

The prospects of building a futuristic Medical Devices Industry in India



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Submission: October 17, 2022; Published: October 21, 2022

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Abstract

With rapid development and the rise in the aging population, the need for cheap and high-quality biomedical devices has increased four-fold. Different organizations define Biomedical Devices in different ways but they can be broadly classified into diagnostic devices and treatment devices. India is among the top 20 producers of Medical Devices in the global market and is fourth only to Japan, China, and South Korea in Asia. It is also the world's largest producer of vaccines. With proper planning and implementation, it shall follow suit as a leading producer of Biomedical Devices as well.

Introduction

The Healthcare Industry in India has shown a remarkable growth in the last decade. Apart from being the world's largest producer of vaccines [1], it has also taken a decent leap in the Global Medical Devices Market as well. India is among the top 20 producers of Medical Devices in the global market and is fourth only to Japan, China, and South Korea in Asia [2]. India holds a really fertile soil in this aspect, the reason being its huge manpower, a never-ending stock of cheap raw materials, a huge domestic market, technical expertise and a strong ecosystem [3]. It is high time for reforms to be made both in the public and private sector so that India can emerge into a manufacturing genius.

Discussion

However, all said and done, currently, India in the manufacturing sector spends only 3\$ on medical devices compared to the global average per capita consumption of 47\$ [4]. The major causes that pose as a threat to the development of industries that could supply medical devices in India include:

a) An unfavorable duty structure whereby the imported products become cheaper as compared to the ones produced locally, due to which importing raw materials as well as some active pharmaceutical ingredients becomes a more acceptable option to the buyers owing to a lower price rate.

b) High import dependency

c) The tarnished image of indigenous industries due to low quality products.

d) Lack of incentives for the development of local industries.
e) Rigid, age old taxes and policies with myopic amendments:

a) The medical devices are regulated by the Central Drugs Standard Control Organization and follows the regulations framed under the Drugs and Cosmetic Rules, 1940. Thus, 'it's everybody's baby but no one's business' [5].

b) Absence of export substitution policy.

'Make in India' is a crucial program launched by the Modi government in September, 2014 [6]. It was a galvanizing call to India's stakeholders and entrepreneurs as well as the foreign investors. The aim is promoting indigenous manufacturing industries, stocking up local raw material by increasing their production, avoiding export of such raw materials, framing newer domestic market friendly policies and making the fiscal ones obsolete, promoting export and rationalizing the unfavorable duty structure.

Making India a manufacturing hub for medical devices shall have its own advantages. These include:

a) Health has been recently announced as a fundamental right. If we compile the current health indicators such as infant mortality rates, maternal mortality rates, morbidity rates and hospital admission rates we will find that the health status of the Indian community is touching base level. Owing to the low

health standards, it shall be a revolutionary change since then the prices of such expensive medical devices will fall due to increased domestic consumption. The thing that should be borne in mind is that both the government as well as the manufacturers should not go on biting off more than they can chew. The aim should be to promote export but not at the stake of the domestic supply of the same.

b) Employment- setting up multiple manufacturing units will provide job opportunities to the numerous unemployed thus raising national incomes which in turn will act like a catalyst for further advancement of these industries.

- c) Development of local R&D and local skills.
- d) Improved foreign exchange.
- e) Sustainability

In addition to the Make in India Campaign, a National Medical Devices Policy has also been proposed in lieu of which, an approach paper has been released by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers [7]. The aim is to convert India into one of the top five global hubs for Medical Devices by 2047. Nearly 80% of the medical devices used in India are imported, the policy shall aim to reduce import and increase local manufacturing by 30% in the next ten years. The draft highlights adopting Public-private partnerships, creating a single window clearance system for licensure of medical devices, promoting local sourcing, encouraging cross-industry collaborations, incentivizing core technology projects and exports, building competitiveness through financial support for development of local manufacturing ecosystems, dedicated funding and incorporation of a framework for coherent pricing regulation.

Other government initiatives in this direction include the **Production Linked Incentive (PLI) scheme for Promoting Telecom & Networking Products Manufacturing in India, promotion and setting up of Medical Devices Parks in** Telangana, Andhra Pradesh, Tamil Nadu, and Kerala to provide a plug-and-play framework for businesses wishing to establish manufacturing operations in India. These specialized hubs will also make it simple to access facilities for routine testing and lower the price of manufacturing devices [3].

What needs to be done?

a) According to the WHO, India spends as little as a meagre 1% of its GDP on health issues [8]. As long as the government does not revolutionize its contribution towards public health, none of these visions shall be realized.

b) Understanding local sentiments is of utmost importance. In India people do not embrace advanced medical care unless the disease they are suffering from is life threatening. According to a study a majority of people suffering from uncontrolled Diabetes

Mellitus live under the illusion that their sugar is under control and they keep bringing minor changes in their dietary habits to resolve the so-called 'minor fluctuations'. A majority of them have no idea that their sugar levels can be checked at home and another majority keeps changing the dosage of the drugs at will. Until and unless mass health education at community level is undertaken the success of any manufacturing unit for medical devices will meet dead ends.

c) Communicating, understanding, assessing and bridging the gap between the health care providers and the manufacturer is the key to the development of India as a manufacturing hub for medical devices since it is the health care personnel who are ultimately going to implement the devices among the masses. The success of launching the device in the market will depend on how much user and patient friendly it is, as well as on the disease behavior of the community. Launching a device that will check the disease load of yellow fever in a country like India will be a futile attempt. Thus, community-based studies should be undertaken frequently too.

d) A specific regulatory body

e) Both the central and the local government have come up with various schemes such as the Rashtriya Swasthya Bima Yojna, Employment state insurance scheme, Central Government Health Scheme etc. Device manufacturers must realize the coverage limits and demographics while putting a price tag on their products so that they get maximum acceptance in the market.

Conclusion

In conclusion, as challenging as it may seem at present, we have various local success stories that can act as an impetus for other manufacturers to come up with the same. We should follow their lead, understand their strategies and put them to national use so that India becomes close to a self-sustaining body as far as health aspects are concerned. It is a very powerful idea of making India a manufacturing ground for medical devices and if it is achieved, the giant push that it will give to the Indian health standards as well as the economy will only provide further fuel to the fire of tremendous development that shall subsequently follow.

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DOI: [10.19080/CTBEB.2022.21.556054](https://doi.org/10.19080/CTBEB.2022.21.556054)

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