

## Managing Director's Message



*We will continue to focus on growing each of our businesses faster than the market in which we operate. R&D investments in developing a differentiated generic pipeline as well as in building our specialty pipeline will continue in the coming years.*

**Dilip Shanghvi,**  
Managing Director

### Dear Shareholders,

Health first - that is the underlying message that the COVID-19 pandemic has reasserted. The pandemic is a health as well as an economic crisis and hence the role of the pharmaceutical industry has become very critical. The pandemic has shaken the global economy, but has given the world an opportunity to correct decades of under-investment in healthcare.

While the pharmaceutical industry has taken significant strides in developing cutting-edge products in immunology, biologics, gene and cell therapy, etc., it has, barring certain exceptions, neglected developing new innovative products in the anti-infective segments. A growing incidence of chronic ailments like diabetes, cardiovascular, cancer etc., coupled with better pricing for products in these segments has resulted in very few new products being developed for infectious diseases. Over the past few decades, anti-infectives have become less attractive as potential areas for R&D due to relatively inferior pricing for such products compared to chronic products. Global innovator companies have reorganised their R&D pipelines to focus more on developing high-end chronic products. The global manufacturing infrastructure for anti-infectives has followed this trend, resulting in very few new capacities being set up for such products. The COVID-19 global pandemic may force both, the industry and governments, to revisit the importance of focusing on infectious disease research.

Over the past many years, governments across the world have given more importance to controlling healthcare costs to balance their overall budgets. The COVID-19 pandemic and the economic costs that it has extracted, may force governments to revisit this presumption and try to strike a balance between providing adequate healthcare and the ability to fund it.

While the pandemic obviously highlighted the importance of having an optimum healthcare infrastructure, it has also ignited a fresh debate on globalisation versus localisation. Supply chain network strategy is evolving as the pandemic has also highlighted the risks associated with vendor and/or location concentration. There is a higher sense of urgency now to achieve a pragmatic balance between outsourcing and self-sufficiency. Achieving higher resilience for supply chain is likely to prompt companies to evaluate diversification of their vendor base. However, in case of the pharmaceutical industry, new vendor identification and qualification will be a time-consuming process.

There is also a gradual realisation that the COVID-19 virus is here to stay and that all of us will have to learn to coexist with the virus till an effective treatment or vaccine becomes available. The industry is trying to develop a potential vaccine at a frantic pace while simultaneously putting in efforts to test existing drugs which can potentially aid COVID-19 treatment.

There will be far-reaching changes in the way in which organisations are likely to operate going forward. Consumer behaviour and consumption patterns are also likely to change due to the global pandemic. Social distancing and maintaining individual hygiene (like using masks and hand sanitisers) have become imperative. Work-from-home (WFH) option has been exercised by most organisations for certain functions and there is a likelihood that it will continue for some more time till the viral infection comes under control. There is a possibility that WFH may become the new-normal for certain categories of corporate work force even after COVID-19 comes under control.

### COVID-19 risk response

In these critical and uncertain times, Sun Pharma has responded quickly and efficiently to meet the challenges at hand. We promptly evolved a COVID-19 Risk Management Plan and formed multiple COVID-19 Risk Response Teams under the guidance of the senior management to tackle the challenges resulting from the global pandemic.

Sun Pharma ensured adequate supplies of medicines to its customers across the world despite the supply chain disruptions and the lockdown restrictions in various countries. In a situation where there were multiple disruptions in manufacturing because of various challenges in terms of availability of intermediates, availability of packaging material, etc., we have ensured uninterrupted supply of our products across markets. Sun Pharma has also supplied some of the medicines used for treating COVID-19 symptoms.

There is now a higher focus on automation, digitalisation as well as increased dependence on analytical tools for decision making. We are leveraging IT technology tools to ensure business continuity as well as to facilitate WFH for many functions in the organisation. Changes at manufacturing facilities have been made to ensure productivity as well adherence to all safety and hygiene protocols.

We are also evaluating the potential of some existing products which can be useful in COVID-19 treatment. These include Nafamostat Mesilate and the phytopharmaceutical, AQCH. Both these products are currently undergoing Phase-2 trials in India.

As part of our corporate social responsibility, we donated certain medicines useful in managing COVID-19 symptoms and hand sanitisers worth about ₹250 Million to support the Indian government's COVID-19 pandemic response. Sun Pharma has also arranged personal protective equipment (PPE) kits, disinfectants, gloves etc. to help fight the pandemic.

### FY20 highlights

We continued our growth trajectory in FY20 with our overall revenues growing by about 13% to ₹323 Billion. Key growth drivers include India, our global specialty business, coupled with growth in the rest of the world and API business.

### Operational performance

For FY20, India formulation sales were at ₹97 Billion, accounting for about 30% of overall revenues. Adjusted for one-offs of last year, the India business has recorded a Y-o-Y growth of 15%. Our India business has done well, and we have started witnessing an increase in our market share. Our leading presence in chronic segments coupled with our strong brand equity with doctors is helping us increase our market share in an intensely competitive market. We have also initiated an expansion of sales force for the India business in order to expand our geographical footprint in India and to ensure that all our brands get the attention they deserve.

Revenues in the US remained almost flat at ₹105 Billion and accounted for approximately 33% of our consolidated revenues for FY20. While we witnessed a ramp-up in sales of our specialty products, the generics business continued to face price erosion, driven by competitive intensity amongst manufacturers, buying consortium pressures and a higher pace of generic approvals from the USFDA. Our subsidiary, Taro, recorded a 4% decline in overall revenues to US\$645 Million for the year.

We grew by 3% in emerging markets for the year. We are witnessing a reduction in tender revenues in our South Africa business. Excluding the impact of the tender sales, we have recorded a low double-digit growth year-on-year for our emerging market portfolio. The depreciation of some emerging market currencies has also reduced our reported growth despite good underlying growth in local currency.

Our sales in the rest of world (RoW) markets grew by 31% for the year, driven by increased sales in some key Western European markets and the full year consolidation of the Pola Pharma acquisition in Japan.

### Research & Development (R&D)

R&D is imperative for any pharmaceutical company's future. Our focus is to continue investing in R&D to develop differentiated generics and innovative specialty products. Our global generic business requires a constant flow of new products and hence R&D capabilities to develop such products and meet the individual requirements of each market are very important. At Sun Pharma, we have multiple R&D centres and a strong R&D team to cater to these requirements.

R&D is also absolutely vital for strengthening our global specialty pipeline. It is a key determinant of the future growth and profitability of the specialty initiative. We expect to continue to invest in specialty R&D in the coming years as we progress further in building the specialty business.

Our R&D investments for the year were approximately ₹20 Billion. We continue to be disciplined in identifying future R&D projects for the US generics market and the focus is on developing differentiated generics. Investments for developing the long-term specialty pipeline are expected to continue.

### Progress on specialty initiatives

As we gain traction in the specialty business, it is becoming an additional growth engine for us. Our global specialty revenues for FY20 were about US\$430 Million and accounted for approximately 9% of our consolidated revenues.

We undertook multiple initiatives during the year as part of our efforts to build the specialty business. These include:

1. New specialty product launches in the US
2. Targeting new markets like Japan and China for our specialty products
3. Evaluating new indications for ILUMYA
4. Reiteration of ILUMYA'S potential through long-term clinical data
5. Enhancing the specialty R&D pipeline by adding pre-clinical candidates

### New specialty launches

During the year, we launched four specialty products in the US market viz., CEQUA, ABSORICA LD, EZALLOR SPRINKLE and DRIZALMA SPRINKLE.

- a) **CEQUA:** In October 2019, Sun Pharma commercialised CEQUA (cyclosporine ophthalmic solution) 0.09% in the US. It is indicated for increasing tear production in patients with keratoconjunctivitis sicca (dry eye), an inflammatory disease that affects more than 16 Million people in the US. CEQUA is the first and only USFDA-approved cyclosporine treatment delivered with nanomicellar (NCELL™) technology, which helps to improve the bioavailability and physicochemical stability of cyclosporine, resulting in improved ocular tissue penetration. CEQUA's launch significantly enhances Sun Pharma's specialty ophthalmology portfolio in the US.
- b) **ABSORICA LD:** In February 2020, Sun Pharma launched ABSORICA LD™ (isotretinoin) capsules in the US for the management of severe recalcitrant nodular acne in patients 12 years of age and older. ABSORICA LD is the only isotretinoin formulation

to feature Sun Pharma's micronisation technology, which utilises micronised particles to optimise absorption at a 20% lower dose and can be taken with or without food.

- c) **EZALLOR SPRINKLE:** In July 2019, Sun Pharma launched EZALLOR SPRINKLE™ (rosuvastatin) capsules in the US for the treatment of three types of elevated lipid disorders in people who have difficulty swallowing, a problem that is estimated to affect approximately 30-35% of long-term care patients.
- d) **DRIZALMA SPRINKLE:** In October 2019, Sun Pharma launched DRIZALMA SPRINKLE™ (duloxetine delayed-release capsules) in the US for oral use. It is a serotonin and norepinephrine reuptake inhibitor (SNRI) designed for the treatment of various neuro-psychiatric and pain disorders in patients who have difficulty swallowing. The availability of DRIZALMA SPRINKLE expands Sun Pharma's portfolio of innovative formulation products designed for individuals with swallowing difficulties, the risk of which increases with age and exposure to age-related diseases and conditions, including depression, anxiety, and pain disorders.

### Targeting new markets for specialty products

During FY20, we took steps to target two important markets for our specialty products viz., Japan and Greater China. In June 2019, we announced licensing agreements with a subsidiary of China Medical System Holdings Ltd. (CMS) for the development and commercialisation of two of our specialty products – Tildrakizumab (for psoriasis and psoriatic arthritis) and Cyclosporine A 0.09% (CsA) eye drops (for dry eye disease) for Greater China market. These licensing agreements will facilitate Sun Pharma's entry into the Greater China market, which is the second largest pharmaceutical market globally.

In August 2019, Sun Pharma announced the filing of an application in Japan for manufacturing and marketing authorisation of ILUMYA for moderate-to-severe psoriasis with the Pharmaceuticals and Medical Devices Agency (PMDA), Japan. The PMDA has recently approved this application and launch preparations have been initiated. This launch in Japan will be a step forward for Sun Pharma in expanding the global franchise for ILUMYA.

We have also recently entered into an exclusive licensing and distribution agreement with Hikma Pharmaceuticals PLC for commercialisation of ILUMYA™ in the Middle East and North Africa (MENA) region.

### Evaluating new indications for ILUMYA

In June 2019, we announced interim results from a Phase-2 study of ILUMYA in patients with active psoriatic arthritis (PsA). The interim analysis revealed that over 71% of patients treated with ILUMYA experienced a 20%

improvement in joint and skin symptoms (ACR20 response), meeting the primary endpoint of the study.

The interim results showed that ILUMYA was well tolerated with a low rate of serious treatment-emergent adverse events. The Phase-2 study interim results also showed that across all patients receiving ILUMYA, 75.3% experienced a 20% improvement in symptoms of PsA (ACR20 response) at week 24 compared to 50.6% of patients on placebo. The findings were similar in patients receiving 100 mg or 200 mg of ILUMYA on a quarterly dosing schedule. For some patients on 100 mg ILUMYA, results were seen as early as 8 weeks. Furthermore, an average of 47.1% of all patients receiving ILUMYA achieved an ACR50 response, with some results seen as early as 12 weeks, compared to 24.1% of patients on placebo.

Given the encouraging Phase-2 study interim results, Sun Pharma is in the process of initiating the Phase-3 trials for PsA. ILUMYA is already approved in the US for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and is being investigated for PsA, which affects up to 42% of people with plaque psoriasis.

### Reiteration of ILUMYA'S potential through long-term clinical data

In October 2019, Sun Pharma presented long-term follow-up data from ILUMYA Phase-3 reSURFACE 1 and reSURFACE 2 trials. The data showed that the significant response rates seen in the initial 52 and 64 weeks, respectively, were maintained over four years for people with moderate-to-severe plaque psoriasis, with more than half the participants achieving at least 90% skin clearance [Psoriasis Area Sensitivity Index (PASI) 90] with no new safety concerns recorded.

Additional study analyses showed that the 75-100% skin clearance achieved with ILUMYA treatment over three years was sustained equally in people with and without metabolic syndrome, a common condition in people with psoriasis. This positive data reiterates the potential of ILUMYA and also indicates that the product provides a sustained response against moderate-to-severe plaque psoriasis, thus giving long-term benefit to the patient.

### Enhancing the specialty R&D pipeline

Developing/adding new innovative specialty products is imperative to ensure a strong R&D pipeline. We have taken multiple steps to strengthen the specialty pipeline.

In August 2019, Sun Pharma entered into a global licensing agreement with the CSIR Indian Institute of Chemical Technology, Hyderabad (CSIR-IICT), for patents related to certain compounds with potential therapeutic activity across multiple indications in Sun Pharma's specialty focus areas. Under the terms of the license agreement, Sun Pharma gets exclusive global license for the said patents and any other future patents covered in the agreement.

This collaboration for developing new drugs is part of Sun Pharma's broader strategy for enhancing its global specialty pipeline. This agreement will facilitate the addition of pre-clinical candidates to Sun Pharma's global specialty pipeline. A successful clinical development of these potential compounds may enable Sun Pharma to commercialise pharmaceutical products for various therapeutic indications over the long term.

We recently presented pre-clinical data for GL0034, a long-acting GLP-1R (Glucagon-Like Peptide-1 Receptor) agonist at the American Diabetes Association Virtual 80th Scientific Sessions. GLP-1R agonists are used to treat patients with type 2 diabetes.

The data demonstrated significant outcomes on various diabetic parameters evaluated, viz. glucose reduction, decrease in HbA1c (an important marker for clinical efficacy), augmented insulin secretion, lowering of glucagon level and a marked and meaningful reduction in triglyceride levels. All these outcomes with GL0034 were found to be higher or significant to the currently marketed once a week GLP-1R agonists compared in the study. GL0034 also induced a larger body weight reduction, 1.9x and 3.8x times higher than the two different standard once a week GLP-1R agonist drugs compared in the study, with similar food consumption. We look forward to validating this data in human clinical trials with the Phase-1 trials likely to commence by Q3FY21.

In May 2020, Sun Pharma in-licensed SCD-044, a new chemical entity targeted as a potential oral treatment for atopic dermatitis, psoriasis and other auto-immune disorders. SCD-044 is entering Phase-2 clinical trials.

### cGMP compliance

With global cGMP standards undergoing constant upgradation over the past many years, the pharmaceutical industry needs to be constantly on its toes with an unwavering focus on 24x7 compliance, which, in turn, raises compliance costs. Adherence to these quality standards and ensuring that each manufacturing facility remains compliant has become a key priority for pharmaceutical companies worldwide.

During the year, many of our facilities underwent successful audits by multiple regulatory agencies, including the USFDA. Our Halol facility was inspected by the USFDA in December 2019, which resulted in 8 deviations. The facility was subsequently classified as "Official Action Indicated (OAI)", which implies that all new approvals for the US market from this facility will be put on hold till it is cleared by the USFDA. We have already initiated the corrective actions required to get the facility back into compliance.

### Focus on improving productivity

We are continuing with our efforts to reduce expenses to achieve an optimum cost structure relevant to today's

business and market realities. These efforts are being implemented in multiple areas of the business with greater involvement of people in order to make the Company more efficient. Further enhancement of manufacturing efficiencies, optimising manufacturing footprint, rationalising generics R&D investments, reducing fixed costs and interest cost are some of the areas targeted for efficiency improvement.

### Overall outlook

We will continue to focus on growing each of our businesses faster than the market in which we operate. R&D investments in developing a differentiated generic pipeline as well as in building our specialty pipeline will continue in the coming years.

Our strategy of developing the specialty business as an additional growth engine has started delivering, with a gradual ramp up in specialty revenues. We expect this momentum to continue over the next few years although the COVID-19 pandemic and lockdowns may throw up some uncertainties in the near-term. The specialty business is also helping us to move up the pharmaceutical value chain and bring in more innovation to our business. We have invested significant resources over the past few years in building this business and are now focusing on commercial execution to ensure that future cash flows justify these significant investments.

Generics will continue to be an important part of the overall healthcare management globally. Focus on healthcare may increase in the post-COVID period and hence generics are likely to retain their importance as an effective and economical health solution. Sun Pharma's strong positioning in the global generics industry and continued investments for the future will ensure that it remains a prominent player in this space.

Despite our proactive COVID risk response initiative, we do estimate some softening of sales in the near term due to the lockdowns and economic slowdown across various countries, although it is difficult to quantify the impact as of now. Our endeavour will be to ensure that we are the least impacted.

### Key focus areas for us will be:

1. Employee protection and keeping workplace COVID-19 free
2. Digital engagement with doctors and patients
3. Supply chain protection, ensuring optimum utilisation of our factories and working closely with vendors to ensure continuity of supply
4. Enabling work from home for employees wherever and whenever it is necessary
5. Focus on cash collection and cash conservation in the business to ensure adequate liquidity
6. Continuing our focus on improving R&D productivity and throughput
7. Focus on cost optimisation and target higher efficiencies
8. Continue to invest in developing new technologies and innovative products

Our talented employees have done a remarkable job of ensuring business continuity despite the multiple disruptions resulting from the COVID-19 pandemic and lockdowns. All our teams, including Supply Chain, HR, IT, Finance, Manufacturing have worked tirelessly to:

1. Maintain adequate supply of our products in various markets
2. Enabling WFH for a large number of employees in a very short time
3. Ensuring overall productivity without compromising on safety protocols

We are also grateful to our Board of Directors for their guidance and support in these uncertain times.

We are thankful for your support as a shareholder and we hope that you will continue to repose your confidence in us in future as well.

Warm regards,

**Dilip Shanghvi**

*Managing Director*

Sun Pharmaceutical Industries Ltd.

## Board of Directors



**Israel Makov,**  
Chairman



**Dilip S. Shanghvi,**  
Managing Director



**Sudhir V. Valia,**  
Non-executive and  
Non-Independent Director



**Sailesh T. Desai,**  
Whole-time Director



**Kalyanasundaram Subramanian,**  
Whole-time Director



**Vivek Chaand Sehgal,**  
Non-executive and  
Independent Director



**Rekha Sethi,**  
Non-executive and  
Independent Director



**Gautam Doshi,**  
Non-executive and  
Independent Director

## Leadership Team



**Abhay Gandhi**  
CEO - North America



**Dr. Pradeep Sanghvi**  
Executive Vice-President,  
Global Head - Oral Solids



**Dr. Sapna Purohit**  
Senior Vice-President,  
Head of Human Resources



**Dr. Azadar H. Khan**  
Senior Vice-President - Corporate Relations  
and CSR, India Regulatory Affairs



**Aalok Shanghvi**  
Senior Vice-President -  
Global BD, Emerging Markets and Global R&D



**C. S. Muralidharan**  
Chief Financial Officer



**Anilkumar Jain**  
CEO - API Business



**Davinder Singh**  
Senior Vice-President,  
Sun Pharmaceutical Global Operations



**S. Kalyanasundaram**  
Whole-time Director and  
Director - Corporate Development



**Kirti Ganorkar**  
CEO - India Business



**Hellen de Kloet**  
Business Head - Western Europe,  
Australia and New Zealand



**Jila Breeze**  
Senior Vice-President, Head -  
Global Quality and Compliance



**Uday Baldota**  
CEO - Taro Pharmaceutical  
Industries Ltd.



**Sreenivas Rao**  
Senior Vice-President,  
Head - Global Supply Chain



**Atanu Roy**  
Senior Vice-President,  
Chief Information Officer



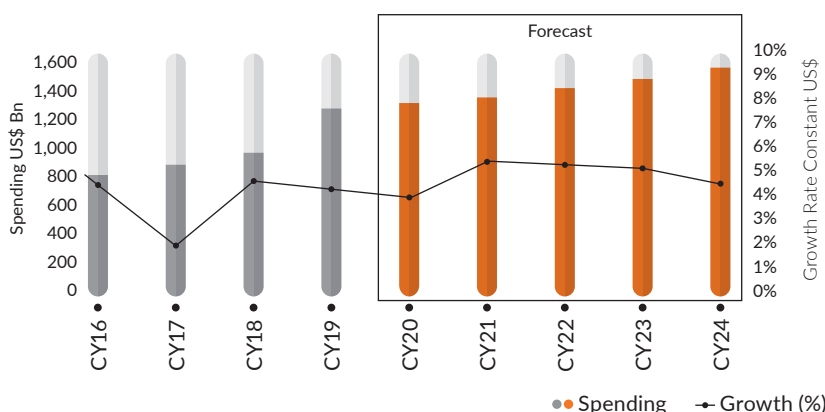
# Management Discussion and Analysis

The views expressed in this analysis and the estimates mentioned were prepared prior to the onset of the COVID-19 pandemic and, hence are subject to change, depending on the evolving situation related to the pandemic.

## Global Pharmaceutical Industry<sup>1</sup>

The global pharmaceutical market, estimated at US\$1.2 Trillion in 2019, is expected to expand at a Compounded Annual Growth Rate (CAGR) of 3-6% to US\$1.5-1.6 Trillion by 2024. Much of this is likely to be driven by the volume growth in pharmerging markets and the launch of high-end specialty innovative products in developed markets. However, overall tightening in pricing and patent expiry in developed markets could offset this growth.

**Chart 1** Global pharmaceutical market<sup>1</sup>



**Table 1** Global pharmaceutical market growth<sup>1</sup>

Regions	2019 (In US\$ Bn)	2014-2019 CAGR	2024 (In US\$ Bn)	2019-2024 CAGR
Developed	822	3.8%	985-1,015	2-5%
Pharmerging	358	7.0%	475-505	5-8%
Rest of the world	71	4.8%	85-95	2-5%
<b>Global</b>	<b>1,250</b>	<b>4.7%</b>	<b>1,570-1,600</b>	<b>3-6%</b>

**Table 2** Global pharmaceutical market 2024 – Share by product type<sup>1</sup>

Spending	Original brands		Non-original brands		Unbranded		OTC, vaccines and other products		Total (In US\$ Bn)
	2019	2024	2019	2024	2019	2024	2019	2024	
Developed	73%	71%	9%	11%	11%	11%	7%	7%	985-1,015
Pharmerging	27%	28%	38%	38%	12%	12%	23%	21%	475-505
Rest of the world	56%	56%	24%	24%	8%	8%	12%	12%	85-95
<b>Global</b>	<b>60%</b>	<b>58%</b>	<b>18%</b>	<b>20%</b>	<b>11%</b>	<b>11%</b>	<b>11%</b>	<b>11%</b>	<b>1,570-1,600</b>

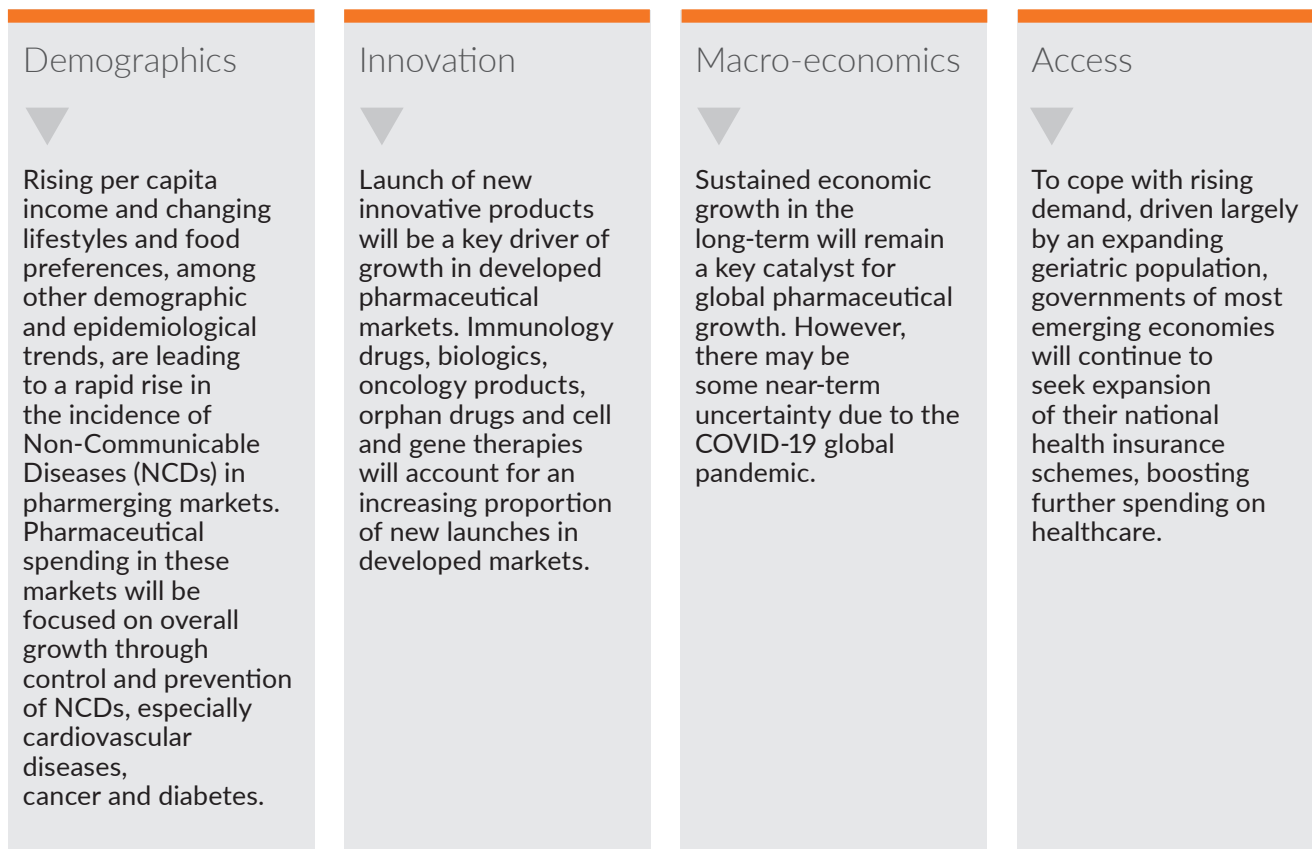
## Outlook, implications and emerging trends<sup>1,2</sup>

The US and pharmerging markets will remain key constituents of the global pharmaceutical industry – the former owing to size, and latter due to their growth prospects. Pharmaceutical spending in the US is estimated to grow at 3-6% CAGR between 2019 and 2024, to reach US\$605-635 Billion by 2024, while the spending in pharmerging markets, including China, is likely to grow at 5-8% CAGR to US\$475-505 Billion by 2024. These two regions will be key contributors to global pharmaceutical growth.

- Pharmaceutical spending in the top five western European markets (WE5) is likely to grow at 3-6% CAGR between 2019 and 2024 to reach US\$210-240 Billion by 2024.
- China's US\$142 Billion pharmaceutical market is expected to grow at 5-8% CAGR to US\$165-195 Billion by 2024, while Japan's pharmaceutical spending growth is likely to remain range-bound at US\$88-98 Billion by 2024.

- Innovator pharmaceutical companies will continue to explore new treatment approaches and technologies, as also breakthrough products to address unmet patient needs. Their key research focus will be immunology, oncology, biologics and cell and gene therapies.
- Global R&D spend is estimated to grow at a CAGR of 3% by 2024, lower than that of 4.2% between 2010 and 2018, partially driven by companies' focus on smaller indications, with lower clinical development costs.
- Digital technologies will be the most transformative force for healthcare. The ongoing uptake for artificial intelligence and machine learning will carry important implications within data science for optimisation of decision-making, ethical handling of patient privacy, and proper use and management of extensive and complex data sets.
- Digital technologies are being leveraged significantly for patient-to-doctor connect currently since a face-to-face consultation may not be possible due to COVID-19. It remains to be seen if this trend will continue in the post COVID-19 period also.
- One of the most dependable sources to generate key patient insights will be genomic data, as it facilitates an understanding of the genetic basis of diseases and treating genetically driven diseases with targeted gene-based therapies.
- Payers (reimbursement companies) are likely to keep working towards reducing costs. While initiatives to improve access to high-priced innovative products are being implemented, cost containment remains high on payors' agendas in the developed markets. This will contribute to a gradual moderation in the overall growth of pharmaceutical companies, especially in developed markets.
- In developed markets, there will be newer treatment options available for rare diseases and cancer, though they may come at a higher cost to patients in some countries. In pharmerging markets, wider access to treatment options and increased spending on medicines will have a positive impact on health outcomes.

## Growth Enablers<sup>1</sup>



### Developed Markets<sup>1</sup>

Pharmaceutical spending in the developed markets grew at ~4% CAGR between 2014-19, and is estimated to grow at about 2-5% CAGR to reach US\$985-1015 Billion by 2024. These markets accounted for ~66% of global pharmaceutical spending in 2019, and are expected to account for ~63% of global spending by 2024.

**Table 3** Developed markets – Pharmaceutical spending & growth<sup>1</sup> (In US\$ Bn)

Region/Country	2019	2014-2019 CAGR	2024	2019-2024 CAGR
USA	510	4.3%	605-635	3-6%
WE5	174	4.0%	210-240	3-6%
Germany	52	4.9%	65-75	4-7%
France	35	1.6%	38-42	0-3%
Italy	34	5.1%	41-45	3-6%
UK	29	4.5%	37-41	4-7%
Spain	25	4.0%	30-34	3-6%
Japan	87	(0.2)%	88-98	(3)-0%
Canada	23	4.6%	26-30	4-7%
South Korea	16	7.3%	21-25	5-8%
Australia	12	3.5%	13-17	3-6%
<b>Developed markets</b>	<b>823</b>	<b>3.8%</b>	<b>985-1,015</b>	<b>2-5%</b>

## USA



USA continues to be the largest pharmaceutical market, accounting for ~41% of global pharmaceutical spending. It recorded ~4% CAGR for 2014-19 and is expected to grow at 3-6% CAGR to US\$605-635 Billion by 2024. The growth is likely to be driven principally by the development and launch of innovative specialty drugs, but will be partly tempered down by expiring patents of existing drugs and cost reduction initiatives by payors.

**Chart 2** US pharmaceutical spending and growth<sup>1</sup>  
(In US\$ Bn)



Year	Spending (US\$ Bn)	CAGR
2019	510	4.3% (2014-2019)
2024	605-635	3-6% (2019-2024)

## Western Europe Top 5 Markets (WE5)



Pharmaceutical spending in the top five Western European (WE5) markets is projected to grow at about 3-6% CAGR to US\$210-240 Billion by 2024. Launch of new-age specialty products will drive this growth. Government-led price control initiatives to improve patient access is likely to act as a counter-balancing force to this growth.

**Chart 3** WE5 pharmaceutical spending and growth<sup>1</sup>  
(In US\$ Bn)



Year	Spending (US\$ Bn)	CAGR
2019	174	4.0% (2014-2019)
2024	210-240	3-6% (2019-2024)

## Japan



The Japanese pharmaceutical market is expected to record flat growth between 2019-24 to about US\$88 Billion. Favourable government policies are resulting in rising generics use, coupled with periodic downward price revisions for pharmaceutical products. This will facilitate savings in healthcare spending, tempering down industry growth despite product innovations.

### Pharmerging Markets<sup>1</sup>

Pharmaceutical spending in pharmerging markets grew at ~7% CAGR during 2014-19 to US\$358 Billion. These markets comprised ~28% of global spending in 2019 and are expected to account for 30-31% of spending by 2024. Pharmerging markets are likely to continue registering faster growth than developed markets, with a 5-8% CAGR through 2024, although lower than the 7% CAGR recorded during 2014-19.

Growth in pharmerging markets will be powered by higher volumes for branded and pure generic medicines led by increasing access among the populace. Some latest generation innovative medicines are likely to be launched in these markets, but given the high price of such products, the uptake may be limited.

**Table 4** Pharmerging Markets – Pharmaceutical spending and growth<sup>1</sup>

(In US\$ Bn)

Region/Country	2019	2014-2019 CAGR	2024	2019-2024 CAGR
China	142	6.7%	165-195	5-8%
Tier 2	71	9.4%	90-120	7-10%
Brazil	32	9.9%	45-49	6-9%
India	22	9.5%	31-35	8-11%
Russia	16	8.4%	23-27	8-11%
Tier 3	145	6.2%	195-225	5-8%
Pharmerging markets	358	7.0%	475-505	5-8%

## India

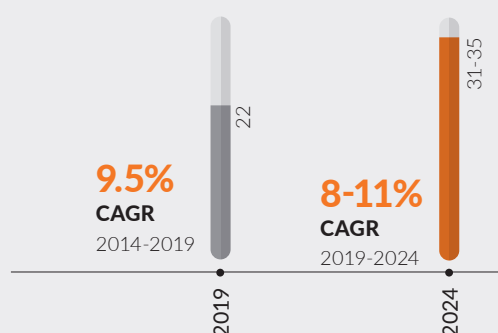


The Indian pharmaceutical industry is one of the fastest growing, globally, and the largest exporter of generic drugs by volume. The domestic formulations market in India has recorded ~9.5% CAGR in 2014-19 to reach US\$22 Billion and is expected to grow at 8-11% CAGR to US\$31-35 Billion by 2024.

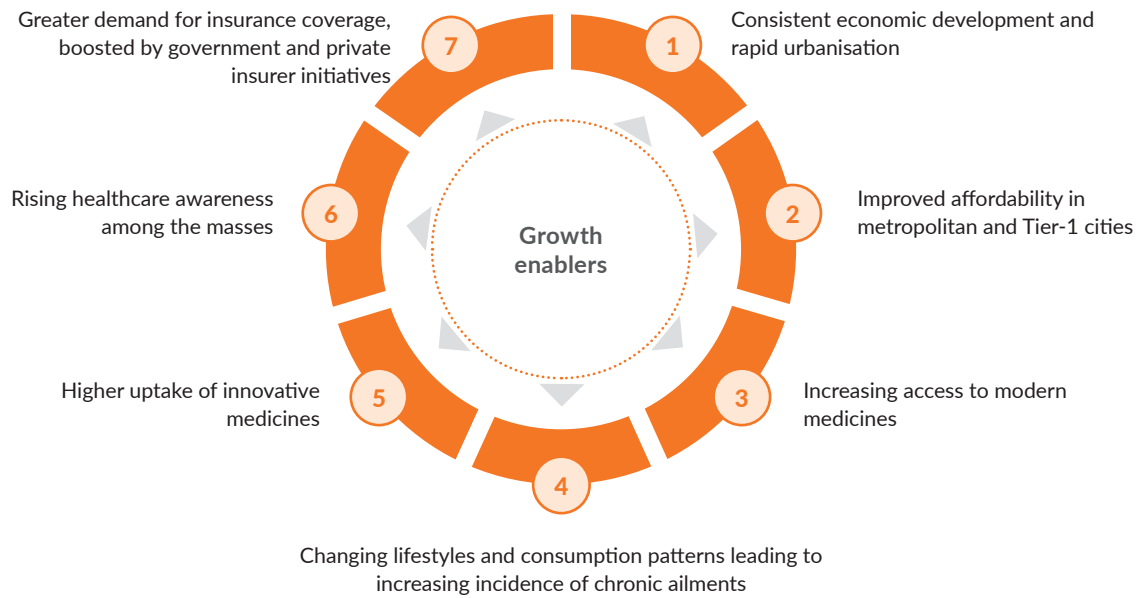
India is uniquely positioned as a crucial supplier of pharmaceuticals by way of chemistry expertise, lower personnel costs and the ability to manufacture quality medicines in compliance with global regulatory standards. It will continue to be an important player in the global generics market.

**Chart 4** India pharmaceutical spending and growth

(In US\$ Bn)



India Pharmaceutical Market - Growth enablers<sup>3,4</sup>



Specialty Medicines<sup>1</sup>

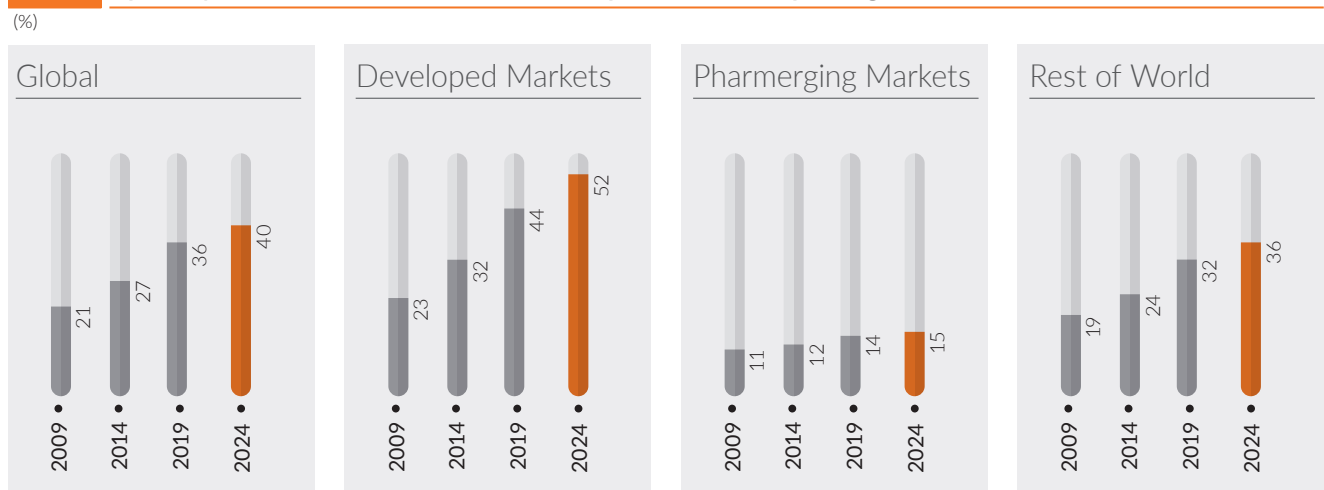
The growing demand of specialty medicines has been a steady growth driver in global pharmaceutical spending during the last decade, especially in the developed markets. Specialty medicines are used in the treatment of chronic, complex or rare diseases, which require advanced research and innovation (biologic drugs for chronic ailments, immunology drugs, orphan disease treatments, gene and cell therapy, among others). These products have made significant difference in patient outcomes.

Given the higher pricing, majority of these products' uptake is likely to be in markets with robust reimbursement systems. In ten years, from 2009 to 2019, the contribution of specialty products to the global pharmaceutical spending rose from 21% to 36%. Additionally, in the

developed markets, contribution increased from 23% to 44%, while in the pharmerging markets, it grew from 11% to 14% by 2019. The uptake of these products is slower in pharmerging markets due to absence of or inadequate prescription insurance coverage for the masses.

The growth trend is expected to continue as more specialty products are developed and commercialised for unmet medical needs. They are likely to account for 40% of global pharmaceutical spending by 2024, with the fastest growth expected to be in the developed markets, where contribution of specialty products is likely to cross 50% by 2024. Oncology, autoimmune diseases and immunology are the main segments in the space, and will likely remain the key growth drivers in the 2019-2024 period.

Chart 5 Specialty medicines – Contribution to overall pharmaceutical spending<sup>1</sup>



### Active Pharmaceutical Ingredients (API)<sup>5</sup>

The global API market is projected to reach approximately US\$232 Billion by 2024, growing at a CAGR of about 6%. Some key factors driving this is the spike in infectious diseases and chronic disorders. The demand is being driven by consumption for manufacturing formulations in the anti-infectives, diabetes, cardiovascular, analgesics and pain management segments. Another factor is the rising use of APIs in novel formulations to pursue niche therapies like immunology, oncology, biologics and orphan drugs.

### Consumer healthcare<sup>6</sup>

Consumer health products do not require prescription from healthcare professionals and can be purchased Over The Counter (OTC) from a pharmacy store. The global OTC consumer health products market size was approximately at US\$141.5 Billion for 2019, recording a growth of 3.9% over 2018. It is projected to grow at 4.3% CAGR to reach ~US\$175 Billion by 2024. Rising disposable income of consumers and spending on healthcare and wellness products are the major factors, likely to foster global market growth of OTC consumer health products.

Today's informed patients believe in taking better healthcare decisions and are engaging in effective health management through digital tools. Leveraging uninterrupted access to information, the consumer is wielding growing power, leading to creation of new market segments and new models of healthcare.

#### Key trends include:

- Increasing prescription to OTC switches
- Growing importance of dietary supplements
- Opportunity for omnichannel distribution – large format stores, shop-in-shop pharmacies and digital modes
- Increasing uptake of value-added products for well-informed consumers

### Sun Pharma's Global Positioning



### Evolving Universe of Sun Pharma

Sun Pharmaceutical Industries Ltd., together with all its subsidiaries (Sun Pharma), is a globally acclaimed specialty generics pharmaceutical company. The Company, along with its subsidiaries and associates, continues to strengthen its market position despite macro-economic headwinds and industry challenges.

A vertically integrated business and a team of highly skilled employees enable it to deliver quality products at affordable prices, and be trusted by customers and patients in over 100 countries (comprising branded and generic markets). The Company has capabilities to manufacture a variety of dosage forms, such as injectables, sprays, ointments, creams, liquids, drug delivery systems, tablets and capsules.

The Company's growing presence is supported by manufacturing facilities across 6 continents. The facilities are approved by multiple global regulatory authorities and run by a multi-cultural workforce comprising 50+ nationalities. The Company fosters excellence through innovation, supported by strong Research & Development (R&D) capabilities across units, with ~6% of annual revenue being invested in R&D.

Sun Pharma is focused on improving efficiencies, cash flows and cost structure to ensure profitable and sustainable growth coupled with reasonable returns. At the same time, it continues its unwavering efforts on building its global specialty business.

**Table 5** Milestones Across Decades

Year	Particulars	Country	Rationale
2020	In-licensed Triferic brand from Rockwell Medical Inc. (USA)	India	Expands nephrology portfolio in India – for treating anaemia in hemodialysis patients.
2019	Licensing agreement with AstraZeneca UK for ready-to-use infusion oncology products	Mainland China	Access to oncology market in Mainland China
2019	Licensing agreement with CMS for Tildrakizumab, Cequa and eight generic products	Greater China	Access to greater China market
2018	Acquired Pola Pharma in Japan	Japan	Access to Japanese dermatology market
2016	Acquired global rights for Cequa and Odomzo	Global	Enhances specialty pipeline
2016	Acquired Biosintez	Russia	Local manufacturing capability to enhance presence in Russian market
2016	Licensing agreement with Almirall for Tildrakizumab for Psoriasis	Europe	Access to European market for Tildrakizumab
2016	Acquired 14 brands from Novartis	Japan	Foray into Japan
2016	Distribution agreement with AstraZeneca	India	Distribution services agreement in India for brand 'Oxra' and 'Oxramet'® (brands of dapagliflozin, used for diabetes treatment)
2015	Acquired InSite Vision Inc.	US	Strengthens specialty ophthalmic portfolio in US
2015	Distribution agreement with AstraZeneca	India	Distribution services agreement in India for brand 'Axcer'® (brand of ticagrelor, used for the treatment of acute coronary syndrome)
2015	Sun Pharma – Ranbaxy Merger	Global markets	Strengthen position as the 5th largest global specialty generic pharma Company, No.1 Pharma Company in India and strong positioning in emerging markets
2014	In-licensing agreement with Merck for Tildrakizumab, a biologic for psoriasis	Global markets	Strengthening the specialty product pipeline
2014	Acquired Pharmalucence	US	Access to sterile injectable capacity in the US
2012	Acquired DUSA Pharma, Inc.	US	Access to specialty drug-device combination in the dermatology segment
2010	Acquired Taro Pharmaceutical Industries Ltd.	Israel	Access to dermatology generic portfolio manufacturing facilities at Israel and Canada
1997	Acquired Caraco	Detroit, US	Entry into the US market

**Business Model**

The business model involves four critical growth strategies to drive sustainable growth and achieve higher efficiencies. Sun Pharma is strategically poised to capitalise on the emerging opportunities in the global pharmaceutical sector, to deliver consistent long-term stakeholder value.

### US business

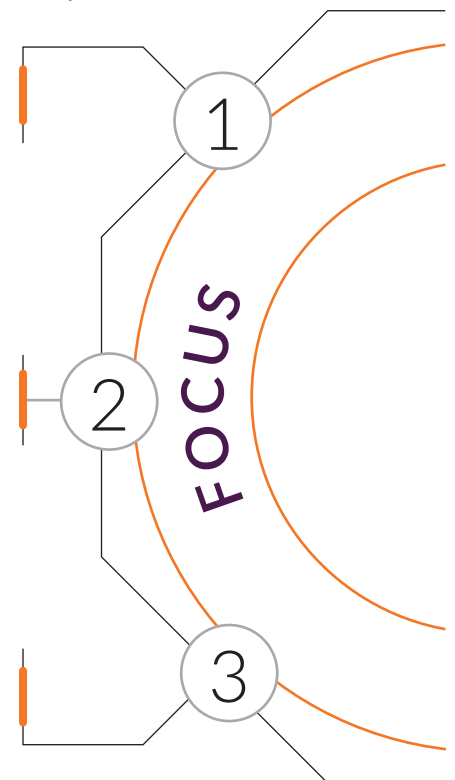
- 9<sup>th</sup> largest generics company in the US with a strong pipeline (98 ANDAs and 5 NDAs awaiting approval)
- Presence in generics, specialty and branded segments with 538 approved products.
- FY20 sales: ₹105,425 Million

### Indian branded generics business

- No.1 company in the Indian pharmaceutical market
- Ranked No. 1 across 11 classes of doctors
- Leading position in high growth chronic therapies
- FY20 sales: ₹97,102 Million

### Emerging markets

- Presence in ~80 countries across Africa, Americas, Asia and Eastern and Central Europe
- Key focus geographies include Russia, Romania, Brazil, Mexico, South Africa, and complementary and affiliated markets
- FY20 sales: ₹55,044 Million



## Growth Strategies

#### Create sustainable revenue streams

- Enhance share of specialty business globally
- Achieve differentiation by focusing on technically complex products
- Focus on key markets – achieve critical mass
- Focus on speed to market
- Ensure sustained compliance with global cGMP regulatory standards

#### Cost leadership

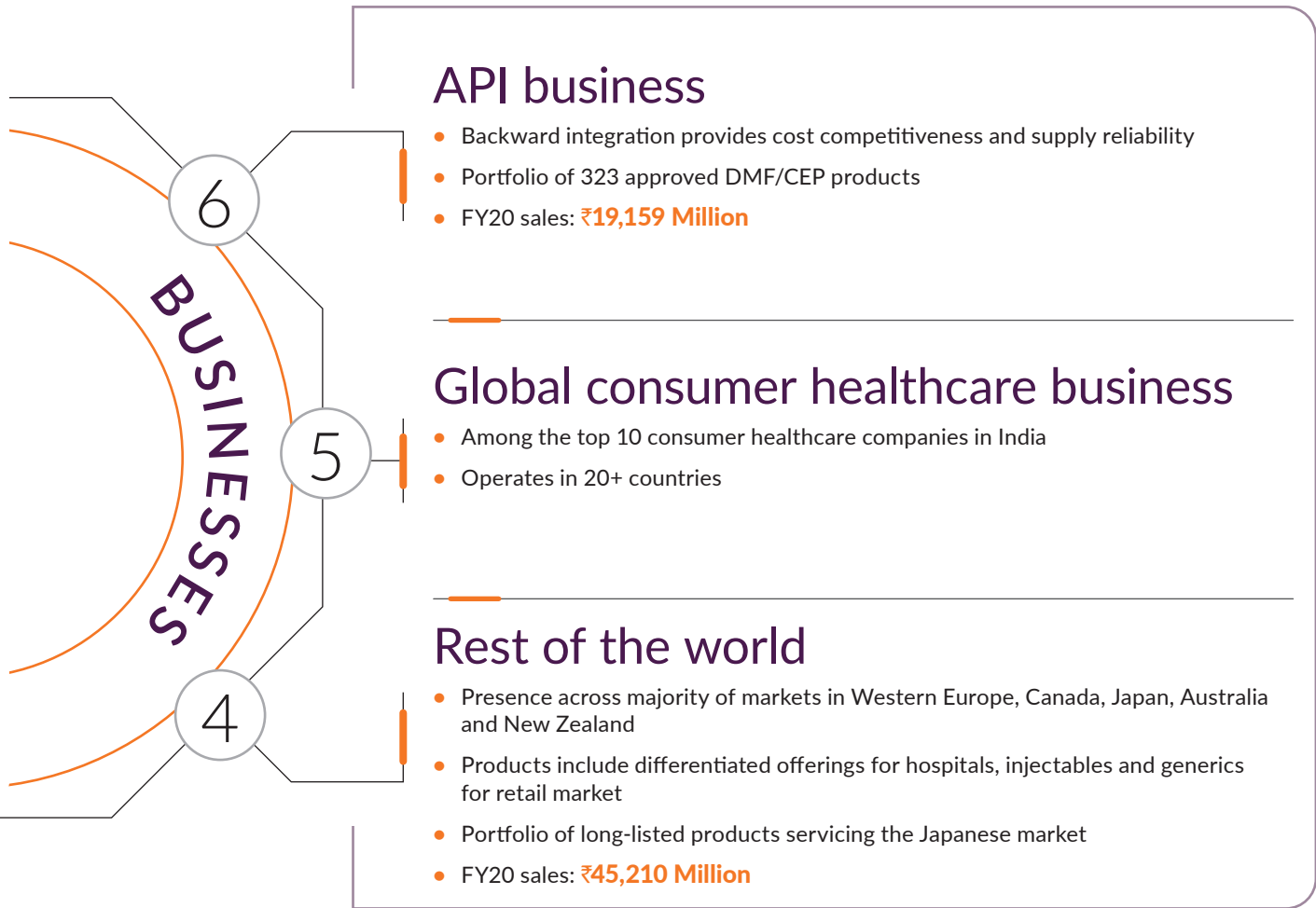
- Optimise operational costs
- Focus on vertically integrated operations
- Rationalise global manufacturing footprint

#### Business development

- Use acquisitions to bridge critical capability gaps
- Focus on access to products, technology, market presence
- Ensure acquisitions yield high return on Investment
- Focus on payback timelines

Data as on March 2020





#### Balance profitability and investments for future

- Increasing contribution of specialty and complex products
- Future investments directed towards differentiated products as well as enhancing presence in key markets

#### Targets for future

- Aim for sustainable and profitable growth
- Focus on improving ROCE
- Increase share of specialty business

Key Performance Indicators



\*\*EBITDA = (Revenue from contracts with customers) - (cost of material consumed + purchase of stock-in-trade + changes in inventories of finished goods, stock-in-trade and work-in-progress + employee benefits expense + other expenses)

\*\*RoW includes Western Europe, Canada, Japan, Australia, New Zealand and other markets

## Financial Ratios

**Table 6** Consolidated

Ratio	Unit	FY 20	FY 19	Variance	Reasons if variance is more than 25%
Return on Net Worth	%	8.3	6.4	29%	Return on Net Worth is higher for the year ended 31 March 2020 due to higher Profit After Tax
Debtors Turnover	times	3.4	3.2	6%	
Inventory Turnover (on cost of goods sold)	times	1.2	1.0	17%	
Interest Coverage Ratio	times	18.4	10.0	83%	Interest coverage ratio is higher for the year ended 31 March 2020 due to higher Profit Before Interest and Tax
Current Ratio	times	2.0	1.8	12%	
Debt/Equity Ratio	times	0.17	0.24	-28%	Reduction in debt and increase in Net Worth
Operating Profit Margin	%	20.0	20.7	-3%	
Net Profit Margin	%	11.6	9.3	25%	Increase in Net Profit

**Table 7** Standalone

Ratio	Unit	FY 20	FY 19	Variance	Reasons if variance is more than 25%
Return on Net Worth	%	13.2	3.6	268%	Return on Net Worth is higher for the year ended 31 March 2020 due to higher Profit After Tax
Debtors Turnover	times	1.9	1.9	-1%	
Inventory Turnover (on cost of goods sold)	times	1.7	1.3	32%	On account of better revenue from contracts with customers, which grew by 22%
Interest Coverage Ratio	times	9.0	4.6	96%	Interest Coverage ratio is higher for the year ended 31 March 2020 due to higher Profit Before Interest and Tax
Current Ratio	times	1.1	0.8	27%	Both Revenue from contract with customers as well as Net Profit during the period has increased resulting in improved current ratio
Debt/Equity Ratio	times	0.26	0.28	-7%	
Operating Profit Margin	%	17.5	12.6	39%	On account of better revenue from contracts with customers which grew by 22%, along with cost containment
Net Profit Margin	%	27.0	8.3	223%	On account of increased total revenue from operations by 22%, along with cost containment

## FY20 operating highlights

- In June 2019, Sun Pharma announced interim results from a Phase-2 study of interleukin-23 (IL-23) inhibitor ILUMYA™ (Tildrakizumab) in patients with active psoriatic arthritis (PsA). The interim analysis revealed that over 71% of patients treated with ILUMYA™ experienced a 20% improvement in joint and skin symptoms (ACR20 response), meeting the primary endpoint of the study. The interim results showed that ILUMYA™ was well-tolerated with a low rate of serious treatment-emergent adverse events. The Phase-2 study interim results also showed that across all patients receiving ILUMYA™, 75.3% experienced a 20% improvement in symptoms of PsA (ACR20 response) at week 24, compared to 50.6% of patients on placebo. The findings were similar in

patients receiving 100 mg or 200 mg of ILUMYA™ on a quarterly dosing schedule. For some patients on 100 mg ILUMYA™, results were seen as early as 8 weeks. Furthermore, an average of 47.1% of all patients receiving ILUMYA™ achieved an ACR50 response, with some results seen as early as 12 weeks, compared to 24.1% of patients on placebo. Given the encouraging Phase-2 study interim results, Sun Pharma is exploring a possible Phase-3 trial for PsA. ILUMYA™ is already approved in the US for the treatment of adults with moderate-to-severe plaque psoriasis, who are candidates for systemic therapy or phototherapy, and are being investigated for PsA, which affects up to 42% of people with plaque psoriasis.

- In June 2019, Sun Pharma announced licensing agreements with a subsidiary of China Medical System Holdings Ltd. (CMS) for the development and commercialisation of two of its specialty products – Tildrakizumab (for psoriasis and psoriatic arthritis) and Cyclosporine A 0.09% (CsA) eye drops (for dry eye disease) in Greater China. Under terms of these licensing agreements, CMS paid Sun Pharma an initial upfront payment, and will also pay regulatory and sales milestone payments, and royalties on net sales. CMS will be responsible for development, regulatory filings and commercialisation of these products in China. These licensing agreements mark Sun Pharma's entry into the Greater China market, which is the second largest pharmaceutical market globally. This is also a step forward in Sun Pharma's efforts towards accessing important markets for its specialty products.
- In July 2019, Sun Pharma announced the US launch of EZALLOR SPRINKLE™ (Rosuvastatin) capsules for the treatment of three types of elevated lipid disorders in people who have difficulty swallowing, a problem that is estimated to affect approximately 30-35% of long-term care residents. With the introduction of EZALLOR SPRINKLE, Sun Pharma continued its commitment of providing a portfolio of innovative formulation products to address the needs of a specific patient segment.
- In August 2019, Sun Pharma announced the filing of an application in Japan for manufacturing and marketing authorisation of ILUMYA (Tildrakizumab) for moderate-to-severe psoriasis with the Pharmaceuticals and Medical Devices Agency (PMDA), Japan. Sun Pharma is committed to growing its global dermatology franchise, with ILUMYA™ as its lead product. The Company continues to build its pipeline and capabilities in this important therapeutic area of significant unmet need. This filing in Japan is a step forward for Sun Pharma in expanding the global franchise for ILUMYA™. It offers a potential new treatment option to patients who struggle everyday with the chronic nature of these ailments.
- In August 2019, Sun Pharma entered into a global licensing agreement with the CSIR – Indian Institute of Chemical Technology, Hyderabad (CSIR-IICT), for patents related to certain compounds with potential therapeutic activity across multiple indications in Sun Pharma's specialty focus areas. Under the terms of the license agreement, Sun Pharma gets exclusive global license for the said patents and any other future patents covered in the agreement. Sun Pharma paid CSIR-IICT an upfront payment and will also pay for potential development, regulatory and sales milestone payments totalling up to ₹2.40 Billion, plus royalties on net sales from commercialisation of the products developed using these patents. Sun Pharma will be responsible for development, regulatory filings, manufacturing and commercialisation of these potential products. This collaboration for developing new drugs is part of Sun Pharma's broader strategy for enhancing its global specialty pipeline. This agreement will facilitate the addition of pre-clinical candidates to Sun Pharma's global specialty pipeline. A successful clinical development of these potential compounds may enable Sun Pharma to commercialise pharmaceutical products for various therapeutic indications over the long-term.
- In August 2019, Sun Pharma granted an exclusive license to a subsidiary of China Medical System Holdings Ltd. (CMS) to develop and commercialise seven generic products in Mainland China. Till date, Sun Pharma and the CMS collaboration covers a total of eight generic products, with an addressable market size of about US\$1 Billion (as per IQVIA data) in Mainland China. This collaboration gives Sun Pharma an entry into the Chinese generic pharmaceutical market. With more than 65% generics penetration, China represents a good opportunity for generic pharmaceutical companies.
- In October 2019, Sun Pharma presented long-term follow-up data from ILUMYA™ Phase-3 reSURFACE 1 and reSURFACE 2 trials. The data showed that the significant response rates seen in the initial 52 and 64 weeks, respectively, were maintained over four years for people with moderate-to-severe plaque psoriasis, with more than half the participants achieving at least 90% skin clearance [Psoriasis Area Sensitivity Index (PASI) 90] with no new safety concerns recorded. Additional study analyses showed that the 75-100% skin clearance achieved with ILUMYA™ treatment over three years, was sustained equally in people with and without metabolic syndrome, a common condition in people with psoriasis.
- In October 2019, Sun Pharma commercialised CEQUA (Cyclosporine ophthalmic solution) 0.09% in the US. CEQUA, which offers the highest concentration of cyclosporine for ophthalmic use approved by the US Food and Drug Administration (FDA), is indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye), an inflammatory disease that afflicts more than 16 Million people in the US. CEQUA is the first and only FDA-approved cyclosporine treatment delivered with nanomicellar (NCELL™) technology, which helps to improve the bioavailability and physicochemical stability of cyclosporine, resulting in improved ocular tissue penetration. CEQUA's launch significantly enhances Sun Pharma's specialty ophthalmology portfolio in the US.
- In October 2019, Sun Pharma launched DRIZALMA SPRINKLE™ (duloxetine delayed-release capsules) in the US for oral use. DRIZALMA SPRINKLE is a Serotonin and Norepinephrine Reuptake Inhibitor

(SNRI) designed for the treatment of various neuro-psychiatric and pain disorders in patients, who have difficulty swallowing – a problem that is estimated to affect approximately 30-35% of long-term care residents. The availability of DRIZALMA SPRINKLE expands Sun Pharma's portfolio of innovative formulation products designed for individuals with swallowing difficulties, the risk of which increases with age and exposure to age-related diseases and conditions – including depression, anxiety, and pain disorders. DRIZALMA SPRINKLE joins EZALLOR SPRINKLE™ (Rosuvastatin) and KAPSPARGO SPRINKLE™ (metoprolol succinate) extended-release capsules as the third product in Sun Pharma's US portfolio designed for individuals in long-term care.

- In November 2019, Sun Pharma entered into a licensing agreement with AstraZeneca UK Ltd. (AstraZeneca) to introduce certain novel ready-to-use (RTU) infusion oncology products in China. The agreement will help to bring cost-effective and quality drugs to patients in China. As per the terms of the agreement, Sun Pharma will be responsible for the development, regulatory filings and manufacturing of the products covered in the agreement, while AstraZeneca will exclusively promote and distribute these products in China. This licensing agreement further enhances Sun Pharma's product portfolio for the China market.
- In January 2020, Sun Pharma entered into exclusive licensing and supply agreements with Rockwell Medical Inc. (Rockwell), to commercialise Rockwell's Triferic, a proprietary iron replacement and haemoglobin maintenance drug, for treating anaemia in hemodialysis patients in India. Triferic is already approved in the US. As per the terms of the agreement, Sun Pharma will be the exclusive development and commercialisation partner for Triferic during the term of the agreement, subject to its approval in India. In consideration for the license, Rockwell is eligible for upfront and milestone payments as well as royalty on net sales. Triferic is indicated to replace iron and maintain haemoglobin in hemodialysis patients via dialysate, during each dialysis treatment. Triferic has a unique and differentiated mechanism of action, which has the potential to benefit dialysis patients.
- In February 2020, Sun Pharma launched ABSORICA LD™ (isotretinoin) capsules in the US for the management of severe recalcitrant nodular acne in patients 12 years of age and older. ABSORICA LD is the only isotretinoin formulation to feature Sun Pharma's micronisation technology, which utilises micronised particles to optimise absorption at a 20% lower dose. ABSORICA LD can be taken with or without food. It makes visibly clearer skin possible within just five months, removes the uncertainty

surrounding timing of dosing, and makes absorption more predictable.

- In March 2020, Sun Pharma committed to donate Hydroxychloroquine (HCQS), Azithromycin, and other related drugs and hand sanitisers to support India's COVID-19 response. It also donated HCQS in the US market.
- In March 2020, Sun Pharma launched a buyback offer in India to buy back 40 Million shares at a price up to ₹425 per equity share, totalling to about ₹17 Billion.

### FY21 Outlook

The COVID-19 outbreak and the lockdown across countries manifested into a healthcare-cum-economic crisis. The situation is uncertain and it is difficult to predict when economies will fully normalise. Hence, FY21 is likely to be a challenging year.

The world population at large, will have to learn to co-exist with the COVID-19 virus till an effective vaccine is developed and a significant portion of the world population is inoculated with the vaccine. Many existing medicines are being evaluated as potential options in COVID-19 treatment. Any positive outcome from the clinical trials of these products may also help in treating patients.

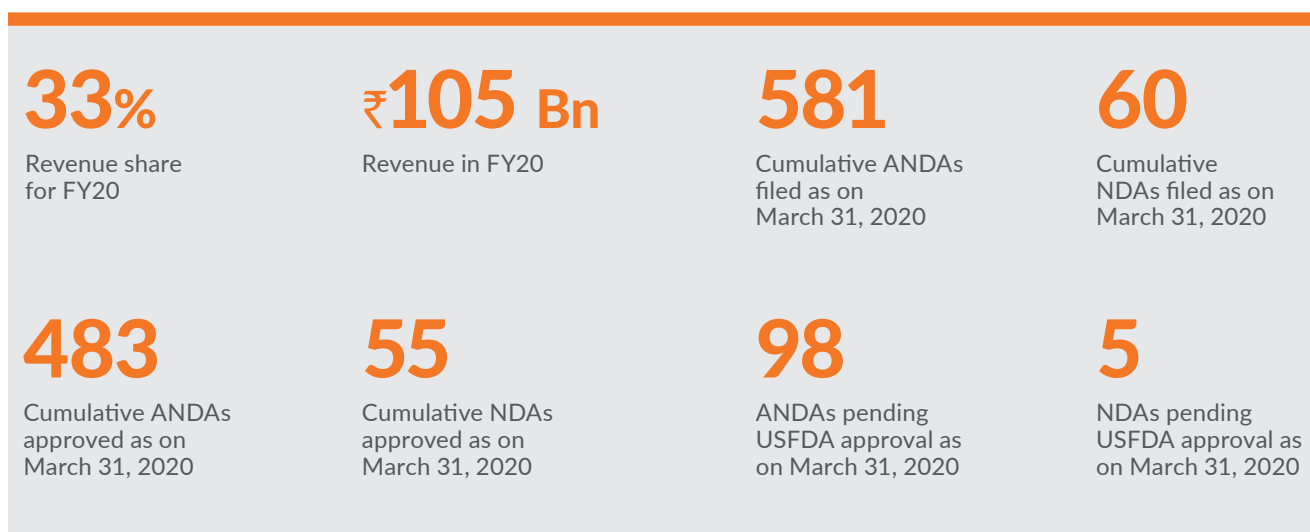
This co-existence with the virus will remarkably change things in the future:

- Since pharmaceuticals are viewed as essential items, the pharmaceutical industry has witnessed relatively less adverse impact of the pandemic, unlike other sectors. Sun Pharma continues to manufacture and distribute its products across the world despite the lockdown.
- The economic disruption linked to COVID-19 will take time to recover, with the outlook for economic activities globally, being inhibited. It may have a consequential effect on GDP across countries, bearing adverse impact on consumption of pharmaceutical products.
- It is possible that a certain percentage of the global workforce will continue to work from home, which will result in significant change in their consumption pattern of products and services.
- Social distancing may become the new normal for everybody till the virus is contained. This will require individuals and corporates to adopt safer protocols in offices, manufacturing facilities, travelling, meetings, amongst others.
- Sales force visit to doctors had stopped as clinics and hospital OPD consultations, were temporarily

- closed. Elective surgeries have been deferred. This will have a near-term impact on marketing and selling of pharmaceutical products and prescription generation for acute care products.
- Lead times for transportation of raw materials and finished goods increased due to the lockdown, but are expected to gradually normalise once the lockdowns across economies are relaxed.
  - Sun Pharma will continue to focus on its objective of growing each business faster than the markets in which it operates. It is focused on profitable growth, sustainable cash flows and controlling costs, objectives that have become more critical during these times of uncertainty. The Company will continue to invest in the development of complex generics and for the enhancement of its global specialty pipeline.

## Business Segment Review

### US BUSINESS



Sun Pharma has been supplying generics to the US for over two decades. Its growth over this period has been driven by a mix of organic and inorganic initiatives. Today, it is the 9<sup>th</sup> largest generics pharmaceutical company in the US, with footprints spanning generics, specialty, branded and OTC segments. It offers a comprehensive portfolio across therapies tailored to the US market, which accounts for 33% of the Company's revenues.

Sun Pharma's key focus areas comprise Central Nervous System (CNS), dermatology, cardiology, oncology and ophthalmic, among others. It is ranked 2<sup>nd</sup> by prescriptions in the US dermatology market.

Among the Indian pharmaceutical companies operating in the US, Sun Pharma enjoys a unique positioning, with capabilities for on-shore and off-shore integrated manufacturing for the US. The Company's manufacturing facilities have the capabilities to manufacture various dosage forms, including liquids, creams, ointments, gels, sprays, injectables, tablets, capsules and drug-device combinations.

**Table 8 US – Key Milestones**

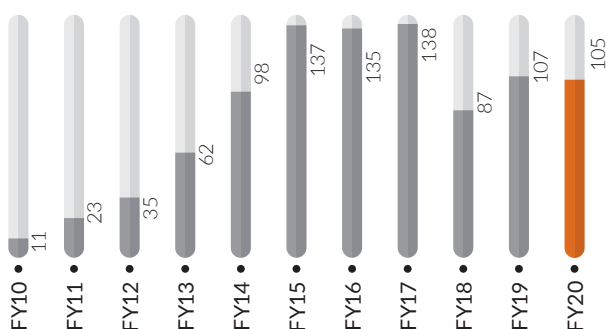
Year	Events
FY20	<ul style="list-style-type: none"> <li>Launched Cequa in the US</li> <li>Launched Absorica LD Capsule in the US</li> </ul>
FY19	<ul style="list-style-type: none"> <li>Launched specialty products, Ilumya, Yonsa and Xelpros in the US</li> <li>Received USFDA approval for Cequa</li> </ul>
FY18	<ul style="list-style-type: none"> <li>Launched Odomzo in the US</li> <li>Obtained USFDA approval for Ilumya</li> </ul>
FY17	<ul style="list-style-type: none"> <li>Filed Ilumya in the US and Europe</li> <li>Acquired Ocular Technologies—gaining access to Cequa—a product for treating dry eyes</li> <li>Launched BromSite in the US ophthalmology segment</li> <li>Acquired Odomzo, a branded oncology product from Novartis</li> </ul>
FY16	<ul style="list-style-type: none"> <li>Strengthened specialty ophthalmic portfolio with the acquisition of InSite Vision</li> </ul>
FY15	<ul style="list-style-type: none"> <li>In-licensed Ilumya (Tildrakizumab)—strengthened specialty dermatology portfolio by gaining access to global rights, including the US</li> </ul>
FY13	<ul style="list-style-type: none"> <li>Acquired DUSA to enter the branded specialty dermatology market</li> </ul>
FY10	<ul style="list-style-type: none"> <li>Acquired Taro Pharma to penetrate the US dermatology market</li> </ul>
FY98	<ul style="list-style-type: none"> <li>Entered the US market through Caraco acquisition</li> </ul>

**FY20 highlights**

- Revenue from the US declined by 1% to ₹105,425 Million.
- The specialty branded business in the US witnessed a boost in revenues with Ilumya, Levulan Kerastick, Cequa and Odomzo being principal contributors. FY20 witnessed the first full-year commercial sales of Ilumya, while Cequa, launched in October 2019, had partial contribution.
- The US generics market remained highly competitive and continues to witness year-on-year price erosion, driven by increased bargaining by customers and speedier generics approvals from the USFDA, thereby intensifying competition.

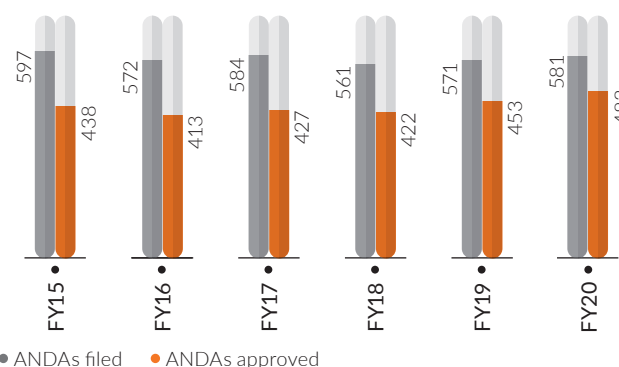
**Chart 6 US sales**

(In ₹ Bn)



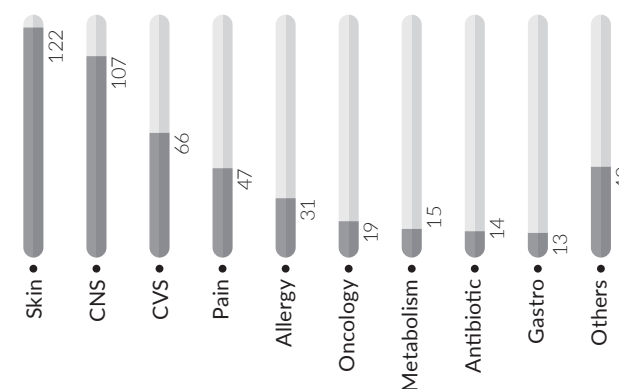
**Chart 7 ANDAs filed and approved**

(Nos.)



**Chart 8 ANDA approvals by therapeutic area as of March 2020**

(Nos.)



Milestones targeted for future

- Enhance share of specialty/branded business
- Develop and commercialise complex generics and products with high entry barriers
- Focus on improving supply-chain efficiencies to ensure best-in-class customer service standards

INDIA BRANDED GENERIC BUSINESS<sup>7</sup>

# 30%

Revenue share for FY20

# No.1

Market position with 8.2% market share

# No.1

Rank by prescriptions across 11 different classes of doctors

# ₹97 Bn

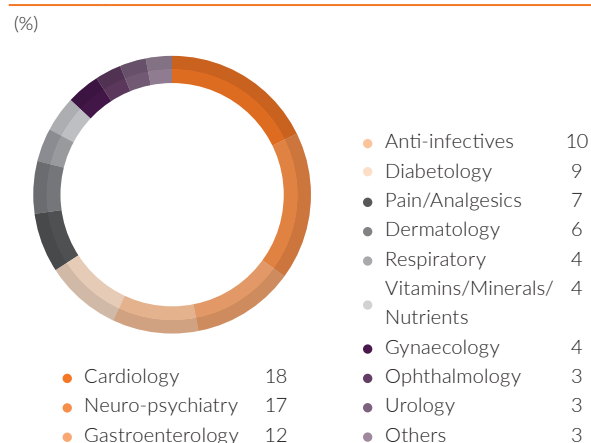
Revenue in FY20

# 31

Sun Pharma brands among the country's top 300 brands

Sun Pharma commands 8.2% share of the Indian pharmaceutical market, with continued leadership in the high-growth chronic segments and specialisation in technically complex products. It has a strong sales force of 9,700+, which reaches 400,000+ doctors across the country.

**Chart 9** Sun Pharma – India therapeutic revenue break-up<sup>7</sup>



**Table 9** Sun Pharma – India prescription ranking<sup>8</sup>

Segment	February 2019	February 2020
Psychiatrists	1	1
Neurologists	1	1
Cardiologists	1	1
Orthopaedic Specialists	1	1
Diabetologists	1	1
Gastroenterologists	1	1
Nephrologists	1	1
Consultant Physicians	1	1
Urologists	1	1
Dermatology	1	1
ENT Specialists	2	1
Ophthalmologists	1	2
Chest Physicians	2	2
General Surgeons	2	2
Gynaecologists	2	2

FY20 highlights

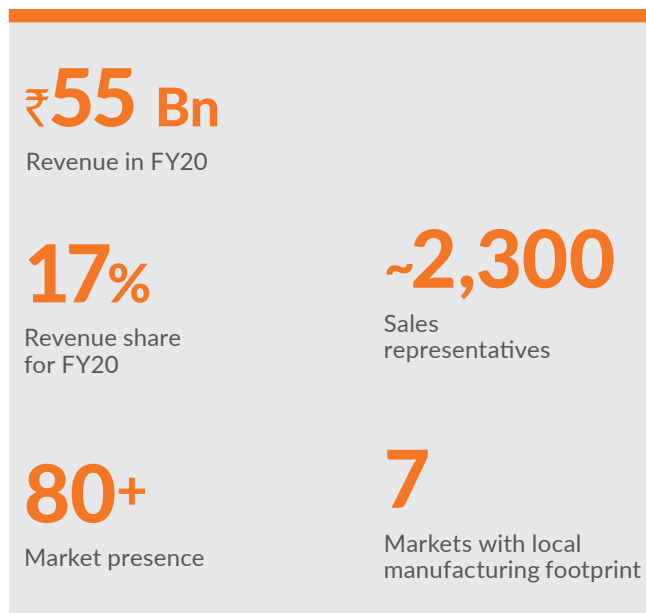
- Revenue from the India formulations business increased by 32% to ₹97,102 Million. Excluding the one-time impact of a shift in product distribution undertaken last year, the underlying growth was at ~15%.
- Key enablers of progress were the following:
  - Leading position in high-growth chronic therapies
  - Broad product portfolio, including new-age, in-licensed patented products
  - High brand equity with doctors



## Priorities for future

- Maintain leadership in a fiercely competitive market
- Innovate continuously to ensure high brand equity
- Evaluate in-licensing opportunities for latest-generation patented products
- Expand geographical and doctor reach

## EMERGING MARKETS



Sun Pharma sells its products in multiple emerging markets with Romania, Russia, South Africa and Brazil being the larger contributors to the business. It is among the largest Indian companies in emerging markets, and offers a wide spectrum of market-specific branded products. The Company has local manufacturing facilities in seven countries, which affords more flexibility in servicing local markets.

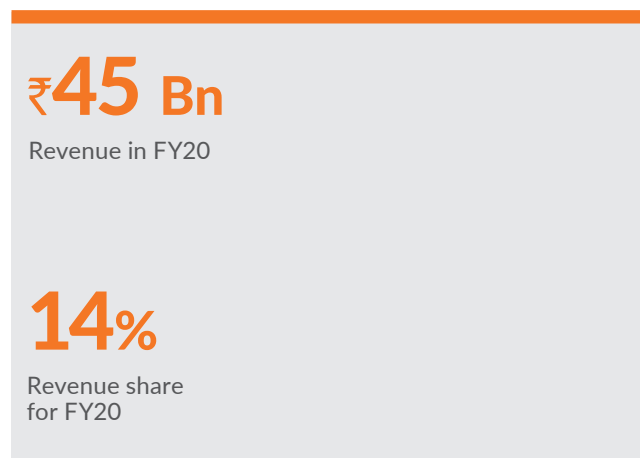
## FY20 highlights

- Revenues from emerging markets grew by 3% to ₹55,044 Million in FY20
- Excluding the impact of lower tender business in South Africa, overall sales have grown by low double-digits for the year

## Key focus areas

- Gain critical foothold in key markets through organic and inorganic initiatives
- Enhance product basket to offer a broad and profitable portfolio
- Launch complex products

## REST OF THE WORLD: WESTERN EUROPE, CANADA, JAPAN, AUSTRALIA, NEW ZEALAND AND OTHER MARKETS



Sun Pharma's Rest of World (RoW) presence includes key markets in Western Europe, Canada, Japan, Australia and New Zealand (A&Z), where ageing population and increasing incidence of chronic ailments are likely to drive pharmaceutical consumption. However, government efforts to tighten healthcare budget in these markets, may act as a counter-balancing force. The portfolio includes differentiated offerings for hospitals, injectables and generics for retail markets and long-listed products in the Japanese market.

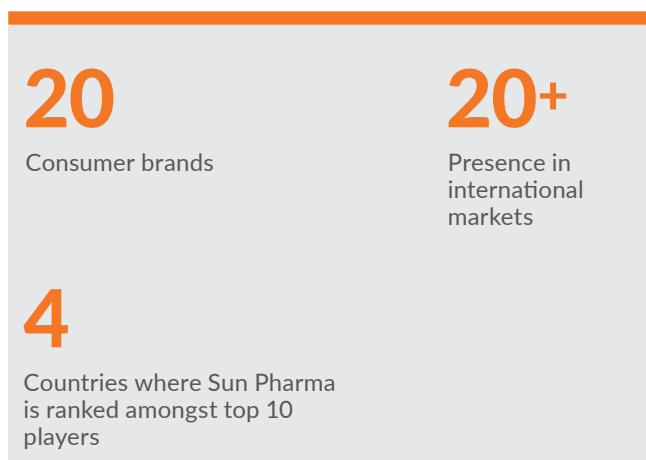
## FY20 highlights

- Revenue from this segment increased by 31% to ₹45,210 Million
- Growth was partially driven by the full year consolidation of the Pola Pharma acquisition in Japan

## Future focus

- Launch differentiated generic products
- Commercialise Ilumya in Japan
- Ramp-up Ilumya prescriptions in Australia

## CONSUMER HEALTHCARE BUSINESS



Sun Pharma features amongst the top 10 consumer healthcare companies in India. Internationally, the Company sells its products in over 20 markets, with a focus on Romania, Russia, South Africa, Nigeria, Myanmar, Ukraine, Poland, Thailand, Belarus, Kazakhstan, Morocco, UAE and Oman. It enjoys prominent brand equity in three countries besides India and ranks among the top 10 consumer healthcare companies in Romania, Nigeria and Myanmar.

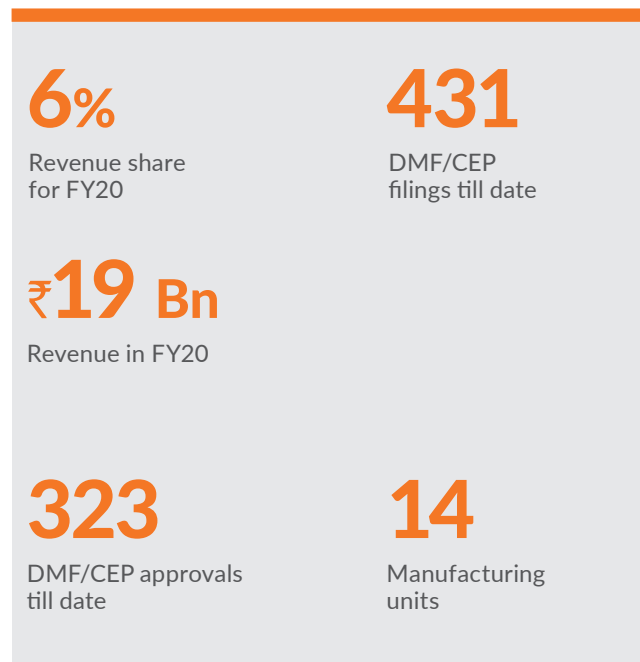
In India, Sun Pharma's key consumer healthcare brands – Volini and Revital H – are ranked 26<sup>th</sup> and 83<sup>rd</sup>, respectively in the Indian pharmaceutical market. The distribution network spans 1,000+ cities and towns, supported by approximately 400,000 retail outlets. New launches in India in FY20 include:

- Volini Maxx Spray – 2% Diclofenac spray – India's strongest pain relief spray
- Volini Maxx Gel – 2% Diclofenac gel
- Volini Joint Xpert Gel – India's only gel that promises pain relief for 12 hours

## Future focus

- Maintain market leadership through brand building, brand extensions and product innovation
- Expand presence in high-growth markets
- Increase retail and online presence
- Use digital communication tools to improve consumer engagement

## ACTIVE PHARMACEUTICAL INGREDIENTS (API) BUSINESS



The Company's API business provides cost competitiveness and supply reliability, reducing dependence on third-party suppliers. Sun Pharma's API portfolio consists of over 300 products across therapeutic segments. Besides using APIs for captive consumption, the Company supplies APIs to external customers also.

## FY20 highlights

- Revenue from the API business increased by 11% to ₹19,159 Million
- Key growth drivers include new contracts and better realisations

## Future focus

- Commercialise strategic APIs for captive consumption
- Seek new customers to grow the API business
- Ensure consistent supplies and service standards

## Research and Development



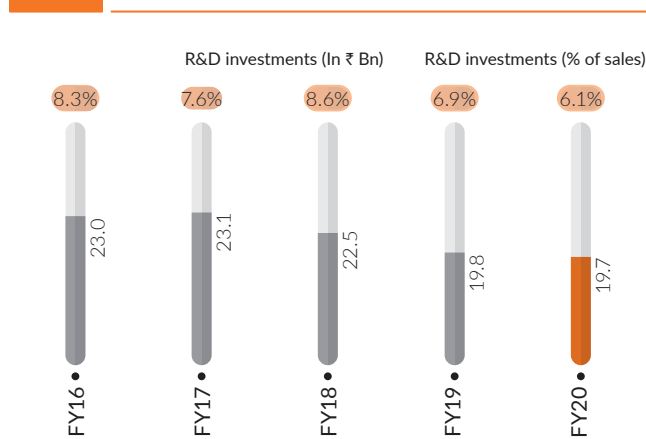
R&D represents the critical catalyst of the business, as it enables Sun Pharma to develop and market differentiated generics and specialty products globally. The Company's R&D capabilities are supported by best-in-class technologies, helping it deliver affordable products globally.

The Company is investing proactively to build a global pipeline for complex generics and specialty products. It has R&D capabilities and intellectual property experts to support development of products across dosage forms like injectables, orals, liquids, ointments, gels and sprays.

Considering the highly competitive nature of the US generics market, the Company continues to be pragmatic in identifying future R&D projects. Investments to develop the long-term specialty pipeline are expected to continue and grow in scale and scope, in the long-term. The Company is also investing in developing specific products for emerging markets and other developed markets.

Sun Pharma has also commenced research on developing an early stage innovation pipeline for its specialty business. Addition of new research candidates is imperative to ensure sustainability of the specialty pipeline in the long-term.

**Chart 10** R&D investments



### Future focus

- Develop complex generics for the regulated markets
- Continue to invest in enhancing the global specialty pipeline
- Strengthen the product pipeline for India and emerging markets
- Develop APIs of strategic importance

## Global Manufacturing Capabilities

Sun Pharma has 43 world-class manufacturing facilities across six continents, enabling the Company to manufacture high-quality and low-cost products to serve patients globally. It is among the few companies to set up integrated manufacturing capabilities to produce oncology, hormones, peptides, controlled substances, and steroidal drugs. These facilities are certified by global regulatory agencies like the USFDA, the European Medicines Evaluation Agency (EMA), the UK Medicines and Healthcare Products Regulatory Agency (MHRA), Australia's Therapeutic Goods Administration (TGA), South Africa's Medicines Control Council (MCC) and Germany's Federal Institute for Drugs and Medical Devices (BfArM). The Company's manufacturing facilities are also certified by the Brazilian Health Regulatory Agency (ANVISA), the World Health Organisation (WHO), South Korea's Ministry of Food and Drug Safety and Japan's Pharmaceuticals and Medical Devices Agency.

The Company has 29 finished dosage manufacturing facilities, while its 14 API facilities provide captive support.

**Table 10** Finished dosage manufacturing facilities

Countries	Production facilities
India	14
US	3
Japan	2
Canada	1
Hungary	1
Israel	1
Bangladesh	1
South Africa	1
Malaysia	1
Romania	1
Egypt	1
Nigeria	1
Russia	1
<b>Total</b>	<b>29</b>

**Table 11** API manufacturing facilities

Countries	Production facilities
India	9
Australia	2
Israel	1
US	1
Hungary	1
<b>Total</b>	<b>14</b>

## People – the core of our strength

With a global team of over 36,000+ people, the Company strives to provide its employees a work environment that is congenial and encourages a balanced, healthy and safe life. It offers various growth opportunities to its people, rewarding and recognising merit. The Company runs multiple training programmes for skill development. It promotes inclusive growth and knowledge-sharing to make its people future-ready.

### Way forward

- Promote inclusive growth and diversity
- Ensure efficient risk management protocols for employee safety
- Focus on improving productivity
- Leverage digital tools for facilitating WFH for employees

### Quality at the core

The Company's research centres, manufacturing units, testing labs and distribution facilities are dedicated to maintaining highest quality standards. Sun Pharma has incorporated a robust quality management system and remains committed to operational excellence. Its global Quality Management Team ensures that every facility and product complies with global regulatory standards on efficacy and safety. It has in place stringent measures to ascertain conformity to regulatory requirements. Sun Pharma has cGMP certifications from global regulatory authorities like USFDA, European Medicines Agency (EMA), WHO and Therapeutic Goods Administration (TGA), among others.

Supported by well-trained quality control processes, Sun Pharma's teams are guided by a Corporate Quality Unit that supervises the implementation of latest GMP updates and guidelines.

In December 2019, the USFDA inspected the Halol facility and issued Form 483 with eight observations. Later, the USFDA classified the inspection status as Official Action Indicated (OAI). The Company is in continuous communication with the USFDA to resolve outstanding issues from the December 2019 inspection, while it continues to manufacture and distribute approved products to the US, from this facility. The OAI status typically implies that the USFDA may put new approvals from the facility on hold till the facility comes back into compliance.

### Way forward

- Ensure compliance with global cGMP standards
- Enhance systems, processes, human capabilities to align with global regulatory standards

**Table 12** SWOT analysis

Strengths	Opportunities	Threats and Weaknesses
<ul style="list-style-type: none"> <li>• Global presence – 4<sup>th</sup> largest global specialty generics company - 9<sup>th</sup> largest generics company in the US               <ul style="list-style-type: none"> <li>- 2<sup>nd</sup> largest by prescriptions in the US dermatology segment</li> <li>- Largest pharma company in India by market share</li> <li>- Enjoys No. 1 ranking with 11 different classes of doctors in India</li> <li>- Amongst the largest Indian pharmaceutical companies in emerging markets</li> </ul> </li> <li>• Largest Indian pharmaceutical company in Japan</li> </ul>	<ul style="list-style-type: none"> <li>• Global efforts to reduce healthcare costs augur well for companies like Sun Pharma who have the ability to supply high-quality pharmaceutical products at affordable prices</li> </ul>	<ul style="list-style-type: none"> <li>• The outbreak of the COVID-19 pandemic across the world and subsequent disruption in economic activities is likely to impact GDP across countries and may indirectly also impact pharmaceutical consumption</li> <li>• Challenging US generics pricing environment driven by customer consolidation and higher competitive intensity, on account of faster pace of generic drug approvals by the USFDA</li> <li>• Significant volatility in the forex market, especially for emerging market currencies, may adversely impact reported growth of these markets, even though they may be recording growth in local currency terms</li> </ul>
<ul style="list-style-type: none"> <li>• Strong R&amp;D skillsets to develop technologically complex products in the generic and specialty space</li> <li>• Ability to drive growth and profitability through a pragmatic mix of organic and inorganic initiatives               <ul style="list-style-type: none"> <li>- A strong balance sheet imparts ability to undertake inorganic initiatives without any significant leverage</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Favourable macroeconomic parameters for India and emerging markets are likely to ensure reasonable volume growth for pharmaceutical products in these markets</li> <li>• Contribution of specialty products is expected to increase in developed markets over medium to long-term. Sun Pharma has already commercialised many of its specialty products in developed markets, and hence will be able to get the benefits of this expanding opportunity</li> </ul>	<ul style="list-style-type: none"> <li>• Governments across the world try to control their healthcare budgets, which may lead to government-mandated price controls on pharmaceutical products</li> </ul>
<ul style="list-style-type: none"> <li>• Ability to supply high-quality products at affordable prices across the world</li> </ul>	<ul style="list-style-type: none"> <li>• Growing penetration of generics in Japan and opening of the China market, present a good long-term opportunity for Indian companies, including Sun Pharma</li> </ul>	<ul style="list-style-type: none"> <li>• The specialty initiative entails high upfront investments for long-term benefits, thus impacting short-term profitability</li> </ul>

## COVID-19 Risk Response

The COVID-19 pandemic has resulted in a new world order. Countries imposed lockdowns on economic activities beyond essential services, restrictions came up on travel and physical contact alongside business operation suspension in most industries. The pharmaceutical sector, being a supplier of essential items, has been relatively less impacted compared to other industries.

Sun Pharma promptly evolved a COVID-19 Risk Management Plan and formed multiple COVID-19 Risk Response Teams under the guidance of senior management to tackle challenges stemming from the pandemic. Following are some priorities for Sun Pharma to ensure business continuity:

1. Employee protection – Keep workplace COVID-19 free, working remotely wherever feasible
2. Doctor and patient engagement – Focus on digital engagement with doctors, patients, healthcare providers
3. Supply chain protection - Keep plants operational with safety protocols, maintain adequate stock levels, ensure timely deliveries, enhance captive consumption, and have close vendor connect to ensure supply chain continuity
4. Support mechanisms and infrastructure – Enable work-from-home and collaboration tools, strengthen security related controls and enable access for remotely operating vendors
5. Financial health – Focus on collections and effective debtor management to maintain adequate liquidity, while simultaneously continuing to focus on cost optimisation

Despite our proactive COVID-19 risk response initiatives, we estimate sluggish sales in the near-term. The impact of the COVID-19 pandemic is difficult to quantify as of now, but the Company will try to ensure that it emerges stronger across its various businesses.

## Internal Control

Sun Pharma believes that internal control is a prerequisite for governance and that business plans should be exercised within a framework of checks and balances. The Company has a well-established internal control framework, which is designed to continuously assess the adequacy, effectiveness and efficiency of financial and operational controls. The management is committed to ensuring an effective internal control environment, commensurate with the size and complexity of the business, which provides an assurance on compliance with internal policies, applicable laws, regulations and protection of resources and assets.

## Global Internal Audit (GIA)

An independent and empowered Global Internal Audit Function at the corporate level, with support from a reputed audit firm, carries out risk-focused audits across our Indian and overseas businesses, to ensure that business process controls are adequate and are functioning effectively. These reviews include financial, operational and compliance controls and risk mitigation plans. The Company's operating management closely monitors the internal control environment and ensures that the recommendations are effectively implemented. The Audit Committee of the Board monitors performance of the Internal Audit Function, reviews key findings and provides strategic guidance.

GIA's functioning is governed by the Audit Charter, duly approved by the Audit Committee of the Board, which stipulates matters contributing to the proper and effective conduct of the audit. The audit processes are fully automated on a 'SunScience' tool, which integrates Internal Audits, Automated follow-ups for closure of observations, Internal Financial Controls (IFC) and Enterprise Risk Management (ERM) modules.

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## Disclaimer

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