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Horizon Scanning for New and Emerging Technologies in HealthTech

What do the present and future hold?



PHILIPS

Foreword

A collaborative, data-driven and evidence based study

The last few years have seen an explosion of technology along with an increasing convergence of the Healthcare, Medical Devices, HealthTech, Pharma and Digital realms. It is imperative that in the midst of this, we keep the patients and their problems at the heart of it all. To effectively do so, understanding continuously evolving patient needs will be critical. And by doing so, we can better solve the real challenges they face and provide solutions to complement current clinical practices and technologies to improve what we at PwC call the 3 As in healthcare: Affordable, Accessible and A+ quality care.

However, with the rapid and exponential pace of technological advancement, how do we keep track of the game-changing and clinically impactful developments? What are the present trends driving these developments, and what are likely future trends? Is there a fit-for-purpose framework that can be applied to assist in the assessment of these technologies? What will be the implications to regulators, health technology assessments (HTA), policy makers, payers, healthcare professionals and any and all other stakeholders? **Horizon Scanning for New and Emerging Technologies in HealthTech** aims to answer these questions. For the purposes of this paper, MedTech refers to the traditional innovation-led, fully integrated medical device industry. HealthTech on the other hand, refers to information technology (IT)-led solutions which are more patient-focused and comprise start-ups and non-traditional players who are causing an industry paradigm shift. In both developed and developing countries, MedTech and HealthTech will complement each other in delivering a holistic patient experience.

Finally I'd like to thank and acknowledge EMeRG and Philips as representatives of the HealthTech industry for collaborating with us and providing content, a case study, facts and figures, and insights that allowed us to write a study that accurately reflects the true challenges and trends the industry as a whole is witnessing today, and Galen Growth Asia for reviewing and sense-checking our report from a HealthTech accelerator's perspective.

Dr. Zubin J Daruwalla

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To remain relevant, it is necessary for organisations to monitor the changing environment

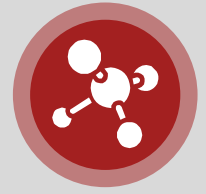
Today, change is the new normal for all players in Healthcare. Many new technologies, such as Big Data, Artificial Intelligence, and cell, tissue and gene therapies, are revolutionising healthcare. New entrants are increasingly challenging traditional approaches by pioneering innovative solutions that enable virtual care anytime, anywhere. Over time, these changes can transform the healthcare system, and policy-makers, regulators and healthcare providers will need to pre-emptively identify the key changes, assess their potential impact and address them.

Horizon scanning and scenario planning techniques have been applied in a variety of industries and businesses. In this time of rapid change, the different stakeholders in the healthcare system may benefit from using such techniques to continuously acquire up-to-date information, understand trends, anticipate issues, and inform critical decision making. The report *New and Emerging Technologies in HealthTech* by PwC provides a horizon scanning framework and methodology that organisations could review to kick-start their own horizon scanning efforts.

This is an exciting time to look ahead and seize the many opportunities enabled by these new technologies and changes to transform healthcare and provide better health for all."

Dr. Mimi Choong

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Making sense of the HealthTech revolution in Asia Pacific

The healthcare landscape is undergoing a period of dramatic change as innovation rapidly blurs the boundaries between traditional medical devices, software, consumer health appliances and medications. With an estimated 25,000 medical device companies¹, greater than 259,000 mHealth apps² and several tens of wearables and miniaturised device developers, the need to identify, track and assess the underlying technologies that drive these innovations is now more critical than ever.

The medical device industry in the Asia Pacific (APAC) region, growing at a CAGR of 8%, is a fertile playing field for a myriad of countless innovations. Home to over 4.5 billion people³, the region is expected to outgrow the European Union as the second largest medical device market by 2020⁴. However, APAC has vast swathes of underserved populations faced with poor awareness and access to quality care, particularly in the rural areas. Additionally, financing and reimbursement policies vary and are in differing maturity levels. In such circumstances, mass dissemination of safe and clinically impactful HealthTech solutions are a potential game-changer and can help plug the gap in traditional MedTech products and service delivery models. From a regulator's perspective, this is indeed a very opportune time to develop a fit-for-purpose framework to conduct horizon scanning on new and emerging technologies.

The Organisation for Economic Co-operation and Development (OECD) defines *horizon scanning as a technique for detecting early signs of potentially important developments through a systematic examination of potential threats and opportunities, with emphasis on new technology and its effects on the issue at hand*⁵. Horizon scanning frameworks have been utilized around the world for over two decades now. As indicated by a survey by International Network of Agencies for Health Technology Assessment (INAHTA) members in 1998, 30% of member agencies had continuing and structured horizon scanning activities then⁶. Such frameworks are being utilized by governments around the world to create long-term strategic approaches while making present policies more resilient to future apprehensions. Countries such as Australia, Canada, Finland, France, Japan, New Zealand and the UK are also utilising these frameworks in other policy areas including national security and the environment⁷.

¹ Commission, E. (2018, August). Medical Devices. Retrieved from European Commission.

² Research2Guidance. (2017). The mHealth apps market is getting crowded. Retrieved from Research2Guidance.

³ Pacific, E. a. (2017). Asia-Pacific Population Journal. Asia-Pacific Population Journal.

⁴ Company, M. &. (2015). Committing at scale to raise standards of care for patients. McKinsey & Company.

⁵ OECD. (2017). Overview of Methodologies. Retrieved from Organisation for Economic Cooperation and Development.

⁶ Section, T. M. (2014, December). Horizon Scanning of Health Technologies. MaHTAS Newsletter.

⁷ Defence, U. K. (2007-2036). DCDC Global Strategic Trends Programme. United Kingdom Ministry of Defence.



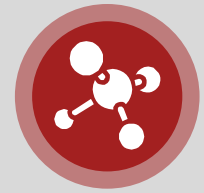


Figure 1: Impact of Horizon Scanning in Healthcare

Estimate potential impact

Estimate potential impact on patient care and the healthcare system

Identify relevant technologies

Identify and describe the evidence on relevant new and emerging healthcare technologies

Assess implications

Assess and inform decision-makers of possible implications of introducing emerging health technologies

Facilitate adoption

Facilitate appropriate adoption and use of new and emerging health technologies

The Canadian Agency for Drugs and Technologies in Health (CADTH) has also created a horizon scanning process to identify and monitor new and emerging health technologies that may have a significant impact on healthcare delivery in Canada⁸. In the US, a horizon scanning framework was established for the first time by the Agency for Healthcare Research and Quality (AHRQ) in 2010 as a publicly funded program and utilised as a systematic process to identify novel healthcare interventions that address significant unmet medical needs⁹. Closer to home in Asia, horizon scanning is being used by the Malaysian Health Technology Assessment Section (MaHTAS) to identify and track innovations in health technologies¹⁰. However, horizon scanning frameworks and practices are yet to be widely adopted in the rest of the APAC region.

While this thought leadership focuses specifically on horizon scanning from a HealthTech perspective and broadly outlines how horizon scanning could be adopted by various APAC regulators, it also recommends a high-level framework that may be adopted to monitor, prioritise and identify technological innovations in the region.

⁸ Health, C. A. (2018). External Processes for Horizon Scanning Program. Retrieved from Canadian Agency for Drugs and Technologies in Health.

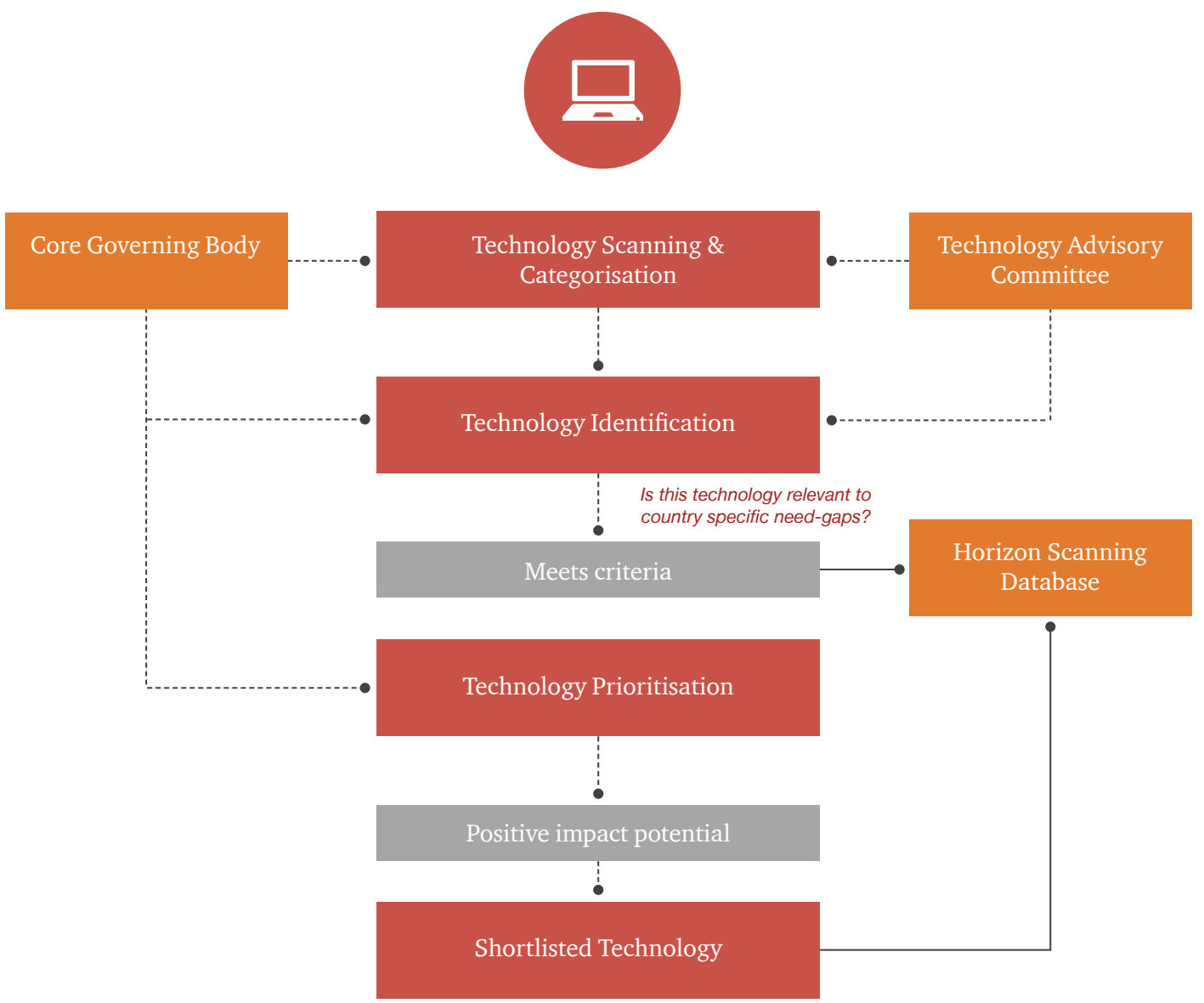
⁹ ISPOR. (2017). Emerging Innovations in US Healthcare. Retrieved from International Society for Pharmacoeconomic Outcomes and Research.

¹⁰ Division, M. D. (2015). Manual On Horizon Scanning of Health Technologies. Malaysian Health Technology Assessment Section, Ministry of Health.

Developing a fit-for-purpose horizon scanning methodology for APAC

In light of persisting healthcare challenges such as lack of access to affordable care, weak primary care systems, and over-emphasised hospital based provisions, the APAC region requires a unique lens to monitor emerging technologies. An effective framework for horizon scanning necessitates adequate correlation of unmet healthcare needs with corresponding technologies that may yield both clinical as well as economic benefits. Figure 2 represents a proposed high-level workflow for horizon scanning, identification and prioritisation.

Figure 2: A proposed high-level workflow for horizon scanning



A typical industry-agnostic horizon scanning workflow would follow a structured funnel approach by first defining a broad timeline for the exercise to assess technologies over a short-term, medium-term and long-term future. This would be followed by detailed scanning and prioritisation of various upcoming technological innovations.

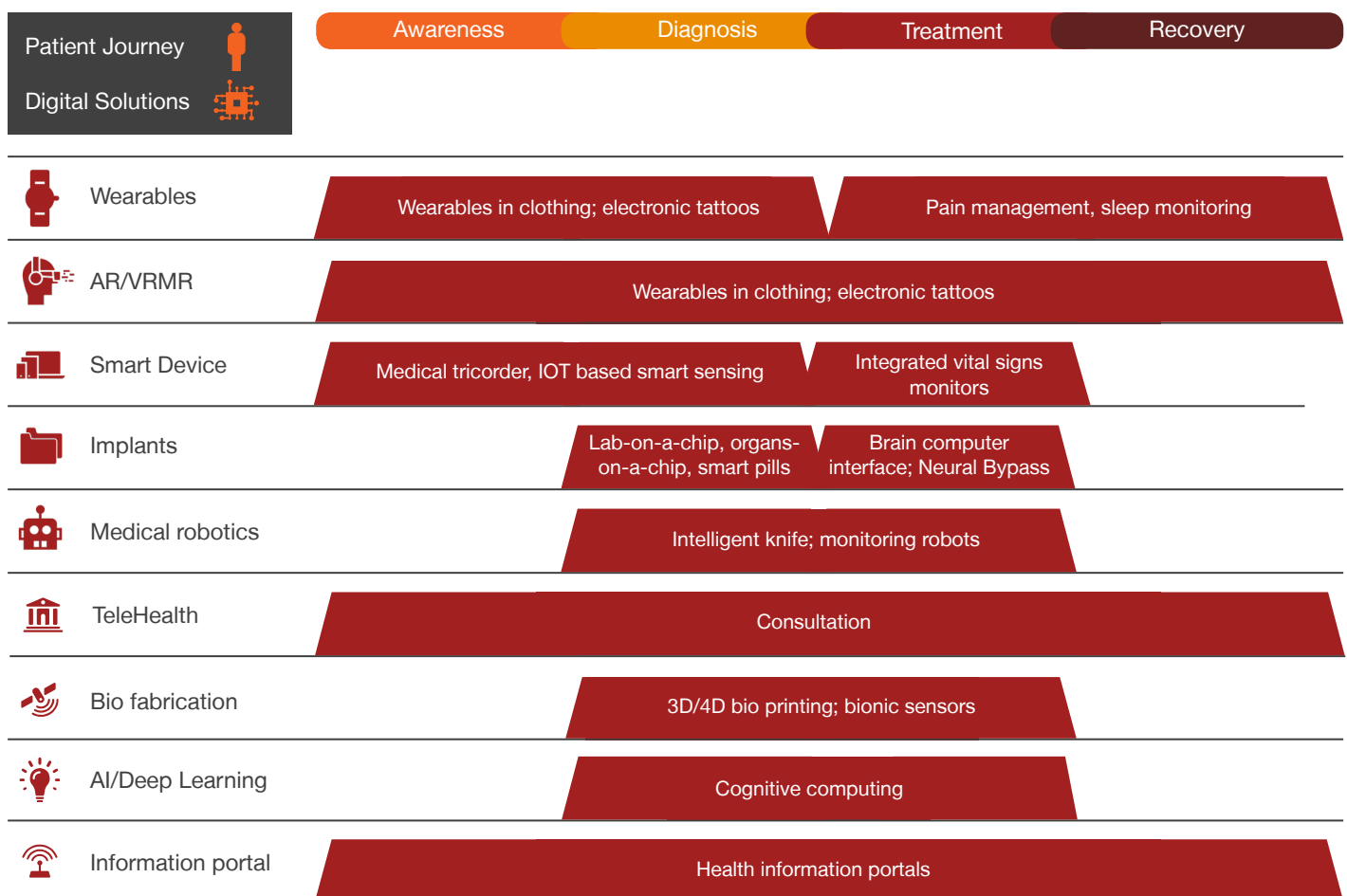


Step 1: Technology scanning and categorisation

An in-depth scanning of emerging medical technologies would begin with the utilisation of various primary, secondary and tertiary information sources. Depending on the resources at the disposal of the governing body, the technology scanning step could be optimised to incorporate the right mix of various methodologies. Primary sources would typically include information gathered directly from commercial developers, manufacturers, research institutes, start-ups and other innovators. As demonstrated by the MaHTAS, pipeline meetings could be utilised to gather valuable information around upcoming technologies that are being planned for certain target geographies¹¹. In addition to various secondary sources, tertiary sources of information from other horizon scanning organisations could be utilised. This may include the EuroScan International Network, Canadian Agency for Drug and Technologies in Health (CADTH) and the UK National Institute for Health Research (NIHR) Horizon Scanning.

Figure 3 represents a preliminary categorisation of a non-exhaustive list of new and emerging technologies based on PwC's analysis of more than 350 health technology companies across various APAC countries. The categorisation has been derived based on a hierarchy that takes into account, various factors such as the route to market, delivery channel and the function served by the technology.

Figure 3: New and Emerging Technology Categorisation in HealthTech in accordance with the patient's journey



With the increasing convergence of Information and Communication Technology (ICT) and medical technologies, devising mutually exclusive technology categories is a challenging exercise. Nonetheless, a dynamic technology categorisation methodology is critical to ensure that technologies are captured and analysed effectively. Moreover, this exercise needs to be revisited and augmented at regular intervals to account for the continual technological evolution.

Step 2: Technology identification

The next step within a typical horizon scanning framework should filter scanned technologies to identify the most relevant innovations. At this stage, it is critical to define filtration criteria relevant to the market needs. Broad, qualitative questions could be utilised as points of reference to identify relevant technologies.

“Does this technology solve a relevant healthcare unmet need in the country?”



“What benefits does this technology deliver over the current standard of diagnosis/treatment?”

Step 3: Technology prioritisation

Key shortlisting criteria that regulators could utilise for technology prioritisation to achieve better financial and clinical outcomes may include:

- Disruptive vs. Incremental innovation – disruptive technologies with unique sensing mechanisms / primary mode of action with potentially significant impact are likely to get a higher priority
- Device classification – addressing technologies such as invasive / implantable innovations that may pose increased safety risk with a greater emphasis
- Horizon scanning timelines – technologies closer to commercialisation timelines in other markets can get a higher priority
- Local vs. Global innovation – can be a filter, depending on the priority areas for the market (Malaysia for instance prioritizes local innovations under its horizon scanning framework)¹². An effective horizon scanning framework should typically include a mechanism to forecast the impact of emerging technologies over a time-frame. This should take into account the critical unmet needs within the specific markets as well as various focus areas outlined by the respective healthcare plans and policies. Figure 4 represents a high-level technology prioritisation framework.



¹²Abu, A. (2014). Malaysian Innovation Ecosystem: A Review of Literature. Journal of Advanced Manufacturing Technology.

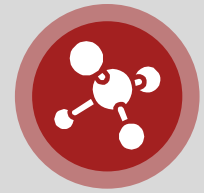
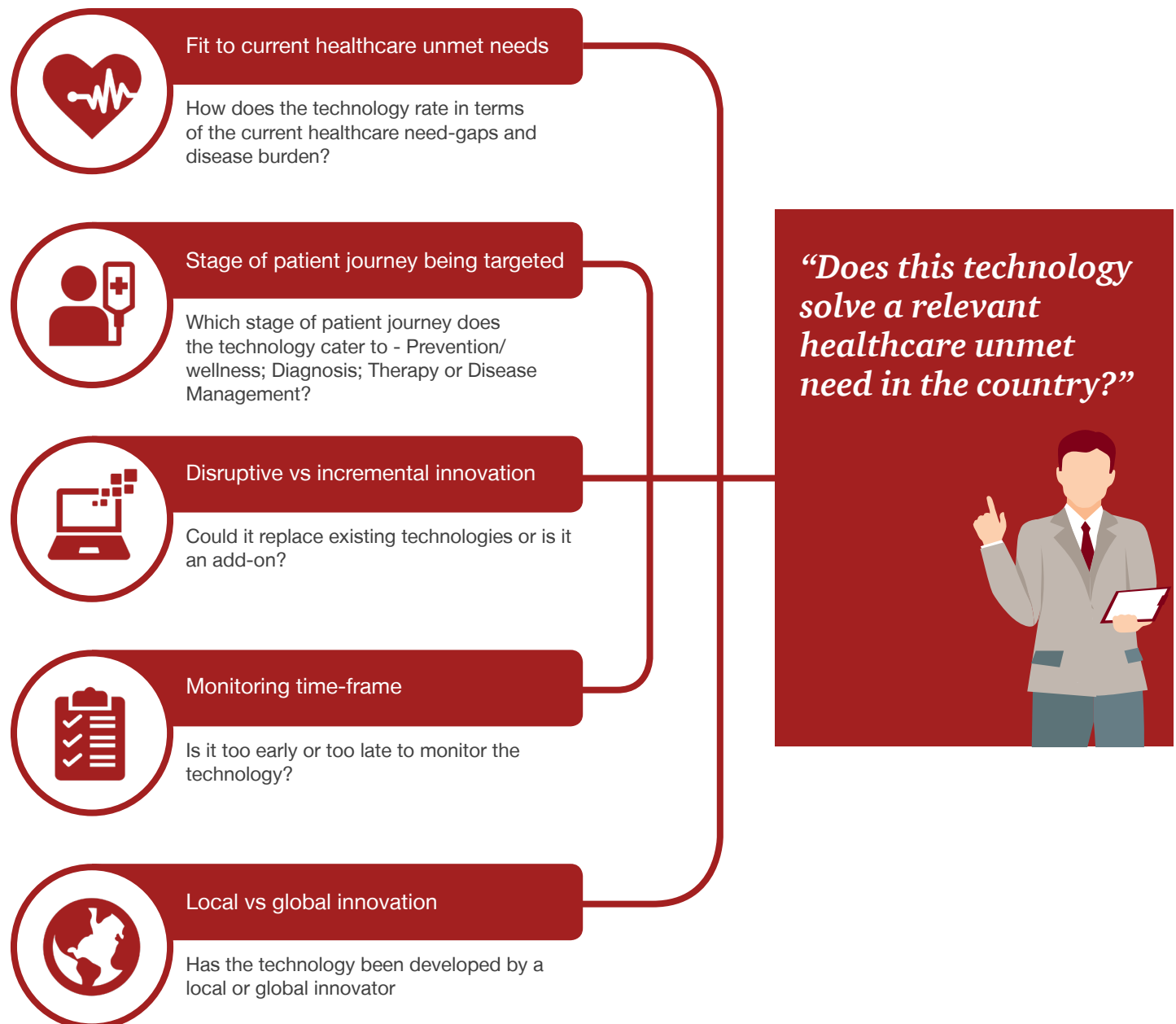



















Figure 4: High-level technology prioritisation framework



A horizon scanning framework could be harnessed effectively by mapping the key unmet needs and disease burden within the market against the technologies being evaluated. While this step may be resource-intensive, it may help prioritise emerging technologies based on the actual needs of the market in scope. Figure 5 represents an illustrative view of potential technology prioritisation based on current healthcare unmet needs.

Figure 5: A framework to map current healthcare unmet needs and priorities to currently available and relevant technologies

Healthcare Unmet Needs / Focus Areas 	Countries 	Relevant technology categories for consideration 
Large undiagnosed population with mental health issues and limited treatment provisions		 Information portal
Limited infrastructure in primary healthcare		 Information portal
Rise of NCDs including cancer, CVD, COPD and diabetes		 Implants
Aging population and management of chronic diseases		 Wearables
Healthcare manpower issues – shortage of primary care physicians and nurses		 Smart Device
Limited access to affordable healthcare especially in rural areas		 Wearables
Focus on improving patient-centricity and patient self-management		 Bio fabrication

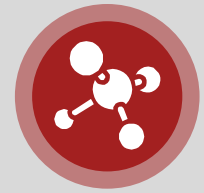
Once correlated with the country's current and planned healthcare focus and policy, various stages of the patient journey could aid prioritisation of the most relevant technologies. For countries such as India, China and Japan where mental illness accounts for a significant proportion of the NCD burden, the need for higher attention and quality of care is on the rise¹³. For a competent horizon scanning exercise, policy makers, healthcare planners and regulators may consider prioritising corresponding technologies that are aimed at early detection and management of mental disorders. Data driven technologies such as the one being developed by Mindstrong Health to objectively measure mental health analysing the usage of smartphone could be included in the priority order in such countries¹⁴. For instance, in markets such as Singapore, Japan and Vietnam, healthcare challenges related to shortage of specialists and nurses may necessitate prioritisation of technologies that enable efficient training of existing resources. This may include technologies such as Biolucid that facilitate efficient training of healthcare workers by utilising Virtual Reality based technologies¹⁵. Additionally in countries battling with rising costs resulting from an aging population the need for better management of various conditions from home-care settings is paramount. Innovations such as the PKG system by Global Kinetics Corporation could potentially aid continuous, objective, ambulatory assessment of movement disorder symptoms, such as tremor, dyskinesia and bradykinesia in a home-care setting¹⁶.

¹³ EIU. (2015). The Shifting Landscape of Healthcare in Asia-Pacific. Economist Intelligence Unit.

¹⁴ Mindstrong. (2017). The Mindstrong Behavioral Healthcare Solution. Retrieved from Mindstrong Health.

¹⁵ Crunchbase. (2017). BioLucid Company Profile. Retrieved from Crunchbase.

¹⁶ GKC. (2017). The PKG System. Retrieved from Global Kinetics Corporation.






A Case for Horizon Scanning: Disruption by New Entrants

The advent of non-traditional entrants in healthcare further necessitates the need for horizon scanning. Armed with fresh perspectives and unconventional approaches to solve existing issues, new entrants are looking to disrupt existing healthcare technologies and commercial models. Key to their success so far has been a data-driven, patient-centric approach aimed at improving product development cycles and optimising costs. The arrival of such non-traditional players is suitably complemented by growing skepticism within patients towards traditional health systems and technologies. In the APAC region, where out-of-pocket expenditure is significant, digital adoption in healthcare provides patients with greater transparency, convenience and value. As indicated by a recent PwC survey¹⁷ consumer distrust could easily translate into a shift towards affordable and convenient alternatives. Of the 1000 adults interviewed in the survey, more than one-third indicated that they were open to digital, home-based electrocardiograms, pacemaker/defibrillator monitoring, urinalysis and chemotherapy treatment, along with online physician consultations. As patients become more demanding of information, improved outcomes and alternatives, non-traditional companies may find their future adoption rather unconstrained.

One of the key non-traditional entrants is Apple whose entry into HealthTech has been marked by a series of targeted acquisitions and partnerships. In addition to the acquisition of Glimpse – a platform to collect and personalise health data, the company is partnering with IBM, Johnson & Johnson and Medtronic on a cognitive computing platform¹⁸. Apple has also been reportedly developing non-invasive sensors to monitor blood sugar levels²³. Other non-healthcare majors including Amazon Alexa, Samsung, Oracle etc., have been targeting the MedTech market through investments in various wearable technologies and connected devices that thrive on patient data and self-usage. In Asia, technology start-ups such as Indonesia based GoJek have forayed into healthcare through a series of acquisitions. In September 2016, Go-Jek acquired Pianta, a market place for home healthcare services, headquartered in India¹⁹. The company had earlier invested in Indonesian HealthTech start-up HaloDoc. Through Halodoc, Go-Jek aspires to be an integrated healthcare platform that brings together doctor consultations and medicines delivery.

Figure 10: Non-traditional players in HealthTech













Company	Technology Category	Product/ Brand	Description
	Wearables	Owlet Smart Sock 2	Uses pulse oximetry to measure and relay infant's heart rate and oxygen levels in real time to a smartphone
	Wearables	Gear Fit 2	Uses various tracking sensors to monitor activity levels including steps taken, calories burned, heart rate, and sleep quality
	Wearables	Apple Watch Beddit 3 sleep monitor	Allows fitness tracking including heart rate measurement tracking and sharing of blood glucose levels etc Collects and analyses sleep data including various measurements such as heart rate, breathing, snoring etc.

¹⁷ PwC. (2018). Whom Do Consumers Really Trust? Pricewaterhouse Coopers.

¹⁸ Dive, H. (2016). What's up with Apple in Healthcare. Retrieved from Healthcare Dive.

¹⁹ TechnAsia. (2016). Go-Jek acquires another Indian startup – this time in healthcare. Retrieved from TechnAsia.

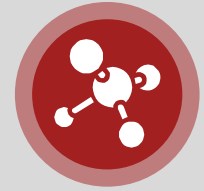
²³ Company Press Releases (2017-18). Retrieved from Company Websites.

Company 	Technology Category 	Product/ Brand 	Description 
	Wearables; connected devices	Proteus Discover	Comprised of ingestible sensors, a wearable sensor patch, a mobile app – allows tracking of medication treatment effectiveness and adherence
	Data-driven technologies	Merge Healthcare	Cognitive data review tool designed to enable discrepancy reconciliation between a patient's clinical diagnosis and administrative records
		Truven Health Analytics	Analytics tools, benchmarks, services, and related expertise to the healthcare industry, for improving quality outcomes.
	Data-driven technologies; connected devices	Teslon	Connected devices for patient monitoring; scalable telehealth platform that enables complete remote care delivery; health analytics
	Data-driven devices	Protego	Fitness app that automatically records walking, cycling, and running activities
	Brain-computer interface	Building 8 Research Group	Brain-computer interface that may allow typing without invasive implants
	Healthcare ecosystem connector	MyDoc	A digital platform that connects patients to doctors, pharmacies, insurers and laboratories
	Virtual-reality platform	Oculus	Revolutionary platform for healthcare and medical training
	Medicine delivery service; mobility	Go-Jek	An app-based medicine delivery service; enables digital payments
	Wearables; data-driven technologies	Verily Lifesciences	Uses AI and technological platforms to offer holistic care management

**In Singapore, a variety of new healthcare business models are being piloted in a controlled environment through the Ministry of Health's Licensing Experimentation and Adaptation Programme (LEAP) under the regulatory sandbox initiative*

While non-traditional entrants continue their rigorous data-driven approach in HealthTech, patient data and confidentiality issues may gain prominence. Events including DeepMind's recent shortcomings with regards to factual and analytical errors in handling sensitive patient data from the NHS would reinstate the need for a proactive regulatory mechanism²⁰. Central to this would be a pre-emptive prioritisation of technologies to ensure optimal regulatory assessment in time.

¹⁷ Verge, T. (2017). Google's DeepMind made 'inexcusable' errors handling UK health data. Retrieved from The Verge. Products, C. f. (2016). Concept paper on developing a guideline on Quality Requirements of Medicinal Products Containing a Device Component for Delivery or Use of the Medicinal Product. European Medicines Agency.

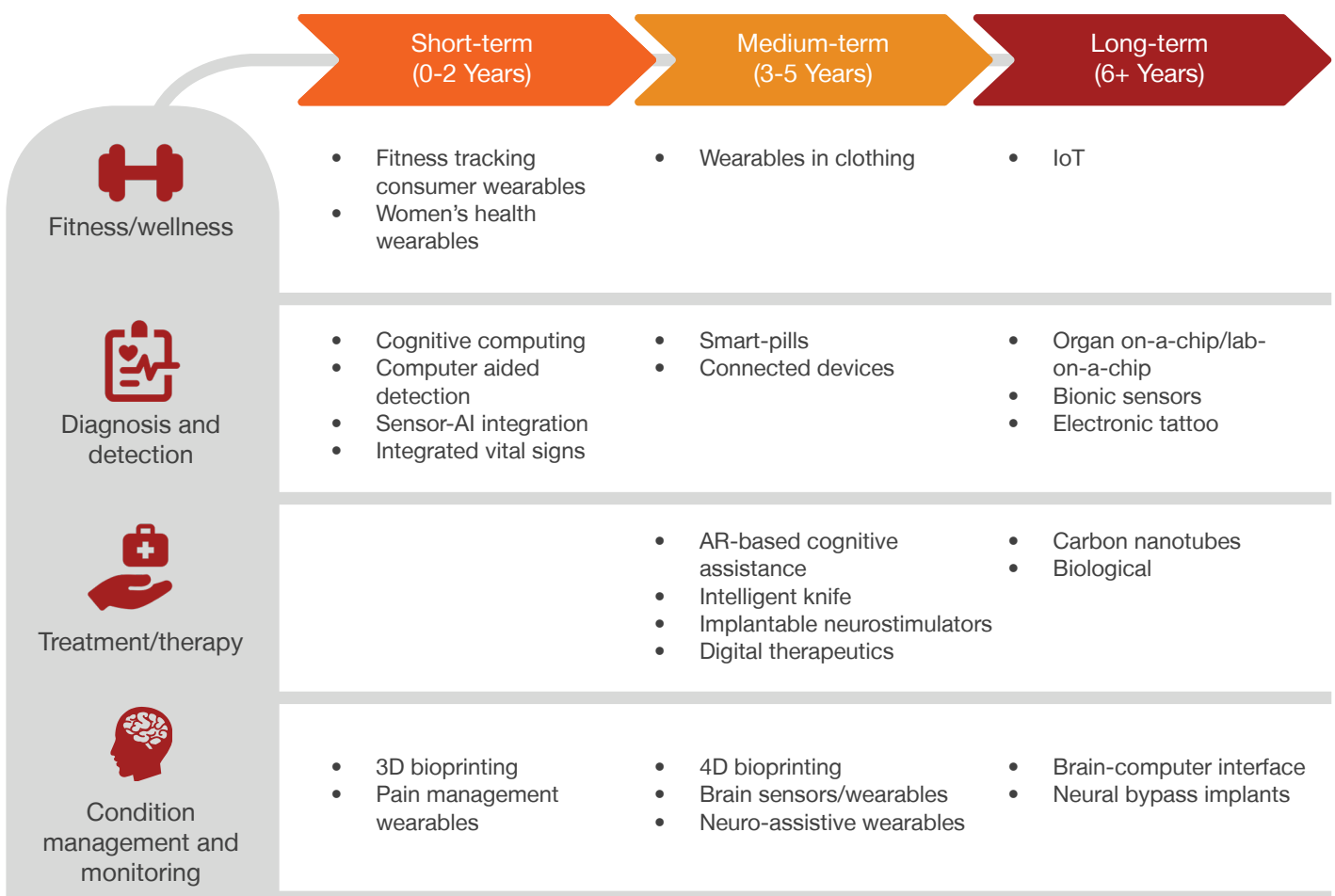


A time-frame for horizon scanning

As new entrants and technologies disrupt healthcare, regulators and key decision makers will be tasked with ways to not only stay aware of the continuously changing landscape but also predict the advent of lesser known technology applications in the medium and long-term. The time-frame of these technologies will be a function of patient awareness, demand and ease of commercialisation within each market.

With an urgent need to improve lifestyle and preventive health, wearables for fitness and wellness will be a big focus in the short-term. Wearables are also likely to impact non-communicable disease management and long-term care. In the medium term, technologies such as smart pills, AR-based cognitive assistance and neuro-assistive wearables are expected to gain prominence. In the long-term, more advanced technologies such as brain-computer interfaces and neural bypasses for neurodegenerative disorders are expected to enter the market.

Figure 11: Key emerging technologies over a short, medium and long-term timeline



Spotlight 1: Heart Failure Telehealth Programme to Transition Chronic Care from Hospital to Home²¹

Singapore's vision for healthcare over the next five years is focused on improving accessibility, quality and affordability. Specifically, Singapore seeks to prioritise four intertwined yet distinct areas namely (1) Making care seamless (2) Emphasizing on Primary care (3) Empowering long term care and (4) Healthy living. A closer look at the country's long-term aspirations indicates a shift towards an ecosystem where care is integrated and patients are empowered to take charge of their wellness and manage their conditions effectively. This is in line with the global paradigm shift towards consumer driven healthcare. This long-term approach may favour prioritisation of technologies that enable fitness and lifestyle habits, seamless integration with various care providers as well as home-based condition management.

Figure 12: A framework to map the current disease burden to currently available and relevant technologies in Singapore

Non Communicable diseases	Non Communicable diseases Disability-Adjusted Life Years (%) ²⁹	Examples of HealthTech categories to be prioritised
Cardiovascular	20	Wearables for disease management; PoC diagnostics; Data-driven technologies
Cancer	19	Miniaturised diagnostics (e.g. - smart pills for cancer screening)
Neurological, vision and hearing disorders	14	AR/VRMR (Cognitive assistance, smart specs)

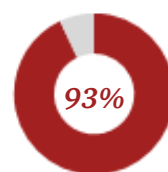
Communicable diseases	Weekly No. of cases ³⁰	Examples of HealthTech categories to be prioritised
Dengue fever	73	Nanotechnology based innovations; Integrated/ PoC diagnostics; Other Health-tech categories
Hand, foot and mouth disease	554	Nanotechnology based innovations; Integrated / PoC diagnostics; Other Health-tech categories
Acute upper respiratory infections	2374	

Philips, in partnership with Changi General Hospital, conducted a Heart Failure Telehealth Program that aimed at improving chronic care management among patients with cardiovascular disease through means of redefining the traditional care delivery model.

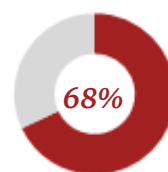
The Heart Failure Telehealth Program essentially integrates three elements of care: (1) Tele-monitoring (2) Tele-education (3) Tele-care support. One hundred fifty heart failure patients from CGH were enrolled in the programme and upon receiving Tele-monitoring support for a year, data were gathered and the results compared against a control group that received support from only phone calls. Fundamentally, the digitalised platform worked on the basis of a Bluetooth-enabled weighing scale and a blood pressure monitor that assisted in the daily measurement of the patients' vital signs upon discharge. Additionally, a personal tablet was provided to the patients to wirelessly capture these vital signs and upload it to the Philips telehealth solution. Physicians and nurses were then able to remotely monitor and intervene when signs of deterioration were detected.

Outcomes

Improved care compliance with self-management



Involved in self-care



More confident and able to maintain their conditions



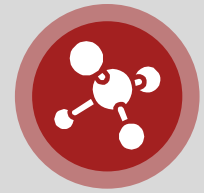
More empowered to engage with their healthcare provider

This virtual interconnectivity resulted in reducing the length of stay for heart failure-related readmissions by a staggering 67%.

Fewer readmissions translated to cost savings for both the patients and the hospitals. From a financial standpoint, total cost of heart failure related care per patient decreased by 42%.



²¹ Philips. Transitioning Chronic Care for Heart Failure Patients from Hospital to Home. Philips and Changi General Hospital.



Spotlight 2: Drug-device convergence will necessitate horizon scanning

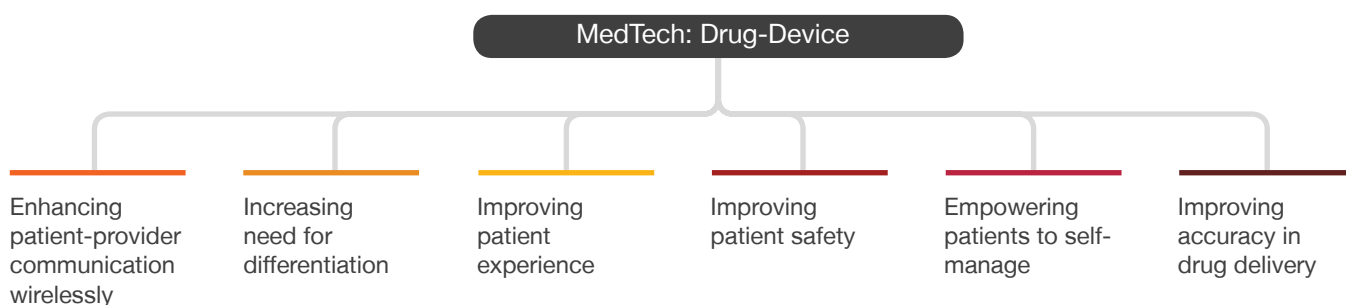
The rapid convergence of drugs and medical devices is creating a new category of innovation that brings enormous complexities from a regulatory standpoint. Market forces and proactive efforts by both the drug and device sectors have ordained the current level of convergence. With the pharmaceutical industry being constrained by pipeline shortages, competition from generics and the subsiding blockbuster model, the push for convergence is gaining momentum. The ever-increasing approvals of biologics is further necessitating improved device technologies to deliver these drugs.

What began as basic integration such as drug-eluting stents, programmable pumps, pre-filled metered dose syringes and pens, is now evolving into deeper avenues of convergence. The number of marketing authorisation applications and requests for scientific advice for drug delivery devices is on the rise²². Miniaturisation is complementing the integration more effectively with future implantable devices being capable of diagnostic and therapeutic delivery at micro and nano levels. The use of micro-electrical mechanical systems (MEMS) for precise delivery of medication along with combination products incorporating gene delivery systems is pointing towards a future where disease prevention, detection and management would become more targeted and individualised.

Major pharmaceutical companies including AstraZeneca, Bristol Myers Squibb, Genentech and Pfizer have also set up their own internal groups to develop devices specific to their therapies as part of their differentiation strategy²³. This trend is also equally noticeable with MedTech companies that have been historically prone to commoditisation threats driven by expedited innovation cycles. MedTech companies are now beginning to reap benefits of new product development and differentiation through integration as opposed to being evaluated on price alone.



Figure 13: Drivers of drug-device convergence



Most recently, in November 2017, the US FDA approved Otsuka-Proteus's ingestible sensor embedded pills for schizophrenia patients. Medtronic's closed-loop system for monitoring and dosing of insulin was launched earlier in the US in June 2017²⁴. Cocoon Biotech is utilising fibroin – a protein derived from the cocoon of silkworm to develop a drug delivery platform²⁵. While combination products open new frontiers in medicine, they are likely to pose distinctive challenges to regulatory bodies. Regulators will need to establish and update guidelines that ensure that underlying sensing technologies, delivery mechanisms, and the primary mode of action (PMOA) have benchmarks to conform to. Additionally, as combination device developers try to establish safety and efficacy, clinical trial evaluation is likely to become more complex. Developing foresight into upcoming innovations that capitalise on the convergence of drugs and devices will be a critical step for preparedness of regulators especially in APAC.

²² FDA. (2018). FDA Approves Automated Insulin Delivery and Monitoring System. Food & Drug Administration.

²³ Company Press Releases (2017-18). Retrieved from Company Websites.

²⁴ Verge, T. (2017). The FDA has approved the first digital pill. Retrieved from The Verge.

²⁵ Cocoon Biotech (2017). About Company. Retrieved from Cocoon Biotech.

The Way Forward

The HealthTech industry is undergoing rapid shifts from incremental breakthroughs to disruptive innovation cycles fueled by new technologies and data-driven patient centric approaches. With the industry aiming to apply various layers of mobile, cloud and analytics to differentiate and solve larger healthcare challenges, several new innovations are likely to queue up for regulatory approval. This will entail a broader role for regulators, making them the new enablers of relevant technologies in a healthcare system.

Healthcare regulators will require a multi-disciplinary approach to track, monitor and assess new innovations. Regulators will need to adopt horizon scanning frameworks that have holistic criteria for identifying, shortlisting and prioritising technologies with high potential impact. Horizon scanning frameworks will need to evolve based on deep inputs and collaboration with a network of domain experts and future-thinkers from public, private and academic sectors. This may also create avenues for international partnerships through various exchange programs as opposed to traditional standalone approaches. This is critical as several new technologies and entrants with a wide range of applications enter the healthcare industry.

In this dynamic environment, ensuring public health safety while not creating a roadblock for innovation will be a delicate balancing act for regulators in APAC. At the same time, regulatory culture will have to be flexible enough to not just facilitate incremental innovation but also to create an ecosystem that supports change in healthcare.



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