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Future of Pharma Industry and Medical Devices after Corona Pandemic

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ABSTRACT

A respiratory disease of unknown cause detected in Wuhan, China was first reported to the WHO Country Office in China on 31 December 2019. The outbreak was declared a Public Health Emergency of International Concern on 30 January 2020. On 11 February 2020, WHO announced a name for the new coronavirus disease: COVID- 19. WHO is working 24 X 7 to provide advice, analyze data, coordinate with partners, help countries prepare, increase supplies and manage networks with experts. By 11 June 2020 - Current evidence suggests that most transmission occurs from symptomatic people through close contact with others very rapidly. Correspondingly, most of recommendations by WHO - on personal protective measures like use of masks and physical or social distancing are based on controlling transmission from symptomatic patients, including those with mild symptoms who are not easy to identify early. Comprehensive studies on transmission from asymptomatic patients are difficult to conduct, as they require testing of large population cohorts and more data are needed to better understand and quantify the transmissibility of SARS-CoV-2. During this global pandemic, the medical device regulatory environment is quickly adapting to meet the challenge of supplying sufficient PPE to front-line healthcare providers and life- saving equipment to those people in medical need. Manufacturers of medical device have to rise up to meet this challenge and embrace these opportunities to bring their device faster to the market and help us to take us out safely on the other side of the COVID-19 curve. One industry that is majorly impacted by this global crisis is the ventilator industry. There's currently thought to be a global shortage of thousands of ventilators as the world attempts to tackle the deadly pandemic. During this pandemic health care systems are overwhelmed, and the effective delivery of medical care to all patients has become a challenge worldwide. Insufficient attention to early warning signs, inadequate stockpiling, lack of access to testing kits and personal protective equipment (PPE), and nationwide variability in the approaches to testing, distribution of PPE, and timing and degree of social distancing measures likely all affected the spread of the disease. Inadequate PPE, overcrowding, and difficulty protecting existing patients are key challenges to the medical industry.

Keywords: Personal protective equipment (PPE), CoV-2

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INTRODUCTION

The coronavirus pandemic is an ongoing pandemic of coronavirus disease which is affecting large no. of population around the globe. It is caused by severe acute respiratory syndrome coronavirus 2 (SARSCoV-2). This outbreak was started in Wuhan, Hubei province, China, in December 2019. The World Health Organization (WHO) declared the outbreak as a Public Health Emergency which is an International Concern on 30 January 2020 and recognized it as a pandemic on 11 March 2020. On 7th of May 2020, approx. 3.77million cases of COVID-19 disease were reported in 187 countries and territories including U.S., India, Italy, Spain, Russia, resulting in approximately 2,64000 deaths. Around 1.25 million people have recovered.^{1,7,9}

Naming the corona virus disease:-

Coronaviruses are a group of viruses which can be transmitted between humans and animals, causing illness that can range from the common cold to more severe respiratory

Syndromes.

The name COVID-19 is derived from words corona, virus, and disease, while the number 19 represents the year that it emerged.

Some official names were announced for the virus responsible for COVID-19 (previously known as “2019 novel coronavirus”) and the disease it causes.

Disease:

Coronavirus disease (COVID-19)

Virus:

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)

Viruses are named on the basis of their genetic structure to facilitate development of Diagnostic tests, medicines and vaccines. Virologists and the broad scientific community do this work, so viruses are named by very famous **International Committee on Taxonomy of Viruses (ICTV)**.

ICTV declared “Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2)” as name of this new virus on 11 February 2020. This name was chosen because this virus is genetically related to the corona virus responsible for SARS outbreak happened in year 2003. While related, the two viruses are different too .⁷

WHO announced “COVID-19” as the name of this new disease on 11 February 2020.

COVID-19 is the respiratory disease caused by recently discovered CORONAVIRUS. The most common symptoms of COVID-19 are following fever, dry cough, tiredness. Some patients may have nasal congestion, runny nose, pain, diarrhea or sore throat. Mostly (80%) people recover from

the disease without any special treatment. Around 1/6 people who get infected become seriously ill and develop difficulty in breathing. Older people, and those with medical problems like high B.P., heart problems, or diabetes, are more likely to develop serious illness.¹

The medicine and healthcare sector is leading this global fight against the virus. For instance, sanitizers, masks, and gloves are in high demand and stocks are running out in all parts of the country. It is the golden opportunity to become the largest supplier in the world's Pharma industry. It will help us to boost our pharmaceutical industries by manufacturing the essential products during the need of the hour. India has already played a vital role in helping its neighbors. So it is the time when we can expand our pharma market, and also boost up Indian economy.^{1,7}

Current status of Pharma Industry -

Pharmaceutical industry is part of the healthcare sector which deals with medications. The industry comprises different subfields pertaining to the development, production, and marketing of medications. These more or less interdependent subfields consist of drug manufacturers, drug marketers, and biotechnology companies.^{3, 8}

Main goal of pharmaceutical industry is to provide drugs which prevent infections, cure diseases and maintain health. This industry is directly affecting the global population, so a number of various International regulatory bodies monitor things like drug quality, patents, drug safety, and pricing. These are some of those regulatory entities:-

- World Health Organization (or WHO)
- US Food and Drug administration
- MHRA which stands for Medicines and Healthcare Products Regulatory Agency.¹¹

The pharmaceutical industry made a great deal of progress over the last decade due to its research-oriented approach which has improved technologies, increased research in the field of bioscience and developed infrastructures. Thanks to biotechnology, various formulations are now developed to cure or stop the growth of several major infections, including HIV and certain types of cancer.^{3,11}

India is the largest provider of generic drugs globally. Indian pharmaceutical sector industry supplies over 50 % of global demand for various vaccines, 40 % of generic medicine demand in the US and 25 % of all medicine in UK. India holds an important position in the sector of pharmaceuticals globally. The country also has a large no. of scientists and engineers who have potential to help and steer the industry forward to even higher levels¹. Presently over 80% of the antiretroviral drugs used globally to combat AIDS (Acquired Immune Deficiency Syndrome caused by HIV) are supplied by Indian pharmaceutical firms.^{3, 8}

Market size-

The pharmaceutical sector has been valued at US\$ 33 billion in 2017. The country's pharmaceutical industry is expected to expand at a CAGR of 22.4% over 2015–20 to reach US\$ 55 billion. India's pharmaceutical exports found at US\$ 17.27 billion in FY18 and have reached US\$ 19.14 billion in FY19. Pharmaceutical exports include bulk drugs, intermediates, biologicals, drug formulations, Herbal and Ayush & products and surgical. ⁴

Indian companies have received 304 Abbreviated- New Drug Application (A-NDA) approvals from the USFDA which stands for US Food and Drug Administration in the year 2017. The country accounts for approx 30% (by volume) and around 10 % (value) in the US\$ 70-80 billion US generics market. India's biotechnology industry which comprises bio- pharmaceuticals, bio-agriculture, bio- services, bio-industry and bioinformatics is expected to grow at an average growth rate of around 30% a year and reach US\$ 100 billion by year 2025.^{4, 13}

Based on the overall revenue the top 15 pharmaceutical companies in India are:-

1. Sun Pharma Industries Limited:- INR 273.28 Billion
2. Aurobindo Pharma Limited :- INR 164.99 Billion
3. Lupin Limited :- INR 159.55 Billion
4. Cipla Limited: - INR 155.77 Billion V. Dr. Reddy's Laboratories :- INR 144.36 Billion
5. Cadila Healthcare Limited :- INR 120.50 Billion
6. Intas Pharmaceuticals Limited :- INR 108.86 Billion
7. Glenmark Pharma Limited :- INR 91.86 Billion
8. Torrent Pharmaceuticals Limited :- INR 63.01 Billion
9. ManKind Pharma Limited :- INR 52.00 Billion
10. Biocon Limited :- INR 43.36 Billion
11. Piramal Enterprises Limited :- INR 43.22 Billion
12. Wockhardt Limited :- INR 40.57 Billion
13. Divis Laboratories Limited :- INR 40.26 Billion
14. Abbott India Limited: - INR 34.24 Billion . ⁴

Investments and Recent Developments:-

Union Cabinet gave its nod for the modification of this existing Foreign Direct Investment (FDI) policy in the sector of pharmaceuticals in order to allow FDI up to 100% under automatic route for manufacturing of medical devices subject to certain conditions .²

The drugs and pharmaceuticals sector attracted cumulative FDI inflows worth US\$

15.98 billion between this time period - April 2000 and March 2019, according to the data released by the DIPP - Department of Industrial Policy and Promotion . ²

Some recent developments or investments in the pharmaceutical sector of India are as follows:

- Between July,2018 to Sep, 2018, Indian pharmaceutical sector.
- witnessed 39 PE investment deals which is worth US\$ 217 million.
- Investment (as % of sales) in research & development by Indian pharma companies* increased to 8.5% in FY18 from 5.3% in FY12.
- In 2017, Indian pharma sector noted 46 merger & acquisition (M&A) deals which is worth US\$ 1.47 billion
- The exports of Indian pharma industries to US will get a boost, as branded drugs which is worth US\$ 55 billion will become off-patent during 2017-2019.

Current Pandemic of Covid-19:-

COVID-19 is an infectious disease caused by a novel(newly discovered) corona virus . Most people infected with the COVID-19 virus will experience mild to moderate respiratory illness and recover without requiring special treatment. Older people, and those with underlying medical problems like chronic respiratory diseases , cardiovascular diseases , diabetes and cancer are more likely to develop serious illness. The best way to prevent and slow down transmission is be well informed about this virus , the disease it causes and how it is spreading . Protect yourself and others from infection by washing hands frequently or using an alcohol(70%) base hand sanitizer frequently and avoid touching face. The COVID-19 virus spreads primarily through discharge from the nose or droplets of saliva when an infected person sneezes or coughs , so it's important that you also practice respiratory etiquette (for example, by coughing into a flexed elbow. Common symptoms are – Fever , Tiredness , Dry cough, Difficulty in breathing , Running nose , Sore throat , diarrhea etc.^{1 ,9}

Some people become infected but don't develop symptoms and don't feel unwell. Around 80% of the infected people recover from this infectious disease without any special treatment. Around 1 out of 6 patient who get COVID-19 becomes seriously ill and develops difficulty breathing. Older people, and the people with underlying health problems like high B.P. , heart problems or diabetes, are more prone to develop serious illness. People with fever, cough and difficulty breathing should seek medical attention.^{6,9}

How does the COVID-19 spread?

People can be infected by COVID-19 from others who have the virus. The disease can spread from one person to another person via small droplets from the mouth or nose which spreads when

a person with COVID-19 coughs or exhales. These droplets land on surfaces and objects around the infected person . There are chances that other people can catch COVID-19 by touching these objects or surfaces, then touching their face especially eyes, nose or mouth. People may also catch COVID-19 virus if they breathe in droplets from a person infected with COVID-19 who coughs out or exhales small droplets. In early studies, it was found that the droplets of Corona virus can travel up to 1 meter. But recently in a hospital it was found that the droplets of pathogen can travel up to 7-8 meter that is why social distancing is very important during this pandemic.⁸

Prevention and control:-

For prevention of infection and slow transmission of COVID-19, following things can be done:

- Wash your hands properly and frequently with soap water
- Or clean them with alcohol(70%) based hand rub
- Maintain at least 6 to 7 meters distance between you and people who are coughing and sneezing
- Avoid touching your face especially eyes , nose , mouth when your hands are not clean
- Cover your mouth and nose while coughing and sneezing
- Stay home if feeling unwell or ill
- Avoid smoking and other activities that weakens your lungs
- Practice physical distancing and social distancing by avoiding unnecessary travel and staying away from large group of people .⁸

Government of India is taking all necessary steps to control the spread of Coronavirus including:-

Social distancing.

Govt. of India recently launched a Mobile Application named “**AAROGYA SETU APP**” , the government’s launched Covid-19 tracker app, is helping the govt. in contact tracing, and also helps in raising one’s alert level if one was nearby of someone who had been tested Covid-19 positive.

City government have collaborated with Fire Department and used fire-tenders, water wash pumps, streets in the Public spaces (including streets, markets, shopping precincts, community centers, parks, playground, and neighbourhood spaces in residential areas) by spraying disinfectants .¹¹

Current status of medical devices:-

A medical device is that device which is intended to be used for medical purposes. Medical devices is beneficial for patients and helps health care professionals in diagnosing and treating patients and helping patients to overcome any sickness or disease, and helps in improving their

quality of life. Medical devices are also helping in to increase the amount of testing required to establish safety and efficacy also increases.^{3,12}

Examples of medical devices includes - *medical thermometer, disposable gloves, ventilators, implants and personal protective equipment kits (PPE kits).*

The global medical device market reached roughly around US\$209 billion in 2006 and was estimated to range between \$220 and \$250 billion in 2013. The United States control ~40% of global market followed by Japan (15%), Europe (25%) and the rest of the world (20%). The largest market shares in Europe (in order of market share size) belongs to Germany, Italy, France, and the United Kingdom. The rest of the world, which comprises regions like Australia, Canada, China, India, and Iran. As per recent studies, the Global medical devices market size was valued at USD 435.5 Billion in 2018 and is expected to reach USD 612.7 Billion by the year 2025, grow at a CAGR of 5.4% 2018 to 2025 .^{3, 12}

MEDICAL SUPPLIES DURING CORONA PANDEMIC: -

- Ventilators
- Oxygen and Oxygen cylinders
- Personal Protection Equipment (PPE) Kits
- N-95 Masks
- Diagnostic kits

Viral Transport Medium (VTM) Kits RNA Extraction Kits

RT-PCR Kits (Manual and Automatic).

VENTILATORS

Available: 19,398

Ordered: 60,884 Total Demand: - 75,000

Ordered to Domestic Mfg . :- 59,884

Make in India – Identified new manufacturers, did handholding to 7 manufacturers

BLE + Skanray: 30,000

Maruti Suzuki + AgVa: 10,000 AMTZ (AP Medtech Zone): 13,500

Personal Protection Equipment (PPE) Kits

Projected Demand: 2.01 Crore Domestic Orders: 1.42 Crore

Total Ordered: 2.22 Crore

Domestic Production/Day: 1.87 lakh

Make in India (earlier no manufacturers, all imports)

- Now 107 domestic manufactures:- 1.43 Crore

More manufacturers in line –

- Domestic manufacturing(30-04-2020) :- 1.87 lakh
- Received :- 17.37 lakh
- Import :- 80 lakh

N-95/N-99 MASKS

Projected Demand:- 2.72 Crore Domestic Orders:- 1.49 Crore Total Ordered:- 2.49 Crore

Domestic Production/Day:- 2.30 lakh

Make in India:-

- 6 (4 BIS certified , 2 DRDO) domestic manufacturers :- 1.49 Crore 7 new manufacturers identified
- Domestic manufacturing on (30-04-2020) :- 2.30 lakh
- Received :- 49.12 lakh
- Import: - 1 Crore .^{12,15}

Future of Pharma Industry

The impact of COVID-19 on pharmaceutical Companies has been unique because these business sectors had to set up their emergency management systems - practically overnight so that “normal” business operations can be maintained , the population also expects pharma companies and medical devices companies to make significant contributions to fight against corona virus (COVID-19).¹⁵

Impact on medical devices Industry

The industries which manufactures medical devices has also taken a hit. The country imports disposables , consumables, and capital equipment which includes orthopedic implants, syringes, bandages , gloves, , computed tomography and magnetic resonance imaging devices from China. Due to the current crisis in the world, the medical device manufacturers across India are finding difficulty to source important raw materials and electronic components from Chinese manufacturers.¹⁵

Even though some of the manufacturing industries in China have restored their operation, shortage crisis of critical electronic parts and raw material still exists. This is adversely affecting the margins of Indian companies which imports medical devices and small components or parts to manufacture finished products. This may also put an upward pressure on costs of medical devices in the short term.^{13,15}

Future growth of medical device market in India as compared to the global market

India is growing fast as a key market for outsourcing of medical devices . The industry has witnessed tremendous growth from the last decade and the current trends of development indicate even greater potential in the coming years. Several joint ventures, agreements and loan licensing procedures have influenced the market. The government has also taken several changes to develop this market by regulating it to bring out more clarity and transparency and by allowing foreign investments in the industry.^{13, 15}

Challenges

The recent move to allow 100% FDI in medical devices outsourcing by the government of India will definitely change the outlook of this industry significantly for the better. In the past, the absence of a clear and consistent regulatory framework and lack of adequate incentives and funding for manufacture device in India has kept the industry from realizing its full potential and worth. Although the changes in policies of FDI will go some way to improve this very sector, there are numerous other challenges which could deter foreign investors from manufacturing in India. High tax rates which were imposed on domestic manufacturers have made this investment unattractive to some of the foreign companies, especially when there is comparatively low amount of tax imposed on various imported medical goods. It is therefore hardly surprising that foreign firm often choose to access India's medical market without establishing a direct presence, many of the companies establish their factories in neighboring countries and export medical devices into India.¹⁵

Advantages

Despite these current challenges of global market, there are some advantages India will continue to offer in these areas like high level of technical expertise, reduced labor costs and funding from governments for Research & Development (R&D) investment to speed up new product development has made India a most favored destinations for outsourcing of manufacturing services. Given more and more multinational companies are looking at customizing products to suit country specific requirements, this segment is only likely to grow further in the coming years. The recently given 'The Drugs and Cosmetics Amendment Bill, 2013' is now expected to recognize the uniqueness of medical devices, medical equipment, consumables as well as diagnostic products. With this disconnection of medical devices from drugs, there will be a very significant reduction in the timelines for approvals or licensing for medical devices. This will help local manufacturing companies to grow significantly and compete on a larger global scale .^{13, 15}

Future Growth

The global size of the sector of medical devices is predicted to reach US \$400 billion this year. As India being a key player in the pharmaceuticals industry globally, of which medical devices are also an important part – which has underperformed so far.¹⁵

The share of country's medical devices market stood at US \$6.3 billion in 2013, which contributes around 7-8 % to overall healthcare expenditures in India as opposed to the 18% contributed by the pharmaceuticals. With each spending estimated to be at less than US \$3, it is obvious that the government is feeling FDI is the only way to induce domestic growth. Despite of such figures, India's medical devices sector is expected to experience unmatched growth during the next decade and by the year 2025, the industry is projected to be worth US \$50 billion. This can be accredited to the middle class growing in the country, an enhancement in the number of hospitals and, consequently, a harsh need for sophisticated medical devices and better healthcare system.^{15, 16}

Some of the growth factors in Healthcare are:

Market Factors

Ageing, growing population, increasing socio-economic inclusion of rural and deprived in mainstream economy, income base and associated disposable income, heightened manufacturing innovation to create customized and modified

products to meet the needs of people from all income segments, growing awareness, changing disease prevalence and among the middle class to focus on early detection of disease and its prevention.¹⁵

Non-market Factors

Development of infrastructure, outsourcing of manufacturing and R&D activities to India, favorable regulations, FDI inflow, initiatives of the government to improve the access of healthcare through various insurance schemes such as RSBY (Rashtriya Swasthya Bima Yojana), Aarogyasri, etc.¹⁵

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