



GROWING AWARENESS

Source: www.gbreports.com

COVID-19

Is likely to bring about increasing awareness of health, medicine and spending on well-being. This will also be on the preventative side rather than just prescribed. This is B2C and higher margin for Pharma companies.

High Vol, Low Margin

India's pharma market has been about competing in low margin generics. However, R&D to sales has increased from 4% to 9% and is heading towards global levels of 15%

Comparative Adv

India has a large employable population, increasing local awareness and affordability of medicines and the potential to supply the world.

PHARMACY TO THE WORLD

Given COVID-19 will be one of the most significant pandemics of our lifetime, there has been an increasing focus on health and medicine. In the need of the hour the shortage of medicines is coming under scrutiny. It would have been hard to fathom this sort of event (significant tail-risk) and build production for it. Once we emerge from this crisis, there is likely to be a far greater focus on medicine and its supply chain.

India has evolved as the world's largest supplier of generic drugs given availability of raw materials, large pool of scientists and engineers and increasing investment into R&D. This investment and growth have been driven by not only exports to the rest of the world, but increased spending on medicine and health insurance and improving accessibility/affordability locally. The country is developing its capability for excellence through entrepreneurship, policy stability (a Pharma Bureau policy think tank), improving compliance and manufacturing standards and creating an ecosystem for development i.e. creating working industry groups, building pharma parks and excellence zones (for example the state of Gujarat is creating two dedicated Pharma Parks – one for drug manufacturing and one for medical devices). The Government of India has been focused on supporting the life sciences industry by granting patent approvals in record times.

Post COVID-19, the industry could benefit from increasing awareness of medicine and spending on healthcare and wellness. With India's size and scale, large employable population, increasing affordability of medicine and a sizeable amount of drugs coming of patent globally, the opportunity stands before companies like Sun Pharma, **Cipla**, Lupin, **Aurobindo Pharma**, **Divi Laboratories**, Dr Reddy, Cadila Health and **Granules India** to name a few.

*India Avenue holds the bolded companies in its equity portfolio

THE PHARMACEUTICAL MARKET

The Global Pharma market is estimated to be around US\$1.3tn in size (2020) and has experienced a growth rate of 6.9% per annum since the turn of the century. However, growth has slowed to 3.9% over the last five years. The US is by far the largest market with 38% of revenue, followed by the Asia-Pacific (21%) and Europe around 16%. Emerging market countries like Brazil, Russia, India and China now have approximately 20% market share. Regions like India are growing at close to 10% in comparison less than half for global growth at present.

Source: Statista.com



Globally there has been an increasing shift from prescription drugs to non-prescription drugs, growing development of personalised medicine and moving away from animal testing are some of the major trends in the pharmaceutical industry. There has been an increasing push towards the development of personalised medicine. The top companies for Pharmaceutical sales include Johnson & Johnson, Novartis, Merck & Co., Roche, Pfizer, AbbVie, Sanofi, AstraZeneca, GlaxoSmithKline i.e. listed in the US or Europe.

India contributes around 6% of the total healthcare market and just over 1% of Pharmaceutical revenue. It is still at a nascent stage in terms of its activities in commercially oriented R&D and innovation. Whilst it is the third largest seller of medicines in the world, it has only produced a handful of commercially viable drug molecules.

We expect that from a structural perspective the attention given to healthcare, wellness and preventative medicine to increase as a fallout of COVID-19. This should increase the pace of global growth of the industry.

INDIA'S SHARE GROWING

India is the largest provider of generic drugs globally (20%)¹ accounting for 20% of global generic drug exports (in terms of volumes). Indian drugs are exported to more than 200 countries in the world (major markets are US, Africa and Europe). Its pharmaceutical industry supplies over 50% of global demand for various vaccines, 40% of generic demand in the US and 25% of all medicine in the UK. The next wave of demand for Indian companies is likely to come from Japan, China, Africa, Indonesia and Latin America.

India's Pharmaceutical (market is 70% generics, 21% OTC drugs and 9% patented drugs) and Biotech Industry (including medical devices) is predicted to grow to US\$100bn by 2025². The country's pharmaceutical industry is around US\$40bn, with pharmaceutical exports close to US\$20bn in FY20. Pharmaceutical exports include bulk drugs, intermediates, drug formulations, biologicals, herbal products and surgical equipment. The medical device market, growing at close to 20-25% per annum and expected to reach US\$40-50bn by 2025. India's aim is to be completely self-sufficient in medical devices.

From 2017-2030, Statista forecasts that India's pharmaceutical sales will experience the most growth at 232%, closely followed by China at 230%, Indonesia 196%, Saudi Arabia 171% and Brazil 169%.

INDIAN MARKET

There are a few factors which make Indian Pharmaceutical market unique:

- Cost of production in India is 2/3rd that of the US. Labor cost is half and cost of setting up the plant is 40% lower than western countries.
- Branded generics dominate the Indian market. The growth is approximately 9-10% per annum at present
- Local players have enjoyed a dominant position driven by formulation development and early investments
- Prices are low, driven by intense competition. While India ranks 10th in terms of value, it ranks third in volumes.
- Growth has been driven by around US\$55bn of product falling off patent from 2017-2019. This should leave a broader market for the generic players

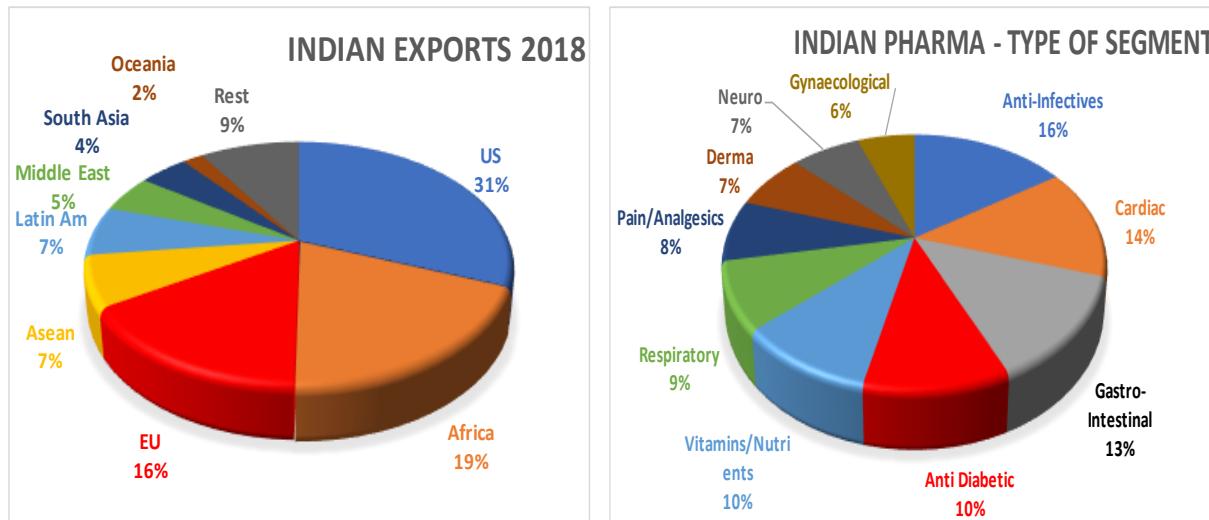
¹ Pharma Knowledge Centre

² Piyush Goyal, Minister for Commerce and Industry

- Despite being the third largest seller of medicines (after US and Germany), India has only produced a handful of commercially viable drug molecules.

With an aging world and a global push by governments to reduce the costs of healthcare, this makes Indian pharmaceuticals very attractive.

Some of the headwinds for the industry has been the significant compliance costs of selling drugs in the US. Additionally, in the extremely price competitive products that the Indian Pharma companies dominate, margins are much thinner and finally mandatory genericisation and lower R&D spend in the past has kept Indian firms grappling with growth from exports. However, growth in the US remains a strategic positive for businesses in an effort to improve their quality, gain global market share (non-US) and eventually growth from their own innovation (R&D to sales have risen from 4% to 9%, but is still lower than 15% globally). Another positive for US market sales is less price erosion relative to markets like India.



Source: Pharma Knowledge Centre

India's biotechnology industry comprising bio-pharmaceutical, bio-services, bio-agriculture, bio-industry and bioinformatics is expected to grow at an average growth rate of around 30% a year and reach US\$100bn by 2025.

As a result, the investments into Indian Pharma from the private sector and foreign investors has been growing. Indian Pharma companies have increased their R&D to 9% of their sales and over the last 20 years FDI investments are a cumulative US\$16.5bn. The Pharma sector is one of the few in India where foreign ownership does not exist. The Government of India unveiled 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug manufacture. Approval time for new facilities has been reduced to boost investments. The National Health Protection Scheme is the largest government funded healthcare program in the world, which is expected to benefit 100 million poor families in the country by providing a cover of up to Rs 5 lakh (US\$ 7,723.2) per family per year for secondary and tertiary care hospitalisation. The program was announced in the Union Budget 2018-19.

CURRENT MARKET EVENTS

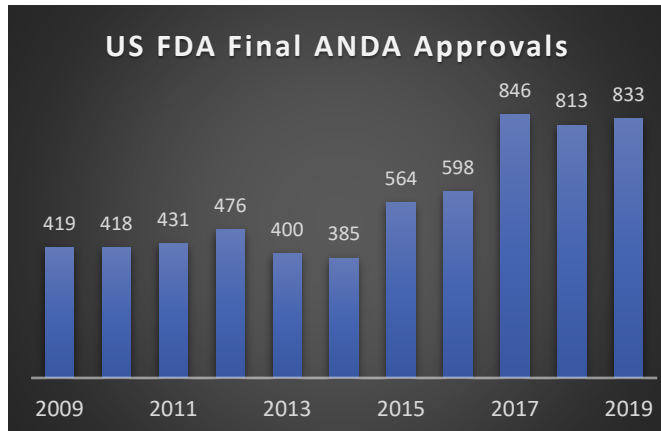
Our discussions with a local broking analyst tell us that approvals locally are happening at a faster pace given COVID-19. Other points to note from the discussion were as follows:

- From a manufacturing perspective, about 3-month worth of supply is in place, but the lockdown will have an impact if it lasts significantly longer
- There may be some delays in FDA approvals
- Freight costs could increase for companies given logistical issues
- The period between April-September could see slower growth
- China's factories re-starting is a positive in terms of raw material supplies
- Some antibiotics are seeing sharp price rises due to stock piling – however this is cyclical and is simply pre-shifting purchases
- Companies are thinking of backward integration i.e. in-house manufacturing in order to secure supply
- Compliant companies with a cleaner record are likely to win out in market share. They will be able to keep costs lower and generate additional sales and thus partake in the "productivity loop"

The concluding comments were that Indian Pharma companies which are survivors through innovation, compliance and productivity will fare the best. It will pay to remain active when selecting winners in this sector.

THE US MARKET – ATTRACTIVE BY HIGH COST

Of the 6203 approvals given from 2009-2019, India has received 2216 or 36% (and 44% in 2019). However, in the US generics business, this comes with significant pricing pressure given compliance costs are high and significant FDA inspections lead to subsequent clean-up missions. Indian companies generally have higher exposure to extremely competitive products, illustrated by 29% of approvals being for products where there are more than 10 active ANDA's, whereas only 14% are for products with three or less ANDA's.



Indian companies received 374 Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA) in 2019. The country accounted for around 30% (by volume) and about 10% (value) in the US\$70-80bn US generics market over the period. The US FDA has upped its approvals per year quite significantly over the past few years.

Source: Statista.com

Currently companies like Aurobindo Pharma and Cadila Healthcare are seeking 50-55 approvals per annum. The larger firms (like Sun Pharma) are looking at 15-20 approvals per annum. Whilst the US generics market has been under tremendous pressure from pricing pressures subsequently eroding margins, it makes sense for these companies to keep lodging ANDA's given they have already invested infrastructure, manpower and capacities – adopting to lower returns, but working on the hope of higher volumes in US generics.

IMPROVING QUALITY

India showed the largest gains in terms of perceived 'quality of API' and 'finished product' manufacturing, proving that industry efforts to align standards more closely with the USA and Europe have clearly been noted. The countries ranking for its finished formulations are improving drastically (equivalent to Germany and most of Europe and second only to the US in quality).

Whilst improving quality is costly, it makes sense for businesses which have already invested in growing their US market share. Additionally, post-FDA approval, it is more likely that it will result in early adoption elsewhere in the world, given the perceived stringent diligence process applied by the FDA.

DEVELOPING IP

The Government has recognised that a top-down governance structure is required which provides leadership, innovation, quality infrastructure and access to talent:

- collaboration and education, infrastructure build and establishment of special economic zones and industrial parks.
- creating sound and effective intellectual property as well as a strong regulatory and legal framework
- financing for research and purchase of medicine
- streamline and fast-track the regulatory approval process (time limits for approval, documentation and appropriate submission)

A Pharma Bureau has now been set up to act as a think tank and conduct policy research to provide suggestions to the Department of Pharmaceuticals. The Bureau will also act as a single point interface for the Pharmaceutical and Medical Device Industry for issues relating to the Government. The Bureau will also take measures to facilitate investment, both foreign and local into the sector.

THE ROAD AHEAD

Medicine spending in India is projected to grow 9-12% over the next five years, leading India to become one of the top 10 countries in terms of medicine spending. Going forward, better growth in domestic sales would also depend on the ability of companies to align their product portfolio towards chronic therapies for diseases such as cardiovascular, anti-diabetes, anti-depressant and anti-cancer that are on the rise.

The Government of India has taken many steps to reduce costs and bring down healthcare expenses. Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian Pharmaceutical companies. In addition, the thrust on rural health programs, lifesaving drugs and preventive vaccines also augurs well for the pharmaceutical companies.

COVID-19 has illustrated that there is too much of a reliance on China to supply raw materials which go into the production of India's drug manufacturing capabilities. There is increasing talk of internalising this capability – not so much to improve margins, but more to have greater control of supply chain via backward integration.

We think that one of the positive impacts that COVID-19 will leave behind is an increasing awareness of health and well-being and a likely increase of healthcare spend out of pocket. This is positive not only for India in general, but also for its Pharmaceutical Industry as it emerges as one of India's true comparative advantages in manufacturing and innovation.

It is our view that companies that have a greater focus on the developing market for pharmaceuticals in India and broader emerging markets will benefit over the next 10 years. However, improving compliance and quality (as measured by the FDA) will be critical to open the door to increasing exports.

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