

Medical Device Industry in India

The Evolving Landscape,
Opportunities and Challenges

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Foreword

The Indian government's 2017 National Health Policy deals with progressive universal healthcare for citizens, envisioning equitable health and well-being for all sections of society. The policy seeks to increase access and adoption, improve quality, and lower healthcare delivery costs in the country. The government has recognized the changing disease patterns in the country, the need to address the significant growing burden of non-communicable diseases, and the emergence of a robust and successful private healthcare industry. The bulk of government spending will be directed towards reviving and strengthening primary healthcare systems, focusing on rural and lower tier urban areas that lag behind in quality and access. The government is likely to take on the role of a payer rather than a provider, resulting in improved outcomes and better utilization of healthcare expenditure in the country.

The global medical device industry is highly innovative and technology driven, changing the face of healthcare worldwide. Globally, it is a rapidly advancing industry impacting and improving aspects such as diagnosis, treatment, and delivery, but in India, it is still very nascent with low levels of penetration and adoption. This presents an exciting opportunity to develop this industry and to play a larger role in the transformation of Indian healthcare. A good understanding of the nature of this industry will help ensure that the country is poised to capitalize on opportunities provided by medical technology to improve national healthcare.

A new national medical device policy is currently being developed and the Indian government is actively engaged in discussions and consultations with various stakeholders. Policymakers working collaboratively with stakeholders in the healthcare eco-system are attempting to lay down a roadmap that provides consistency and predictability. The path to realizing healthcare goals is complex, and various fundamental issues and challenges need to be addressed and solved holistically. Long-term plans need periodic policy and regulatory interventions to ensure fair conduct within the industry while providing the support needed for profitable and sustainable growth. These activities will enable the medical device industry to accelerate rapidly and play a key role in making India healthier and stronger.

AdvaMed has partnered with SKP to publish this paper entitled - *Medical Device Industry in India - The evolving landscape, opportunities and challenges*. The paper also examines various policies and regulations impacting the industry and attempts to make recommendations on the way forward from the perspective of different stakeholders. Extensive research, both primary and secondary with deliberations and discussions with several stakeholders across the healthcare chain have served as inputs for this paper.

AdvaMed and SKP would like to thank everyone for their insights and valuable contributions towards this paper.

We hope that this paves the way for further deliberations and helps in shaping the industry in a positive manner.



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Executive Summary

The healthcare industry in India has made rapid progress in the last decade, but significantly lags behind other nations in availability and quality of equitable medical care and services for citizens. This in turn presents an enormous opportunity given the large population, growing economic prosperity, and the disease burden. Major issues such as availability of adequate infrastructure, trained human resources, geographic spread, rapidly changing disease burden, and high/often catastrophic out of pocket expenditures are challenges that the government is keen to address. The Indian government is committed to raising public expenditure on health to 2.5% of the GDP. Public and private sectors need to play equally important but different roles in bringing rapid change to the healthcare scenario in the coming decade.

The medical devices industry in India is currently valued at approximately USD 6 billion and has expanded at a significant double digit growth rate over the past few years. The industry is still at a nascent stage with sub-optimal penetration and usage of medical devices. Currently, India comprises only 1.7% of the world market, the industry is significantly import dependent, and current demand does not offer scale in various product categories. This will transform as demand significantly escalates to realize potential.

The Make in India initiative is intended to attract both Foreign Direct Investment (FDI) and domestic investment

in this sector. Government initiatives around opening up FDI and infrastructure development are welcome initiatives that will enhance the ecosystem for investment. The Indian medical device industry appreciates government's efforts to remove bureaucratic hurdles and improve the ease of doing business, but believes that additional steps can be taken to strengthen its approach.

Our discussions with the industry leaders indicate that given the lack of scale in many products, the government should prioritize certain products for manufacturing in India. High volume, low-tech, labor intensive manufacturing sectors should be the initial target. Very rapid import substitution may not be practical or desirable. It is also felt that the government should position and promote India as a global manufacturing hub or destination, rather than focus on just the domestic market. Frugal innovation is a significant strength that India can offer the world. Innovation to develop new products for emerging markets should be encouraged, and this will also ensure manufacturing volumes needed for profitable operations. This approach will help India attract the right technology, upgrade manufacturing processes and quality, and build local R&D capability.

The Indian medical device industry believes inclusive policy making by the government, and understanding and addressing legitimate concerns will greatly benefit the healthcare industry as a whole. The recent pricing

control regulation and the new Public Procurement Policy with preferential Market Access do not fully reflect this and has alarmed many industry participants. A clear long term vision and roadmap for the industry and predictability of policy would excite the industry. The government needs to provide policy support for both the supply and demand side of the medical device industry to successfully accelerate growth. Industry and government need to work together to improve awareness, access, adoption, and affordability for medical devices in India. The government has indicated that in the new healthcare policy that they will focus strongly on preventive and primary healthcare and in facilitating build-up of the required medical, paramedical, and allied health human resources in the country. Leaving secondary and tertiary healthcare delivery largely in the hands of the private sector will result in significant improvement in efficiency of spends. The private sector also plays a very significant role in training medical and allied resources in the latest technology, innovations, and procedures and in bringing in global standards in delivery and care. The government has indicated that they will take on an increasing role as a payer, facilitate widening insurance coverage significantly, and use resources to purchase services from the private sector for the underprivileged through cost effective modalities, including public-private partnerships.

Healthcare industry participants including medical device players suffer from poor public perception regarding their conduct and practices. It is crucial for the government and the industry to work together to improve this image and perception. There is a need to assess the information asymmetry that exists, and bring in transparency in areas such as pricing and cost at the product and services/procedures level. While guarding against profiteering, regulators need to ensure that the healthcare industry is profitable and can grow and upgrade to bring in all required technological advancement. Data suggests that healthcare costs in India are among the lowest in the world even when adjusted for purchasing power. Analysis of available financial statements do not indicate profiteering either in the medical device or healthcare delivery sector.

The industry feels that the recently announced price control policy, while intended to improve affordability, needs reconsideration and change before roll-out to other categories. As formulated and implemented today, the policy will have limited impact on patient cost and could also deprive India of new technology in the future, besides stifling sectors like medical tourism. The government needs to consider options that include more tiers in pricing and give new technology the benefit of being spared from price control for a certain number of years. The industry believes that trade margin regulation should be approached by first looking at essential products based on burden of disease and recommends the government review essentiality of devices when

determining devices to price regulate. Issues like high trade margins can be tackled with conversations with all stake holders. Bulk purchasing of specific devices at low prices to support government schemes that serve the underprivileged and using the insurance industry to determine reimbursement prices and co-pay levels could also ensure value in the usage of devices and delivery.

The government has moved in the right direction by separating out medical devices from drugs from a policy/ regulations perspective, but more work is still required. Improved understanding of important differences between the two sub sectors will continue to help shape appropriate policy. Key to this is an appreciation of the industry's technology and innovation lifecycle, and a willingness to reward technology and continuing innovation. The industry believes that a full separation of drugs and devices via a separate medical devices act and regulatory body and expanding the coverage and scope of the medical device rules to cover most if not all devices, will ensure that devices marketed in India meet global standards of quality and safety. This combined with a drive to ensure accreditation by NABH will strengthen the quality of care and improve outcomes. It is important for the government to build the capability to conduct robust Healthcare Technology Assessment (HTA) in the country. Establishing a functioning Medical Technology Assessment Board (MTAB) will help the evaluation of the differentiation and value of various medical devices.

Industry participants also strongly feel that the government should broaden its vision from Make in India to include both *Innovate in India and Heal in India*. With attractive healthcare costs, a well-trained and qualified medical and technical work force, and a vibrant private sector, such a strategy has the potential to be very rewarding for the country. A faster-growing healthcare delivery sector will boost demand for medical devices and also lead to significant employment generation in services. Additionally, this focus will help India innovate, establish global standards in products and services, and improve the balance of trade favorably especially with medical tourism growth. Such a strategy could also help cross-subsidize healthcare for the under privileged segments to a degree, again boosting demand at the lower end.

The healthcare and medical device industries are at a critical threshold where growth can be significantly accelerated to ensure that India embraces the benefits of advancing medical technology to uplift standards of healthcare sharply in the next decade. A vibrant and profitable private sector is critical for success. By proactively listening to and understanding each other better, government and industry can collaborate effectively to realize the vision of the 2017 National Health Policy.

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