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Back to Growth: Pharmaceutical sector overview and interview with Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance



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Sector overview

- 3rd largest third pharmaceuticals market globally by volume with major segments including generic drugs, Active Pharmaceutical Ingredient (API)/bulk drugs, Over-the-counter (OTC) drugs, vaccines, contract research and manufacturing, and biosimilars and biologics.
- #1 largest provider of generic medicines; accounts for 20% of global generic drug exports by volume.
- 500+ APIs, 60,000 generic brands across 60 therapeutic categories.
- Largest supplier of low-cost generics, vaccines, and affordable HIV medicines.
- Leading pharmaceutical exporter, exporting to 200+ countries with exports reaching \$20.58 bn during 2019-20.
- Highest number US FDA approved plants outside the US.
- The cost of pharmaceuticals manufacturing is ~35% of that in US.
- Indian pharmaceuticals market is expected to reach \$130 bn by 2030.

Demand drivers

- Rising affordability expected to drive 73 million households to the middle class over the next 10 years.

- World's largest government-sponsored healthcare insurance programme, with 500 million beneficiaries covered up to INR 5 lakh/family and a total of 125+ million e-cards issued till date, along with a total of 1,53,75,989 hospital admissions under the program.
- World's largest pharma chain globally, operating since 2008 to provide affordable, quality medicines across outlets in India (with currently over 6800+ outlets covered)
- Launch of National Digital Health Mission - to increase access to digital healthcare and ensure accountability via health ID card - health ID, digidoctor, telemedicine, ePharmacy, healthcare registry and personal digital health records.
- Patient pool expected to increase over 20% in the next 10 years, given population growth and lifestyle changes.

Policy Support and Incentives

FDI Policy

- 100% under automatic route for greenfield projects and under government route for brownfield investments
- 74% under automatic route for brownfield investments

New Drugs and Clinical Trials Rule 2019

- Approvals granted (else deemed) within highly competitive timelines.
- New drugs approved for use in select developed markets will be automatically allowed in India provided global trials includes Indian patients.

Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of 53 identified critical KSMs/Drug Intermediates and APIs

- A financial incentive will be given to eligible manufacturers of identified 53 critical bulk drugs (covering 41 products) on incremental sales over the base year (2019-20) for 6 years.
- Financial Outlay: INR 6,940 cr (\$938 mn)
- Tenure: 2020-21 to 2027-28

Scheme for Promotion of Bulk Drug Parks

- One-time grants-in-aid will be given to states for the development of 3 Bulk Drug Parks with common infrastructure facilities including solvent storage systems, logistics, testing and effluent treatment plant facilities.
- Amount: INR 1,000 cr (\$135 mn) / bulk drug park
- Tenure: FY 2020-2021 to 2024-2025

Production Linked Incentive (PLI) Scheme 2.0

The Cabinet has also approved a PLI 2.0 Scheme for Pharmaceuticals in November 2020 for which a financial outlay of INR 15,000 crore has approved (over the next 5 years). The categories of drugs covered are included below, and further details are to be released.

Category 1

1. Biopharmaceuticals
2. Complex generic drugs
3. Patented drugs or drugs nearing patent expiry
4. Cell based or gene therapy products
5. Orphan drugs
6. Special empty capsules
7. Complex excipients

Category 2

1. Active Pharma Ingredients (APIs) /Key Starting Materials (KSMs) and /Drug Intermediaries (DIs)

Category 3

1. Repurposed Drugs
2. Auto-immune drugs, Anti-cancer drugs, Anti diabetic drugs, Anti Infective drugs, Cardiovascular drugs, Psychotropic drugs and Anti-Retroviral drugs
3. In-vitro Diagnostic Devices (IVDs)
4. Phytopharmaceuticals
5. Other drugs not manufactured in India
6. Other drugs as approved

Investment Announcements (Jan'19- Dec' 20)

- Italian API manufacturer Olon announced the completion of the acquisition of Mahad plant, Maharashtra in India, the site will be used for exports.
- Carlyle to buy 74% stake in sequent for INR 1,587 cr.
- AstraZeneca earmarks \$90 mn in India investments over next 5 years.
- Ferring pharma invests \$250 mn in new Hyderabad facility.
- Lonza to invest \$94 mn to expand capsule manufacturing capacity across key markets including India (Haryana facility).
- Ajinomoto bio-pharma services expands small molecule manufacturing capabilities at its (Vizag) India facility.
- US pharma giant, Baxter to set up global R&D headquarters in Ahmedabad.
- QPS expands its global footprint with new facilities in the Netherlands, India, and China

Interview

How do you see the major trends that you witnessed during Covid-19 in the pharmaceutical sector pan out in 2021?

The COVID-19 pandemic has had a profound impact on life and businesses across the world leading to lockdowns in many countries, restrictions on movement, travel, social gatherings, among others. In these unprecedented times, the Indian pharmaceutical industry emerged as a dependable partner by supplying uninterruptedly the life-saving medicines not only in India but across the world and demonstrated tremendous commitment towards patient welfare. It was also a transformational moment for the pharmaceutical industry in India. There is a changing paradigm for access to health in the new normal. Companies are being compelled to examine, re-examine, at multiple levels, the way they do business. Many of those changes may ultimately prove difficult to reverse. At the same time, the world needs effective COVID-19 vaccines and treatments.

The IPA-BCG 'Future of Work' study highlights the major trends accelerated by COVID-19 pertaining to digitalization in manufacturing, process, commercial, and overall corporate organization. Additionally, there is a changing consumer behavior with a significant acceleration towards teleconsultations and e-pharmacy. There is an increased uptake of teleconsultations and e-pharmacy sales across the globe and India. Teleconsulting guidelines issued by the Government of India during the lockdown in March 2020 have further provided a much-needed boost to the growth of teleconsulting platforms with both health tech start-ups as well as hospital chains, exploring this channel of care. We need to work on regulatory system to guard the privacy of the individuals while facilitating the growth of digital platforms.

Where do you see the sector going ahead in 2021?

Pharmaceutical industry plays a key role in not only driving better health outcomes but also driving the economic engine of India. The industry contributes \$ 41 Billion annually which accounts for approximately 1.72 per cent of India's GDP, as reported by the Department of Pharmaceuticals. The industry has also contributed significantly to the economy by providing employment to approximately 2.7 Million people and generating \$ 13 Billion in trade surplus (FY 20). India enjoys a key position in the global pharmaceutical industry. The country is the world's largest supplier of generics, accounting for 20 per cent of global exports. India supplies over 60 per cent of global demand for various vaccines and 40 per cent of the demand for generic products in the US. The pharmaceutical companies will continue to grow both organically and inorganically through alliances and partnerships. They will continue to focus on improving operational efficiency and productivity.

What potential do you see in the sector for job creation in the coming period?

The pharmaceutical sector has always been driven by knowledge, technology and skills and has a great potential to create new job opportunities. A recent survey showcased life sciences as the most preferred sector that is predicted to attract talent, ahead of IT and FMCG, this year. The growing collaboration between Indian and global pharmaceutical companies will help leverage innovation and scale, resulting in better use of human resources and reduced risk of layoffs.

Your take on how sector-specific reforms (IBC, PLI, Bilateral Netting etc.) by the government helped the sector thrive and be resilient during the Covid19 period?

PLI scheme by the government is a positive and significant step towards creating a sustainable healthcare system. Additionally, another required boost has been observed in the 'Promotion of Domestic Manufacture of Bulk Drugs Scheme,' which has already set the motion for bulk drug industry.

Implementation of the schemes will be key in achieving the objective of self-reliance and incentivising the industry will go long way in creating a stable and sustainable self-reliant healthcare in India. Indian pharma industry not only needs a boost in R&D and innovation to move up the value chain for future but also needs to be supported for enhancing export competitiveness of the industry.

Going ahead, what are the 3 most important things that you would want in Budget 2021 for the pharmaceutical sector?

The pharmaceutical industry has played a pivotal role during the unprecedented times of COVID-19. The overall policy ecosystem should help increase thrust on healthcare and build healthcare infrastructure to cater to the societal needs as healthcare is fundamental. In this upcoming budget, the pharma industry will look for incentives in R&D and innovation.

The following three heads need strong support in the Budget:

- Incentivizing investment by pharmaceutical companies in R&D and innovation by reintroduction of 200 per cent tax deductions on R&D related expenses
- Providing direct funding support to academia and industry
- Easing access to external sources of funding

Moreover, the Union Budget should focus on increasing exports competitiveness of pharmaceutical products through various schemes such as RoDTEP, PLIs, incentivizing R&D and innovation in pharma sector.

Pharmaceutical industry is a knowledge driven industry and India needs to

move forward to make and discover in India from Make in India. This sector is not only an asset to our country but to the world and has to be given importance in the upcoming budget.
