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Brief Report

Economics of Medical Devices in India

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ABSTRACT

Most of the industrial sectors of India have undergone major changes in the post-liberalization period. During this period, India has become self-reliant in drugs; however, still, 75% of the medical devices are imported in India. According to WHO, almost all devices present in the developing countries have been designed for use in the industrialized countries. With the increase in incidence of non-communicable diseases and decrease in communicable diseases; increase in survival rates and decrease in mortality rates, and increase in ageing population, the healthcare demands have changed in the last decade. In addition to these parameters, aware patients and healthcare professionals, requirement of achieving national targets of healthcare and close proximity to the developed world, is giving a push to the development of indigenous medical device industry. However, the rules and regulations governing medical devices are ambiguous and vague. The Health Ministry of India has notified Medical Devices Rules, 2016, for regulating manufacturing/import/sale/clinical investigation and other related matters concerning medical devices. In addition, the government is funding the start-up industries in medical devices sector. Furthermore, government has taken the initiative of inverted duty structure in India. Also, special med tech zones are being set-up, which will enhance the production at local levels for the local population and will also generate employment for local people.

Keywords: medical devices, India, make in India, AMTZ, cost effective.

Introduction

In the last two decades, India has witnessed major advancements in most sectors, such as health care, infrastructure, industry, and agriculture. The health care sector has achieved significant strides in patient care. There has been a decrease in mortality rates and incidence of communicable diseases and an increase in survival rates and in per-capita total expenditure on health in the last decade [1]. From 2000 to 2012, the life expectancy at birth for both sexes increased by 5 years [1]. The number of deaths caused by diarrheal diseases and lower respiratory tract infections also decreased in this last decade [1].

Nevertheless, the health care sector of India needs continuous improvement to match the developed world. Even after so many years of independence, the difference in the urban and rural health care is still wide. India, along with other South Asian countries, is having a decrease in birth and death rates, but concurrently there is an increase in longevity and aging population [2]. This elderly population is at a higher risk of noncommunicable diseases (NCDs) such as cardiovascular diseases, diabetes, cancer, and chronic airway diseases [2]. World Health Organisation (WHO) data from the year 2011 show that NCDs are responsible for 53% of deaths in India [3]. Ischemic heart disease (12.4%) is the leading cause of mortality among Indians, followed by chronic obstructive pulmonary disease (10.8%) and stroke (9%). Although the place of first two causes of mortality has not changed in the last decade, stroke has gone up the ladder and mortality caused by diarrheal diseases and lower respiratory tract infections has decreased [1]. India also has a continuously increasing population of patients with type 2 diabetes mellitus (T2DM). By 2040, the present population of 69 million with T2DM will increase to 140 million [2].

Amidst this increasing prevalence of NCDs, health care insurance is also taking fast initial steps in India. Because the national health care budget is low in India, the health care expenditures are generally out of pocket (OOP) [4]. This leads to expensive, unaffordable health care for majority of the Indians. The latest WHO analysis shows that private expenditure on health as percentage of total health expenditure is more than double the government expenditure [1]. The OOP expenditure as a percentage of private expenditure on health care has decreased from year 2000 to 2011 from 91.8% to 86.3% [1]. Over the last decade, health care insurance has been expanding to decrease the health disparities and to reduce health care costs [5]. Health care insurance

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business has grown by 25% per annum in the last few years, with a major share of the private insurance sector [6].

Nevertheless, the present government is making efforts to turn the tide and improve the health care system. India is the first country in the world to accept the WHO's global action plan for the prevention and control of NCDs from 2013 to 2020. India has accepted the target of reducing the global premature deaths from NCDs by 25% by 2025 [7].

Role of Medical Devices in Health Care Delivery

Advancement in medical technology is one of the key steps in achieving the target goals in health care. Starting from prevention to treatment and rehabilitation, progress in medical technology has its share in improving the health of the human beings. The availability of highly sensitive and specific diagnostic techniques has helped in decreasing the incidence of diseases (e.g., decrease in incidence of carcinoma cervix among females). Further, diagnosis of diseases has become more accurate and quicker. Also, these have provided treatment alternatives for cardiovascular, orthopedic, endocrinology, and oncologic diseases (e.g., use of insulin infusion pumps) [8–10]. All these have helped in achieving a healthier and longer life of people [11]. World over, the technological advancement has helped the disabled people lead an independent life, contribute to the community, study and work similar to the rest of the population [12].

Development of accurate, sensitive, specific, cost-effective, safe medical devices has been a part of progress in medical technology. Nowadays, the practicing physician increasingly relies on medical devices for patient care. Nevertheless, the definition of medical device is not as simple as it looks. Medical device according to the recently proposed Medical Device Regulation draft is [13]:

i *any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including the software, intended by its manufacturer to be used specially for human beings or animals for one or more of the specific purposes of:*

- *Diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder; diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; investigation, replacement or modification or support of the anatomy or of a physiological process; supporting or sustaining life; disinfection of medical devices; control of conception; which doesn't achieve the intended action in or on the human body or animals by any pharmacological or immunological or metabolic means, but which may be assisted in its intended function by such means, and covered under sub-clause (iv) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940);*

ii *an accessory to such an instrument, apparatus, appliance, material or other article;*

iii *substances covered under sub clause (i) of clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 923 of 1940) used for in vitro diagnosis which is a reagent, calibrator, control material, kit, instrument, apparatus, equipment or system, specimen receptacle, whether used alone or in combination with any other reagent, calibrator, control material, kit, instrument, apparatus, equipment or system, that is intended by its manufacturer to be used in vitro for examination of any specimen, including any blood or tissue donation, derived from the human body, solely or principally for the purpose of providing information, concerning a physiological or pathological state or a congenital abnormality; to determine the safety and compatibility of any blood or tissue donation with a potential recipient thereof; or to monitor therapeutic measure; substances in the nature of medical devices covered by sub-clause (b) of section 3 of the Drugs and Cosmetics Act, 1940 (23 of 1940).*

It is significant to have such an extensive, nonambiguous definition of medical devices because medical devices are not free of risks. Similar to the drugs, careful administration of medical devices is mandatory for success of the treatment.

Medical Device Industry in India

The aforementioned definition is a part of the long-awaited proposal by Central Drug Standard Control Organization of India, which is the focal point for regulations of medical devices.

Parallel to the implementation of Trade Related Intellectual Property Rights (TRIPS), the governance of medical devices has also undergone modifications since 2005. Before this time, medical devices were classified as drugs. Then some devices, such as disposable syringes, needles, stents (cardiac and drug eluting), catheters, cannula, intraocular lenses, heart valves, orthopedic implants, and internal prosthetic replacements were classified as notified medical devices [14]. Others such as intrauterine devices were grouped as non-notified medical devices, for which no registration was required. Later, in the following years, the list of notified devices slowly increased to 160.

Imports meet over 75% of the India's total demand for medical devices, and 30% of these are supplied from the United States alone [15]. This high percentage of import is not only an economic burden, but also leads to a mismatch between the design of the technologies and the actual clinical scenario, health care infrastructure of India, and the needs of the patients [15,16]. Lack of incentives under the earlier systems, deficient rules and regulations, import-friendly tax system, and poor research and development setups are some of the factors leading to a high percentage of import of medical devices in India. Higher import duty had to be paid for raw materials rather than finished medical device, thus increasing the likelihood of import of devices rather than production in the country. Also, there was lack of tax incentives for setting up medical device manufacturing units. The OOP health care spending system, deficient insurance cover, and lack of continuous training of medical practitioners also have acted as barriers for the growth of medical device industry in India [15].

Nevertheless, some medical device manufacturers have succeeded in creating a niche for themselves. TTK Group has been involved with manufacturing of medical devices since 1991 and now it is known for TTK Chitra heart valve and knee surgical implant [16,17]. Others such as Appaswamy Associates have been successful in providing very cheap intraocular lens of global standards. Others such as Aurolab and Trivitrion Health Care succeeded in creating a market for their intraocular lens and in vitro diagnostics. Companies like XCyton got successful in developing indigenous ELISA based kits and polymerase chain reaction (PCR) kits; ReaMatrix developed a proprietary dried reagent for the national AIDS Control Organization (NACO) program; and Bigtec developed PCR-based microfluidics platform for detection of infectious diseases in India. Embrace, a US based company has been successfully making portable and safe warmers for low-birth infants, cheaper than the already available ones and designed in a way, so as to not to catch fire, which is usually seen with the available electric radiators [15]. These countable manufacturers succeeded as they understood the Indian market, the health insurance sector, and the importance of maintaining global standards in quality. These targeted the hospitals that were associated with insurance companies and started export to Middle East, South Asia, and Africa.

Legislative Changes in Indian Medical Device Industry

The government of India has initiated crucial amendments to the 2014 Consolidated Foreign Direct Investment (FDI) Policy regarding the medical device industry. Despite the fact that the medical devices are different in nature and function from the drugs, the previous FDI policies treated both of them alike. This occurred because of the notification of certain medical devices and other medical products as Drugs under Section 3(b)(iv) of the 1940 Drugs and Cosmetics Act by the Ministry of Health and Family Welfare and the government of India. Because of the nonexistence of separate legislation for regulating medical devices in India, the import, manufacture, distribution, and sale of medical devices were being regulated by the 1945 Drugs and Cosmetics Act and rules.

Nevertheless, the 2008 National Industrial Classification considered medical devices as medical and dental instrument supplies under sector code 3250. The Department of Industrial Policy and Promotion identified the need for a separate FDI framework for the medical devices by linking the sectors and activities of FDI policies and the 2008 National Industrial Classification, respectively, in 2015 [18]. Consequently, the Ministry of Health and Family Welfare and the government of India issued a new set of guidelines, namely the 2016 Medical Devices Rules, enabling highest quality and safety control assurance to medical devices.

According to the 2016 Medical Devices Rules, the devices have been classified to different classes based on the patient risk, thereby restricting the access to unsafe and substandard products. This policy also recommends the formation of National Medical Device Authority (NDMA), which promotes the local medical device sector in India [19]. More recently, the government of India has been considering developing a separate ministry that governs the medical device regulation [20].

Future of Medical Device Industry in India

Although these countable few success stories of medical device industry cannot make India self-reliant in medical devices, the medical device industry is changing because of the new tax systems established by the government. The global medical device industry has crossed 350 billion USD in annual revenue as of 2011 [9]. In this fast-growing sector, India is trying to catch up by promoting local manufacturing and research and development in this sector. First and foremost, the primary step of regulating this industry has been initiated by preparation of the draft of the 2016 Medical Device Rules. The draft proposed by the Central Drug Standard Control Organization of India has taken care of many negative aspects of the earlier rules. Until now, unlike other countries, the medical devices were not classified on the basis of risk of use in India. There was a 10-device category of medical devices and the devices were regulated as drugs [14]. Nevertheless, the draft has categorized the medical devices, other than in vitro diagnostics depending on the severity of risk associated with it [13]. In addition, the extensive document has tried to clear the ambiguity regarding the definitions, the requirement of clinical studies, and the import of medical devices. It is not only the Indian medical device industrial step up that is requiring modifications; world over, even the US Federal Drug Administration and European Union (EU) rules of medical device industries are being constantly evaluated and modified [9].

Currently, the increased push for cost-effective and safe medical devices in India is being driven by the awareness of the patients and health care professionals about the availability of treatment options in the developed world, the changing disease conditions, increase in insurance coverage, and national targets of better health care. The Indian government is giving an impetus by promoting local manufacturing and funding the R&D of the industry. The aforementioned companies, XCyton and Bigtec, benefitted from the loans and grants from the government of India. Local specialized units are being setup to promote production according to the Indian needs.

Second, the government of India in consultation with various ministries, trade bodies, and associations is taking steps toward rationalization of policies and duties to give impetus to its credo of “Make in India.” One such initiative has been the announcement on the inverted duty structure in India. Under the Correction of Inverted Duty Structure, the basic customs duty on raw materials, parts, or accessories required for medical devices manufacturing has been reduced to 2.5% as per notification issued by Ministry of Finance (Department of Revenue) No. 4&5/2016-Customs, dated the January 19, 2016. On the other hand, the basic custom duty on finished products as medical devices has been increased from 5% to 7.5%. The impact of this dual change can lead to incremental cost difference of about 20% or more between indigenously manufactured medical devices as compared to an imported one.

Even if raw materials constitute a minimum of 25% of the total production value of medical devices, the impact on raw materials, parts, or accessories for use in manufacture of devices under HS Code 9018, 9019, 9020, 9021, or 9022 and corresponding HS codes over the value of total product segment can reduce cost by 24%. For a 35% raw material value composition threshold, the benefit of this duty reduction could be 33%.

Outcomes of Local Manufacturing of Medical Devices

Dedicated MedTech zones are being established to give a further stimulus for the “Make in India” concept. The inverted duty structure correction could provide a net competitive advantage of 30% at the minimum to the domestic indigenous industry, which is aggregate of the benefit of 24% cost reduction of domestically manufactured good along with 6% contributed by increase in duty on import of finished goods. It may be too early to see a significant impact for each of the 78 items that were subjected to tariff changes; however, their average for the three quarters of 2015 to 2016 (April to June, July to Sept, and Oct to Dec) was 611.36 million USD. This reduced marginally to 611.14 million USD in January to March 2016, but more significantly the downward trend continued to 595.58 million USD in April to June 2016. On further analysis, quarterly import of April 2016 to June 2017 is significantly lower at 318.31 million USD than the average of the previous year for HS Code 9018, which was 346.12 million USD. Similarly, for HS Code 9022 it is 135.1 million USD down from 143.36 million USD.

The Andhra Pradesh MedTech Zone Limited, Vishakhapatnam, is the first one to be started by the Government of Andhra Pradesh with support from various departments of the government of India. Such an industrial setup enhances production, advancement in research and development, and funding from both government and private sector [21]. Such industrial units will target the Indian population, especially the low-resource segment. This will decrease the cost of the device and generate local employment.

Conclusions

The medical device industry is a vast sector, extending from the simple stethoscope, glucometers, and nanoparticle covering to the highly efficacious and complicated cardiac stents to surgical implants; it is vital to have strict, growth-centric rules and

regulations. With aging population, increase in NCDs, and a large underprivileged population, India needs cost-effective and population-specific medical devices. Thus the earlier regulations are being modified and the nonambiguous rules will be formulated soon. The government is trying to promote local manufacturing to generate employment and produce Indian population-specific medical devices. Large med tech zones are being developed that will help in filling the gap and making India self-reliant in medical devices as well.

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