

# MANAGEMENT DISCUSSION AND ANALYSIS

## Industry Structure and Developments

The Indian Pharmaceutical Market has witnessed a healthy double digit growth over the last decade. However, the growth slowed down last year due to various factors like price cuts, temporary impacts of demonetization and Goods and Services Tax (GST). For the year ended 31st December 2018, IQVIA estimates that the Indian Pharmaceutical Market size is approximately Rs.1,325 billion growing at 11.5% over the previous year, reflecting a revival after the disruptions seen last year.

The IQVIA Prognosis Report September 2018 projects the market growth at ~9.7% (+/-3%) per annum over the next four years (2017-2022). This growth will be driven by factors such as improving healthcare access, increasing awareness and diagnosis around non-communicable diseases, newer products being launched with greater speed, expanding hospital infrastructure, e-pharmacies and expansion of insurance coverage especially under government schemes. Branded generics which constitute over 80% of the market in value terms will continue to play a significant role.

In March 2017, the Government of India approved the National Health Policy 2017. It aims at achieving universal health coverage and delivering affordable and quality healthcare services to all. The policy advocates a positive and proactive engagement with the private sector to fill critical gaps in achieving national goals. It envisages private sector collaboration for strategic purchasing, capacity building, skill development programs, awareness generation, developing sustainable networks for the community to strengthen mental health services and disaster management. The policy proposes to raise public health expenditure to 2.5% of the GDP by 2025.

The goals of the National Health Policy are complemented and expanded by the Ayushman Bharat National Health Protection Scheme (AB-NHPS), which was unveiled in February 2018 in the Central Government's budget for 2018-19. According to the government, AB-NHPS will be the largest health insurance initiative in the world. AB-NHPS has two components: The first is a National Health Protection Scheme that promises insurance for around 500 million people for secondary and tertiary care, including pre-hospitalization and post-hospitalization expenses. The second component is about 150,000 sub-centers and primary health centers that will be transformed into Health and Wellness Centers providing comprehensive primary care services close to communities including free essential drugs and diagnostic services.

The industry continues to face challenges on account of price controls, which were expanded significantly with the implementation of the Drug Price Control Order 2013 (DPCO), and the scope was increased further after the updates of the National List of Essential Medicines (NLEM). The government intends to set up a Standing National Committee on Medicines (SNCM), which will meet every six months to consider changes to the list. The key reasons for this change include the need to keep the NLEM up to date and to broaden its coverage.

## Financial Performance

During the year ended 31st December 2018, your Company registered Revenue from Operations of Rs. 27,708 million as against Rs. 24,914 million in the previous year, representing a growth of 11%.

Net revenue from India, which constituted 70% of Net Revenue from Operations, increased from Rs. 18,345 million in 2017 to Rs.19,515 million in 2018, reflecting a growth of 6%.

Exports revenue, which contributed 30% of Net Revenue from Operations, increased from Rs. 6,569 million in 2017 to Rs. 8,193 million in 2018, representing a growth of 25%.

Profit before Tax increased from Rs. 5,146 million to Rs. 6,098 million, a growth of 18% for the year ended 31st December 2018.

The Profit after Tax increased from Rs. 3,806 million to Rs. 3,260 million, a growth of 17% for the year ended 31st December 2018.

## Operating Performance

The products manufactured by the Company are distributed in India and exported to many developed as well as developing countries.

## Performance in Indian Market

Over the last 63 years, your Company has been at the forefront in providing innovative and affordable medicines for patients in India. It offers a wide array of medicines for therapy areas such as Diabetes (both Insulins and Orals), Cardiology, Thrombosis, Anti-infectives, Central Nervous System, Allergy and Vitamins, Minerals & Supplements.

In the Indian market, your Company ranks at number 20 as per IQVIA TSA MAT December 2018 and enjoys a market share of 1.6%. Four of the brands of your Company viz. Lantus®, Combiflam®, Amaryl® M and Allegra® feature in the top 100 pharmaceutical brands in India.

Given below are the key highlights and developments on key priority areas for the Company during the year 2018. The value and volume growth of various products mentioned in this section are as per IQVIA TSA MAT December 2018.

### Diabetes Care:

As per the latest International Diabetes Federation estimation, India ranks second in terms of patient load with 74 million adults with Diabetes. Your Company strives to improve lives of patients with Diabetes, by offering a range of quality medicines and patient support programs. Your Company is among the leading companies in Diabetes care with a significant presence in Insulins.

The Insulin portfolio continued to grow double digits through its brands Lantus®, Insuman® and Apidra® in 2018. Our leading brand Lantus® touches the lives of nearly 2.5 million people in India. In 2018, Lantus® grew by 16% in value terms and continues to be the number 1 brand in the Basal analog Insulins market. Allstar™ pens, indigenously manufactured by your Company, help reduce the overall cost of treatment.

In 2018, our Insulin portfolio was further strengthened with the launch of Toujeo™ (Glargine U300) in India. The launch of Toujeo™ has enabled your Company to offer an advanced standard of care and reach even more patients suffering from Diabetes.

The oral Anti-diabetic drug portfolio continued to grow in volumes led by Amaryl®. In 2018, Amaryl® group grew 7% in value despite significant price cuts on line extensions.

Your Company is playing stellar role in reshaping Sulfonylurea market in Asia with its signature initiative 'Safe & Smart'. In 2018, the Indian oral Anti-diabetic team led this initiative with 27 countries from Asia, Africa & Middle East to consolidate data on modern Sulfonylureas. Your Company was conferred with prestigious 'Oral Anti-Diabetes Company of the year 2018' by Frost & Sullivan for its work in the oral Anti-diabetic market.

### Established Products:

The Established Products portfolio of your Company comprises brands which are standards of care for treatment in multiple therapy areas such as Cardiology, Thrombosis and Epilepsy.

Our flagship brand in Cardiology, Cardace® group, grew by 8% in value and continues to be the number 1 ACE Inhibitor prescribed by Cardiologists, Diabetologists and Consulting Physicians.

In Thrombosis segment, Clexane® continues to be the leading Anticoagulant brand. In India, there is a pressing need for awareness of VTE (Venous Thromboembolism) prophylaxis. It is estimated that every day, more than 1,600 people die due to VTE with up to 60% of all cases being hospital associated. Your Company is actively engaged in building awareness and treatment protocols in hospitals towards achieving the vision of a 'VTE FREE INDIA'.

In the Anti-epilepsy market, your Company has a leading position with brands like Valparin® and Frisium® which continue to grow in volumes.

### Consumer Healthcare:

Your Company has structured its Consumer Healthcare business in three verticals i.e. Allergy, Pain relief and Vitamins, Minerals & Supplements (VMS).

Allergy: The strong growth in the Allergy vertical was led by Allegra™ which continues to be the number 1 Anti-histamine brand in India registering a growth of 13% in 2018.

Pain-relief: Year 2018 was a challenging year for Combiflam® but a number of new activities were carried out to stabilize the brand's growth. Combiflam® continues to be amongst the top 5 brands in the Nonsteroidal Anti-inflammatory Drugs (NSAID) market.

New communication was developed for Combiflam Icy Hot™, which is the first OTC extension of Combiflam®.

Vitamins & Mineral Supplements: DePura by Sanofi™ registered a value growth of 41% and climbed to the 4th position in the highly competitive Vitamin D market. New evidence and awareness programs for the scientific community helped growth of E-Cod Plus®, Primosa® (for pre-menstrual syndrome) and CoQ® (for PCOS induced sub-fertility).

#### Building capabilities:

The healthcare ecosystem is transforming rapidly driven by the widespread access to internet, emergence of new technologies, and entry of many new startups in the area of digital health. Your Company is focused on building necessary capabilities in the organization to leverage these emerging opportunities. Some of these initiatives are:

1. Partnerships with startups which provide digital engagement platforms for Healthcare Professionals (HCP). Our teams in Cardiology, Diabetes and Consumer Healthcare have engaged over 25,000 HCPs through such channels.
2. Integrated Digital campaigns for Diabetes care have been introduced, including the launch of a new website ([www.intolife.in](http://www.intolife.in)) for building awareness and clearing misconceptions around usage of Insulin.
3. New software tools for DMS (Distributor Management Service), Sales Force Automation (SFA), Customer engagement, and Business Intelligence for real time data and actionability.
4. Large scale upskilling of teams in the area of digital health, delivered through in house training and exposure to external partners.

#### Winning responsibly – Ethics, Business Integrity, Safety and Social Responsibility:

Your Company has a detailed ethics and compliance program which defines the Company's expectations when conducting the business. It is provided as a resource to guide employees in dealing with issues, both inside and outside the Company. Employees are trained to use the Code of Ethics as a part of their day-to-day functional responsibilities and raise concerns, if any.

Your Company also has a detailed Health, Safety and Environment policy and Management Program that covers the Company's employees and external partners. These policies and programs focus on human health, environmental protection by taking measures on energy conservation i.e. Water & Waste Management philosophy of 3R's (Recycling, Reprocessing and Reduction), indoor air quality, noise protection, energy efficient installations and has ongoing programs on these topics.

Your Company is committed to working in collaboration with relevant stakeholders to increase access to healthcare and quality medicines designed to improve people's health within an economically sustainable framework that supports innovation. Sanofi's aim is to meet the needs of the greatest number of patients. The details of the Company's Corporate Social Responsibility programs have been discussed in detail in the Corporate Social Responsibility Report annexed to the Directors' Report.

#### **Performance in Export Market**

During the year ended 31st December 2018, the Company exported its products to 59 countries, with Germany, Australia, United Kingdom and Russia ranking as the main markets. Volumes continued to be the main growth driver for exports. The other key products were Paracetamol & Codeine tablets, Metformin tablets, Festal dragees and the Allstar™ pen (reusable Insulin device).

The Company also was conferred with the coveted Authorized Economic Operator (AEO) Tier 2 certificate by the Central Board of Indirect Taxes and Customs, Ministry of Finance, Government of India.

During the year ended 31st December 2018, exports revenue contributed 30% of Net Revenue from Operations.

A significant part of export business caters to the European Generics business of the Sanofi group. In June 2018, Sanofi group and Advent International, Global private equity (Advent), announced that they have finished negotiations for Advent to acquire Sanofi group's European generics business in a share purchase agreement worth Euro 1.9 billion. On 1st October 2018, Sanofi group and Advent announced closure of this transaction. As part of this transaction, Sanofi group signed 5 years supply agreement with Advent.

Sanofi group intends to continue sourcing its requirements of products from your Company for the duration of this supply agreement. Meanwhile, your Company will diligently initiate review of its longer term manufacturing strategy.

## **Manufacturing Operations**

Manufacturing operations strengthened its commitment to Quality, Safety and Customer Service in 2018 through a number of initiatives.

In continuation of the dual sourcing plan to support global generics volumes (Ramipril, Metformin, Ibuflam), the required capacity additions were delivered in 2018 in the areas of granulation, compression and packing lines, serialization and aggregation implementation at Ankleshwar and Goa sites. Upgradation of the sites was done by replacement of existing machinery with state-of-the-art high-speed lines. Investments in core production processes were also complemented with capex for warehousing improvement, site infrastructure development and quality infrastructure improvements. After the success of the first cogeneration investment in Ankleshwar API facility, your Company went ahead with the second cogeneration investment in 2018 to increase the reliability, efficiency and competitiveness of the energy costs. Ankleshwar site participated in global industrial pharma sites benchmarking and was able to improve its global ranking in terms of product quality, cost and productivity.

Sanofi sites manufacture products with the stringent global quality guidelines. The sites hold various GMP accreditations viz. for Ankleshwar Chemistry site: US-FDA, Russian MOH, ANSM, EDQM and PDMA – Japan whereas for Pharma site: Germany - Regierungspräsidium Darmstadt, Australia - TGA, Taiwan - TFDA, India - state FDA, Russian MOH, SAUMP and NAFDAC. Your Company has also taken up some projects to enhance the data automation and integrity in production process documentation.

The Company has dedicated significant resources towards ensuring a safe working place at the manufacturing sites. These include CAPEX as well as initiatives like 'Managerial Safety Visit' and 'ONE hour Safety Stop' of operations.

For environmental sustainability, there is a constant emphasis on conservation of resources across manufacturing sites and reducing waste. All plants strictly adhere to global safety and environmental norms and hold ISO 14001 and BS OHSAS 18001 certifications.

## **Medical Affairs**

In 2018, your Company continued to focus on physician education to support patient needs and generation of Real World Evidence. The medical affairs team received the OPPI Medical excellence award for Real World Evidence generation in October 2018.

Some of the focus areas in 2018 were:

1. Consensus meetings to deliberate on holistic patient management in Diabetes treatment viz. 'BE-SMART' and 'Safe and Smart 360 degrees'. The 'Safe and Smart' guidance also found its place in the privileged 'API text book of medicine' and the 'Goodman Gillman textbook of Pharmacology'.
2. Continuation of LANDMARC study to generate evidence on the prevalence, progression of Diabetes, occurrence of complications and analysis of baseline data.
3. Poster presentations at International Diabetes Federation Congress at Malaysia on innovative Diabetes Integrated Care Projects like MyDoseCoach App and Diabetes with Dignity. SEAD program for Thrombosis - Vascular surgeons, Hematologists, Intensivists came together and created a guidance document to improve VTE prophylaxis.
4. Evidence in a set of Indian population on VTE and Carotid Aortic Pressure (CAP) in Hypertension management were presented in international forums.

## Human Resources

Your Company had 3,301 employees as on 31st December 2018.

The overall industrial relations atmosphere continued to be cordial.

A wage settlement has been signed with the Medical Representatives union which will be in force till 31st March 2019.

For Goa factory, the wage settlement for the period April 2014 to June 2017 was signed. A fresh charter of demands and negotiations are continuing for a new wage settlement.

The Charter of Demands has been signed with the Union representing the workmen in the Ankleshwar factory in 2017. The wage settlement will be in force till 30th June 2019.

Top Employer Institute, a global certification company has recognized your Company as 'Top Employer 2019' for excellence in creating an environment wherein employees thrive and develop professionally. Your Company was selected from a group of over 1,200 participating organizations which underwent a robust validation process. This seal is an acknowledgement that your Company is committed to adopting progressive practices in the areas of employee welfare, talent development and building a future-fit organization.

## Internal Audit and Control

Your Company's internal systems are adequate and commensurate with the size of operations. These controls ensure that transactions are authorized, recorded and reported on time. They ensure that assets are safe guarded and protected against loss or unauthorized disposal.

The Internal Audit department carried out audits in different areas of your Company's operations. Post-audit reviews were carried out to ensure that audit recommendations were implemented. The Audit Committee of the Board of Directors reviewed the audit program and findings of the Internal Audit department.

## Opportunities and Risks

The key growth opportunities in Indian Pharmaceuticals Market, especially in the areas of your Company's interest, are likely to be in the following areas:

1. Increasing affordability among the fast growing middle class coupled with improving medical infrastructure and rising insurance penetration.
2. Better diagnosis of chronic, non-communicable diseases (like cardiovascular diseases, respiratory diseases and type-2 Diabetes).
3. Expansion of insurance coverage through public and private initiatives.

Additionally, new opportunities may arise in areas like distribution, e-commerce, public-private-partnerships and digital health.

The business of your Company is also exposed to a few risks:

1. Expansion of NLEM to include more products from our portfolio.
2. Proposal to mandate prescriptions only by generic name. In case of implementation of this proposal, the Company will have to rework its promotional strategies.
3. A part of export business caters to the European Generics business of the Sanofi group. In a global transaction, Sanofi group sold its European generics business to Advent. As part of this transaction, Sanofi group signed 5 year supply agreement with Advent. Sanofi group intends to continue sourcing its requirements of products from your Company for the duration of this supply agreement. Any unforeseen change in the demand scenario from Advent may pose risk on this business in next 5 years. After completion of 5 years, this business may face competition from other suppliers.

## **Outlook**

Due to the price cuts on various products, and temporary impact of demonetization & GST, the growth of Indian Pharmaceutical Market was muted since the year 2017. The IQVIA Prognosis Report September 2018 projects the market growth at ~9.7% (+/-3%) per annum over the next four years (2017-2022).

The growth of domestic business of your Company is likely to be in line with the market growth in the therapy areas it participates. The export business volumes are likely to be maintained.

Your Company will continue to work on productivity enhancement and efficiencies in all areas of operations.

## **Cautionary Note**

Certain statements in the above Report may be forward looking and are stated as required by legislations in force. The actual results may be affected by many factors that may be different from what is envisaged in terms of future performance and outlook presented above.