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Accelerating IVD Innovations in APAC

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Not always perceived as the most exciting field as therapeutics, the diagnostics industry is gaining momentum and growing and changing just as fast. At a rapid pace with projected sales growth between 2012 and 2018 from $43.6 billion to $58.8 billion (CAGR of 5.1 percent), the industry looks appealing (EvaluateMedtech). Despite global economic and industry challenges, in-vitro diagnostics (IVD) markets are growing robustly at double the rate of the global pharmaceutical industry in some segments. Growth in emerging markets and next-wave emerging markets, particularly in the Asia-Pacific (APAC) region, are the most important factors in formulating future strategies.

Ever- evolving diagnostics landscape

Among IVD segments, molecular diagnostics is one of the most prominent segment. Molecular diagnostics is an emerging segment in APAC, and companies who are facing stagnant growth in mature markets have the option of tapping pharmerging countries. Significant rise in healthcare expenditure, universal coverage, ageing population and willingness to pay among consumers are key aspects for companies to focus on APAC region.

“Economic growth in the region is fuelling investment in national healthcare infrastructures and expanding access to healthcare. While signs point to continued growth for the foreseeable future, there are challenges in the medical diagnostics space, especially increasing market complexities and competition from both local and multi-national players. We believe China, India and emerging Southeast Asia countries, such as Indonesia, are key markets. They already are large markets for medical diagnostics but also have substantial underserved pockets that present significant growth potential. Effectively penetrating those markets will require data-driven insights and breaking with traditional practices. Leveraging innovative technology solutions will be key”, says Wilson Tan, Senior Director, IQVIA Analytics, Medical Devices & Diagnostics Asia while talking about how the medical diagnostics landscape is evolving in APAC region.

There is an increased health awareness across APAC region. As a comparative, the consumer and clinical healthcare diagnostics landscape differs in different countries, in terms of potential in business growth and adoption. Alexis En, Regional Marketing Director of Omron Healthcare Asia Pacific comments, “Typically, the emerging markets have large populations where consumers are relatively less aware of the need for home healthcare diagnostics such as blood pressure monitoring.

That said, there is a lot more opportunity and unrealised potential to influence and support the public health education in such markets. With weaker public healthcare infrastructure, we are seeing an increased demand for home healthcare solutions in these countries. For developed markets where aging populations are common, consumers tend to be more well-informed and do look for healthcare solutions to help them in achieving better quality of life as well as healthy ageing."

Incorporating innovations in diagnostics

Asia- Pacific presents huge opportunities for most IVD segments, well attributed to a deep base of consumers in all socioeconomic strata. According to estimates from Boston Biomedical Consultants (BBC), the APAC IVD market expanded by over 14%in 2016 in comparison to the worldwide IVD market growth of only 5% in that same timeframe.

APAC's ageing populations and changing epidemiological trends create demand for new types of diagnostic tests and business models, often tailored specifically to individual countries and cultures. Kuldeep Singh, CEO, Biofourmis says, "We see the interest from payer and providers to assess new innovative methods to deploy and enhance medical diagnostics. China has a huge potential with a vibrant industry. Mature markets like Australia, where government policy and funding reform is incentivising precision medicine, Telcos are investing millions to increase coverage to all corners of the country, insurers are investing in new member health services that benefit greatly from enhanced diagnostic capability and the population are one of the highest technology adopters, provides significant opportunity for research and development and new commercial partnerships."

New technologies power some of these innovations. Lab automation tools, for example, are bringing efficiencies to regions suffering from workforce shortages and skills gaps. Point-of-care diagnostics are increasing access to testing in remote areas. And improvements in connectivity are ensuring that the data from all these technologies are collected and analysed, opening new possibilities for medical research and population health management.

Localisation will be key to ensuring that these new technologies are effectively deployed in Asia- Pacific. Also, diagnostic services may need to be recalibrated to meet the price points of low-resource settings. Explaining the various pricing models that diagnostic and medical devices follow, Mr Kuldeep says, "Bundling and volume discounting are common. Often there is a backend system/machine needed to read/analyse/report data from the point of care device. Discounting of the initial set up cost is common providing there is guaranteed volume turnover. Revenue is often generated through fixed costs after sales service fees, extended warranties and replacement schedules. Future outlook for shifts towards more outcome based pricing may affect the device industry and their pricing models will need to adapt accordingly."

Asia has an exquisite emerging R&D ecosystem. This has led to producing more of its own IVD products and services. Countries like China, Japan and Singapore are going beyond localisation and playing a growing role in breakthrough innovation.

Cancer diagnostics is one of the main area of focus and has witnessed substantial investment and M&A activity in the past year. In March 2017, China's Tencent participated in a US$900 million funding round of Grail, an American company working on novel methods for diagnosing cancer from blood samples. Japan's Softbank led a US$360 million investment in Guardant Health, which is working on similar technologies in May 2017. And in July 2017, Japan's Konica Minolta announced plans to buy Ambry Genetics, another cancer screening company, for US$889 million.

Other innovations are rooted in novel partnerships between IVD companies and other stakeholders. A few diagnostics companies, for example, are partnering with insurers to distribute DNA testing kits for policyholders. By encouraging early detection of disease and disease risks, partnerships like these could improve health outcomes for individuals and thus reduce claims costs for insurers – a win for everyone. Partnerships between IVD companies and governments, NGOs, providers, and even technology firms can provide similar opportunities.

IVD market in Asia- Pacific region

1. **China**

The in–vitro diagnostics(IVD) market in China has been growing rapidly in the past few years and is expected to grow steadily in the next few years, with major growth potential in segments such as infectious disease testing, chronic disease testing and diagnosis in early stages of disease. The China In Vitro Diagnostics Market is expected to reach more than US$ 10 Billion by 2021 with strong double-digit growth rate from 2016 to 2021 (Frost and Sullivan).

Some of the major factors driving the growth of this market are the rising incidences of chronic lifestyle diseases, public health awareness, growing aging population, demand of tests in rural areas stimulated by the healthcare reform plan,

increasing demand from the middle class for high–end products and an increase in the number of private hospitals and independent testing laboratories. However, low reimbursement rate, absence of quality products by the local companies, population factors and foreign companies faces difficulty to enter the low end IVD products market are restraining the growth of this market.

2. **Japan**

Japan's market for In-Vitro Diagnostics is currently estimated to be worth USD 3 billion in the year 2014 and is expected to reach USD 3.91 billion by the end of 2020. The CAGR during this period of the forecast is 5.44% (GlobalData's additional report, Japan (JP) In Vitro Diagnostics Market Outlook to 2024). Japan's IVD market is considered the most growing sector after China.

Some of the factors contributing to the growth of market are rapid increase in the chronic & infectious disease population, technological advances, rapidly aging population and advent of point of care diagnostics. However, some of the factors limiting the growth of the market are a lack of proper reimbursement policies and stringent regulatory framework.

3. **South Korea**

The South Korean market for in-vitro diagnostics was estimated at USD 2.7 billion for the year 2016 and is projected to reach USD 3.18 billion by the end of 2021 at a CAGR of 5.40% during the forecast period from 2016 to 2021 (Frost and Sullivan). IVD products used in the infectious disease area account for the largest share, followed by oncology, which is the fastest growing segment owing to the increasing prevalence of cancer.

South Korea's contribution to the growth of the Asia-Pacific market, in terms of financials, is increasing gradually. This is because of the increasing demand for quality healthcare. Many players in this market are trying to expand their product portfolio in order to top the global market. Some companies have adopted product innovation and new product launches as their key business strategy to ensure their dominance in this market. South Korea's market is expanding its growth by merger & acquisition activity. The acquisition of SD Diagnostics by Inverness in 2010 is a prominent example.

Some of the **key players** in the market are Abbott Laboratories, Bio-Rad Laboratories, Inc., Danaher Corporation, Johnson & Johnson, Roche Diagnostics and Siemens Healthcare

Trends indicate that the IVD market in South Korea will continue its upward trajectory with opportunities proliferating in infectious disease testing and early diagnosis. Applications such as molecular testing and POCT are poised to fuel market momentum. International IVD companies that have a comprehensive product line to cater to laboratory needs hold sway over the market. Japanese companies, in particular, have a greater presence in South Korea owing to Japan's proximity and the preference for Japanese products. Domestic conglomerates such as Samsung and LG have realized that diagnostics is one of the growth engines of the South Korean economy and have invested huge sums of money into research and development. These companies are synergizing biotechnology, medical technology, and information technology to differentiate their products. The growing acceptance of molecular diagnostic tests has spurred the development of new tests by innovative regional companies.

4. **India**

IVD market in India is growing at an extraordinary pace and the country has the potential to emerge as a global manufacturing hub in the medical devices space. India is the fourth largest market for IVD devices in Asia after China, Japan and South Korea. Demand for personalized medicines, innovations in diagnostic techniques, increasing preference for point-of-care testing among the general population, a growing geriatric population base and increase in disposable incomes is driving the growth of the IVD sector in India.

Advances in surgical techniques, emerging trends in emergency diagnostics and evolutions in patient care systems point to the fact that hospital laboratories would be the key determinants in deciding the designing and marketing strategies of IVD makers. Clinical laboratories will also form an important client base for the country's IVD sector with the need for revamped devices and testing capabilities. The rapid growth in the home healthcare segment is also set to govern the parameters on which IVD players would position their product portfolios.
Global IVD companies are expanding their operational footprint in India which presents a growing market for their products like ready-to-use test kits equipped with features like high specificity and acute diagnostic analysis. There is a growing need for advanced diagnostic products which include sequencers and molecular test analyzers for servicing the rapidly rising rural healthcare sector.
The medical devices industry in India is still in a nascent stage and its efficacies are largely restrained by a fragmented

structure and its import centric nature. “Numerous manufacturers find India a tough market in which to operate because of its high complexity and extremely competitive domestic players. India isn't a single market. It's a combination of many very different market segments, each with separate sets of requirements, purchase drivers, and ability to pay. Understanding these segments and devising and executing strategies to serve each is the formula for effectively penetrating India”, noted Wilson Tan.

5. **Singapore and Malaysia**

IVD manufacturers seeking marginal growth are focusing on regional markets. The whole of Southeast Asia represents a unique opportunity for healthcare providers and their various industry suppliers, including the IVD industry.

Singapore is the nexus of regional trade as well as the leading port and center for the entire Asia-Pacific. The city-state features the most developed and highest rated healthcare system in Southeast Asia and serves as the headquarters and regional manufacturing center for some medical device, biotechnology, IVD, and pharmaceutical companies. Its neighbour Malaysia has arguably the second-most developed healthcare system in Southeast Asia. Through Singapore or Kuala Lumpur, IVD companies have access to approximately 35 million potential patients, over 700,000 annual medical tourists, and healthcare systems with higher per capita spending than anywhere else in Southeast Asia or anywhere in Asia outside of Japan, Australia, or Korea. Singapore and Malaysia present IVD markets and opportunities with healthy prospects and solid fundaments in clinical demand.

Multinational companies participate in the Singaporean and Malaysian market. Some key players are Abbott Laboratories (Singapore) Pte Ltd., Beckman Coulter Singapore Pte Ltd., Becton Dickinson Medical (Singapore) Pte Ltd., Bio-Rad Laboratories (Singapore) Pte Ltd., bioMérieux Singapore Pte Ltd., Life Technologies Holdings Pte Ltd., Roche Diagnostics Asia Pacific Pte Ltd., Siemens Healthcare Diagnostics Pte Ltd. and Sysmex Asia Pacific Pte Ltd.

6. **Australia**

Australia represents a highly competitive IVD market with established international players, a highly developed export-intensive domestic industry, and highly consolidated clinical lab and testing industry. While other developed IVD markets in North America, Europe and Japan are not estimated to be achieving above 3% annual growth, the Australian IVD market has grown at an average of roughly 5% through the past five years. This rate of growth is projected to more or less continue with a stable funding environment through Medicare and a performing economy.

With universal healthcare and a high level of doctor visits providing access to medical technology and labs using competitively priced complex testing, Australia represents a premier in vitro diagnostics (IVD) market in the Asia-Pacific with excellent per capita IVD spending on par with Japan. Approximately half of every dollar spent on clinical testing or pathology services in Australia is provided by the universal public health insurance program, Medicare. According to Kalorama Information, the Australian IVD market is estimated to grow a bit faster than the world IVD market between 2012 and 2017.

7. **Indonesia**

The Indonesian IVD Market is $233 million, according to *Indonesia IVD Market Analysis.* Indonesia is experiencing increasing per capita income among working professionals and middle class, which is triggering a movement from self-medication to clinical and hospital treatment, with the help of subsidized healthcare services.

Indonesia's clinical testing market is at par with those of its neighbours, for instance the Malaysian IVD market. The country is the 4th largest in the world in terms of population after China, India, and USA and an important and prospective market for diagnostics and medical device manufacturers. Worth mentioning is that in the Indonesia IVD market, foreign IVD companies are banned from making any direct sales. Only local distribution companies, who have distribution licenses, can engage in IVD sales in the country. Therefore, assistance of a local legal firm is the best way for a foreign company to set up its operations in Indonesia.

Growth in the future

Based on the emergence of new, more user-friendly tests, innovations and technologies, increasing access to healthcare, and the prevalence of several chronic and infectious diseases, the IVD market in APAC and around the globe is likely to remain vigorous.

“We see the industry moving towards a greater reliance on data, gathered in near real-time, to inform decision-making for products in market and predictive forecasts for market entry strategy. Additionally, the barriers to high-value design and manufacturing will be lowered due to advancements in bench-top simulation models and 3D printing using new mediums

beyond polymers and alloys", says Mr Wilson Tan.

Harmonization across regulatory bodies on risk classifications and submission requirements is needed. This will create efficiencies in bringing new, innovative devices to market. Realizing better patient care from these new devices should not be hobbled by regulatory inefficiencies, especially when more and more health ministries themselves are providing seed funding to foster diagnostics development and growth.

Emphasizing on the gradual shift towards early detection, thanks to sensor technology and wearables, Mr Tan adds,"Current trends point toward a focus on oncology, cardiovascular disease and diabetes, with an emerging focus on mental health conditions. This will add to the deluge of healthcare data - which in turn will drive advancements and adoption of data science and artificial intelligence (AI) to organize and glean actionable insights from the data. Ultimately this should benefit individual patients through faster diagnosis and targeted therapies based on their genetic makeup."

Mr Kuldeep Singh couldn't agree more. He concludes, "Medical diagnostics will become more consumer aka patient focus – and start incorporating the IoT into its delivery. We are also driving for AI to enhance what we have now alongside remote care models to realise better healthcare. Regulatory wise it needs to take the form of a governance structure which is still flexible enough to enable innovation to occur. Infrastructure is already making its ways into the further reaches of any geography with that the ability for patients to access care models not previously available. One of the biggest advances over the next decade will be achieving greater levels of diagnostic precision at the individual level by being able to capture and process multiple objectives and patient reported variables in the context of the environment in which the person lives using machine learning. This will in turn give rise to the other significant advancements in the next decade. Also, the usage of diagnostic precision to generate personalised prescriptions of care that have a demonstrable health benefit. To scale these new advances, the medical diagnostic industry and its partners will need to compensate/incentivise and insure people for use of personal data and be willing to risk share for outcomes."

The importance of global regulatory harmonization in the field of diagnostics has long been acknowledged. However, the rapid technological innovation that characterizes the IVD industry is outpacing current regulatory frameworks. Safety to patients and evidence is crucial. While innovation is important, we probably also need to have a safety test of these innovations without having to be incumbent by a lot of these processes that have been put down by years. Sometimes, innovations disrupt the standard process. For regulators to deal with innovations, an innovation sandbox might be helpful which will also deal with the regulatory challenges."

~ Dr Sidney Yee, CEO, Diagnostics Development Hub (DxD Hub)

Executive Vice President, Incubation & Startup Management Division