

India: Rise of a diagnostics superpower

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Increasing personal wealth and awareness about health is pushing Indians into seeking better medical options. Today hospitals and diagnostic centers across the country are armed with the best in class medical and diagnostic devices. Companies that offer these devices are increasing their investments and product portfolio in the country—an unlikely scenario at the start of this decade but a familiar situation across India.

Various diagnostics devices manufacturers who skipped India to find better markets elsewhere today find India a red hot market in which to do business and are finalizing both business and manufacturing deals anticipating huge uptake for their devices. They should. India is home to one-sixth of humanity, 30 percent of population is below the age of 25, increasing government expenditure on healthcare and even expanding medical insurance coverage is helping people to care more about their health. The number of tests conducted in the last decade has doubled from 180 million to more than 425 million. There are over 12,000 hospitals and 15,000 diagnostic laboratories in the country that utilize large volumes of diagnostics.

Although India hasn't become a full-fledged manufacturing hub for medical devices, things are changing. There are many local companies that produce diagnostic kits, reagents and kits for blood grouping, serology, clinical chemistry, pregnancy detection, HIV detection and other rapid tests that are accepted globally and imports of such products in finished form is almost negligible. According to Netscribes, the medical diagnostics market is just 10 percent of the healthcare sector's revenues and was estimated to be about Rs 37,900 crore in 2008. In India, 60-70 percent of medical treatments are based on laboratory diagnostics tests.

Markets for medical devices booming

In a recent report for the Department of Pharmaceuticals, Ahmedabad-based National Institute of Pharmaceutical Education and Research (NIPER) said the medical devices supplies market in India will be approximately \$1.70 billion by 2010—growing at 23 percent annually. Currently, the market for medical devices supply is Rs 5,750 crore or \$1.19 billion.

In its report NIPER said diagnostic kits are a fast growing segment of the entire devices market growing at 30 percent, annually. With over 50 companies vying for business, the business will only grow. However, experts say it is difficult to determine the exact size of the market in India, as the diagnostic market is highly fragmented as it involves different segments such as home segment, urine chemistry, diagnostic kits, and reagents. The entire market for diagnostic kits and urine chemistry will be about Rs 275 crore, discounting the cheap unbranded Chinese kits that are available in plenty in the grey market.

Another area of growth is the in-vitro diagnostic (IVD) market that includes diagnostic test services and diagnostic products. This market has grown substantially in the last five years making India one of the important business areas for IVD. The market however is dominated by the MNCs, who between themselves have cornered 65 percent of the market.

Another business that has seen growth is market for clinical chemistry which is approximately Rs 490 crore. Instruments market is estimated at Rs 185 crore while the reagents market is at Rs 305 crore. The reagent market is further divided into “closed systems” at Rs 85 crore and the actual served open market at Rs 220 crore.

The leading players in this segment include Transasia Bio-medicals which was ranked as the top IVD company in India by McEvoy & Farmer, a US-based experts on IVD markets. The other major players in this group are Roche Diagnostics, J Mitra, Johnson & Johnson, Beckman Coulter, Trivitron, Accurex, Tulip/Crest, Bayer-Siemens, Agappe, Randox, Span, Wipro Biomed, Merck, Ranbaxy, NPIL-DiaSyS. Apart from these, there are 30 other smaller players operating in this market segment.

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According to international reports, the Indian healthcare sector is currently valued at \$34 billion and by 2012, it will be valued at approximately \$40 billion and out of this market, the diagnostic and pathology market is around 2 percent. The diagnostic market has been growing at 15-20 percent and by all indications shall continue to grow for another 10 years at this rate.

Diagnostic market includes diagnostic test services market and diagnostic products and instruments market. Diagnostics and pathology lab test services market in India holds 44 percent of the medical devices and diagnostics market, valued at Rs 12,587 crore in 2007. According to Cygnus Business Consulting and Research, Indian diagnostic and pathological labs test services market is valued at Rs 5,590 crore (2007) and is estimated to reach Rs 13,900 crore by 2012.

Increasing health consciousness and preventive care have changed the landscape of healthcare services market. Whether it is wellness checkups, preventive care checkups or insurance-related checkups, diagnostics and pathology laboratories are growing significantly, fueled by the growth in outsourcing diagnostics tests and clinical research. The Indian diagnostic and pathological labs test services market was valued at Rs 6,687 crore in 2008, says the Cygnus report.

There are about 40,000-50,000 pathology labs spread across the country with less than 100 having accreditation. Out of these only a few labs are operating as referral centers and about 1,000 labs are automated. The major players in diagnostics and pathological test labs market are Metropolis, Religare SRL Diagnostics, Dr Lal's Pathology, Piramal Diagnostics (formerly Wellspring), Thyrocare and Anand Labs.

Lifestyle diseases make a large market

India has the largest number of people suffering from diabetes while hypertension, respiratory diseases and obesity are increasing as lifestyle changes. This has led to the growth of consumer home-use medical device markets. As per industry forecasts, personal use device segment will reach over \$5 billion by 2011.

India is also fast emerging as the diagnostic capital of the world, currently there are about 40.9 million Indians suffering from diabetes. But the concept of Self Monitoring Blood Sugar (SMBG) is still not well-known in India as compared to the West. In India a meager 0.3 percent of diabetics use SMBG as opposed to almost 22 per cent in developed countries. Lack of awareness regarding complication of diabetes and benefits of regular monitoring are key factors for this.

Imports constitute over 50 percent of this market. Most imported products have high gross margins. Currently, the high value imported products include cancer diagnostic, polymerase chain reaction technologies among others. However, the market is becoming increasingly competitive due to low entry barriers, relaxed laws, increasing competition and users.

The duty exemption for diagnostic kits used to detect life threatening diseases is another area of contention. NIPER noted that the duty waiver continues to only apply to basic techniques that are increasingly replaced by newer and more precise methods like the polymerase chain reaction (PCR) test. At present only tests like the ELISA and CLIA enjoy the duty waiver while the PCR kits attracts 37 percent. Customs duty in spite of applications in the diagnosis of diseases like TB, hepatitis or bird flu, increase the cost of tests done using the advanced technique. These budgetary tax measures coupled with an

already anomalous customs tariff structure are expected to escalate the cost of treatments and burden the patients and ultimately constraint the delivery of modern healthcare, the report noted.

As a measure to tackle the increasing duty structure and dependency on imports, Indian companies are looking forward to having alliances with foreign companies either to import and distribute their products in the Indian territory or become licensed manufacturers and distributors of the foreign companies.

For example; Japan-based Arkray, has entered into a 49:51 joint venture with Piramal Healthcare and formed Arkray Piramal Medical to market diagnostic products, mainly SMBG (Self Monitoring Blood Glucose System) in the Indian market. Arkray Piramal is currently looking at strengthening its position in the SMBG space.

Investments

India as a major bioindustry and IVD manufacturer needs to invest in dedicated research and development to boost the delivery of increasingly sophisticated equipments and quality kits. Steps need to be taken to cross the current chasm to fulfill responsibilities to doctors and patients in meeting and exceeding their needs for reliable, affordable and innovative medical diagnostic systems.

Looking at the opportunity and growth of the market, local companies are now investing on R&D and developing a range of kits for the local market. However, there are a few hi-tech products like Elisa, PCR, a few cancer markers and many other products for which there are very few manufacturers in the country. This area is also developing very fast.

Xcyton, had recently launched a PCR-based diagnostic kit for eye infections. The project was supported by the Ministry of Science and Technology, and was a collaborative effort involving research institutions like Shankara Netralaya, LVP Eye Institute, the Centre for Cellular and Molecular Biology, and the All Indian Institute of Medical Sciences.

The level of R&D spending in the medical device and diagnostics industry, as a percentage of its sales, has been consistently increasing from 5.4 percent in 1990, to 8.4 percent in 1995, to 12.9 percent post 2000, says NIPER.

NIPER has asked the government for creation of more academic centers to meet the technological and regulatory demands; interdisciplinary and combinatorial research projects; testing facility for devices and pre-clinical and clinical studies for medical devices as some of the measures to assist the sector.

The emerging industry structure is headed towards providing healthcare services as an integrated comprehensive package rather than the traditional concept of providing healthcare infrastructure and reactive medical care. Growing health consciousness among middle and high-income families in India is heralding a new business opportunity—preventive healthcare. This has shifted focus from in-patient treatment to a regular preventive health check. Corporate companies offer annual health check for their employees; insurance companies conduct pre-insurance policy check; and self paid health checks also give out a potential business opportunity.

Private equity (PE) and venture capital (VC) investors are looking to step up the pace of investments in the healthcare sector in India. In the recent past though, specialty PE firms have emerged to invest exclusively in this segment. Evolve India LS, India Ventures and Sabre Capital's Spring Healthcare fund are some PE funds in this category.

According to Venture Intelligence, 'There are very few corporate hospitals and PE and VC funds see this as an opportunity to bring smaller hospitals together to scale-up.'

In July 2008, Mauritius-based private equity fund New York Life Investment Management and Jacob Ballas India Fund invested \$22 million in Mumbai-based Themis Labs. In February this year, India Venture invested \$18 million in Tamil Nadu-based Kavery Medical while IFC invested \$30 million in Max India. Sabre Capital has a \$100 million fund focused on investing in mid-size existing hospitals or in start-ups. ChrysCapital, which focuses on the pharmaceutical sector, is looking at opportunities in the healthcare space especially in hospitals, medical diagnostics and devices. It may invest anywhere between \$30-300 million with a long-term view of 5-10 years.

Venture Intelligence noted that over 42 percent of PE and VC investors felt there was a strong opportunity to tap the market for healthcare services in semi-urban and rural areas. The investors also identified diagnostic services, medical devices/equipment, hospital chains and wellness products and services as favorite sectors for investments.

The emerging trend in the healthcare sector and initiatives mooted by the government and interests from the PE/VC community will boost the upcoming and growing diagnostic market in India.

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