Available online on 15 June, 2020 at https://ijdra.com/index.php/journal
International Journal of Drug Regulatory Affairs
Published by Diva Enterprises Pvt. Ltd., New Delhi
Associated with Delhi Pharmaceutical Sciences & Research University

Review Article

Journey of Indian Medtech Sector from Import Dependence towards Self-Reliance: *COVID-19 wakes-up the Giant*

Suchita Markan*[,a], Rajiv Nath[b]

[a]*Assistant General Manager, Biotech Consortium India Limited (BCIL), New Delhi, India 110002*
[b]*Forum Coodinator, Association of Indian Medical Device Industry (AiMeD), New Delhi, India 110002*

Abstract

COVID-19 has been declared as a pandemic by WHO due to its alarming levels of spread and severity. During this global pandemic, medical devices and diagnostics have a key role to play to effectively manage the rising number of cases globally. At its onset, the situation was particularly challenging in India with huge population and highly import dependent medical devices sector. Amidst the pandemic, the Government of India through its flagship 'Make in India' initiative relied heavily on the Indian manufacturers to meet the rising demand of essential healthcare equipments for the country. This was the time for the Indian medical device industry to scale-up and balance the demand-supply issues. The Industry, during these testing times, experienced various challenges and opportunities. With enabling policies provided by the Govt. of India, the Industry stood upto the challenges and scaled-up multiple folds to provide medical devices and diagnostics as per the country's requirements and even meet a part of the global requirements through exports. Now when India surges to become self-sustainable or Aatm Nirbhar, the medical device industry seeks Government support in terms of various policy initiatives to create an enabling ecosystem for the indigenous medical device industry to realise its potential. This article covers the various challenges and opportunities faced by the Indian medical device industry during this phase, how the indigenous industry responded to these challenges and the way forward for making the country Self-Sustainable and a leading exporter of the world in the medical device sector.

Keywords: COVID-19, Corona Virus, Pandemic, Medical Devices, Diagnostics, CDSCO, Make in India, Policy, Self-Sustainable, Aatm Nirbhar, Regulations

Article Info: Received 22 May. 2020; Review Completed 15 Jun. 2020; Accepted 15 Jun. 2020

Cite this article as:
Markan S, Nath R. Journey of Indian Medtech sector from import dependence towards self-reliance COVID-19 wakes-up the giant. International Journal of Drug Regulatory Affairs [Internet]. 15 Jun 2020 [cited 15 Jun 2020]; 8(2):44-54. Available from:
http://ijdra.com/index.php/journal/article/view/403

DOI: 10.22270/ijdra.v8i2.403
*Corresponding author Tel.: +91-11-29562642;
E-mail address: suchitamarkan@gmail.com (Suchita Markan).

1. Introduction

COVID-19 has been declared as a pandemic by WHO due to its alarming levels of spread and severity. (1) Amidst the Corona virus pandemic, the hopes of the entire country hinged on the Medical devices including the diagnostic devices, which were considered as the key saviours to manage this disease. (2) The healthcare sector, particularly the medical devices, is at the epicentre of this unprecedented global pandemic challenge. During this pandemic, the global medical device industry experienced major challenges, on account of shutting down of factories in China, the global hub for making available electronics and device components to India, change in the priorities of USA, Europe and other key medical device manufacturing hubs to primarily cater to their own local needs, as per their Government's directive. (3) Apart from the global supply chain issues, there were various other challenges faced by the Indian medical device industry including compromised operational capabilities, lack of COVID positive serum sample availabilities, regulatory policy bottlenecks and other issues due to nation-wide lockdown. During this time, the new avatar of '*Make in India*' driven by the Govt. of India primarily relied on the Indian medical device manufacturers to manufacture and meet the local healthcare demand. (4, 5) The Indian medical device sector which is highly import dependent was not in readiness to scale-up and meet the sudden huge upsurge in the demands of the Country. However, within a period of 2-3 months, the Indian Medical device sector valiantly stood-up to the expectations and scaled-up to meet the country's demand and also contribute significantly to meet the global requirements through exports. Now, when India is being looked at globally as possible 2nd factory to the World after China, the Indian

medical device manufacturers urge for suitable policy interventions by the Govt. for creating an enabling sustainable ecosystem for the Indian manufacturers to rise up to the expectations. This paper covers the status of medical device industry in India before and during the COVID-19 outbreak, the challenges and opportunities experienced by the industry and the way forward for creating a self-sustainable, Aatm Nirbhar Bharat.

2. Data sources Study selection

The data for this study has been taken from the Government of India websites including from Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Ministry of Health and Family Welfare, Central Drugs Standard Control Organization (CDSCO), Make in India, Ministry of Commerce etc.

Some reports and policy papers published by globally recognized consultants and Industry associations have also been referred to in this article. Numerous press releases undertaken by various organisations covering COVID updates with reference to medical device sector and policy initiatives have also been referred to in his article. The data on medical device industry numbers and their manufacturing capacities before and during the COVID pandemic is the real-time data compiled and provided by Association of Indian Medical Device Industry (AiMeD), the lead association of Indian Medical device manufacturers. The data on Indian Medical device Industry status provided by AiMeD is till May end, 2020 and the same has been included in this study. This is a dynamic status and this number is expected to increase further on weekly basis till July end, as per the industry estimates.

3. Medical Device Industry in India- Pre-COVID Outbreak

The medical device industry in India, currently valued at USD 15 Billion (Rs. 1,05,000 Crores), by retail sales, is highly import dependent. (4) Currently, India is counted among the top 20 global medical device markets and is the 4th largest in Asia after Japan, China and South Korea. (4, 5) The sector is experiencing a double-digit growth rate of about 15.8% CAGR and is poised to grow to USD 50 billion by 2025 as per industry estimates. (7) The medical device market is dominated by imported products which comprises around 80% of total sales. (7) The domestic companies are largely involved in manufacturing low-end products for local as well as international consumption. Lately, many multinational companies have established their local presence by acquiring established domestic companies or by starting a new business.

The industry size is small with 750–800 domestic medical devices manufacturers in India, with an average investment of USD 2.3–2.7 mn and an average turnover of USD 6.2–6.9 mn. (8) Around 65% of the manufacturers are mostly domestic players operating in the consumables segment and catering to local consumption with limited exports. (6)

As domestic COVID-19 cases spiked and with the declaration of the global pandemic by WHO, the requirements of India to manage the pandemic could not be met through imports. Countries like US and Europe with maximum imports to India were putting all their resources to support their own local population. (9) Considering the contagious nature of the disease, the Government of India (GoI) further imposed import and export restrictions. (9) The demand side from the various ministries of the GoI increased the burden of providing the basic healthcare products such as masks, sanitizers, ventilators, PPEs etc. to manage COVID-19 pandemic, on the Indian medical device manufacturers, who had negligible or limited capacities to respond to the huge unprecedented demand. The COVID-19 pandemic presented a mixed bag of challenges and opportunities for India which was well taken-up by the Indian Medical device manufacturers.

4. Challenges faced by the Medical Device Industry at the onset of COVID Pandemic

The key challenges faced by the Indian medical device industry includes the supply chain issues, operational challenges, infrastructure related issues, policy challenges, serum sample availability related challenges and limited indigenous capacities as against the requirements to effectively address the huge upsurge in unprecedented demand during the pandemic.

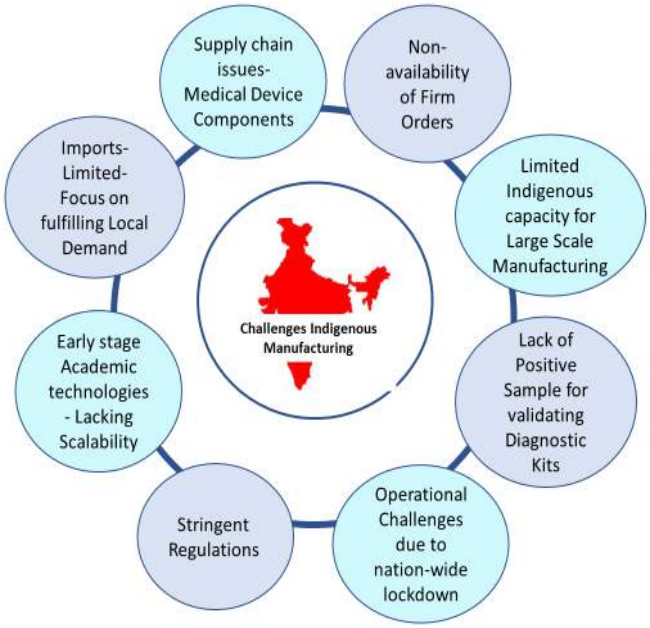

Figure 1. Challenges faced by the Indian Medical Device Manufacturers.

India imports consumables, disposables and capital equipment including syringes, bandages, magnetic components, ventilator parts, electronic components etc. from China. (10) Due to the current crisis in China, the medical device manufacturers across India are finding it difficult to source important raw materials and electronic components from Chinese factories. The industry experienced huge supply chain issues due to the raw material and electronic components dependency on China. (10) Ventilator manufacturers globally are clustered in USA and Europe, and they could not meet the requirements of India as they were more focused in meeting their own local demands. There were huge

operational challenges also due to nation-wide lockdown. (11)

In such a situation when the medical device needs of the country could not be met by imports, the GoI shifted its focus on the supplies to be met by the Indian medical device manufacturers. The Indian medical device manufacturers had limited indigenous capacity for large scale manufacturing of PPEs, ventilators, diagnostics etc. (4, 12) There was also lack of sufficient inventory of testing kits, PPEs and ventilators, as exports were not banned in time by the Government and other countries were piling-up the products for meeting their local needs due to sudden increase in the number of cases. (4, 12) The Government initially experienced huge gap in the demand and supply of Made in India devices due to import dependency. The industry was also not reassured due to non-availability of firm orders from the Govt.

The factories and warehouses of medical device companies were either shutdown or were operating at 20-30% of the capacity, thereby impeding the supply of medical devices to the GoI. (3) There were manufacturing constraints, as the industry was unable to work with full operational/production capacity, as to ensure the safety of the production teams was their priority. The supply chain issues could not be resolved through indigenous manufacturing of components due to lack of adequate infrastructure facilities. (10) Further, it is much more cost effective to import components such as semiconductors, displays and other very capital intensive electrical equipments from China than to manufacture them at scale in India as their manufacturing requires, *inter alia*, large, stable sources of clean water and electricity which are much costlier in India. (9) These also need a high degree of policy certainty as these require high upfront investments. The Indian industry faces much higher costs of inputs such as electricity and much higher logistics costs than Chinese firms. (9)

As far as the manufacturing of indigenous diagnostic kits is concerned, the manufacturers faced issues in getting access to COVID positive serum samples which is an essential requisite for validating the essential parameters regarding workability of the kits. Further, the country had limited infrastructure facilities for handling hazardous materials. Clinical validation of the kits is another challenge which was faced by the diagnostic industry due to lack of adequate samples and the panel (Figure-1). (13)

Early during the COVID pandemic, the industry also faced few policy related challenges including stringent/ unclear regulations, lack of inter-linkages among the ministries with overlapping functions leading to delays in decisions.

In view of the limited level of knowledge about the new virus and need for new indigenously developed kits and other critical care equipments, the need for technologies being developed at Academic/Research institutes which can be adopted and scaled-up by the Industry also became critical. The technologies developed at academia were early stage technologies, developed at TRL-3 or 4 which lacked scalability **(Figure-1).**

5. Gearing up- During the Outbreak

During the outbreak of COVID pandemic, nationwide lockdown and in view of extreme dependency of the country on imports, the capacity of the Indian manufacturers to address the huge demand of the country for providing healthcare essential equipments and products was very limited. For effectively managing the healthcare emergency in the country, Association of Indian Medical Device Industry (AiMeD), the leading association of Indian medical device manufacturers in the country was approached by the Govt. of India for helping them to ramp up the existing capacities of the Indian manufacturers and assisting them in proper planning and making available healthcare products and equipments. AiMeD is an umbrella organisation with over 350 members nationwide whereby medical device manufacturers of all types of technologies have come together on one platform. AiMeD covers within its ambit, all type of medical devices including consumables, disposables, equipments, instruments, implants, electronics and diagnostics. With a primary membership of over 350 manufacturers and additionally of over 200 associate members, AiMeD represents the interest of nearly all Indian manufacturers of medical devices to address their problems. (14)

At the onset of the COVID pandemic, the Indian manufacturers had limited capacities for manufacturing PPEs, Gloves, ventilators, masks, goggles and swabs. None of the AiMeD member was involved in manufacturing RNA extraction kits; COVID RT PCR based diagnostic kits or COVID 19-Rapid diagnostic kits during the initial stages of the COVID 19 outbreak in India, by early 2020. (11,12,15)

The healthcare product supply capacities of the Indian manufacturers were further beset by supply bottlenecks due to extreme dependency on China, cost overruns and labour shortages. This was delaying their efforts to produce indigenous affordable devices. However, within a period of 2-3 months, the Indian medical device industry manufacturers and start-ups took a leap frog and worked hard to start manufacturing and increasing their capacities for providing the medical device products as per the Indian healthcare requirements. Many Indian medical device manufacturers took up this challenge and started working to manufacture and make available these medical device products critically required to deal with the COVID pandemic.

As per the details available with AiMeD till May end 2020 about their member medical device manufacturers, there were 20 manufacturers manufacturing PPE before COVID outbreak and within a period of 2-3 months of the COVID-19 outbreak, the number of manufacturers increased to 40 in number i.e. by 100 % increase in the number of such manufacturers.

Likewise, the number of Indian manufacturers manufacturing gloves increased from 20 to 26 (30%), ventilator manufacturers from 8 to 14 in number (75% increase), mask manufacturers from 21 to 43 (100%), swab manufacturers 0 to 3 and sanitizer manufacturers increased from 35 to 47 (34%) in number (Figure-2), (Figure-3). None of the AiMeD member companies was

in the business of manufacturing goggles or had capacities to make RNA extraction kits, RT-PCR or Rapid diagnostic kits for COVID-19. However, they took-up the challenge and a number of manufacturers came forward to start developing these products. This included 14 manufacturers for goggles, 8 for RNA extraction kits, 5 manufacturers for RT-PCR based kits and 2 Rapid diagnostic kit manufacturers **(Figure-3).**

As the number of COVID positive cases increased in the country and there was an urgent need to increase the indigenous kits for disease surveillance, the Indian medical device manufacturers stood upto the challenge and significantly increased their production capacity for manufacturing RNA extraction kits to 129.48 million pieces per annum.

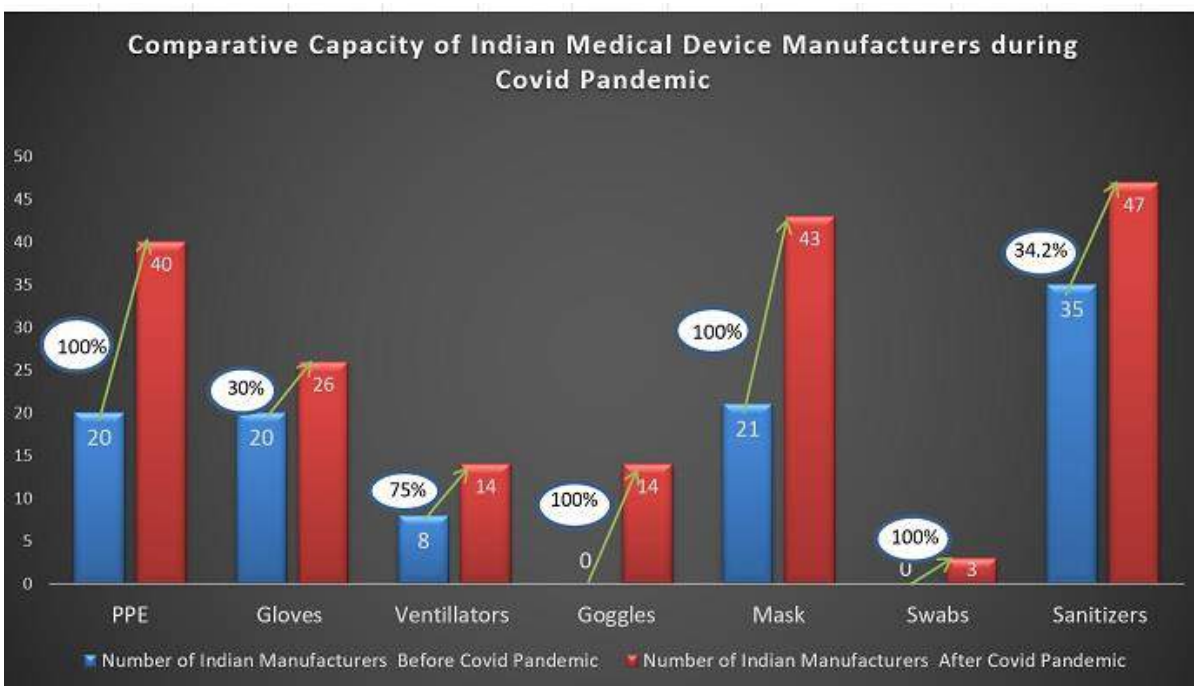

Figure 2. Comparative number of Indian Medical Device manufacturers before and during the COVID-19 outbreak

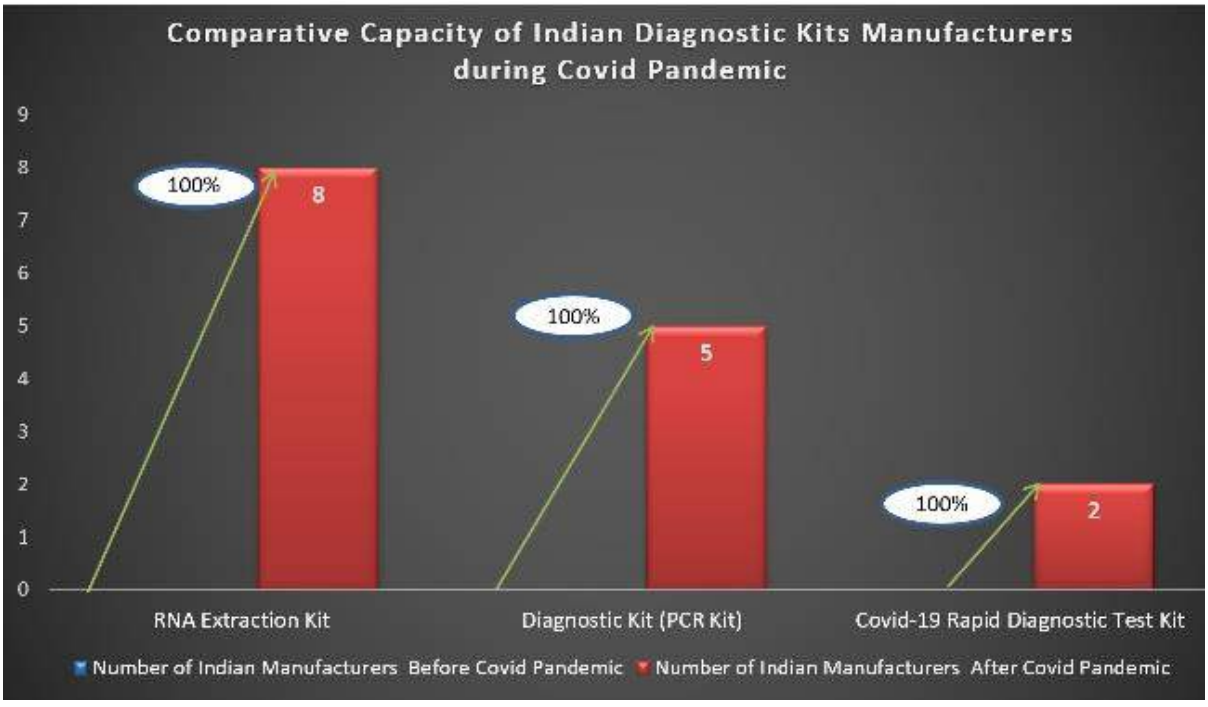

Figure 3. Comparative manufacturing capacities of RNA Extraction Kits and Diagnostic Kit Manufacturers in India

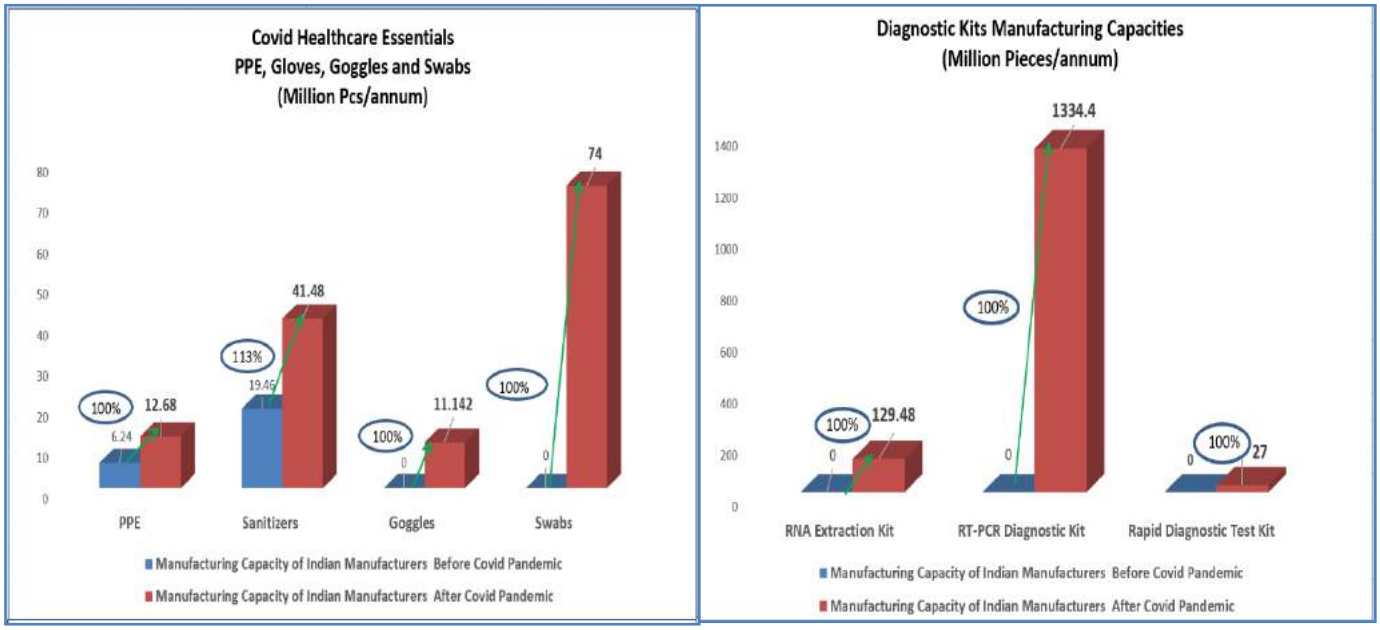

Figure 4. Comparative Manufacturing Capacities of Indian Manufacturers for COVID healthcare Medical and Diagnostic Kits during COVID-19 outbreak.

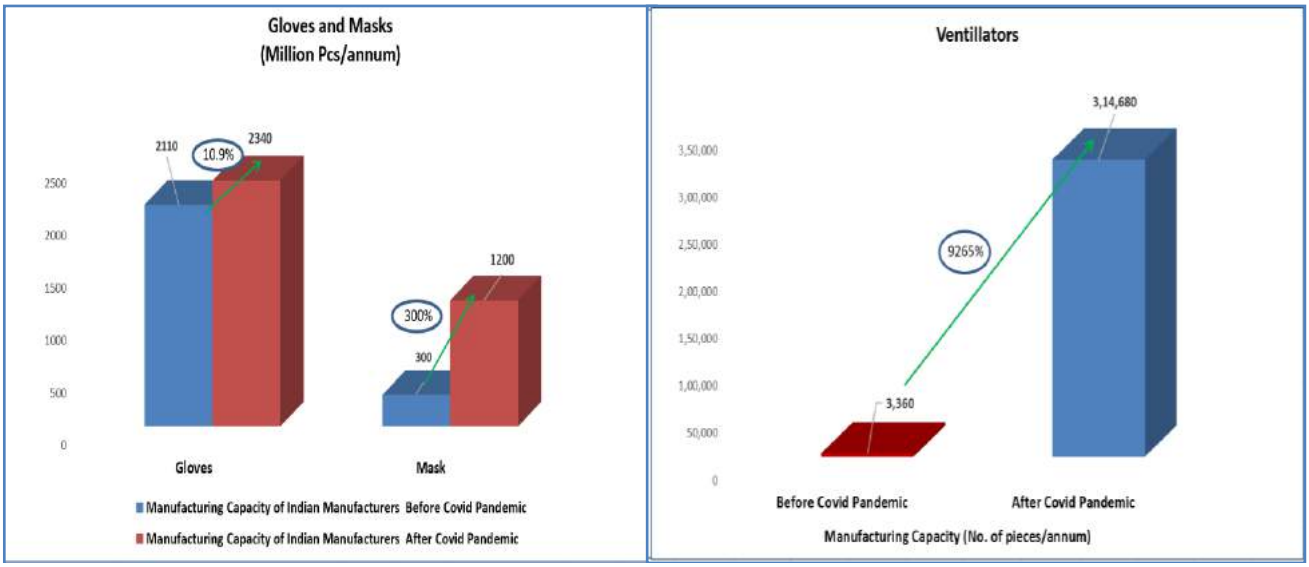

Figure 5. Comparative manufacturing capacities of Indian Manufacturers for Gloves & Ventilators.

With initial no indigenous capacity to manufacture RT-PCR based kits and Rapid diagnostic kits for COVID 19 diagnosis, today the Indian manufacturers stand by the manufacturing capacity of 1334.4 million kits per annum and 27 million kits per annum respectively **(Figure-4).** Similarly, the PPE manufacturing capacity increased from 6.24 Million pieces per annum to 12.68 million pieces per annum (100 % increase), sanitizer manufacturers from 19.46 to 41.48 million pieces per annum (113%), goggle manufacturers from zero to 11.142 million pieces per annum and swabs from zero to 74 million pieces per annum **(Figure-4).**

The glove and mask manufacturers increased their production capacities from 2110 to 2340 million pieces per annum (10.9%) and 300 to 1200 million pieces per annum i.e. four times increase in production capacity. The ventilator manufacturers despite having huge dependency of components on imports increased their production capacity from 3360 pieces per annum to more than 3,00,000 pieces per annum i.e. 90 times increase in manufacturing capacity **(Figure -2 & Figure-5).**

6. Unprecedented Role of the Indian Government in boosting-up Indian Medical Device Manufacturers

In view of the COVID pandemic striking the country and its urgent management requirements, the Govt. of India took-up a holistic multi-pronged approach to effectively manage the spread of this contagious disease in the country. The various approaches adopted by the Government included declaration of a Nation-wide lockdown for disease containment and healthcare readiness, stringent monitoring of the COVID spread by a Task force being run directly under the supervision of

the Honourable Prime Minister (PM) and Government's think tank NITI Aayog, technology mapping to identify technologies that can be scaled-up and adopted, announcement of focussed funding schemes with fast track approvals, Regulatory liberalisation, Government-Industry-Academia partnerships and various other policy initiatives to drive *Make in India* and *Aatm Nirbhar* India (Self-Reliant) (16, 21).

To foster Make in India for medical devices and take strategic decisions for effective disease management, the GoI set-up a COVID-19 Task Force. (17,18) The COVID-19 task force was set up by the Indian Government on March 29 and it directly operates under the PM for executing the Government's responses for disease management. This task force, with handpicked bureaucrats and key officials, operates around the Prime Minister's Office. The Task Force was advised to map COVID-19 related technology capabilities in the country. The COVID-19 task force is multifaceted and deals with all aspects of the crisis. It collates information from the two important groups set up by the Government, one of Ministers and another of Secretaries. The Task Force with members from Indian Council of Medical Research (ICMR), Department of Biotechnology (DBT), Ministry of Environment & Forest (MoEF), Council of Scientific & Industrial Research (CSIR), Atal Innovation Mission- NITI Aayog collectively undertook country-wide technology mapping to find technologies which can be scaled-up. Within a short period of about one month, 500 technologies were mapped by the Task Force for developing products/solutions for COVID crisis management. (18, 19)

Most S&T arms of the GoI launched COVID-19 specific funding calls including CAWACH by DST, CSIR, Department of Biotechnology- Biotech Industry Research Assistance Council (DBT-BIRAC) announced COVID-19 Research Consortium Call, Technology Development Board (TDB) and Invest India also announced funding calls for supporting COVID product development proposals. (20-24) Various incubators across the country also joined hands to help the Government in managing the funding calls and providing start-up incubatees mentorship and space for further technology development. These incubators included IKP Knowledge Park (IKP), Venture Center, SINE IIT Bombay, Centre for Cellular and Molecular Platforms (C-CAMP), SIIC-IIT Kanpur, AIC-CCMB and Foundation for Innovation and Technology Transfer (FITT) IIT Delhi, amongst others. Incubators such as IKP and Venture Center launched their COVID-19 action plan to not just provide funding but also pro-actively provide support in connecting start-ups with mature products to scale them by connecting them to manufacturers, procurement agencies and hospitals. The various COVID specific funding calls were announced to seek Industry or Industry-academia joint proposals with a focus on diagnostics, vaccines, novel therapeutics, repurposing of drugs or any other intervention for control of COVID-19. (20-25)

To strengthen the infrastructure facilities required for COVID testing and to enable the testing facilities to reach into the remote and interior places, the DBT under its National Biopharma Mission launched the country's first mobile I-Lab (Infectious disease diagnostic Lab). (26) The I-Lab was created by a team from the Andhra Pradesh MedTech Zone Limited (AMTZ) in a record time period of eight days. DBT supported this initiative under its Covid-Command strategy for building of mobile testing labs (I-Labs) through AMTZ for providing last mile COVID-19 testing access. The I- lab is a BSL-2 facility with on-site ELISA, RT-PCR and Biochemistry analysers required for diagnosis of COVID cases. It has a capacity to run 50 RT-PCR reactions and about 200 ELISA in a day. (26) The I-Lab developed by AMTZ can be deployed in remote areas and can be lifted from automotive chassis and can be put on goods train for sending to any location in the country. AMTZ is also playing a lead role in meeting the supply chain requirements of the medical device sector in the country and in manufacturing ventilators and PPEs for COVID healthcare management. (26)

During the COVID pandemic era, the GoI worked hand-in-hand with the medical device manufacturers to facilitate *Make in India* for devices. National Pharmaceutical Pricing Authority (NPPA), from being a regulator, became a facilitator and along with India Invest Team and DOP worked to resolve individual Manufacturers' issues with local administration to get approvals to run factories as essential products, access to trucking, logistics support by Speed post & Railways and later by Air India and Spice Jet to import critical components and machinery. They also coordinated opening of upstream and downstream supply chains for access to raw materials, components and packaging to make essential products with ongoing severe lock down conditions as an exception. (10) Every bottleneck was resolved or clarified with Policy decisions and Circulars by NPPA or via an Empowered Committee chaired by Secretary Department of Pharma through Home Ministry within 1-3 days.

Manufacturers were encouraged to add to their product basket by quantifying needs of COVID specific Medical devices and urgencies, Testing bottlenecks for compliance to Standards were addressed by the South India Textile Research Association (SITRA), Defence Research and Development Organisation (DRDO) and Defence Research and Development Establishment (DRDE), initially with Ordinance, Railways, with Defense Forces also pitching in and Bauru of Indian Standards (BIS) permitting sharing of test facilities to encourage new licensing. Ministry of Textile roped in Garment and Textile Manufacturers and motivated them to make PPE and Masks. (27)

All the stakeholders worked round the clock using modern tools of technology and communication by creating groups for separate Product Categories like Ventilator, PPE (Coverall), Masks, IVD Diagnostic Manufacturers along with and discussed issues in real time.

AiMeD worked with Quality Council of India (QCI) to expedite ICMED Plus Certification as well as with Consultants Consortium to provide online training on

Quality Management System certification to new entrepreneurs from Automakers, Garments, Textile and Autoparts Industry who had ventured into Medical Devices manufacturing to build capacity & capabilities to meet QCIs ICMED Certification so that they could have confidence to seek Global Certification of CE and US FDA compliances. 4 batches of over 115 Manufacturers or their representatives were trained using 7 modules over 11 sessions spread over 2 weeks.

Considering that the COVID-19 is a new microorganism, with not much knowledge available, research is an important integral component of the response to be able to identify key knowledge gaps and research priorities, and thereby accelerate the generation of critical scientific information and the most needed medical products to contribute to the control of COVID-19 emergency. Keeping this in mind, various research initiatives were also announced by the Government to enable industry and academia to develop indigenously developed affordable products for wide-spread adoption. The DBT also floated development of National Biomedical Resource Indigenisation Consortium (N-BRIC) to drive focused indigenous innovation (23). DBT constituted N-BRIC as a public-private-partnership to drive indigenous innovation especially in developing reagents, diagnostics, vaccines and therapeutics for COVID-19. The consortium aims to provide a collaborative platform to build indigenous biomedical resources towards a self-reliant biotech ecosystem. (23)

To expedite access to devices intended to prevent or treat COVID-19 and safeguard supply of other critical IVDs, Indian regulator- Central Drugs Standard Control Organisation (CDSCO) published several notices since mid-March in response to the ongoing pandemic (28-30). The regulators also announced prioritization of COVID-19 IVD test kits for expedited approval. Manufacturers who already had approval for an IVD in another market were encouraged to contact the Drugs Controller General of India (DCGI) to discuss fast-track approval or for soliciting guidance on the applicable regulatory pathway. The regulators processed the COVID management applications within seven days of its submission. As part of the expedited approval process, the CDSCO also eased out the data requirements for clinical performance evaluations on a case-by-case basis. (28-30).

A regulatory framework for rapid COVID-19 response was also developed and adopted by the CDSCO to fast-track the regulatory approval process for vaccines, diagnostics, prophylactics, and therapeutics designed to prevent or treat COVID-19. As part of this initiative, the CDSCO created a dedicated coronavirus unit to address inquiries on the development of these products. (28-30).

The ICMR, the apex body in India for the formulation, coordination and promotion of biomedical research and communicable disease management played a lead role in strategizing COVID-19 testing and formulating various guidelines for sample collection, testing, kits validation, disease management and COVID-19 surveillance survey. ICMR took a lead in facilitating independent validation of the COVID test kits at National Institute of Virology (NIV), Pune for facilitating expeditious approvals from the CDSCO. It also joined hands with the industry for spearheading development and clinical validation of the much needed COVID vaccine by the country. (31, 36) The various initiatives by the GoI brought in various scientific institutions and start-ups to develop the COVID-19 tests, masks, sanitizers, personal protective equipment (PPEs) and ventilators for addressing the healthcare needs of the country.

7. Opportunities for Indian Medical Device Manufacturers to Shine

With the advent of COVID outbreak, when the supply chain issues piled-up, the inter-country borders were sealed impeding import of medical devices and considering that the foreign medical device manufacturers focused primarily on managing their local needs, making available the medical devices by indigenous manufacturing for effective disease management became the Government's priority. There was a huge demand-supply gap of ventilators and other critical equipments at a global level, which opened-up opportunities for Indian medical device manufacturers not only for India but also globally. The *Make in India* initiative of the Government experienced a new Avtaar, wherein it emphasized hugely on Made in India medical devices. This further experienced a surge as preference was given by the Government for procuring indigenous medical device products. The country witnessed an unprecedented demand of indigenous medical devices and supplies from healthcare providers to manage the increasing load of COVID patients, and a number of others awaiting effective diagnosis. The Honorable Prime Minister of India declared the need for a "Self-Reliant India" or "Atam Nirbhar Bharat" which had a multiplier effect in terms of policy initiatives, funding opportunities and drive for the Indian manufacturers to manufacture and scale-up indigenous medical device manufacturing (16, 32). This was a huge opportunity for the Indian medical device manufacturers considering increased reliance and acceptability of indigenous medical technology solutions in the country.

The other opportunities for medical device manufacturers included regulatory policy liberalization. The CDSCO, Ministry of Health and Family Welfare notified acceleration of regulatory approval process for new diagnostic products or other products required to manage SARS-corona virus-2 in the country. (27-30) With a global surge to develop medical devices, healthcare essentials and diagnostic kits to manage the global pandemic, the medical device industry also witnessed increased Global collaboration opportunities. Considering the urgency for developing products, the country experienced universal collaborations with world-wide leaders, all working on a single topic -COVID-19 **(Figure-6).**

The collaborative spirit of the Indian ecosystem experienced a boost wherein the Industry, Academia and the Government all stood together to develop medical device solutions for meeting the increasing demands of the country. The collaborations were further strengthened for meeting the essential eligibility requirements for the funding calls floated by the

Government requesting proposals in a public-private partnership mode **(Figure-6).** In view of the economic crisis in the country, the Government had the compulsion to generate new revenue streams and boosting indigenous manufacturing of the medical devices for COVID management could be a promising global opportunity for generating new revenue streams in view of global pandemic. This was also a great opportunity for Indian start-ups; many of them took up the challenge and started developing innovative products which could be scaled-up through collaborations with established companies. The Government also urged the Indian citizens to be "Vocal for Local" to boost the Indian medical device sector. (33)

Figure 6. Opportunities for Indian Medical Device Manufactures during COVID-19 outbreak.

8. Policy Interventions required for Self-Sustenance in the Medical Device Sector

Amidst the global pandemic, when global and economic cooperation has been impacted, the Self-Reliance/Aatm Nirbhar Bharat is the new mantra specially for the medical device sector, which uptil now was highly import dependent. India also sees this as a golden opportunity to scale-up the indigenous medical device sector which has immense growth potential. The Dark Cloud of COVID has one Silver Lining - Make in India of Medical Devices which became a valued entity as the few factories that are there, not only took up the challenges to meet the demands of the buyers in scenario of disrupted supplies of about 80% import dependent market but are being looked at globally as possible 2nd factory to the World after China.(33)

The new version of the Make in India seeks to protect domestic manufacturers and push them up the value chain. However, various policy interventions would be required to make the medical device sector self-sustainable. This will include infrastructure strengthening, tax exemptions, comprehensive and predictable regulatory regime, preferential market access policies, strengthening of R&D systems, favorable tariff policies, Industry-Academia collaborations in translational health etc.

To be self-sustainable in the medical device sector, there is a need to develop the electronic components in-house and upscale it. Government needs to undertake major reforms for Indian Industry to play a key role in global supply chain and be self-reliant. Many of the components being imported eg. semiconductor display, magnets, capital intensive equipments can only be made at scale by Indian manufacturers, if they are given high degree of policy certainty as they require high upfront investments.

As the labor and electricity cost of manufacturing the components in the country is very high, the manufacturers are not able to reach economies of scale. To decrease the input costs of manufacturing products, there is need for the Government to provide infrastructure and logistic support to enable manufacturers to decrease the cost of inputs and produce products at a much cheaper rate. The Indian medical device industry needs more flexibility in labour laws, subsidized charges for electricity and land for upscaling local manufacturing of medical device components. The country needs increased indigenous capacities for electronic component and other medical device component manufacturing at low costs. To make this happen, many exclusive medical device parks like Andhra Pradesh Medtech Zone (AMTZ), needs to be developed and supported which will serve as medical device manufacturing hubs for the country. Developing sector specific hubs for fostering product development by the Industry is also required for focused sub-sector specific product development in the country **(Figure-7)**

The Government may also consider giving Tax incentives for Make in India products. To boost indigenous manufacturing in this sector and persuade people to decrease import dependency, the customs duty may be increased to 15% on Medical Devices as done for Mobile phones up from current Zero to 7.5%. This will prevent the manufacturer from importing cheaper products. The Indian medical device manufacturers need a policy push and market pull for scaling-up their product lines. Make in India policy linked with preferential procurement policy for indigenously developed products can go a long way in boosting Make in India for medical device sector. Preferential price on sale to public healthcare as permissible by GFR 153 & WTO based on domestic content percentage e.g.15% for 50% domestic content, 10% for 40% domestic content and 5% for 25% domestic content may be considered for adoption by the Government.

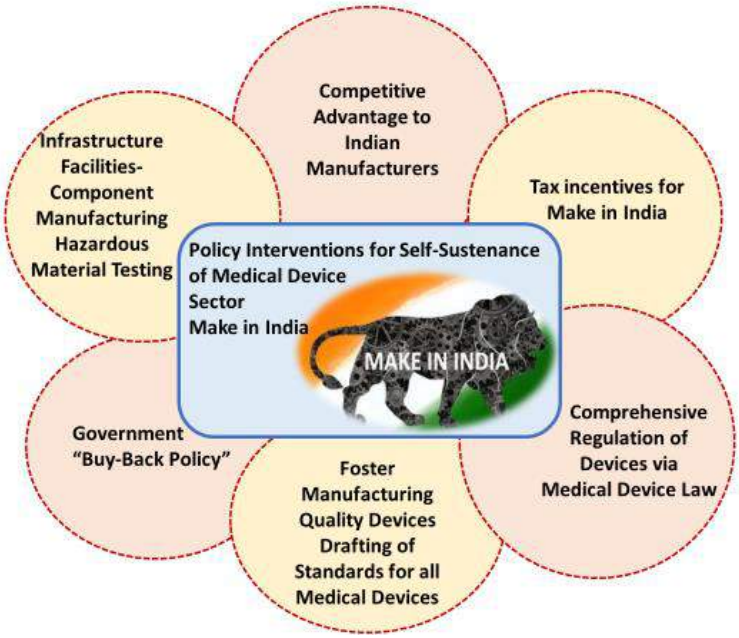

Figure 7. Ecosystem requirements of Indian Medical Device Industry to be self – sustainable.

As all Medical devices are not regulated in the country, with only notified devices mandating regulatory approvals, Made in India medical devices lack credibility. Medical devices being engineering products, very different from the drugs, need a separate regulation through Medical Devices Act and not under the Drugs and Cosmetics Act. There is also a need to develop and adopt standards for all medical devices and equipments including innovative devices for manufacturing quality products as per international standards **(Figure-7).**

Science and Technology has also a lead role to play moving forward. The Minister of Science and Technology, Government of India emphasized to RE-START– 'Reboot the Economy through Science, Technology and Research Translations', considering the advent of new virus COVID-19 needing development of new S&T solutions for its effective management. Rebooting the economy requires new-age technologies, appropriate national missions, programs and schemes to get into quick action. (35) Wherever readymade solutions are not available, as in the present case, research and development needs to be more profound, relevant, speedy, impactful and strongly connected to the industry. There is also need to provide impetus to R&D to develop products in a mission mode. The healthcare spending of India also needs to be increased for putting systems in place to manage healthcare challenges of the country. India's healthcare spending is 0.9% of GDP as compared to 19% in US, which is a 19 trillion-dollar economy, their healthcare budget is more than the budget of our country as a whole. As a long-term strategy, the GoI also needs to consider increase in the budget for optimum healthcare management in the country.

9. Conclusions

COVID-19 outbreak in India has given tremendous opportunities to the Indian Medical device manufacturers to shine by addressing indigenous needs and be a credible global player for medical device manufacturing and supply. The Indian Medical device industry has been growing at double-digit rates and has evolved significantly in the last decade. However, a number of challenges need to be addressed in providing access to quality, affordable healthcare and making this sector self-sustainable.

Technology can change the way we live our lives and the way we do things in future, particularly so in the post-COVID era. This is an opportunity for the Government, Research institutes and Industry to gear up for the future that lies ahead, and a better-equipped R&D workforce and ecosystem will prepare India better for future challenges. In the post-COVID era, the Government is expected to boost R&D in translational sciences, catalysing product development through public-private partnerships. Considering that most of the healthcare

problems are evaluated locally but are globally relevant, the post-COVID era is also expected to experience increased global collaborations driven through WHO, UN agencies, Bill and Melinda Gates Foundation, NITI Aayog, DBT, ICMR and the like to address global healthcare challenges.

Considering that the new era of medical device innovation will focus on self-reliance in Critical Care devices, as its mantra, the era is expected to truly bring Healthcare at Home. There will be more reliance and demand of virtual screening solutions, tele-ventilators, Artificial Intelligence (AI) based products, Internet of things (IoT), telemedicine for low-risk patients etc. With digital transformation, the use of medical technological devices, the application of AI in the care of people is expected to become more common. Emphasis will be more on wearable devices, dissemination of a 5G infrastructure, personalized care equipments, critical-care equipments for home settings with real time monitoring, devices for remote monitoring, wearable sensor based devices and the likes. The post COVID era will also boost development of equipments for preventing spread of communicable diseases such as spit disposal solutions, Air filtration systems, Hospital robots for communicable disease management and mental health products to manage issues developed due to global shut-down and extreme fear and illness created due to this global pandemic. With more reliance on the technologically advanced and digital solutions, the need for training and teaching components is also expected to experience a surge.

As the World is now looking at India to be the hub for providing cost effective medical device components and devices, India being globally established IT leader has the potential to lead the era of digital healthcare solutions. It is the time for the Indian Government to take multiple policy initiatives for creating an enabling ecosystem and catalyze the holistic development of Indian medical device industry to shine. India has the potential to provide quality medical device products at affordable price points, which is unique to India. Therefore, India can be a leader in the medical device sector and be GLOCAL- manufacture quality medical device products locally at minimum price points and be a global leader.

Acknowledgements

We would like to express our gratitude to the International Journal of Drug Regulatory Affairs who gave us the opportunity to publish this article, promptly considering it is a very important and relevant article amidst the COVID pandemic globally including India.

Financial Disclosure statement: The author received no specific funding for this work.

Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article.

References

1. World Health Organisation, WHO Director-General's opening remarks at the media briefing on COVID-19 [Internet]. WHO; 2020 Mar 11 [cited 2020 Jun 03]. Available from: https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19-11-march-2020
2. Muttreja P. Think Global Health, Coronavirus in India: Mitigating the health effects of COVID-19 beyond the immediate [Internet]. 2020 Apr 21 [cited 2020 Jun 02]. Available from: https://www.thinkglobalhealth.org/article/coronavirus-india
3. Medical device sector needs urgent Govt. support to overcome COVID-19 challenges, by Healthcare Radius [Internet]. 2020 May 04 [cited 2020 Jun 04]. Available from: https://www.healthcareradius.in/clinical/25949-medical-device-sector-needs-urgent-govt-support-to-overcome-covid-19-challenges
4. Gupta S. COVID-19: 'Make in India' push for ventilators, PPEs. Times of India [Internet]. 2020 Apr 05 [cited 2020 Jun 02]. Available from: https://timesofindia.indiatimes.com/india/covid-19-make-in-india-push-for-ventilators-ppes/articleshow/74988501.cms
5. Make in India plan in works to attract medical device companies. The Economic Times [Internet]. 2019 Aug 17 [cited 2020 May 15]. Available from: https://economictimes.indiatimes.com/industry/healthcare/biotech/healthcare/make-in-india-plan-in-works-to-attract-medical-device-companies/articleshow/70709202.cms?from=mdr
6. Medical Devices. Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India [Internet]. 2020 Feb 03 [cited 2020 Jun 01]. Available from: https://pharmaceuticals.gov.in/medical-devices
7. Desai N and Associates. The Indian Medical Device Industry Regulatory, Legal and Tax Overview [Internet]. 2020 Mar [cited 2020 Jun 02]. Available from: https://www.nishithdesai.com/fileadmin/user_upload/pdfs/Research%20Papers/The_Indian_Medical_Device_Industry.pdf
8. Make in India sector survey: Medical Devices [Internet]. 2020 Apr 03 [cited 2020 May 27]. Available from: http://www.makeinindia.com/article/-/v/sector-survey-medical-devices
9. Critical self-reliant healthcare life-supporting supply chain to emerge post COVID-19-Opinion, Biospectrum Asia Edition [Internet]. 2020 Apr 20 [cited 2020 May 23]. Available from: https://www.biospectrumasia.com/opinion/27/15822/critical-self-reliant-healthcare-life-supporting-supply-chain-to-emerge-post-covid19.html
10. Coronavirus disease can impact India's medical devices industry, says Global Data, Future Medicine FM News Network [Internet]. 2020 Mar 11 [cited 2020 May 21]. Available from: https://www.futuremedicineindia.com/coronavirus-disease-can-impact-indias-medical-devices-industry-says-globaldata/
11. There Aren't Enough Ventilators to Cope with the Coronavirus, The New York Times [Internet]. 2020 Mar 26 [cited 2020 May 25]. Available from: https://www.nytimes.com/2020/03/18/business/coronavirus-ventilator-shortage.html
12. Kalra A, Ghoshal D. India needs at least 38 million masks to fight coronavirus: agency document, Reuter [Internet]. 2020 Mar 28 [cited 2020 May 21]. Available from: https://www.reuters.com/article/us-health-coronavirus-india-equipment/india-needs-at-least-38-million-masks-to-fight-coronavirus-agency-document-idUSKBN21F0HO

13. Private Indian firms who got govt. approval to make antibody tests hit a hurdle - the govt [Internet]. 2020 May 16 [cited 2020 Jun 01]. Available from: https://theprint.in/health/private-indian-firms-who-got-govt-approval-to-make-antibody-tests-hit-a-hurdle-the-govt/422647/
14. Association of Indian Medical Device Industry (AiMeD) [Internet]. 2020 May 12 [cited 2020 Jun 01]. Available from: https://aimedindia.com/about-us
15. Self-reliant India: Which sectors depend on imports, and which do not [[Internet]. 2020 May 14 [cited 2020 Jun 03]. Available from: https://indianexpress.com/article/explained/self-reliant-india-which-are-the-sectors-dependent-on-imports-which-are-not-6408407/
16. "Self-Reliant India" or "Aatm Nirbhar Bharat [Internet]. 2020 May 13 [cited 2020 Jun 05]. Available from: https://www.jagranjosh.com/current-affairs/what-is-atmanirbhar-bharat-abhiyan-pm-narendra-modi-unveils-package-to-make-india-self-reliant-1589351112-1
17. COVID-19: Task force to map technologies [Internet]. 2020 Mar 27 [cited 2020 Jun 02]. Available from: https://economictimes.indiatimes.com/small-biz/startups/newsbuzz/COVID-19-task-force-to-map-of-technologies-to-fund-nearly-market-ready solutions/articleshow/74839708.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
18. Mahurkar U. COVID-19 task force [Internet]. India today; 2020 Apr 09 [cited 2020 Jun 04]. Available from: https://www.indiatoday.in/india-today-insight/story/inside-pm-modi-s-covid-19-task-force-1665239-2020-04-09
19. India- Recommendations of the Task force on the medical Devices sector in India - 2015. Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India [Internet]. pharmaceuticals.gov; 2020 Feb 12 [cited 2020 Jun 02]. Available from: https://pharmaceuticals.gov.in/important-document/recommendations-task-force-medical-devices-sector-india-2015
20. Funding opportunities and drive for the Indian manufacturers to manufacture and scale-up indigenous medical device manufacturing [Internet]. 2020 May 13 [cited 2020 Jun 02]. Available from: https://www.jagranjosh.com/current-affairs/what-is-atmanirbhar-bharat-abhiyan-pm-narendra-modi-unveils-package-to-make-india-self-reliant-1589351112-1
21. COVID-19 specific funding calls - CAWACH [Internet]. 2020 Apr 09 [cited 2020 Jun 01]. Available from: https://www.investindia.gov.in/team-india-blogs/understanding-newly-launched-cawach-initiative-department-science-technology
22. COVID-19 Research Consortium Call [Internet]. 2020 [cited 2020 Jun 14]. Available from: https://birac.nic.in/webcontent/1586013981_covid_19_consortium.pdf
23. India. DBT floats N-BRIC to drive PPP in innovation to fight COVID-19 [Internet]. 2020 May 14 [cited 2020 Jun 04]. Available from: http://www.nbric.in/
24. India. CAWACH - An Overview - 2020. National Science & Technology Entrepreneurship Development Board (NSTEDB), Department of Science and Technology (DST), Government of India [Internet]. 2020 Jun 02 [cited 2020 Jun 05]. Available from: https://isba.in/cawach/
25. Diagnostics, Vaccines, Novel Therapeutics, Repurposing of Drugs or any other intervention for control of COVID-19. COVID-19 Research Consortium. Department of Biotechnology (DBT) and Biotechnology Industry Research Assistance Council (BIRAC) [Internet]. 2020 Jun 02 [cited 2020 Jun 05]. Available from: https://birac.nic.in/webcontent/1586013981_covid_19_consortium.pdf
26. PIB Press Release, Ministry of Science & Technology- Dr Harsh Vardhan Launches DBT – AMTZ Mobile Diagnostic Unit for Covid Testing- I-Lab [Internet]. 2020 Jun 18 [cited 2020 Jun 18]. Available from: https://pib.gov.in/PressReleasePage.aspx?PRID=1632393
27. Ministry of Textiles- COVID-19 information, [Internet]. 2020 Jun 12 [cited 2020 Jun 15]. Available from: http://texmin.nic.in/TexC19Orders.html
28. CDSCO Public Notification regarding COVID - 19 [Internet]. 2020 Jun 11 [cited 2020 Jun 15]. Available from: https://cdsco.gov.in/opencms/opencms/en/Latest-Public-Notices/
29. Emergo by UL; India's CDSCO responds to COVID-19 with new approval, import, and safety measures [Internet]. 2020 Apr 08 [cited 2020 Jun 05]. Available from: https://www.emergobyul.com/blog/2020/04/indias-cdsco-responds-covid-19-new-approval-import-and-safety-measurse
30. CDSCO created a dedicated coronavirus unit [Internet]. 2020 Mar 28 [cited 2020 Jun 02]. Available from: https://www.hindustantimes.com/india-news/dedicated-units-to-fast-track-approval-of-new-testing-kits/story-4tewdFsWDCC3B1SUxqfm2I.html
31. ICMR Apex Body [Internet]. 2020 [cited 2020 Jun 03]. Available from: https://www.icmr.gov.in/aboutus.html.
32. The Honorable Prime Minister of India declared the need for a "Self-Reliant India" or "Aatm Nirbhar Bharat [Internet]. 2020 May 13 [cited 2020 Jun 04]. Available from: https://www.jagranjosh.com/current-affairs/what-is-atmanirbhar-bharat-abhiyan-pm-narendra-modi-unveils-package-to-make-india-self-reliant-1589351112-1
33. The Government also urged the Indian citizens to be "Vocal for Local" to boost the Indian medical device sector [Internet]. 2020 May 13 [cited 2020 Jun 08]. Available from: https://www.jagranjosh.com/current-affairs/what-is-atmanirbhar-bharat-abhiyan-pm-narendra-modi-unveils-package-to-make-india-self-reliant-1589351112-1
34. 2nd factory to the World after China [Internet]. 2020 May 23 [cited 2020 Jun 07]. Available from: https://indiamedtoday.com/indian-medical-device-industry-has-potential-for-1000-billion-yen-70000-cr-%E2%82%B9-investment-in-next-5-years/
35. RE-START – 'Reboot the Economy through Science, Technology and Research Translations [Internet]. 2020 May 30 [cited 2020 Jun 05]. Available from: https://dst.gov.in/india-well-poised-reboot-economy-through-st-dr-harsh-vardhan#:~:text=Vijay%20Raghavan%2C%20pointed%20out%20how,in%20the%20post%2DCOVID%20era.&text=According%20to%20him%2C%20rebooting%20the,to%20get%20into%20quick%20action.
36. Bhargava B. We need an enabling ecosystem for development of vaccines, studies on new diseases [Internet]. 2020 Jun 04 [cited 2020 Jun 09]. Available from: https://indianexpress.com/article/opinion/columns/covid-19-pandemic-medical-research-icmr-testing-6441368/