL management and financing. Thus, market access is defined here as "bringing of products or solutions to the right patient at the right price points in a timely manner through the efficient enablement of registrations, reimbursement, listing, training and supply".

To successfully achieve this, policymakers, payers, patient advocacy associations, healthcare workers, hospital administrators, academia, service providers, and medical technology players need to collaborate differently to solve the region's common health care challenges. Partnerships are at the heart of APACMed's patient centric mission, and the Association engages with all stakeholders to raise awareness of, and advocate evidence-based policies that meet the demands of diverse and complex healthcare markets in Asia Pacific.

MedTech players are continually challenged to rethink and transform their business models, to adapt to an increasingly complex and heterogenous regional landscape, whilst trying to harness the potential of disruptive innovations, in their endeavour to address vast unmet patient needs.

The findings presented in this report are informed by meaningful discussions held during a joint IQVIA and APACMed in August 2018. We are indebted to both the IQVIA Team for preparing the report, and to the many other contributors for sharing their time and perspectives.

Fredrik Nyberg, Chief Executive Officer, Asia Pacific Medical Technology Association

About APACMed

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 harmonisation. APACMed engages with medical device associations and companies in Asia Pacific to jointly advance regional issues, code of ethics and share best practices.

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

DEFINING MARKET ACCESS

Changing landscape of Asia medtech market

Regardless of category types, the de facto go-to-market entry strategy for a medtech company large or small, had mostly been to hire a local distributor to take on the standard service output demands of availing products to market while they focus on larger (and more attractive) markets and R&D activities.

These distributors are commonly chosen for their knowledge and experience in the specialty, ability to provide clinical services (such as scrub-ins), positive relationships with KOLs and rarely for their business and operational savviness. This results in less than ideal situations when the company desires to scale or invest in the markets through alternative means or other more direct form of involvement which tends to be construed suspiciously and met with resistance when they feel that their control is threatened.

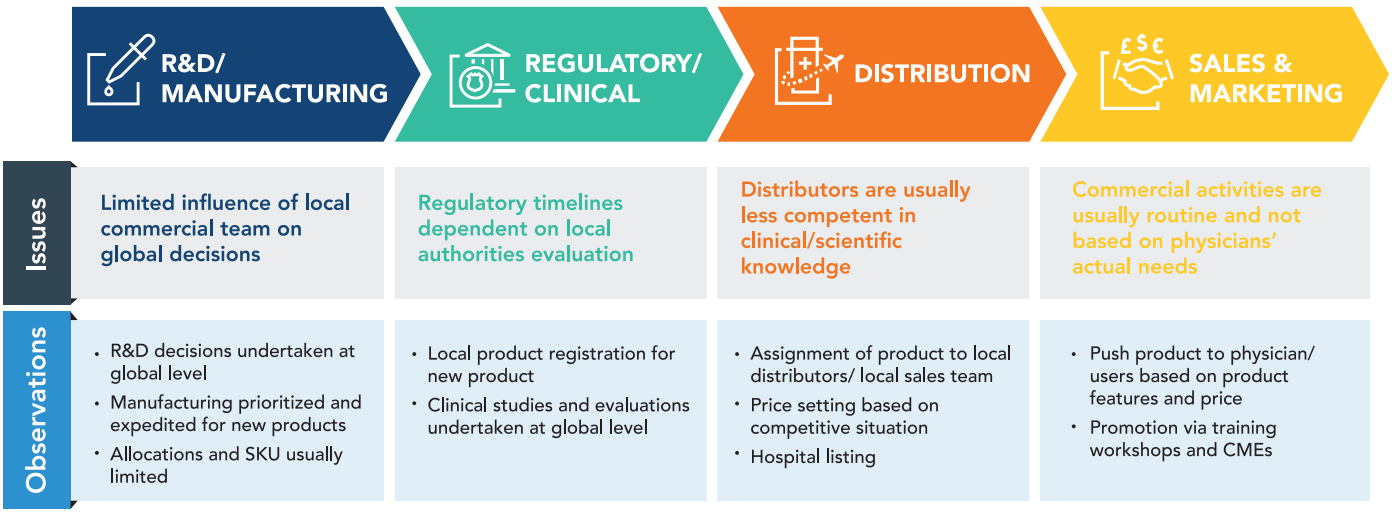
As it is with this conventional business model, other functions also tended to take a western or larger market-centric focus. This is seen with R&D, Clinical, Regulatory and Supply Chain functions which operates out of the global business units and are often resourced to meet the needs of the home country and other markets with more promising potential. Most of Asian markets (with the exception of Japan and Australia) then, became used to a deprioritized status having to resort to creative solutions or scream for support and being met with suboptimal assistance at best.

Current ways of managing business is inadequate

With rise of China and other Asian economies, companies are now pivoting towards the region attracted to its high growth and underserved markets. Countries too, are introducing ever more sophisticated ways of regulating the industry and delivering care to its population in a cost effective and beneficial level, focusing on outcomes and healthcare spending like never before.

While regulators and assessment bodies had been more placid with medtech sector compared with pharmaceuticals, they are now providing specialized routes for the evaluation and regulations of technologies and taking cues and guidance from more mature countries. This was evident when recently established HTA agencies in Singapore and Malaysia joined the ranks of Australia, Thailand, Taiwan, South Korea while the rest of the region have publicly expressed their intentions to do the same.

Fig 1. Limitations in conventional model of bringing products to market in Asia



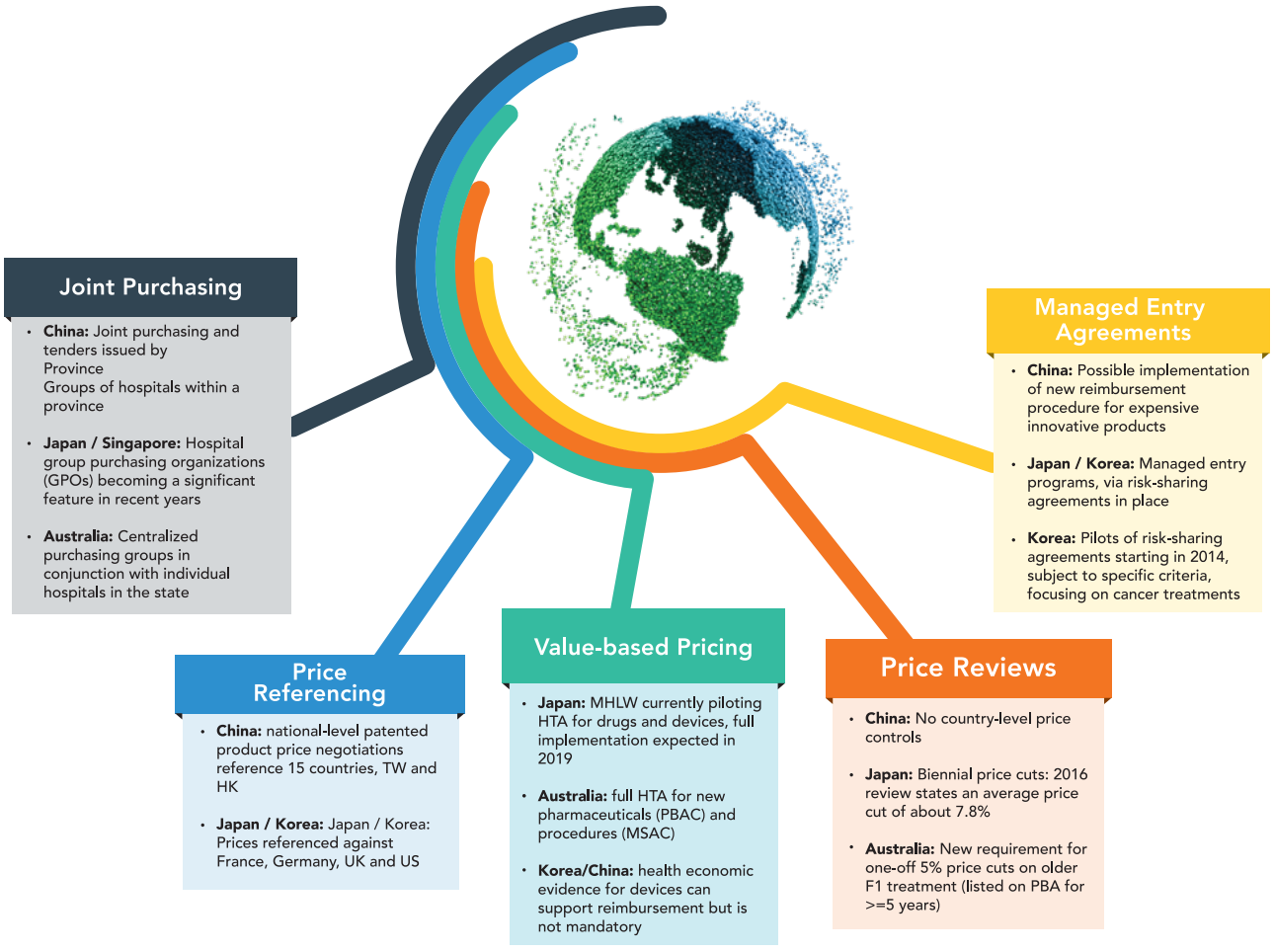
Policies and Pricing trends

Throughout Asia, healthcare budgets are getting strained due to a common aspiration to provide greater care across this highly populous region.

In Indonesia, the Badan Penyelenggara Jaminan Sosial (BPJS) was introduced with a goal to achieve universal healthcare coverage by 2019[1]. Such policies are driving public expenditure significantly upwards. In a bid to reduce the healthcare spending, the government introduced the e-catalog online procurement system in 2015 which is managed by the Services Procurement Policy Institution (LKPP). It aims to improve efficiencies, reduce costs and prevent corruption by listing goods and services online, while also providing buyers the full list of prices, suppliers and contractors[2].

Changes in policies are observed even in developed reimbursement markets. This was the case when South Korea, a key market for most medtech companies in Asia, announced to implement 'Mooncare', a policy introduced by President Moon Jae-In which aims to expand reimbursement coverage to from 63.4% in 2015 to 70% by 2022. It cites reduction of costs to patients as a main objective by introducing an expanded national health care service through 2022 for 3,800 non-covered treatment categories (where patients have previously been responsible for all costs), such as including magnetic resonance imaging (MRI) scans, robot surgery, and two-person hospital rooms. The plan was part of measures to expand health insurance coverage announced by Moon on 9 August 2017[3].

Fig 2. Pricing pressures in region reflecting global pricing policy evolution and local budgeting[1]



Such a populist policy, which may spell some positive news for manufacturers, is nevertheless causing additional strains on an already heavily burdened budget.

As an industry matures and technologies become more ubiquitous, pricing becomes more elastic. This is why MNCs, already facing fierce competition from lower cost local manufacturers, are eager to manage price erosions liberally doled out by the authorities.

From the perspective of the payer, various challenges are affecting its ability and willingness to pay:

- Increase in ageing population leading to higher number of patients to care for
- Availability and adequacy of insured population still not at optimal levels
- Introduction of new technologies - digital health and infrastructural developments required
- International reference pricing becoming easier due to improved communications and globalization
- The advent of Value/ Outcome based healthcare

Third-party payers (both private and government programs) are keen to re-evaluate their payment policies to constrain rising healthcare costs expected to limit reimbursement growth for hospitals, which form the largest market for medical devices. Such practices will likely persuade hospitals to scrutinize medical purchases by i) adopting higher standards to evaluate the benefits of new procedures and devices, and ii) taking on a more disciplined price bargaining stance[4].

Fig 3. Policy trends impacting pricing of medical devices and technologies

	APAC OUTLOOK	LIKELY PRICING IMPACT
Joint Purchasing	Group purchasing and tendering will increase among payers, geographies and hospitals	↓ Downward pressure on all products
Price Referencing	References to other markets will increase for new and exisiting products as global price transparency increases	↓ Generally downward pressure on most products
Value-based Pricing	Cost-effectiveness and HTA will increasingly be required and incorporated into pricing and reimbursement evaluation	↔ Some products may justify higher pricing reducing total treatment costs
Price Reviews	Price reviews will increase in rigor and frequency, with low-cost treatment applying pressure on innovative technologies	↓ Downward pressure on innovative products
Managed Entry Agreements	Agreements gaining traction for expensive treatements such as novel/HDE devices and cancer treatments	↔ Some products may enter markets faster but may face restrictions

Definition of market access and why it matters

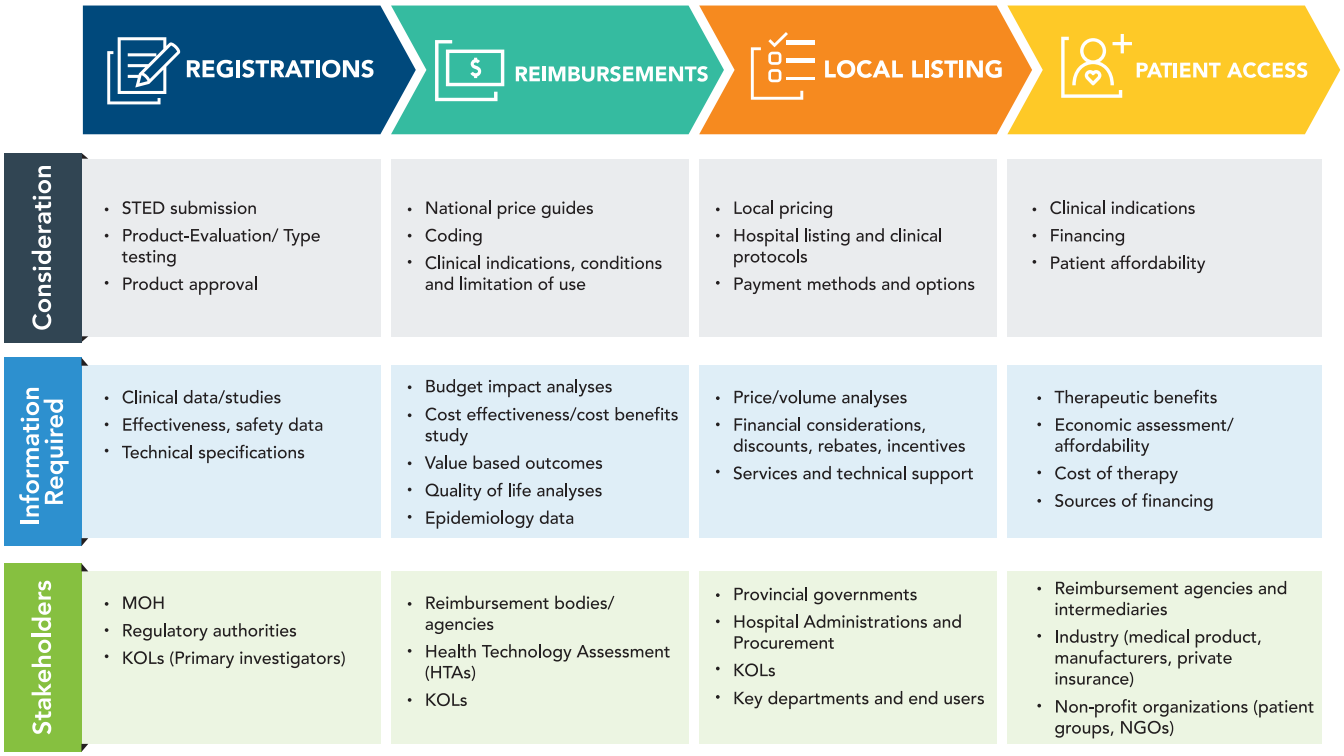
Health Economics is a scientific discipline that aims to improve the health of populations through the efficient use of public healthcare resources. It compares health technologies on the basis of value for money by considering their long-term clinical and economic impact. Some commonly performed evaluations are Budget Impact Analysis and Cost Effectiveness Analysis.

Market access has previously been more focused on pricing and reimbursement. However, driven by the ever-changing healthcare macro-environment, the move from price-based to value-based approaches and companies developing more unconventional business models, other elements such as regulatory, supply chain & channels, training & education (beyond physicians), stakeholders & KOL management and financing are becoming increasingly relevant. (Refer to Fig 4)

Therefore, market access can be simplistically defined by the bringing of products or solutions to the right patient at the right price points in a timely manner through the efficient enablement of registrations, reimbursement, listing, training and supply. These must be done through early and active engagement of stakeholders at each stage of the market access process by addressing their concerns and meeting their needs.

Market Access is defined by the bringing of products or solutions to the right patient at the right price points in a timely manner through the efficient enablement of registrations, reimbursement, listing, training and supply.

Fig 4. Overview of market access requirements and stakeholders



STAKEHOLDERS AND THEIR NEEDS

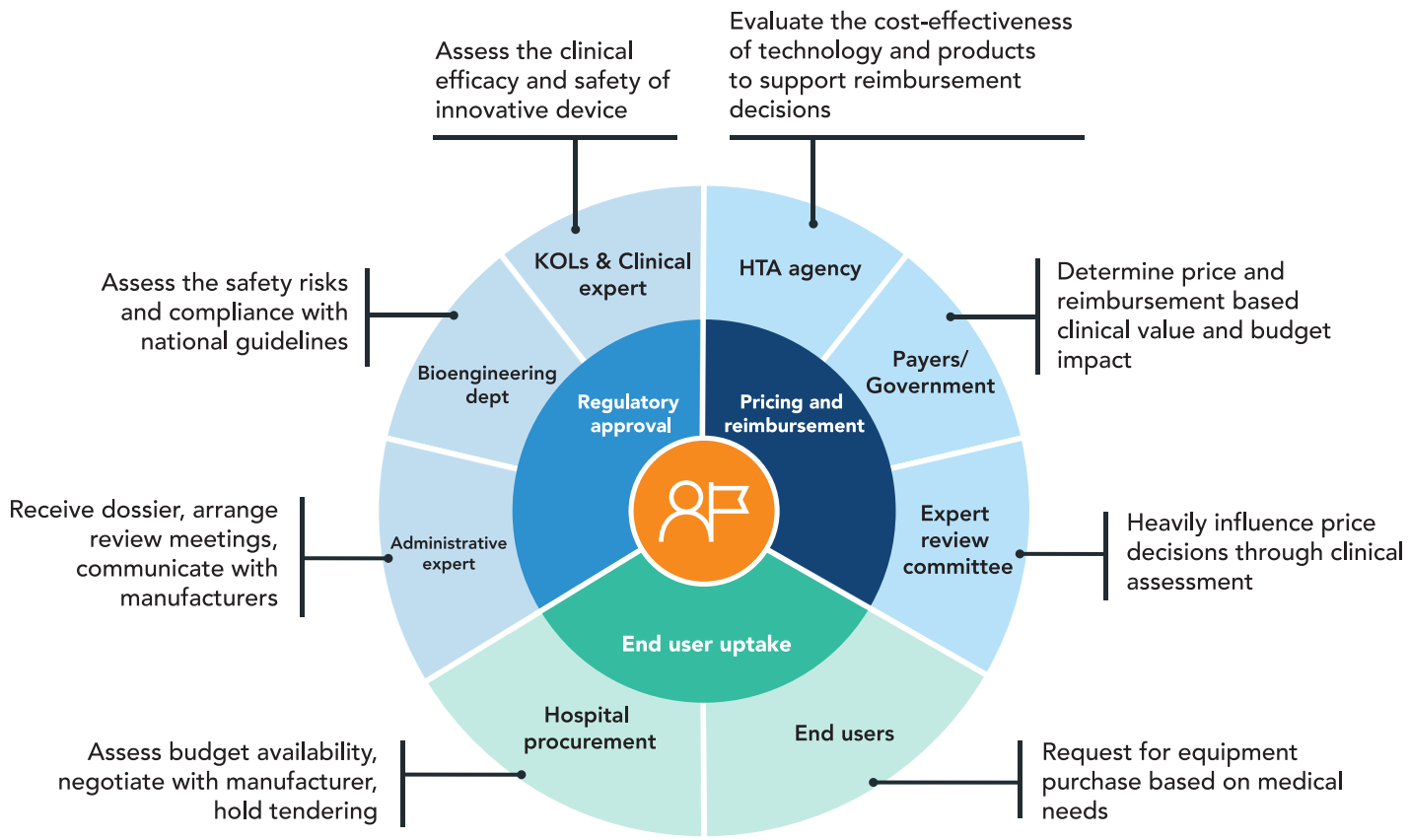
Multiple stakeholders leading to fragmented decision making

Early in the process, regulators are preoccupied by clinical evidence while reimbursement bodies are concerned about healthcare budget impact and KOLs by the availability of the latest technologies and products to treat patients. The extent of each stakeholders' needs can vary substantially, and they will require very different manner of engagement as well as provision of tools to meet their criteria.

It is thus becoming inappropriate to apply outdated business and market engagement models to this dynamic Asia market landscape. Companies will need to realize that the days of hiring a full service distributor that is able to manage their business in its entirety is getting harder to find and that in order to win, they will have to develop a robust strategy ahead to engage better across a larger pool of stakeholders locally as power shifts had occurred and decision making is becoming fragmented.

In this new market access environment, a sample of stakeholders include the government (or Health Ministries/ Departments), regulatory authorities, HTA and Reimbursement bodies, KOLs, hospital administrators, procurement and tender departments, professional clinical societies and patient groups. (Refer to Fig 5) All of whom have their own unique concerns and performance indicators. The decisions they make independently will overlay into confined potential for companies.

Fig 5. Stakeholders and their unique roles in market access



Manufacturers will have to be accustomed to engaging with stakeholders in an iterative manner before, through and post- commercialization to reap the benefits that come with a sustained market access strategy:

Early engagement (pre-commercialization)

- Allows adequate mapping of stakeholders' needs and expected outcomes
- Seek payers' input to maximize understanding and acceptance
- Execute effective and compelling value propositions to increase probability of favorable outcomes
- Understanding payer perceptions and work with reimbursement
- Understanding the market access challenges and incorporating such thinking early to drive product innovation and development may be advantageous

Maintaining and improving access (post-commercialization)

- Provide additional evidence and information to support supply and price
- Consider value adding through innovative partnerships or services
- Expansion of indications to access higher volume of patients
- Reducing access restrictions or limitations of use
- Work with academia to develop guidelines and evidence

Another aspect to consider are patients who possesses buying power in some markets such as China and India where the practice of balanced billing is permitted. Also, in South Korea, nuanced payments in which patients pay full freight for non-reimbursed products are allowed. This type of cost-sharing billing changes the dynamics of pricing from a company's perspective.

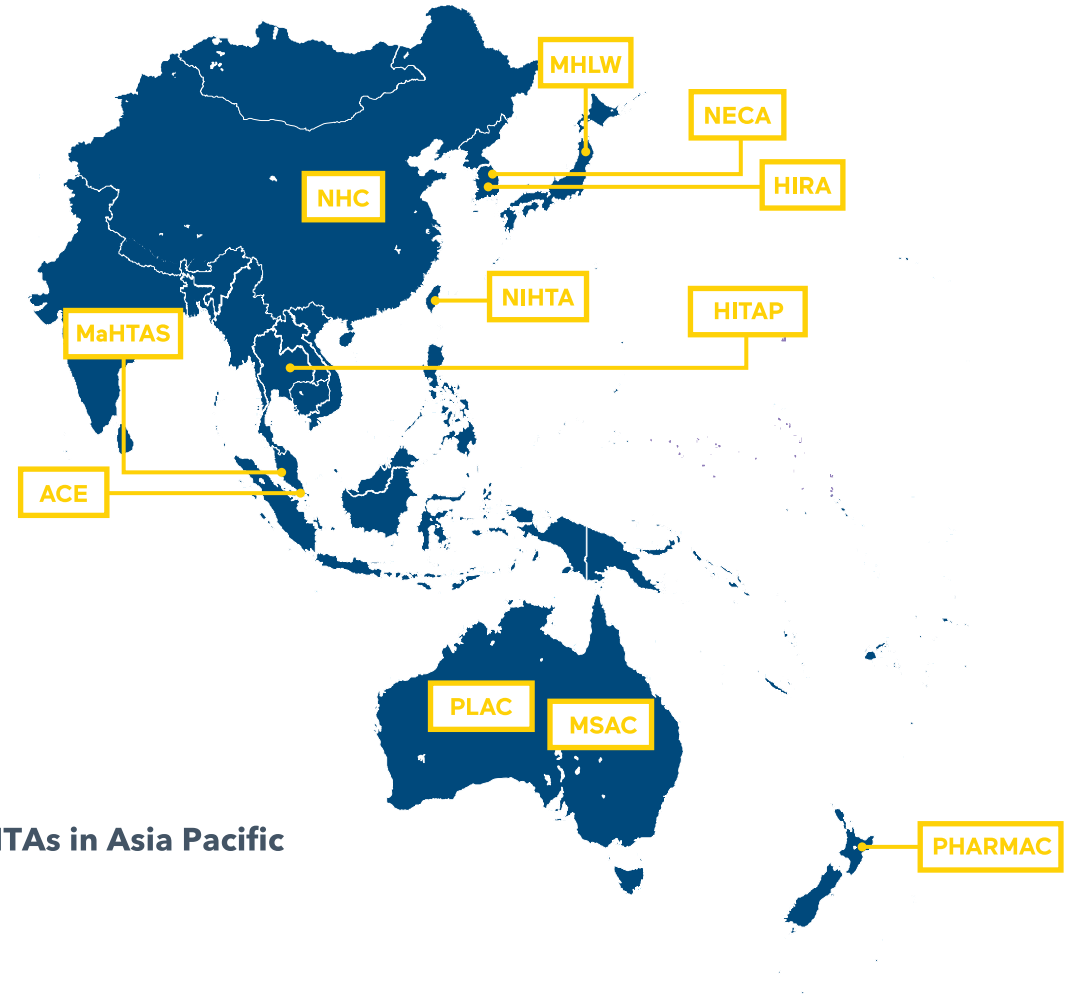


Fig 6. HTAs in Asia Pacific

The rise of HTAs in Asia Pacific

In recent years, many countries have established Health Technology Assessment (HTA) agencies to study the value of programs and services to be included in universal healthcare programs as well as new therapies as part of their reimbursement decision making process. While most of the activities thus far have been concentrated which services to add to benefit packages and on pharmaceuticals, extension to device-based procedures is inevitable.

A prime illustration of a well organized HTA is the HiTap of Thailand. It has been in operations since 2007 and widely recognized as a sophisticated model that has been consulted and studied by its neighbors in Indonesia and Singapore. It is even contracted with India. However, its maturity also limits industry engagement at the current moment as most policies of the evaluation of services/ drugs or devices before their addition to benefit packages are already firmly in place. Another illustration of this is the recent recommendation in Singapore in which the newly established HTA body (Agency for Care Effectiveness), together with The MOH Medical Technology Advisory Committee, considered the evidence presented for the technology evaluation of bilateral cochlear implants for children with severe-to-profound sensorineural hearing loss in both ears. ACE conducted the evaluation in consultation with an MOH expert working group comprising clinicians, audiologists, medical social workers, and educators[5]. This marks the first recommendation for a non-drug treatment in Singapore which is likely to extend to other devices in future. It also provides a glimpse into the multi-disciplinary approach in a disciplined evaluation process.

Table 1: Snapshot of Health Tech Assessment Bodies in Asia[6,7,8,9,10,11,12,13,14,15,16,17,18,19,20]

Country	HTA	Established	Sectors	Evidence and Data Required	Reimbursement
Australia	MSAC	1998	New procedure codes	• CEA • Different evidence may be required for by the different organizations for their respective assessments • Comparative effectiveness • BIA	Different schemes available for different therapeutics
China	NHC	2018	-	-	Only devices approved by CFDA can be reimbursed
Japan	In progress	-	-	-	-
Korea	NECA	2009	Rx + MDD	• Comparative effectiveness	Reviewed by HIRA
Singapore	ACE	2015	Rx + MDD	• CEA • BIA	Different factors such as clinical needs and overall benefit are considered
Taiwan	NIHTA	2013	Rx + MDD	• CEA • BIA • Comparative effectiveness information/ clinical trial results (no requirements for comparative data or source of data)	Reviewed by BNHI
Thailand	HiTAP	2007	Rx + MDD	• CUA • CEA • CBA	

Legend: BIA: Budget-Impact Analysis; CBA: Cost-Benefit Analysis; CEA: Cost-Effective Analysis; CUA: Cost-Utility Analysis; - : unavailable information

Definition of HTA is still inconsistent across the region.

HTA informs transparent and evidence-based decision making. Some key features of a good HTA system include:

- HTA (value for money) shouldn't be the only criteria for reimbursement: other key considerations include unmet clinical need, efficiencies, budget impact etc.
- There are important differences between HTA for drugs and devices which should be recognized (and often are not)
- A good HTA process is transparent with clear guidelines, reasonable timelines and multiple opportunities for clinical, patient, and industry input

For effective value-based discussions to occur, companies will have to identify each group of stakeholders and understand their dilemmas in order to engage them effectively with value-based rather than cost-based propositions.

Fig 7: Key Principles for HTA Process[23]

1. Allow "coverage with evidence" or "funding with evidence"
2. Clearly defined roles: HTAs vs. coverage funding decisions vs. clinical guideline
3. Clear evaluation methods and submission guidelines
4. Multiple opportunities for public input
5. Transparency of decision making
6. Recognize distinctions between drugs and devices
7. Use all types of evidence... not simple RCTs
8. Opportunity to "appeal" decision drugs and devices
9. Periodic reassessment
10. Confidentiality of comparing data

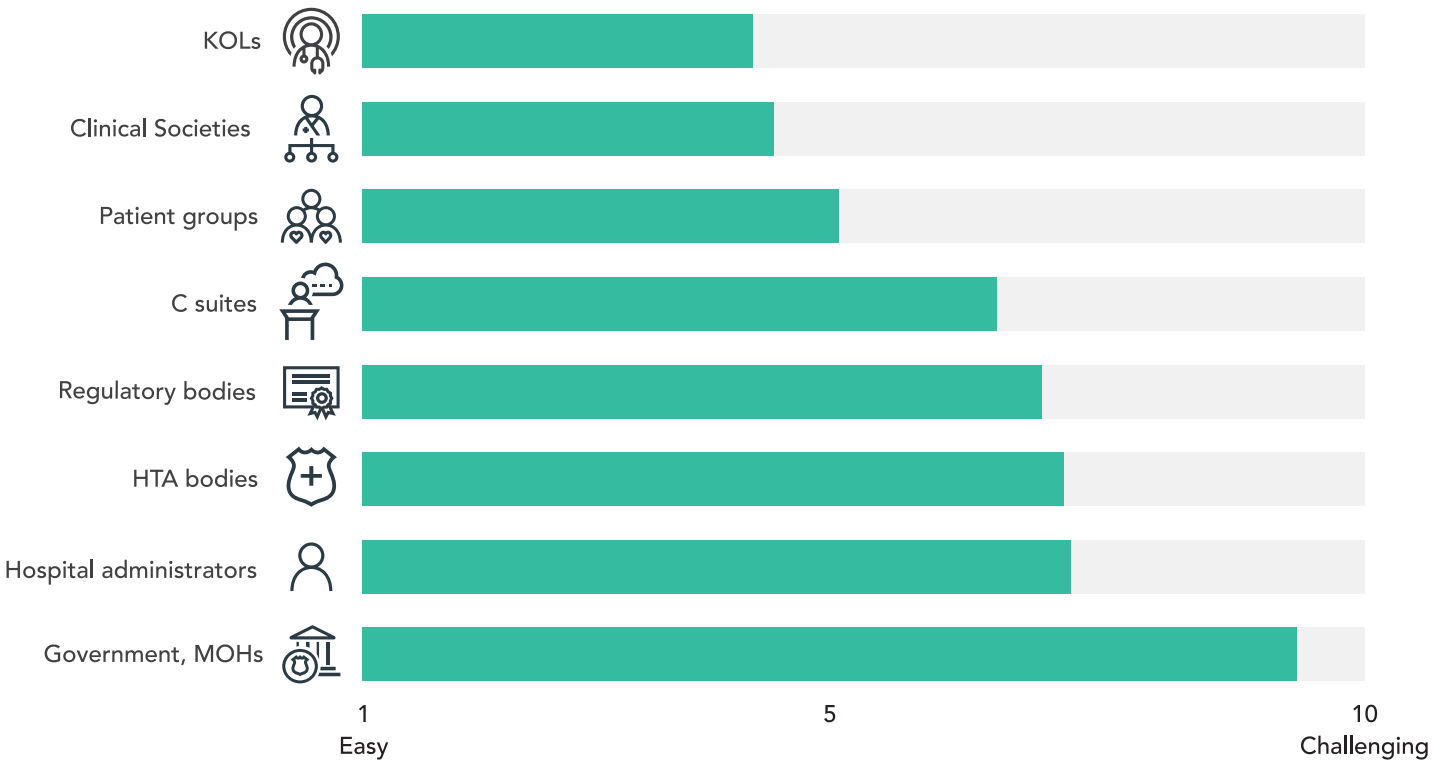
Is the current level of engagement adequate?

An August 2018 survey of regional medtech business executives at a market access event has revealed that government and hospital administrators are perceived as the most challenging to engage. This might indicate an asymmetry as companies will gravitate towards the usual engagement with KOLs and HCPs, and refraining from engaging with government bodies as it requires considerable effort[21].

Companies who are willing to invest effort into upstream engagement with policy makers and regulators might find reciprocal acknowledgement as they seek to inform. This is especially useful when disruptive technologies continue to roll off the R&D runway and requires greater interpretation of the impact on the healthcare system. While authorities generally do not allow influences on decisions, they tend to accommodate dialogue at the early stage of fact finding.

For instance, Japan, which had been planning a cost effectiveness evaluation since 2012, decided to hold back the planned 2014 implementation in order to gather more information and capabilities to enable better collective decisions. It seeks the participation of stakeholders, balancing academia and other sectors including pharmaceutical and medical device manufacturers[10].

Fig 8: Perceived level of difficulty in engagement among stakeholder groups by medtech executives in Asia



By engaging beyond the immediate marketplace, companies can position their products and services as solutions by focusing on the pertinent issues their solutions can address instead of selling on the price and features of their products.

Why the product is not the solution

Traditional models of industry engagement often involve physicians and other healthcare professionals as the end users. Such discussions are often based upon clinical usage and product features while procurement decisions lie with economic buyers who are mainly concerned about cost and staying within budgetary controls.

Understandably, it becomes difficult to sell products when stakeholders are focused on the price of the products instead of their value. This is even more onerous for companies with undifferentiated product offerings. This has driven companies to become more active in the area of healthcare innovations such as business model innovations, solution based selling and partnerships.

Business model innovation - Stakeholders tend to welcome discussions with companies who are able to define the problem that they are facing to come up with mutually beneficial solutions. This creates 'value' in the process making downstream pricing negotiations more acceptable. Stakeholders are also becoming receptive to companies willing to offer innovative business models or funding options, reducing the reliance on national budgets.

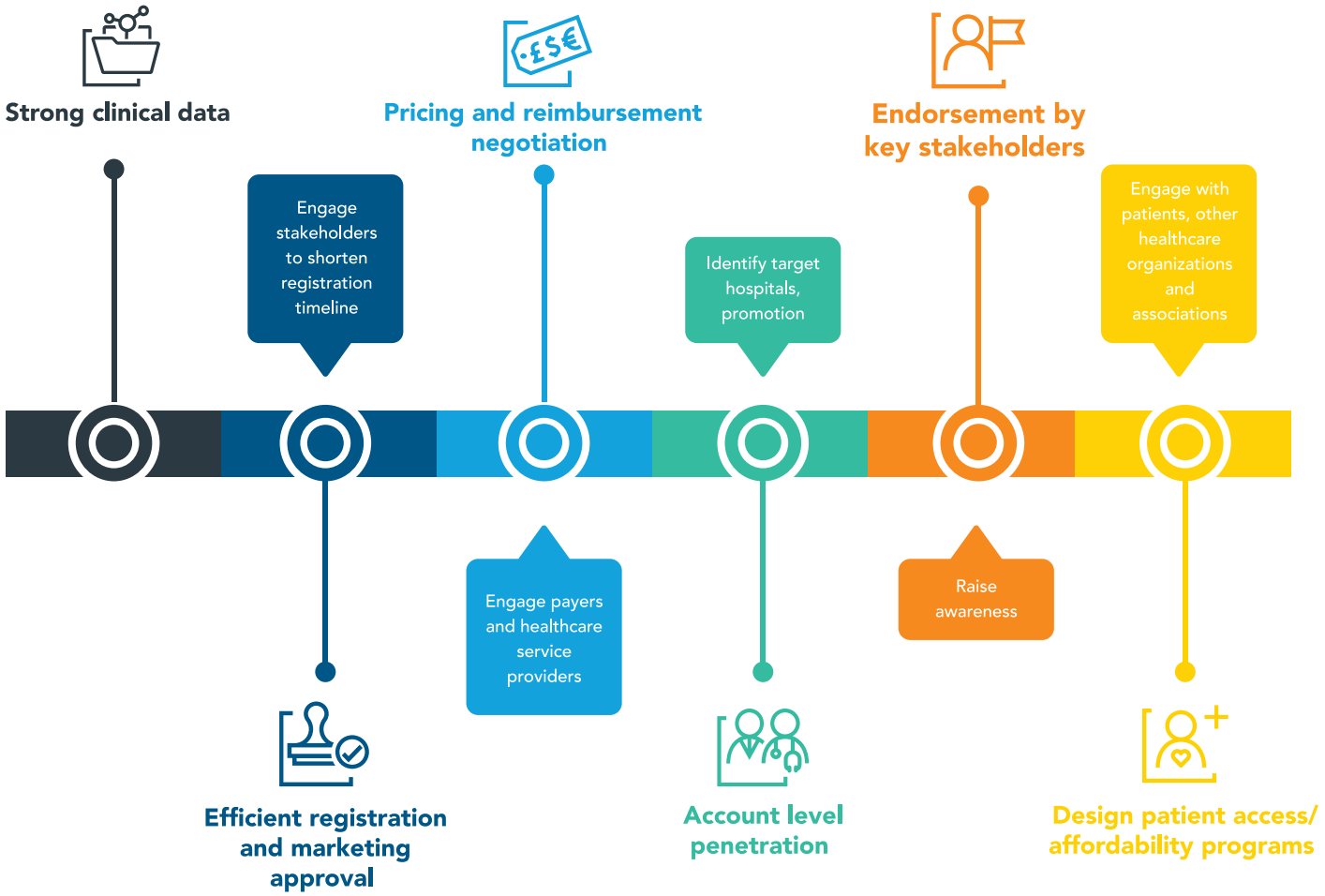
Partnerships - Automation and analytics are often bundled to services along with products to optimize the continuum of care. When more elements are added to bolster and enhance the base offering, the

value creation becomes stronger and more compelling. Increasingly, strategic partnerships among complementary technologies are being utilized to address the needs throughout the continuum and develop far stronger business propositions.

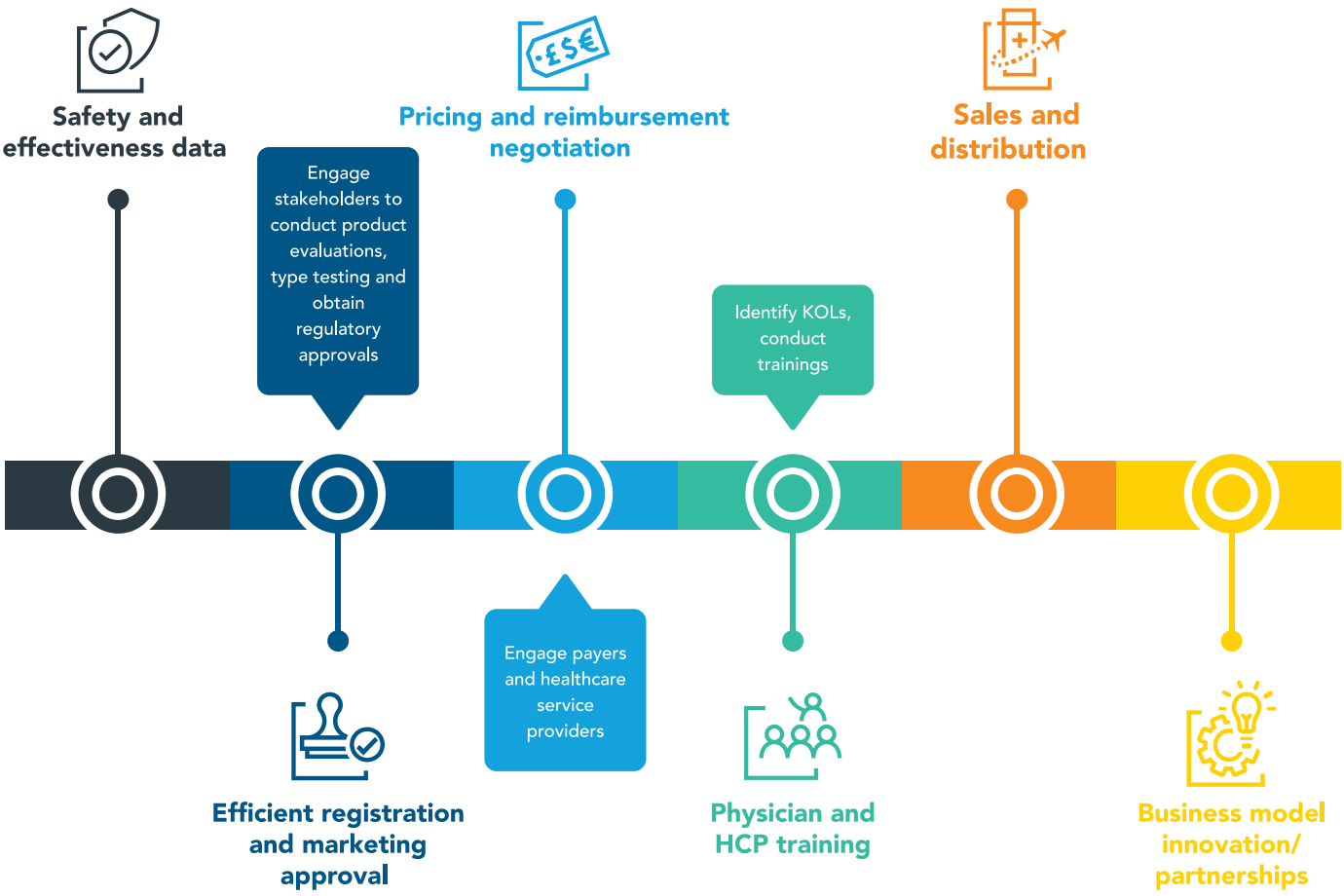
A very important but less obvious stakeholder group is the 'Patients'. While many executives had expressed that patient are integral parts of their work, few actually base their business decisions upon their needs. Patients in developing countries often rest product decisions on their HCPs who in turn base their choices largely on insurance coverage and affordability. Thus, the responsibility lies upon market leaders and innovative players to engage at the policy maker level to discuss plausible solutions that can improve the efficiency of healthcare budgets and addressing other issues such as socio-economic impact of diseases. Competing only at a product, indication or procedural level limits the pace of innovation and growth.

Summarily, products are analogous to pieces of a puzzle. As single pieces, it is difficult to find the place for them without looking at the entirety-frame and all. Within that context, the medical product should be one element of any proposed solutions for the unique healthcare situation. Market access professionals will have to wholly understand the situation to decipher the various elements of a viable solution so as to maximise the benefits.

Fig 9: Differences in Market Access elements between Pharma and Medtech



Key elements and activities of Market Access in Medtech:



TOWARDS MARKET ACCESS ENABLED ORGANIZATIONS

New capabilities and skillsets to navigate dynamic new environment

Medtech companies will have to accept that with the expansion of stakeholders groups they now have to engage with, they must also develop the human capital needed to develop capabilities and skillsets within Asia that were previously optional. Specialised roles such as Government Affairs to engage with policy makers; Regulatory & Quality Affairs for registrations; Health Economics & Market Access experts to develop regional strategies and localised evidence to drive this panoptic process.

To secure patient access, companies will need to anticipate changing evidence requirements and develop local data to fit the needs of HTA agencies and reimbursement bodies.

For example, as more hospitals and governments are utilizing HTA recommendations to support their purchase or shape their poliicies, it might be worthwhile to reconsider their activities in the region. Japan which had always done without any cost effectiveness data for medical devices is intending to implement HTA in 2019, motivated by an ageing population and the rise of healthcare expenditure in recent years[10].

A poll of medtech companies in APAC reveals that Regulatory and Government Affairs are the only function that exists in sufficiency while market access and HEoR expertise is still mainly in its infancy[21].

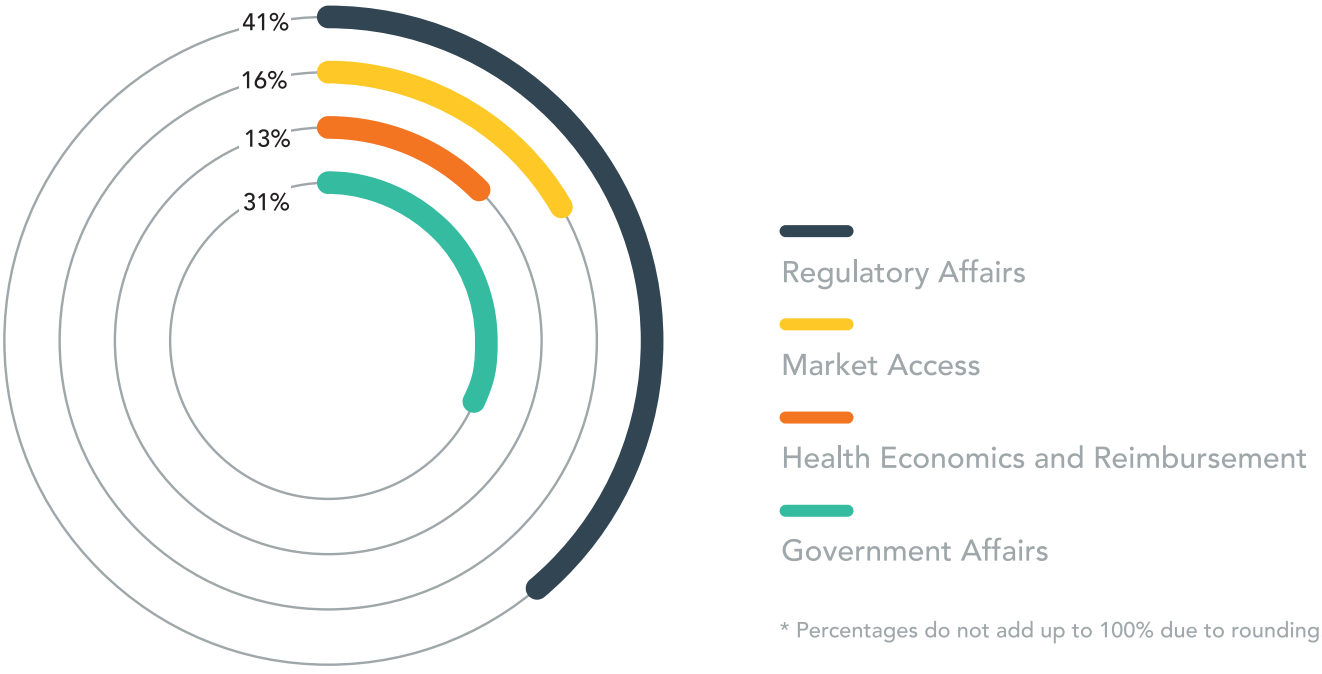
Traditionally only large MNCs with regional headquarters are willing to develop specialized functions to support the local markets, but recent years have seen more small to mid-sized companies investing to get closer to the markets as they understand that mastery of Asia require a nuanced approach and that unlocking the bounteous potential of the region is no longer an opportunistic undertaking but rather, a calculated and proactive one[22].

The role of industry association in market access

For the industry to continue to thrive, and meaningfully address the regions' vast unmet needs, effective engagement with the appropriate stakeholders is critical. A key enabler can come in the form of industry associations such as the Asia Pacific Medical Technology Association (APACMed) that represents both manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, national industry associations, startsups and SMEs.

The Association drives advocacy work across a multitude of issues, proactively engaging with bilateral, regional and local government bodies to shape policies, demonstrate the value of innovation and promote regulatory harmonisation. In doing so, it presents a credible, unified voice the industry across the region.

Fig 10: Availability of specialized functions in Medtech companies



* Percentages do not add up to 100% due to rounding.

Leveraging the industry to engage with government bodies can be an effective strategy. This is particularly key for non-reimbursement markets where there are fewer avenues to approach governments directly. Medtech companies should seek to collaborate under the guidance of an industry association to engage the government body as a single entity. Surfacing the issues through an industry group can sometimes give greater focus, weight and transparency to issues. This will help governments obtain a clearer understanding of the overall business and industry context and to steer the dialogue away from a narrow focus on expenditure.

Some best practices:

- Adopt a collaborative, partnership-centric mind-set among the industry players.
- Proactively share with the other stakeholders on what the industry is doing for the society/ population/ healthcare system instead of unilaterally asking for approvals, concessions, etc.
- Take on an open, long-term and committed approach to engage with governments
- Regularly produce white papers, communiques on various relevant subjects such as the plight of patients, technologies to address healthcare burden and diseases, providing health economics and other data to supplement specific subject understanding.

Industry associations such as APACMed provide a valuable platform for knowledge exchange and best practice sharing and in doing so, foster a vibrant and active business community.

CONCLUSION

Healthcare policies within Asia are rapidly developing. It is thus impossible to apply a standard strategy across the entire region. Local knowledge is critical to identify the structure, stakeholders and processes. Medtech companies looking to enter or scale in Asia will have to consider long-term implications of how the market landscape is evolving and build up their capabilities to deliver measured and meaningful propositions backed by impactful data in order to build up sustainable businesses in the region.

Leveraging the industry to engage with government bodies can be an effective strategy. Medtech companies should seek to collaborate under the guidance of an industry association to engage the government body as a single entity.

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