Management Discussion & Analysis

Shilpa Medicare Ltd (SML) is a global pharma company and operates in the Active Pharma Ingredients and Formulations segments. SML has also forayed into Oral Dissolving Films, Transdermal Patches and Biosimilars. The Company derive its business from International and domestic markets. SML is active in oncology and non-oncology therapeutics.

CURRENT OPERATING SCENARIO

Due to COVID-19 pandemic, the global economy is expected to contract by 3% in 2020 (as estimated by IM). It is further expected that the impact of CVID-19 may subside in the second half of 2020 and the global economic activity may resume to normalcy and grow by 5.8% in 2021. India is expected to register 1.9% growth in 2020 and 7.4% in 2021. Effective policies are essential to forestall the possibility of worse outcomes. Necessary measures to reduce contagion and protect lives are important investments for long-term human and economic health.

1. Global Pharmaceutical Sector

By 2023, the world wide pharma market is expected to exceed US$ 1.5 trillion from an estimated 1,2 trillion in 2018. US with a share of 38% is the largest pharmaceutical market in the world.

Key Trends in the Global Pharma Sector

PHARMA M&A

CY2019 was a landmark year for the global pharma sector 2019 looks set to become a record year for pharma M&A – deals announced in the first alone amounted to around $195 billion. M&A activities are aimed at broadening the product pipelines and improve the profit-making capabilities.

NEW PRODUCTS

Average spending level on new pharma products launched in 2019-2023 is expected to reach $45.8 billion, slightly greater that the $43.4 billion observed for products launched in 2014-2018. This year and the next one are expected to show the bigger number of new launches, especially in the specialty, orphan, biologics and oncology areas. A study by IQVIA, as quoted by many media channels, expects the launch of some 70-90 new oncology products in the next five years, out of the more than 700 currently in late clinical development. Other emerging therapeutic areas that might see the launch of new products include nonalcoholic steatohepatitis (NASH), migraines, neuromuscular diseases, autism and other developmental disorders, and a range of molecular targets for cell and gene therapies.

PATENTS CLIFF OFF

Many branded products are losing their exclusivity with the corresponding generic or biosimilar product versions of the drug being launched. The impact on the market for small molecule-based products is expected to exceed **$121 billion in the next five years** (+15%) in the developed areas, and to reach $17.0 billion in 2023 for biologics.

BIOSIMILARS

The US is expected to present the greater growth of the biosimilar market, even if introduction of new biosimilars should continue to occur more rapidly in Europe. The **introduction of incentives** for this sort of medicinal products and an improved communication of their benefits to patients and providers are also envisaged by the report.

SPECIALITY MEDICINES

With aging number of patients suffering from chronic deceases are also increased across the world. Increasing chronic deceases with complex and rare diseases, is the target of specialty medicines. A market that will represent around 50% of the total in 2023, when spending for specialty products is expected to reach $475–505 billion. Oncology, autoimmune, immunology, HIV and multiple sclerosis are the most interesting therapeutic areas, says IQVIA, covering 74% of the expected growth in developed countries.

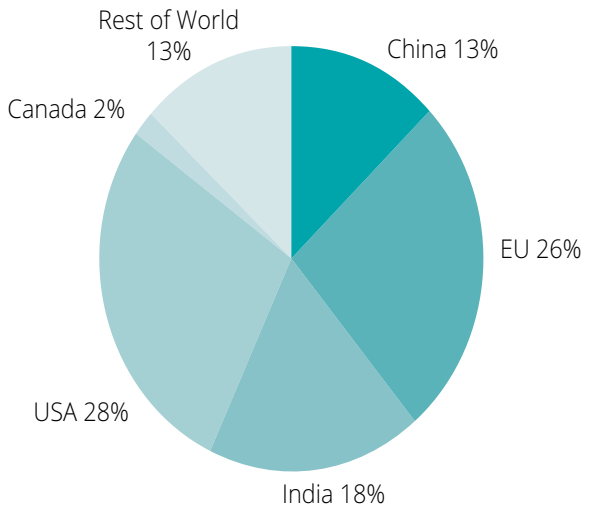
APIS – GLOBAL SCENARIO

The global active pharmaceutical ingredient market is estimated to reach USD 245.2 billion by 2024 from USD 182.2 billion in 2019, at a CAGR of 6.1 per cent during the forecast period. Global Small Molecule API Market is expected to rise from its

initial estimated value of USD 151.30 billion to an estimated value of USD 254.38 billion by 2026, registering a CAGR of 6.71 per cent in the forecast period of 2019-2026. (Galus Asutralis).

Many countries in Asia, Middle-East, Easter Europe and Latin America are engaged in building up or expanding their generic pharmaceutical industry. According to an article by Daara Patel, Secretary General of Indian Drugs Manufacturers Association (IDMA) in Express Pharma on 20 June 2020, Indian generic industry will see a growth of 15 per cent to $55-bn by 2020 as against global growth of 5 per cent. API for these generic manufacturing expansion across the globe will come from India and China as 80% of the API supply demand is expected to be met by these two countries. Industry analysts predict that there is an emerging trend among large MNC captive API manufacturers to withdraw from API manufacturing and outsourcing the production. If this trend gains momentum it's a large opportunity for API manufacturers in India.

Percentage of API Manufacturing Facilities for All Drugs by Country or Region, August 2019



Courtesy USFDA

2. Indian Pharmaceutical Sector

India is a source of about 20% of the world's generic drugs supply. India's pharma spend expected to grow to around US$ 32 billion from US$ 20 billion in 2018. Drug and pharma exports from India rose 11.7% on year to touch $19.15 billion in the 11 months to February 2020.

India is the largest provider of generic drugs globally. Indian pharmaceutical sector industry supplies over 50 per cent of global demand for various vaccines, 40 per cent of generic demand in the US and 25 per cent of all medicine in the UK. India enjoys an important position in the global pharmaceuticals sector. The Country also has a large pool of scientists and engineers who have the potential to steer the industry ahead to an even higher level.

Medicine spending in India is projected to grow 9-12 per cent 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 therapies for chronic diseases such as cardiovascular, anti-diabetes, anti-depressants and anti-cancers that are on the rise.

Indian pharmaceutical sector is expected to grow to US$ 100 billion by 2025. Pharmaceuticals exports from India stood at US$ 19.14 billion in FY19 and US$ 13.69 billion in FY20 (up to January 2020). Pharmaceutical exports include bulk drugs, intermediates, drug formulations, biologicals, Ayush & herbal products and surgicals. Indian companies received 304 Abbreviated New Drug Application (ANDA) approvals from the US Food and Drug Administration (USFDA) in 2017 and received a total of 415 product approvals in 2018 and 73 tentative approvals. The country accounts for around 30 per cent (by volume) and about 10 per cent (value) in the US$ 70-80 billion US generics market. India's biotechnology industry comprising biopharmaceuticals, bio-services, bio-agriculture, bio-industry and bioinformatics is expected grow at an average growth rate of around 30 per cent a year and reach US$ 100 billion by 2025. India's domestic pharmaceutical market turnover reached ₹ 1.4 lakh crore in 2019, growing 9.8 per cent year-on-year (in ₹) from ₹ 1.29 lakh crore in 2018. As on August 2019, the moving annual turnover (MAT) for biosimilar molecules sold in the domestic market stood at ₹ 1,498 crore.

Unlike the developed markets like US, where drug prices are market-controlled, In India the government and regulators play a pivotal role in the entire process. Regulators fix both the price

companies pay for bulk drugs and the price at which they sell their products in the market, leaving little leeway to build profitable businesses. The list of price-controlled drugs, by the department of pharmaceuticals under the ministry of health and family welfare, has swelled from 74 in 1995 to almost 860 in 2019.

This regulated environment has a twin effect on the sector - The pressure on margins have left the India pharma players battling in their pursuit to increase the R&D capabilities and persistently find ways to streamline the operations through cost control and lean manufacturing methodologies.

Indian pharma companies are also investing in building their specialty drugs pipelines. Specialty drugs are high value prescription medications used in the treatment of chronic, complex or rare diseases, and require advanced scientific research and innovation. While specialty drugs are more expensive to develop compared to generics, limited competition with fewer players in this space mean better margins (around 20 to 40 per cent, compared to eight to ten per cent from generics).

PHARMA EXPORTS

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Exports of APIs from India increased by around 11 per cent in 2019 compared to the previous year and the global API market is expected to reach US$ 245 billion (6.1 per cent CAGR) by 2024. This growth is encouraging the Indian pharma industry to focus on timely development and commercialisation of APIs, expanding the scale and scope of API operations, and developing reliable relationships with global customers.

In response to the erosion of generic drugs prices in the US and Europe, generic drug manufacturers in India are exiting drug portfolios where margins are deemed unsustainable. Currently the leading pharma companies like SML are are focusing on developing differentiated complex generics (including biosimilars). IQVIA predicts that, by 2023, the developed market will see the share of specialty drugs rise to 50 per cent of overall pharma spend, demonstrating the attractiveness of this market for the Indian Pharma sector

This shift in focus is primarily due to the fact that complex generics are harder to develop, face less competition and command higher margins than generics. Indian pharma companies also aim to be the first-to-file and first-to-market complex generics and generics to gain a competitive advantage. In 2019, the FDA approved 110 complex generics drugs (11 per cent of the generic drug approvals) and 107 applications for first generics with no generic competition (30 per cent of which were application from Indian companies).

For consolidating the respective positions in the global markets India pharma companies are focusing on the following.

- improving R&D productivity through getting products filed, approved and launched expeditiously, while rationalizing and releasing generic resources to be deployed in specialty business
- Reducing selling, general and administrative (SG&A) expenses
- Building agility in supply chain
- Bringing efficiency in raw material procurements.
- Prudent risk management

EXPORT PERFROMANCE IN FY2020

The exports started doing well in 2019-20 and it has been a good year for the first three quarters with cumulative growth rate of 11.5 per cent during April-December 2019, the growth rate in February and March has gone down recording 7.7 per cent and -23.24 per cent respectively, resulting in the negative growth of - 2.97 per cent in the fourth quarter.

As an impact of the COVID-19 lockdown and resultant supply chain breakdowns, the exports were $20.58 billion during the year as against the targeted $22 billion. Despite this, there was 7.57 per cent overall growth in exports in FY '20 over 2018-19.

REGULATORY COMPLIANCE

Historically, compliance lapses have remained a pain-point for the Indian pharma industry and the past few years saw increased regulatory scrutiny

and compliance challenges to meet Current Good Manufacturing Practice (cGMP) guidelines, which provide systems that assure proper design, monitoring, and control of manufacturing processes and facilities. Indian pharma companies have started to address the quality and compliance issues by deploying India-specific interventions coupled with global best practices.

KEY STRATEGIES OF INDIAN PHARMA COMPANIES

The Indian pharma industry's current strategies and priorities are focused on growth. Some of these strategies, such as rationalising their generic drugs portfolio, increasing specialty products in the pipeline, cost optimisation, and focus on quality and compliance, will deliver results in the near future. Other strategies, like API business revamping, intensification of R&D investment, and long term strategic investments, will likely take longer to deliver results. Nevertheless, these steps should strengthen the industry's global footprints.

Indian pharma companies are currently betting on inorganic growth through mergers and acquisitions (M&A), collaborations, partnerships, joint ventures and in-licensing to create high-value and high-margin asset pipelines. As global pharma companies are looking to reshape their portfolios through divestments, Indian pharma companies are looking to build their specialty drugs and complex generics pipeline.

POLICY INITIATIVES

The Indian government has taken several 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 Indian pharmaceutical companies. In addition, the thrust on rural health programmes, lifesaving drugs and preventive vaccines also augurs well for the pharmaceutical companies. The exports of Indian pharmaceutical industry to the US will get a boost, as branded drugs worth US$ 55 billion have become off-patent during 2017-2019. Under Budget 2020-21, allocation to the Ministry of Health and Family Welfare is ₹ 65,012 crore. The government has allocated ₹ 34,115 crore towards the National Health Mission under which rural and urban people will get benefited. ₹ 6,400 crore has been allocated to health insurance scheme Ayushman Bharat – Pradhan Mantri Jan Arogya Yojana (AB-PMJAY). As per Economic Survey 2018-19, government expenditure (as a percentage of GDP) increased to 1.5 per cent in 2018-19 from 1.2 per cent in 2014-15 for health. The National Health Protection Scheme is the largest government funded healthcare programme in the world, which is expected to benefit 100 million poor families in the country by providing a cover of up to ₹ 5 lakh per family per year for secondary and tertiary care hospitalisation. The programme was announced in Union Budget 2018-19. The Government of India is planning to set up an electronic platform to regulate online pharmacies under a new policy, in order to stop any misuse due to easy availability. 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 government introduced mechanisms such as the Drug Price Control Order and the National Pharmaceutical Pricing Authority to deal with the issue of affordability and availability of medicines.

3. Review of Operations

The Company carries on business operations relating to pharmaceuticals and related activities which is identified as a single segment for operational reviews.

KEY DEVELOPMENTS DURING THE YEAR

- In FY 19-20, Shilpa and its group companies have filed 72 patent applications taking the cumulative total to 357 patent applications in India and other countries. Shilpa received grants for 14 patents during FY 19-20.
- In FY 19-20, Shilpa filed 4 ANDAs & 1 NDA including one as a First to File (FTF).
- We increase our API facility for Tranexamic Acid by nearly 100%.
- The Company has received 2 Establishment Inspection Reports (EIR) for our API unit-I and 1 EIR for our formulations facility at Jadcherla from the US Food and Drug Administration (USFDA). API Unit 1 & 2 also received various GMP Certification based on inspections.
- Aggressively pursing growth from Biologicals, Oral Dissolving Films, Transdermal Products and Dermatological Formulations.

- For better operational synergies and strategic focus, our Biologicals unit was transferred to our wholly owned subsidiary Shilpa Biologicals Pvt. Ltd.
- Stepping into FY2021 we acquired FTF Pharma an integrated drug development company.

REVIEW OF FINANCIAL PERFORMANCE

During the year Company made significant progress . The launched important products and increased research and manufacturing capacity. Our key strategies includes organic and inorganic diversifications to strengthen our research and operations. Our total revenue on a consolidated basis improved 24 % year on year to 925 Crores. Profit After Tax in FY20 is 155 Crores which is 41% improvement year on year. Our revenue from APIs and Formulations increased year on year 15% and 15% respectively.

Key Financial Ratios

Particulars	2019-20	2018-19	% change	Explanations for material change
Debtors Turnover	3.56	3.65	-3%	NA
Inventory Turnover	3.91	3.76	4%	NA
Interest Coverage Ratio	54.78	56.86	-4%	NA
Current Ratio	2.52	2.27	11%	NA
Debt-Equity Ratio	0.26	0.15	80%	i) During the period Company has availed Term Loan's from Bank for its existing ongoing project to complete in time frame. (ii) Additional working capital has been availed from bank to fulfill working capital requirement of the business.
Operating Profit margin	29.42	23.93	23%	Revenue from operation has shown substantial growth of 20% with incremental growth in Formulation Segment (including Services & License Fee) by 43.08% which is key drive during the year under review, and gain from discontinued operation on sale of Biological division.
Net Profit margin	23.56	18.33	28%	
Return on Net Worth	13.25	9.72	36%	

4. Internal control systems and their adequacy

The Company has implemented various internal control systems with an object to have reliability of financial reporting, timely feedback of the operations and compliance with laws and regulations. SAP has been set-up for better financial reporting and to have proper checks to plug loopholes in financial leakages. Apart from implementation of various monitoring software systems, several other information and control systems have been implemented to have proper checking and reporting at production, materials and marketing departments.

The Company has internal audit on regular basis to check the proper working of the internal controls and their as their effectiveness. Internal Auditors as part of their regular checking of internal control systems, also identify the risks to plug. Periodically the controls will be evaluated and improved to make systems more effective and efficient.

5. Human Resources/ Industrial Relations

Human resource plays a vital role in the growth and success of an organization. The Company has maintained cordial and harmonious relations with employees across various locations. The Company currently has 2015 full-time employees. During the year under review, various training and development workshops were conducted

to improve the competency level of employees with an objective to improve the operational performance of individuals. The Company has built a competent team to handle challenging assignments. During the year under review, he Company has maintained cordial and harmonious industrial relations.

6. Opportunities, risks, concerns and threats

It is assumed that the COVID-19 would altogether change the conventional business models forcing the companies to work on new dynamics. The Government's recent decision on promotion of domestic manufacturing of critical APIs and Key Starting Materials shall be good potential for the growth of the pharmaceutical industry. Increased domestic supply shall also help greatly in stabilizing the API prices. The Government has been working to revise the National List of Essential Medicines hoping that it would result in better quality of medical care, better management of medicines and cost-effective use of healthcare resources.

Apart from the general business risks and industry related risks, there would be several other risks such as foreign exchange fluctuations, regulatory policy changes etc. As and when the risk is identified the same will be reviewed at the concerned department level to take necessary steps or will be brought to the notice of management to address the issue.

The Company has a Risk Management Committee to periodically review the risks and report its recommendations to the Board.