



Health Technology and Medical Devices: Bedrock of Futuristic Healthcare

Shakti K. Gupta

MBBS, MHA(AIIMS), FIMSA, FNAMS, FIHE, FAHA, MACHE(USA)

Executive Director & CEO, All India Institute of Medical Sciences (AIIMS), Jammu, India

Available Online: 17th August, 2022

Over the last 50 years the Indian Healthcare system has scaled great heights, particularly in terms of health Technology which has become one of India's largest sectors, both in terms of revenue and employment. This change has become significantly more evident over the last decade, with a renewed focus from the government and growing market demand for healthcare services and products. The Indian population has a growing elderly population. Rapid economic growth, rising middle-class incomes, and increased market penetration of health insurance are fueling growth in the industry. For every 10,000 Indians, there are 6 doctors, while China has 20 doctors for every 10,000 people, Australia has 249, UK has 166, and US has 548. In addition, changing demographics and a shift from chronic to lifestyle diseases have led to a boom in healthcare spending. The Indian healthcare industry is expected to reach \$370 billion by 2024-2025 due to increased demand for specialized and higher-quality healthcare facilities.

The industry's rapid development is fueled by large investments from existing corporate hospital chains and new entrants backed by private equity investors. However, considerable challenges and key concerns exist regarding easy accessibility of quality healthcare and affordability to the citizens at large. According to the Global Burden of Disease Study (GBD), released by the Lancet Medical Journal in 2018, India ranks 145th among 195 countries on the healthcare index. India's healthcare access and quality (HAQ) index score has improved recently, from 44.8 (out of 100) in 2015 to 67.3 in 2020.

The government has proposed to increase the public spending on healthcare to 2.5% of GDP by 2025, with a special focus on the underprivileged. As expenditures in the Indian healthcare sector increase, there will be a corresponding growth in the medical equipment market. The term **HEALTH TECHNOLOGY** encompasses a wide range of healthcare products (devices, equipment, and consumables/ supplies) intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes.

Technology in the last two decades has revolutionized healthcare delivery worldwide. It has greatly aided patients and providers alike by enhancing the quality of delivery, reducing the turnaround time of workflows and thus the overall cost, and bringing higher accountability into the system. Advancements

in medical technology are playing a positive role in saving lives. The influence of medical technology is all-pervasive - its positive impact is felt across various strata of society but has also helped the poorer lot, e.g., reduction in IMR/MMR due to usage of the right technology, e.g., incubators, warmers, better OT equipment.

The **Urban-Rural divide** is still to be bridged in Healthcare delivery. The limited healthcare facilities available in the country are skewed more in favour of the affluent category of the population. On one end, India has world-class doctors, clinics and technologies and attracts international medical tourists in growing number, while even today, the majority of India's population cannot afford anything better than the most basic healthcare.

High-end medical technology products are largely imported into India. Imports constitute about 75% of the Indian medical technology market. It is interesting to note that while India's medical technology industry is primarily import-dependent, at the same time, nearly 60% of what is being manufactured is being exported. The diagnostic kits represent one of India's fastest-growing segments of the medical technology industry, enjoying an annual average growth rate of over 30%.

Indian medical technology industry needs "**low-end disruptions**" which target customers who do not need the full performance valued by customers at the high end of the market, as well as **incremental innovations** that make changes to existing products to launch no-frills or lower-end versions. These innovations can impact a larger segment of the population which is price conscious and driven by affordability. One such innovation is GE's Mac series, an ultra-portable electrocardiogram (ECG) machine. The device was conceptualized, designed and manufactured in India according to the requirements of the domestic market. With the Indian market in mind, the MAC 400 is priced at one-third that of imported ECG systems of similar quality, battery-operated to deal with power outages in many parts of India, lightweight to be portable so they could reach more patients, comes with commercially available components instead of customized ones.

Indian medical device market is estimated at \$10 billion. India's market has undergone significant economic growth over the last twenty-five years, but it remains difficult to

navigate. India tends to be a price-competitive market, primarily producing lower-to mid-tech items. International competition has also been rigid and India is often described as a “crossroads” market in the middle of many producers and trade routes. The Government of India’s (GOI) newly introduced production linked incentive (PLI) scheme in medical device manufacturing aims to encourage domestic manufacturing, attract significant investments, and reduce reliance on imports in this industry.

Biotech is one of the fast-growing segments of the life sciences sector and represents a diverse opportunity for foreign firms. The Indian biotech industry comprises about 800 companies, and market size of \$5 to 7 billion constitutes approximately two percent of the global biotech industry. India is also a leading destination for clinical trials, contract research, and manufacturing activities due to growth in the bio-services sector. Supplying equipment and medical consumables will provide significant opportunities for Indian companies to serve this growing market. India has become one of the leading destinations for high-end diagnostic services, with tremendous capital investment for advanced diagnostic facilities. Other growth areas include diagnostic kits, reagents, hand-held diagnostic equipment, and operating room simulations. Hand-held/portable diagnostic equipment (e.g., blood sugar and blood pressure testing) is also a fast-growing segment as India has around 45 million diabetics, a number expected to swell to 70 million by 2025.

Digital Healthcare/ telemedicine, though still in its infancy, has expanded rapidly due to the COVID-19 pandemic. People are slowly adapting to new health technologies and intelligent solutions to reduce barriers between hospitals and patients. Telemedicine technology and artificial intelligence (AI) will provide a significant opportunity for Indian firms in the coming years. Major players such as Apollo, AIIMS, and Narayana Hrudayalaya have adopted telemedicine services.

The Ministry of Health and Family Welfare, along with NITI Aayog, has recently released official guidelines for telemedicine practices that allow registered medical practitioners to provide remote consultation under the National Medical Commission (NMC) supervision. Healthcare services in rural India are not readily available, with the average rural Indian traveling over 62 miles to receive affordable healthcare at the nearest facility. Rural Indians will benefit from the increased focus on digital healthcare technologies by the GOI and the private sector as India adjusts to the post-COVID era.

To ensure quality healthcare, the GOI increased the list of medical devices covered under the Drugs and Cosmetics Act of 1940, bringing several categories of implantable devices under the provision of medical device rules (MDR) 2017. In January

2020, the GOI categorized all medical devices (including instruments, implants, and software intended for medical use for humans or animals) as ‘drugs’, bringing them under the purview of Drugs and Cosmetics Act, 1940. Currently, 37 medical devices have been classified as drugs, and are regulated under the Drugs and Cosmetics Act. Of these, cardiac stents, drug-eluting stents, knee implants, condoms, and intra-uterine devices are included in the NLEM and are subject to price caps.

In June 2020, the Department for Promotion of Industry and Internal Trade (DPIIT) amended its 2017 Public Procurement Order, prioritizing local companies whose products contain 50% or more local content. Products less than 20% local content are categorized as ‘non-local suppliers’, and cannot participate in government tenders.

Effective June 2021, the National Pharmaceutical Pricing Authority (NPPA) issued orders to bring oxygen concentrators (OCs) under price control in line with the trade margin rationalization (TMR) approach. NPPA capped the trade margin up to 70% of the price to distributor (PTD) level, and directed manufacturers to fix the maximum retail price of the non-scheduled drug OCs as per the TMR formula. TMR is the difference between the price manufacturers sell to the trade and the price to patients (MRP). NPPA introduced the TMR policy for medical devices and drugs in 2018 to protect and provide affordable and accessible healthcare to consumers.

In June 2021, The Quality Council of India (QCI) and the Association of Indian Medical Device Industry (AIMED) added new features to the Indian Certification for Medical Devices (ICMED) Scheme (2016). This new scheme, ICMED Plus, will undertake verification of the quality, safety, and benefits of medical devices and help agencies identify counterfeit products and falsified certifications. In addition, the new rules eliminated the need for re-approval of manufacturing and import licenses, which are now valid unless suspended, terminated, or surrendered. An approved central licensing authority must license devices for manufacture, sale, or distribution.

The growing demand for quality healthcare and the absence of matching delivery mechanisms pose both a challenge and an opportunity. The construction, equipping, managing, and financing of super-specialty hospitals in India is a future growth area.

Innovations in products alone won’t suffice to tap the unique needs of the growing Indian market. There is a need to rethink and redesign the entire business model. The health technology industry needs to reboot from merely supplying devices and equipment to the healthcare industry to providing integrated solutions for improving health outcomes.