## Managing Director's Message



Most of our businesses have recorded growth for FY21 despite the challenges related to the global COVID-19 pandemic. Our India business outperformed the average industry growth. We are also enthused by the growth in our global specialty business. We believe that all our businesses are well positioned and our endeavour will be to grow the overall business. We also expect the momentum for our global specialty business to continue.

Dilip S. Shanghvi Managing Director

#### Dear Shareholders,

The COVID-19 pandemic has disrupted economies across the world and the pharmaceutical industry is at the forefront in the fight against the global pandemic. The industry has quickly adapted itself to the changed dynamics and has ensured continuity of supply so that patients continue to get access to their medications. The industry has also stepped in to supply medicines for the treatment of COVID-19 symptoms and other associated ailments. Some of the pharmaceutical companies have developed COVID-19 vaccines in record time. The pandemic is accelerating a significant change across the healthcare ecosystem in various countries and forcing public and private health systems to adapt and innovate at a pace like never before.

Governments across the world have increased spending on healthcare to counter the pandemic. There is also an increasing realisation in middle and low income economies that healthcare related investments need to be increased, which will lead to better/earlier diagnosis and appropriate treatment for patients.

Another area of focus is making the supply chain resilient. This will require striking a pragmatic balance between outsourcing and self-sufficiency. Recognising the important role of the pharmaceutical industry and to strengthen its competitiveness, the Government of India has floated Production-Linked Incentive (PLI) Schemes. The objective of these schemes is to enhance India's manufacturing capabilities to meet global scale apart from encouraging higher investment in R&D for the development of innovative and complex products that will enable the Indian pharmaceutical industry to meet the global demand of pharmaceutical products.

#### **COVID-19 RISK RESPONSE**

Sun Pharma has focused on a multi-pronged approach to overcome the challenges of the COVID-19 pandemic. The Company has focused on:

- 1. Ensuring continuous supply of medicines and maintaining continuity of the supply chain
- 2. Increased focus on use of technology tools to facilitate business
- 3. Focus on the safety and well-being of employees
- Enhancing supply of multiple therapeutics used in the treatment of COVID-19 and associated ailments, such as Remdesivir, Favipiravir, Itolizumab, Liposomal Amphotericin B, Hydroxychloroquine, etc.
- 5. Donation of COVID-19 medicines and other items like PPE kits, masks, sanitisers, gloves, food items, etc.

#### **FY21 HIGHLIGHTS**

FY21 was a unique year. It witnessed the full brunt of the COVID-19 pandemic across the global economy and various sectors. Governments globally were forced to resort to stringent lockdowns/restrictions to prevent the spread of the pandemic, which were gradually relaxed in the second half of FY21.

Being a supplier of essential products, the pharmaceutical industry continued to manufacture and supply pharmaceutical products. However, the lockdowns across the countries resulted in temporary closure of doctor clinics, restrictions on travel of the medical representatives, and a significant reduction in patient visits to the doctor's clinic. Non-critical treatments and elective surgeries were postponed in many cases. Online medical consultation could only partly compensate for face-toface interactions. This led to lower demand for pharmaceutical products in the first half of the year and a gradual recovery was witnessed only in the second half, as governments lifted the lockdown restrictions.

It is against this backdrop that we reported a 2.5% growth in our overall revenues which stood at ₹331 Billion for FY21. Last year's sales included a one-time special business in the US and hence, while the US business showed a decline, all our other businesses have recorded growth for the full year despite the challenges related to the global COVID-19 pandemic.

Our EBITDA for the year grew by 25.5% driven by better product mix, efficiency initiatives and reduced marketing, selling and distribution and travelling expenses across markets. Some of these cost savings can be termed as temporary in nature and are mainly related to the pandemic restrictions and may reverse over a period of time as the COVID-19 situation normalises.

#### **OPERATIONAL PERFORMANCE**

For FY21, India formulation sales stood at ₹103 Billion, up 6.5% and accounted for about 31% of overall revenues. Our India business has outperformed the average industry growth, driven by our leading presence in chronic segments coupled with our strong brand equity with doctors. As per AIOCD AWACS March 2021 data, we have witnessed an increase in our market share to 8.2% on MAT basis compared to 8.1% in the previous year.

As per SMSRC data for February 2021, Sun Pharma is ranked No. 1 by prescriptions with 10 different classes of doctors. Despite the COVID-19 pandemic, we continued our new launches momentum with 96 new introductions in India.

The field force expansion undertaken in Q4 of last year, was completed during the year and the new medical representatives have commenced their field work. Our field force strength now stands at 10,900+.

Revenues in the US declined by about 4% to ₹101 Billion and accounted for approximately 30% of our consolidated revenues for FY21. Despite the challenges of the pandemic, we witnessed a ramp-up in sales of our specialty products for the year. The generics business continued to face price erosion, driven by the competitive intensity amongst manufacturers, buying consortium pressures and a higher pace of generic approvals from the USFDA. Our subsidiary, Taro, recorded about 15% decline in overall revenues to US\$549 Million for the year.

We grew by 5% in Emerging Markets (EM) for the year. The Y-o-Y depreciation of some EM currencies has reduced our reported growth. The constant currency growth for EM revenues was about 6.4% for the year.

Our sales in the rest of world (RoW) markets grew by 6.6% for the year, driven by some key Western European markets, Canada and Australia.

#### **RESEARCH & DEVELOPMENT (R&D)**

Our R&D investments for the year were approximately ₹21 Billion at 6.5% of overall sales. During the year, we continued our R&D efforts to develop complex generics and innovative specialty products. Some of the clinical trials for our specialty products witnessed a delay of a few months during the year due to the pandemic, and have gained momentum after the lockdowns were lifted gradually. Investments for developing the long-term specialty pipeline are expected to continue.

We continue to invest in R&D related to our global generic business, for developing and filing products across markets. At Sun Pharma, we have multiple R&D centres and a strong R&D team to cater to these requirements. We continue to be disciplined in identifying future R&D projects for the US generics market, with the focus being on developing complex products, which may attract less competition.

#### SPECIALTY BUSINESS PERFORMANCE

We are enthused by the momentum of our global specialty business which grew by 11% to US\$475 Million during the year despite the various challenges resulting from the global pandemic. Global Ilumya sales grew by 51% over last year to touch US\$143 Million in FY21.

The first half of FY21 witnessed temporary closure of doctor clinics in the US because of the lockdown restrictions (to counter the pandemic), resulting in reduction in patient footfalls and postponement of certain treatments. This impacted our specialty sales in the first half, including sales of Ilumya, Cequa and Levulan. It also impacted the ramp-up of Absorica LD, which we had launched in February 2020. The lockdown restrictions were gradually lifted in the second half, resulting in a recovery in our specialty sales. Post the close of the year, a generic for Absorica entered the market in April 2021.

#### **PROGRESS ON SPECIALTY INITIATIVES**

Key initiatives during the year for the specialty business include:

- 1. Presented positive results from the ILUMYA<sup>®</sup> five-year study, which demonstrated that patients with moderate-to-severe plaque psoriasis who continued to receive ILUMYA<sup>®</sup> through five years of continuous treatment, maintained consistent and extensive skin clearance with no new safety issues, regardless of baseline level of skin disease, age or background illnesses.
- 2. Launched ILUMYA<sup>®</sup> in Japan
- 3. Expanding market presence for ILUMYA During the year, Sun Pharma entered into an exclusive licensing and distribution agreement for ILUMYA<sup>™</sup> with Hikma for the Middle East & North Africa (MENA) region.
- 4. Presented clinical data analysis for ODOMZO and LEVULAN KERASTICK – Long-term analyses of the ODOMZO clinical study confirmed that treatment with ODOMZO provided clinically meaningful outcomes to patients with locally advanced basal cell carcinoma (laBCC) who were taking common concomitant medicines, such as medicines for cardiovascular, inflammatory and auto-immune diseases. For LEVULAN KERASTICK + BLU-U, a post hoc analysis of the Phase 3 trial showed significantly greater clearance of lesions and a significantly larger percent of cumulative disease area cleared with no clinically significant adverse events.

- Update on specialty R&D pipeline During the year, we initiated multiple clinical trials for our specialty portfolio:
  - a. Ilumya Commenced Phase-3 clinical trials for psoriatic arthritis; the Phase-2 clinical trial interim results released last year demonstrated that the trial met its primary endpoint with over 71% of patients on Ilumya achieving ACR20 response (20% improvement in symptoms) with no evident safety concerns. A successful Phase-3 trial, subject to regulatory approval, is likely to expand the addressable market for llumya.
  - b. SCD-044 Initiated Phase-2 clinical trials for a potential oral treatment for atopic dermatitis and moderate to severe plaque psoriasis. SCD-044 is a selective S1PR1 modulator resulting in better cardiac safety profile. The molecule met therapeutically relevant levels of lymphocytopenia at safe doses in Phase-1 study.
  - c. MM-II Commenced Phase-2 trials for a potential treatment for knee pain in patients with symptomatic knee osteoarthritis. MM-II is a product with empty multi-lamellar liposomes (first of its kind) for treatment of pain in osteoarthritis.
  - GLP-1R (Glucagon-Like Peptide-1 Receptor) agonist

     Initiated Phase-1 clinical trials for treating diabetes.
     The pre-clinical data had demonstrated significant outcomes on various diabetic parameters, viz. glucose reduction, decrease in HbA1c, augmented insulin secretion, lowering of glucagon level, meaningful reduction in triglyceride levels and larger body weight reduction. We look forward to validating this data in human clinical trials.

#### **cGMP COMPLIANCE**

Adherence to global cGMP standards is a key priority for us. Pharmaceutical manufacturing units need to be constantly upgraded to ensure compliance with global cGMP norms. We have an unwavering focus on 24x7 compliance to ensure continuity of supplies to our customers and patients worldwide.

During the year, due to the travel restrictions related to the pandemic, we did not undergo any USFDA audit. For our Halol facility, which was classified as an "Official Action Indicated (OAI)" in March-2020, we have already completed all the corrective actions required to get the facility back into compliance and are awaiting a re-inspection from the USFDA. However, due to the ongoing COVID-19 pandemic and associated travel restrictions, the re-inspection is delayed.

#### FOCUS ON IMPROVING EFFICIENCIES

During the year, we continued our efforts to improve efficiencies across the organisation. Enhancing manufacturing efficiencies, optimising manufacturing footprint, rationalising generics R&D investments and reducing fixed costs are some of the areas targeted for efficiency improvement.

#### **DEBT REDUCTION**

During FY21, the Company has repaid debt of about US\$580 Million, the benefit of which is visible in the reduction in finance cost.

#### **OVERALL OUTLOOK**

Given the uncertainties of the pandemic in the near term, we have refrained from giving a guidance for FY22. However, we believe that all our businesses are well positioned and our endeavour will be to grow the business, notwithstanding the near-term uncertainties related to the COVID-19 pandemic. We also expect the momentum for our global specialty business to continue, if there are no more pandemic-related lockdowns in the regulated markets.

We will continue our R&D investments in developing a differentiated generic pipeline as well as in building our specialty pipeline in the coming years.

Generic pharmaceutical products have been an important component of the overall global healthcare system. The COVID-19 pandemic and the resulting increase in healthcare awareness further reinforces the role of generics in global healthcare management. 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.

#### Top priorities for FY22 will be:

- 1. Business growth
- 2. Safety and well-being of employees including facilitation of COVID vaccination for employees and their immediate family
- 3. Supply chain continuity and inventory optimisation
- 4. Continued focus on cost and operational efficiency
- 5. Increased investments in IT to facilitate business and digital transformation
- 6. Focus on improving return ratios

Our employees have put in extraordinary efforts during the past year to ensure business continuity despite the multiple disruptions resulting from the COVID-19 pandemic and lockdowns. We have been able to maintain adequate supply of our products in various markets while simultaneously ensuring overall productivity without compromising on safety protocols.

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

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

Warm regards,

#### Dilip Shanghvi

Managing Director Sun Pharmaceutical Industries Limited

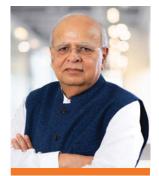
# **Board of Directors**



Israel Makov Chairman, Non-executive and Non-Independent Director



Dilip S. Shanghvi Managing Director



Sailesh T. Desai Whole-time Director



Kalyanasundaram Subramanian Whole-time Director



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



Rekha Sethi Non-executive and Independent Director



Vivek Chaand Sehgal Non-executive and Independent Director



Gautam Doshi Non-executive and Independent Director



Dr. Pawan Goenka Additional Independent Director (appointed with effect from May 21, 2021)



Rama Bijapurkar Additional Independent Director (appointed with effect from May 21, 2021)

# Leadership Team



Abhay Gandhi CEO - North America



Dr. Pradeep Sanghvi Executive Vice-President, Head - US R&D



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 Executive Vice-President, Head - Emerging Markets Head - Global Generics R&D, Business Development



C. S. Muralidharan Chief Financial Officer



Anilkumar Jain CEO - API Business



Davinder Singh Executive Vice-President, Sun 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 Executive Vice-President, Global Head - Quality



Uday Baldota CEO - Taro Pharmaceutical Industries Ltd.



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

## Management Discussion and Analysis

#### **GLOBAL PHARMACEUTICAL INDUSTRY<sup>1</sup>**

The pharmaceutical industry is at the centre of the fight against the global COVID-19 pandemic and has contributed significantly in terms of supply of critical medications for treatment as well as in developing and manufacturing COVID-19 vaccines. The industry has ensured continuity of supplies of all other medicines to meet the needs of patients across the world.

The global pharmaceutical market size in 2020 was estimated at US\$1.27 Trillion and is expected to expand at a compounded annual growth rate (CAGR) of 3-6% to US\$1.6 Trillion by 2025 (this estimate excludes the additional spending on COVID-19 vaccines).

The factors driving global medicine spending will be sustained growth in the pharmerging markets and the consistent launch of high-end specialty innovative products in developed markets. However, slower growth across developed markets due to losses of patent exclusivity for original brands will be an offsetting factor.



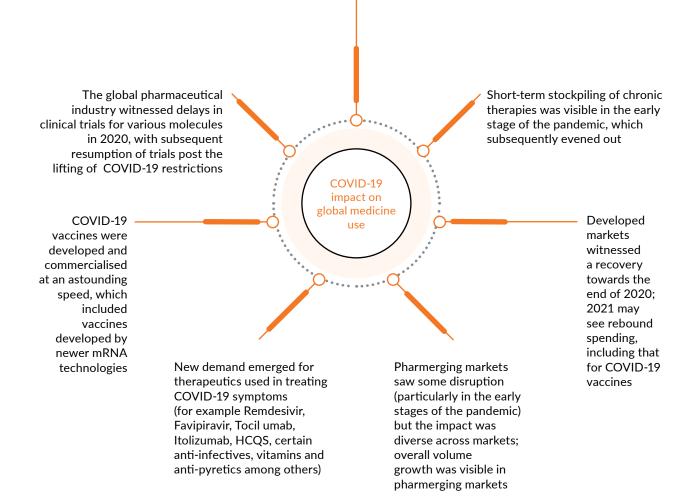
#### Table 1 Global Pharmaceutical Market (US\$ Billion)<sup>1</sup>

Regions	2020	2016-2020 CAGR	2025	2021-2025 CAGR
Developed Markets	959.5	3.8%	1130-1160	2-5%
Pharmerging Markets	290.8	7.4%	415-445	7-10%
Other Markets	15.0	3.9%	18-22	3-6%
Global Market	1,265.3	4.7%	1580-1610	3-6%

Region Year	Orginal brands (%)		Non-orginal brands (%)		Unbranded generics (%)		OTC, vaccines and other products (%)		Total (US\$ Billion)	
	2020	2025	2020	2025	2020	2025	2020	2025	2020	2025
Developed Markets	74	70-71	11	15-17	5	4-5	10	8-9	959	1130-1160
Pharmerging Markets	29	30-35	37	34-38	22	18-21	12	10-16	291	415-445
Other Markets	35	28-41	42	33-45	17	11-18	6	6-9	15	18-22
Global Market	63	59-60	17	21-22	9	8-9	11	9-11	1,265	1,580-1,610

Table 2 Global Pharmaceutical Market – Share by Product Type<sup>1</sup>

The outcome of COVID-19 on pharmaceutical spending across countries was diverse depending on the extent of viral infections and the responses by various governments to counter the infections



#### Emerging Trends and the Way Forward<sup>1</sup>

Expansion of access to healthcare, increase in per capita income and increasing insurance coverage in pharmerging markets have driven the overall growth in pharmaceutical consumption over the past decade, but slowing growth in these markets will bring down global growth over the next 5 years.

Use of medicines in developed countries is typically higher than in pharmerging countries owing to higher income levels. This trend is expected to continue in future as well. Chronic medications to treat diseases like cardiovascular, diabetes, respiratory, and mental health conditions will continue to witness increasing demand globally driven by higher incidence of such diseases and changing lifestyles and food consumption. The global COVID-19 pandemic has been a wake-up call to governments across the world. It may prompt them to increase healthcare budgets and encourage higher investments in pharmaceutical R&D and manufacturing.

Over the next five years, an average of 54-63 new active substances (NAS) are expected to be launched globally per year. In the next five years, the impact of patent expiries is estimated to be about US\$166 Billion; while it will be partly offset by spending on associated generics and biosimilars.

#### Oncology and

immunology are the two leading global therapy areas that are forecast to grow at CAGR of 9-12% through 2025. Oncology attracts the largest spending with consistent launch of new treatments but the impact of biosimilars will slow down growth for some widely used therapies. Gene and cell therapy is another area, which is generating significant interest as far as future R&D efforts are concerned.

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

# Demographics

Rising per capita income and changing lifestyles and food preferences, among other demographic and epidemiological trends, are leading to a rapid rise in the incidence of Non-Communicable Diseases (NCDs) in pharmerging markets. Pharmaceutical spending in these markets will be focused on overall growth through control and prevention of NCDs, especially cardiovascular diseases, cancer and diabetes

## Innovation

The launch of new and innovative products will be a key driver of growth in the developed pharmaceutical markets. Immunology drugs, biologics, oncology products, orphan drugs and cell and gene therapies will account for an increasing proportion of new launches in developed markets

# Macro-economics

Sustained economic growth in the long term will remain a key catalyst for global pharmaceutical growth. There may be some nearterm uncertainties due to the COVID-19 global pandemic. However, this may also be an opportunity for the pharmaceutical industry to increase its focus on R&D and thereby develop/launch COVID-19 medicines and vaccines to reduce hospitalisations and mortality rates linked to **COVID-19** infection



Access

To cope with rising demand, governments of most emerging economies will continue to seek expansion of their national health budgets, boosting further spending on healthcare

While these growth drivers remain intact from a long-term perspective, the multiple waves of COVID-19 infections across economies and the resulting restrictions/lockdowns imposed by various governments may have implications, although it is difficult to estimate the actual impact of such restrictions.

#### **DEVELOPED MARKETS<sup>1</sup>**

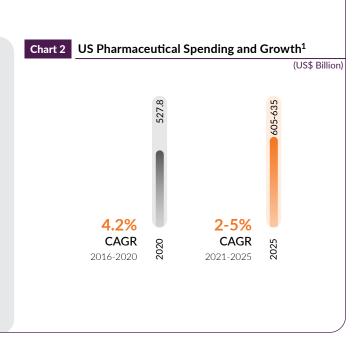
The developed pharmaceutical markets grew at ~4% CAGR between 2016-20 and are estimated to grow at about 1.5-4.5% CAGR to reach US\$1,130-1,160 Billion by 2025. These markets accounted for ~76% of global pharmaceutical spending in 2020, and are estimated to account for ~71-72% of spending by 2025. New and specialty drug launches, offset by patent expiries and competition from generics and biosimilars, are expected to continue to be the main factors influencing medicine spending and growth in developed markets.

#### Table 3 Developed Markets – Pharmaceutical Spending and Growth (US\$ Billion)<sup>1</sup>

Region/Country	2020	2016-2020 CAGR	2025	2021-2025 CAGR
USA	527.8	4.2%	605-635	2-5%
Top 5 Western European Markets (WE5)	180.4	4.4%	215-245	2-5%
Germany	54.9	5.3%	65-85	3.5-6.5%
France	36.3	2.4%	43-47	1-4%
Italy	33.3	4.2%	38-42	2-5%
UK	30.2	5.3%	38-42	2.5-4.5%
Spain	25.7	4.6%	28-32	1.5-4.5%
Japan	88.2	(0.2)%	75-95	(2)-1%
Canada	22.8	4.8%	28-32	2-5%
South Korea	16.2	6.8%	18-22	4.5-7.5%
Australia	11.8	3.3%	13-17	1-4%
Other Developed Markets	112.3	4.2%	125-155	2.5-5.5%
Total Developed Markets	959.5	3.8%	1130-1160	1.5-4.5%

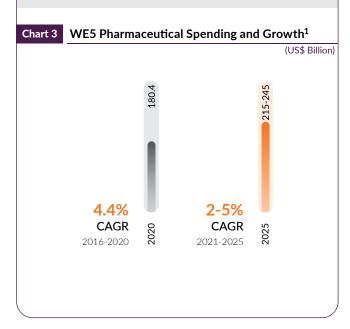
# US<sup>1</sup>

The US continues to be the largest pharmaceutical market in the world. It recorded ~4% CAGR growth between 2016-20 and the market is expected to grow at 2-5% CAGR to US\$605-645 Billion by 2025. Rising discounts and rebates are expected to slow spending growth over time. In addition, ongoing market dynamics around new launches, impact of patent expiries, new generics and biosimilar competition will continue to act as balancing factors over the next five years.



# Top 5 Western European Markets (WE5)<sup>1</sup>

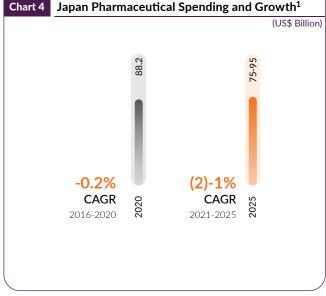
Pharmaceutical spending in the top five Western European Markets (WE5) markets is projected to grow at about 2-5% CAGR to US\$215-245 Billion by 2025. Increasing consumption of generics and a maturing biosimilars market, coupled with future patent expiries will lead to muted overall growth.



#### PHARMERGING MARKETS<sup>1</sup>

Pharmerging markets reported 7.4% CAGR in pharmaceutical spending between 2016-20 to reach US\$290.8 Billion in 2020. These markets contributed to ~23% of the overall global spending in 2020 and are expected to account for ~26-27% of spending by 2025. Spending across major pharmerging markets is expected to grow at a CAGR of 7-10% through 2025, driven by the largest countries — China, Brazil, India and Russia — but

## Japan, the third largest global market, is projected to grow at about (2)-1% CAGR to US\$75-95 Billion by 2025. Periodic government mandated price-cuts and increasing shift to generics will lead to a tepid growth. Going forward, rising spending on patent-protected original brands coupled with regulatory policies will be the key dynamics impacting overall pharmaceutical spending.



outperformed by the smaller pharmerging markets, which are expected to grow at the rate of 8.5-11.5% during the same period.

Relatively high rates of growth in pharmaceutical spending in these markets belie the relatively low levels of per capita medicine use. However, pharmaceutical consumption continues to increase in these countries driven by growing incidence of chronic ailments, increased healthcare awareness and rising medical insurance coverage.

#### Table 4 Pharmerging Markets - Pharmaceutical Spending and Growth (US\$ Billion)<sup>1</sup>

Region/Country	2020	2016-2020 CAGR	2025	2021-2025 CAGR
China	134.4	4.9%	170-200	4.5-7.5%
Brazil	28.7	10.7%	43-47	7.5-10.5%
India	22.0	9.5%	28-32	7.5-10.5%
Russia	17.5	10.8%	33-37	11-14%
Other pharmerging markets	89.1	9.6%	120-150	8.5-11.5%
Total Pharmerging markets	290.8	7.4%	415-445	7-10%

(US\$ Billion)

28-32

2025

Indian Pharmaceutical Spending and Growth<sup>1</sup>

7.5-10.5%

CAGR

2021-2025

# India<sup>1</sup>

The Indian pharmaceutical industry is the world's third largest in terms of volume and ranks 11<sup>th</sup> in terms of value. It is among the faster-growing markets and the largest exporter of generic drugs by volume. Outside of the US, India has the largest number of USFDA-approved pharmaceutical manufacturing facilities. Over the last year, India played a crucial role in supplying therapeutic drugs for COVID-19 treatment across the world and is also one of the key manufacturers of some of the COVID-19 vaccines. Going forward, India is likely to maintain a leadership position in the manufacture and supply of high-quality generic medicines as well as a major manufacturer of COVID-19 vaccines.

The Indian pharmaceutical market recorded ~9.5% CAGR between 2016-20 to reach US\$21 Billion. It is expected to grow at 7.5-10.5% CAGR to US\$28-32 Billion by 2025.

#### **Growth Enablers**

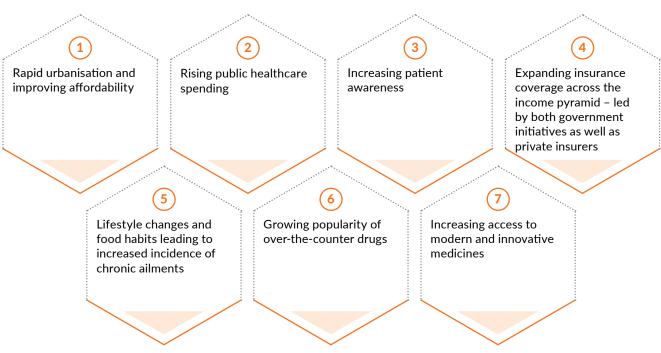


Chart 5

9.5%

CAGR

2016-2020

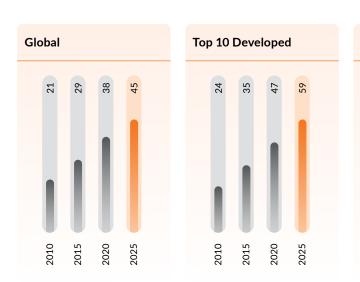
2020

#### SPECIALTY MEDICINES<sup>1</sup>

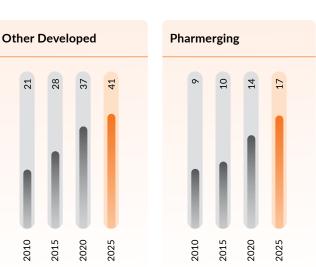
Global pharmaceutical spending on specialty innovative products has consistently increased over the last ten years. Specialty medicines treat chronic, complex or rare diseases. These include biologic drugs for various chronic ailments, immunology drugs, medicines developed for orphan diseases and the latest generation gene and cell therapies. These highly innovative specialty products made a significant difference in medical outcomes for patients over the last ten years.

The share of specialty products in overall global pharmaceutical spending increased from 21% in 2010 to ~38% by 2020. It is expected to further rise to 45% by 2025. This growth has been driven mainly by developed markets in the past and this trend is expected to continue in the future as well. Spending on specialty products rose within pharmerging markets also, but has been constrained by higher pricing and limited purchasing power. The ten largest developed countries and other high and upper middle-income countries are witnessing consistent increase in the share of spending on specialty medicines. These products are expected to contribute to nearly half of global spending in 2025 and almost 60% of the total spending in developed markets.

(%)







#### **ACTIVE PHARMACEUTICAL INGREDIENTS (API)**<sup>2</sup>

The market size of global active pharmaceutical ingredients was valued at US\$187.7 Billion in 2020 and is expected to grow at a CAGR of 6.6% between 2021-28. Growth drivers include advancements in API manufacturing and the rising prevalence of chronic diseases. Favourable government policies for API production, along with changes in geopolitical dynamics, are expected to further drive market growth.

The global API market is undergoing immense changes due to supply chain disruptions caused by COVID-19 in early 2020. There is an increasing trend around diversification of the supply chain, with India being viewed as one of the critical suppliers of API for the future.

Traditionally, the API market has been dominated by drugs in categories such as, anti-infectives, diabetes, cardiovascular, analgesics, and pain management. However, driven by emerging R&D trends, the demand is shifting toward the development of complex APIs used in novel formulations, targeting niche therapeutic areas.

#### **CONSUMER HEALTHCARE<sup>3</sup>**

The needs of health-conscious consumers are fast evolving in keeping with their lifestyles and behavioural patterns, leading to growing consumption of consumer healthcare products. The global over-the-counter (OTC) market was valued at US\$190 Billion in 2020, recording 5% Y-o-Y growth. Cold & Flu segment witnessed a decline while the Vitamins, Minerals & Supplements (VMS) category grew substantially, driven primarily by increased consumption of such products during the COVID-19 outbreak.

COVID-19 accelerated three key trends (1) superior self-care, (2) focus on mental health and (3) consumer convenience. Global consumer healthcare companies are educating consumers, reviewing product portfolios, increasing focus on digital channels and improving marketing capabilities to enhance their competitive advantage.

#### WORLD OF SUN PHARMA

Sun Pharmaceutical Industries Limited, and its subsidiaries together constitute the universe of Sun Pharma. It is a leading specialty generics pharmaceutical company with a strong presence in India and the US markets. It is also amongst one of the leading Indian pharma companies in emerging markets. The Company, along with its subsidiaries and associates, continues to service its customers across geographies, on the strength of its innovative R&D efforts, efficient and low-cost operations and culturally diverse skilled human resources. The Company has manufacturing capabilities for a variety of dosage forms, such as injectables, sprays, ointments, creams, liquids, hormones, drug delivery systems, tablets and capsules. It aims to deliver quality products at affordable prices, and over the years, has earned the trust of patients and medical professionals across its key markets.

Sun Pharma is growing its portfolio of specialty products, branded generics and pure generics across 100+ countries globally. In-depth Research & Development (R&D) and use of high-end technology are integral to the Company's progress. The Company has always focused on both organic and inorganic growth, with proactive acquisition of businesses and in-licensing of specialty molecules.

#### **Prominence in Key Markets**



Largest specialty generic pharma company globally<sup>4</sup>



Countries in terms of market reach



Pharma company in India<sup>5</sup>

**44** Global manufacturing

sites across 6 continents

**10**<sup>th</sup>

Largest generic pharma company in the US<sup>1</sup>

**37,000**+ Global employee strength Among the **Largest** 

Indian pharma companies in emerging markets

50+ Employee nationalities

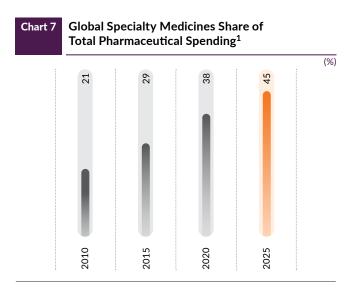
#### Table 5 Key Milestones

Year	Event	Rationale
2020	Exclusive licencing agreement with Hikma for Ilumya	Commercialisation of Ilumya in the Middle East & North Africa (MENA) markets.
2020	Licencing agreement with SPARC for SCD-044	Potential treatment for atopic dermatitis, psoriasis and other auto-immune disorders across the globe
2020	In-licenced Triferic brand from Rockwell Medical Inc. (USA)	Expands nephrology portfolio in India to treat anaemia in hemodialysis patients
2019	Licencing agreement with AstraZeneca UK for ready-to-use infusion oncology products	Access to oncology market in Mainland China
2019	Licencing agreement with CMS for Tildrakizumab, Cequa and 8 generic products	Access to Greater China market
2019	Acquired Pola Pharma in Japan	Foray into the Japanese dermatology market

Year	Event	Rationale
2016	Acquired global rights for Cequa and Odomzo	Enhance specialty pipeline across the globe
2016	Acquired Biosintez	Local manufacturing capability to enhance presence in Russian market
2016	Licencing agreement with Almirall for Tildrakizumab for psoriasis	Access to European market for Tildrakizumab
2016	Acquired 14 brands from Novartis	Entry into Japan
2016	Distribution agreement with AstraZeneca	Distribution services agreement in India for brand 'Oxra' and 'Oxramet'® (brands of dapagliflozin, used for diabetes treatment)
2015	Acquired InSite Vision Inc.	Strengthens branded ophthalmic portfolio in the US
2015	Distribution agreement with AstraZeneca	Distribution services agreement in India for brand 'Axcer'® (brand of ticagrelor, used for the treatment of acute coronary syndrome)
2015	Sun Pharma – Ranbaxy Merger	•Strengthen position in the global generic pharma industry
		•Top Pharma Company in India
		•Strong positioning in the emerging markets
2014	In-licencing agreement with Merck for Tildrakizumab, a biologic for psoriasis	Strengthening the specialty product pipeline across the globe
2014	Acquired Pharmalucence	Access to sterile injectable capacity in the US
2012	Acquired DUSA Pharma, Inc.	Access to specialty drug-device combination in dermatology segment in the US
2010	Acquired Taro Pharmaceutical Industries Ltd.	Access to dermatology generic portfolio as well as manufacturing facilities in Israel and Canada
1997	Acquired Caraco	Entry into the US Market

#### Our global specialty initiatives<sup>1</sup>

Specialty medicines are latest generation products, which are targeted at treating chronic, complex and rare diseases. They accounted for about 38% of the global pharmaceutical spending in 2020 (up from 29% in 2015) and are estimated to account for approximately 45% of global pharmaceutical spending in 2025.



Sun Pharma commenced investing in building a global specialty business 2014 onwards. Significant resources were deployed in gaining access to specialty products, their clinical development, commercialisation and in developing a future R&D pipeline of specialty products. Upfront investments were made in establishing the front-end sales force, reimbursement (market access) teams and in branding and promotion of specialty products.

The Company has, till date, commercialised 12 specialty products across different markets, which contributed ~11% to the Company's consolidated revenues for FY21. Sun Pharma also has a pipeline of 4 molecules undergoing clinical trials.

The key molecules are:

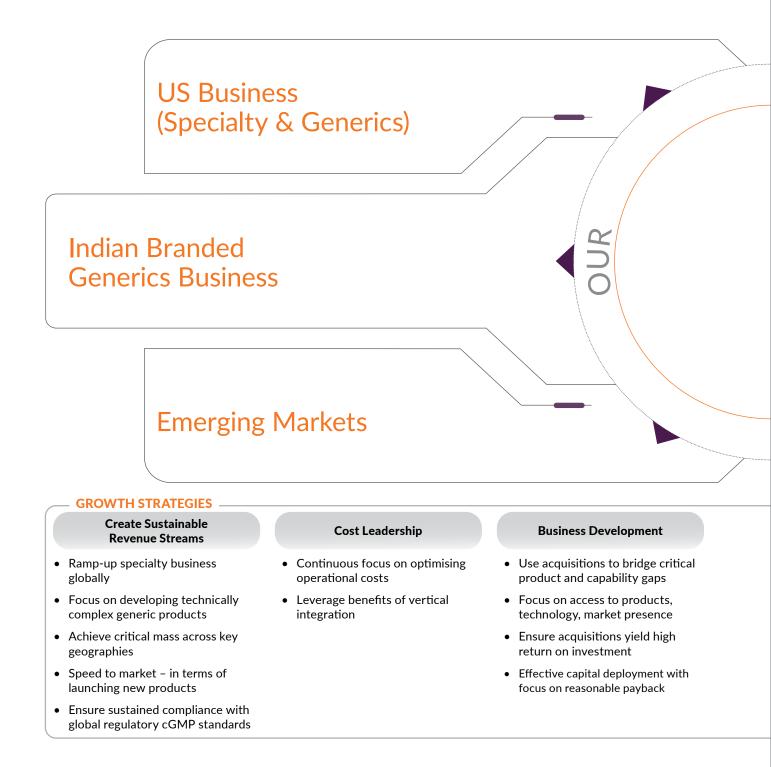
- 1. Ilumya is undergoing Phase-3 trials for psoriatic arthritis indication.
- 2. SCD-044 is undergoing Phase-2 trials for atopic dermatitis and moderate to severe plaque psoriasis.
- 3. MM-II is also undergoing Phase-2 trials for treatment for knee pain in patients with symptomatic knee osteoarthritis.
- 4. GLP-1R agonist is in Phase-1 trials for diabetes.

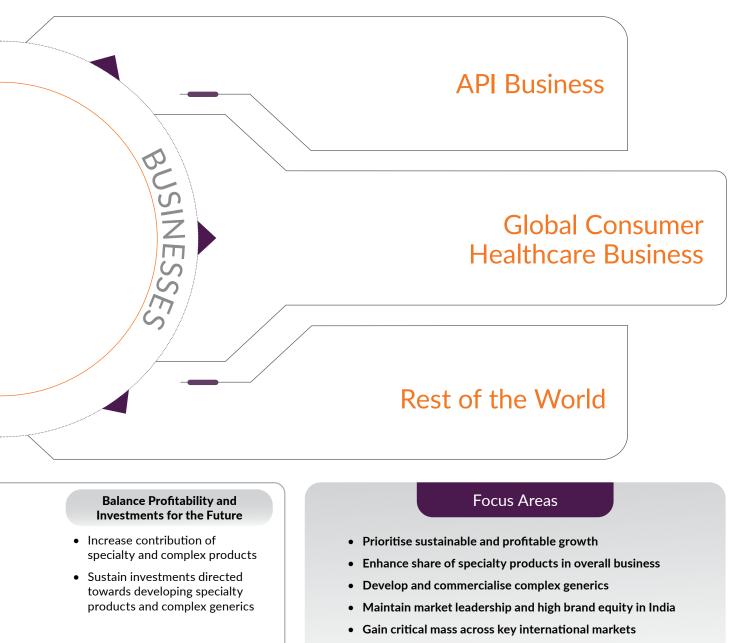
Product	Indication	Introduction in key geographies		
llumya/llumetri	Plaque psoriasis	<ul> <li>Launched in the US and Australia in 2018</li> <li>Phased launch in Europe by Almirall, starting December 2018</li> <li>Out-licenced to CMS for Greater China in 2019</li> <li>Launched in Japan in 2020</li> </ul>		
Cequa	Dry eye disease	<ul><li>Launched in the US in 2019</li><li>Out-licenced to CMS for Greater China in 2019</li></ul>		
Absorica/Absorica LD	Severe recalcitrant nodular acne	• Launched Absorica LD capsules in the US in 2020		
Levulan Kerastick	In combination with BLU-U (Blue Light Photodynamic Therapy Illuminator) for treatment of minimally to moderately thick actinic keratoses of the face, scalp, or upper extremities	Currently marketed in the US		
Odomzo Locally Advanced Basal Cell Carcinoma (LABCC)		• Currently marketed in the US, Germany, France, Denmark, Switzerland, Australia and Israel		
Yonsa	Metastatic castration-resistant prostate cancer in combination with methylprednisolone	• Launched in the US in 2018		
Bromsite	Prevention of ocular pain and treatment of inflammation following cataract surgery	Launched in the US in 2019		
Xelpros	Reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension	Launched in the US in 2019		
Infugem/InfuSMART	Gemcitabine (chemotherapy product) in pre- mixed, ready-to-use bags	<ul><li>Launched in Europe in 2016</li><li>Introduced in the US in 2019</li></ul>		
Sprinkle Portfolio				
1. Drizalma Sprinkle (duloxetine delayed- release capsules)       Various neuro-psychiatric and pain disorders in patients who have difficulty Swallowing		• Launched in the US in 2019		
2. Ezallor Sprinkle (rosuvastatin capsules)	Elevated lipid disorders in people who have difficulty swallowing	Launched in the US in 2019		
3. Kapspargo Sprinkle (metoprolol succinate extended release capsules)	Hypertension, angina pectoris and heart failure in people who have difficulty swallowing	Launched in the US in 2018		

## Table 6 Commercialised Global Specialty Portfolio

## **BUSINESS MODEL**

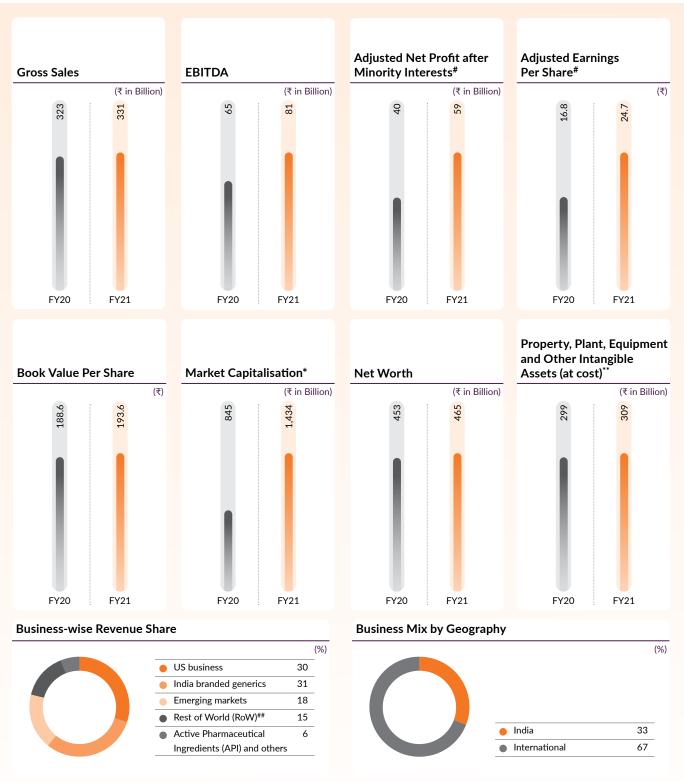
Our strategy is to create sustainable long-term shareholder value inspired by our Vision of - Reaching People And Touching Lives Globally As A Leading Provider Of Valued Medicines.





• Focus on improving return ratios

#### **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) \* As on March 31

\*\* Property, plant, equipment and other intangible assets (at cost) includes Capital work-in-progress & Intangible assets under development

# Adjusted Net Profit after Minority Interests and Adjusted Earnings Per Share exclude the impact of exceptional items

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

#### **FINANCIAL RATIOS**

#### Table 7 Consolidated

Ratios	Unit	FY21	FY20	Variance	Reasons if Variance is More than 25%
Return on Net Worth (%)	%	6.2%	8.3%	-25%	Return on Net Worth is lower for the year ended March 31, 2021, due to lower net profit. Reduction in net profit is mainly on account of exceptional item
Debtors Turnover	times	3.7	3.4	7%	-
Inventory Turnover (on cost of goods sold)	times	1.0	1.2	-18%	-
Interest Coverage Ratio	times	51.2	18.4	178%	Interest coverage ratio is higher for the year ended March 31, 2021 due to higher profit before interest, tax and exceptional items and also due to reduction in interest cost compared to last year, driven by debt repayment
Current Ratio	times	1.9	2.0	-6%	-
Debt Equity Ratio	times	0.08	0.18	-56%	Reduction in debt and increase in net worth
Operating Profit Margin (%)	%	24.5%	20.0%	22%	-
Net Profit Margin (%)	%	8.8%	11.6%	-25%	Due to lower profits on account of exceptional item

#### Table 8 Standalone

Ratios	Unit	FY21	FY20	Variance	Reasons if variance is more than 25%
Return on Net Worth (%)*	%	8.5%	13.2%	-35%	Return on Net Worth is lower for the year ended March 31, 2021, due to lower net profit. Reduction in net profit is mainly due to lower other income compared to last year, and exceptional items
Debtors Turnover*	times	2.0	1.9	2%	-
Inventory Turnover (on cost of goods sold)	times	1.5	1.7	-13%	-
Interest Coverage Ratio	times	9.7	9.0	8%	-
Current Ratio	times	1.4	1.1	36%	Reduction in short-term borrowings has helped improve current ratio
Debt Equity Ratio	times	0.27	0.26	2%	-
Operating Profit Margin (%)	%	21.5%	17.5%	23%	-
Net Profit Margin (%)	%	17.0%	27.0%	-37%	Due to lower net profit on account of lower other income and exceptional item

#### **FY21 Business Highlights**

**COVID-19 Response** Sun Pharma has a multi-pronged approach to overcoming the challenges of the global pandemic. The Company has focused on the following:

- 1. Maintaining manufacturing continuity to ensure regular supply of medicines to customers/patients across the world
- 2. Focus on safety and well-being of employees across all our offices, R&D centres and manufacturing units

- 3. Increased focus on automation, digitalisation and leveraging IT technology tools to ensure business continuity as well as to facilitate work from home (WFH) for many functions in the organisation
- 4. Supply of multiple therapeutics used in treatment of COVID-19 like Remdesivir, Favipiravir, Itolizumab, Hydroxychloroquine, among others
- 5. Donated medicines and other items like PPE kits, masks, sanitisers, gloves, and so on

#### • Strengthening the Specialty Pipeline

In May 2020, Sun Pharma concluded a worldwide in-licencing agreement with Sun Pharma Advanced Research Company Ltd. (SPARC) for SCD-044, a potential oral treatment for atopic dermatitis, psoriasis and other auto-immune disorders. The in-licencing of SCD-044 strengthens Sun Pharma's specialty pipeline of innovative dermatology products and demonstrates its commitment to this important segment with significant unmet medical needs.

# • Presented Clinical Data Analysis on Treatment of Skin Cancer

In June 2020, at the American Academy of Dermatology (AAD) Virtual Meeting Experience, Sun Pharma presented data analyses for ODOMZO<sup>®</sup> and LEVULAN<sup>®</sup> KERASTICK<sup>®</sup> + BLU-U<sup>®</sup>, offering clinical insights to treat people with or at risk of skin cancer. Long-term analyses of the ODOMZO clinical study confirmed that treatment with ODOMZO provided clinically meaningful outcomes to patients with locally advanced basal cell carcinoma (laBCC) who were taking common concomitant medicines, such as medicines for cardiovascular, inflammatory and auto-immune diseases. For LEVULAN KERASTICK + BLU-U, a post hoc analysis of the Phase 3 trial supports the efficacy and safety benefits of the product, with photodynamic therapy (PDT) in treating minimally to moderately thick actinic keratoses on the upper extremities. It showed significantly greater clearance of lesions and larger percentage of cumulative disease area was cleared with no clinically significant adverse events.

 Expanding Market Presence for ILUMYA<sup>™</sup> In June 2020, Sun Pharma entered into an exclusive licencing and distribution agreement for ILUMYA<sup>™</sup> with Hikma Pharmaceuticals PLC (Hikma) for the Middle East & North Africa (MENA) region. Under this agreement, Hikma will be responsible for the registration and commercialisation of ILUMYA across the MENA markets and Sun Pharma will be responsible for supply.

#### • Introduced Cost-Effective Formulation of Favipiravir for COVID-19 in India

In August 2020, the Company launched FluGuard<sup>®</sup> (Favipiravir 200 mg) in India at ₹35 per tablet, for the treatment of mild to moderate cases of COVID-19 in India. Favipiravir is the only oral, anti-viral drug approved in India for the potential treatment of patients with mild to moderate COVID-19.

#### • Launched ILUMYA<sup>®</sup> in Japan

In September 2020, Sun Pharma introduced ILUMYA<sup>®</sup> Subcutaneous Injection 100 mg Syringe in Japan for the treatment of plaque psoriasis in adults, who have an inadequate response to conventional therapies. ILUMYA<sup>®</sup> is Sun Pharma's first innovative drug in the Japanese market and offers a new, safe and effective treatment option for plaque psoriasis to doctors and patients in the country. Japan has ~430,000 people suffering from psoriasis.

 Presented Positive Results from the ILUMYA<sup>®</sup> Five-Year Study

In October 2020, Sun Pharma presented positive, five-year Phase 3 data for ILUMYA® (tildrakizumabasmn) from the combined reSURFACE 1 and reSURFACE 2 extension studies at the 29<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Virtual Congress. The study found that patients with moderate-to-severe plague psoriasis, who continued to receive ILUMYA<sup>®</sup> through five years of continuous treatment, maintained consistent and extensive skin clearance with no new safety issues reported. In patients treated with ILUMYA 100 mg, clear or almost clear skin (PASI 90) was achieved by 65.9% of patients and 32.8% of patients achieved completely clear skin (PASI 100) at week 244. The standard goal of treatment, a PASI 75 response, was achieved by 88.7% of patients at week 244. The long-term analyses also showed absolute PASI <1/<3/<5 scores at week 28 (50.8%, 85.1% and 96.4%, respectively) were sustained through week 244 (47.7%, 78.8% and 88.7%, respectively). Absolute PASI scores can indicate the extent of residual disease after treatment. Achievement of an absolute PASI score of <3 has been proposed as comparable to a PASI 90 response, which is equivalent to clear or almost clear skin. These results demonstrate that ILUMYA remains effective year on year, maintaining a high level of skin clearance and a durable safety profile, regardless of baseline level of skin disease, age or background illnesses.

# Initiated Phase 2 Clinical Trial of SCD-044 In January 2021, the Company announced the initiation of Phase 2 clinical trial for SCD-044 (a novel, orally bioavailable sphingosine-1-phosphate (S1P) receptor 1 agonist) in patients with moderate-to-severe plaque psoriasis. SCD-044 is also being

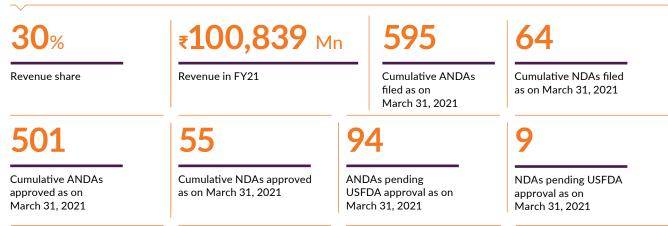
#### • Introduced Affordable Epilepsy Treatment in India

evaluated in other indications like atopic dermatitis.

In February 2021, Sun Pharma pledged to introduce the complete range of Brivaracetam at an affordable price for epilepsy treatment in India. The Company's brand, Brevipil (Brivaracetam) tablet 25 mg/50 mg/75 mg/100 mg was launched on Day-1, following the patent expiry of innovator product. Brevipil oral solution (10 mg/ml) and injectable (10 mg/ml) were made available subsequently over the next few weeks. Brivaracetam is approved by the Drug Controller General of India (DCGI), as an adjunctive therapy in treatment of partial-onset seizures among patients 16 years of age and older, suffering from epilepsy.

#### **BUSINESS GEOGRAPHIES**

**US Business** 



Sun Pharma entered the US pharma market—the world's largest pharmaceutical market—in 1997 and has, since then, established its prominence in the generics market. It subsequently expanded its portfolio to include specialty branded products and over-the-counter (OTC) products. As per IQVIA data, It is the tenth largest pharmaceutical company in the US generics market with the US business accounting for ~30% of annual consolidated sales.

The Company manufactures and markets various dosage forms, including liquids, creams, ointments, gels, sprays, injectable, tablets, capsules and drug-device combination for the US market. It focuses on the Central Nervous System (CNS), dermatology, cardiology, oncology, ophthalmic segments, among others in the US. Over the last two decades, Sun Pharma has grown in the US as a valued supplier to some of the largest wholesalers, distributors, and chain drugstores. The Company has fostered long-standing relationships with care providers and payors in the country. A vertically integrated organisation with a global presence, Sun Pharma has on-shore and offshore manufacturing capabilities, coupled with a strong distribution network to service customers in the US.



In the US dermatology market (by prescriptions)<sup>1</sup>

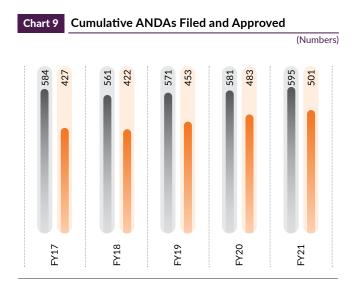
Year	Major Initiatives
FY21	<ul> <li>Presented long-term insights into the clinical use of Ilumya at the American Academy of Dermatology (AAD) Virtual Meeting</li> <li>Presented clinical insights for Odomzo and Levulan at AAD Virtual Meeting</li> <li>Pre-clinical data for GL0034 (GLP-1R agonist) presented at the American Diabetes Association (ADA) Virtual 80<sup>th</sup> scientific sessions</li> </ul>
FY20	Launched Cequa and Absorica LD
FY19	<ul> <li>Launched Ilumya and Yonsa</li> <li>Received USFDA approval for Cequa</li> <li>Launched Xelpros</li> <li>Launched Ready-to-Infuse INFUGEM<sup>TM</sup></li> </ul>
FY18	<ul> <li>Launched Odomzo</li> <li>Received USFDA approval for llumya</li> </ul>

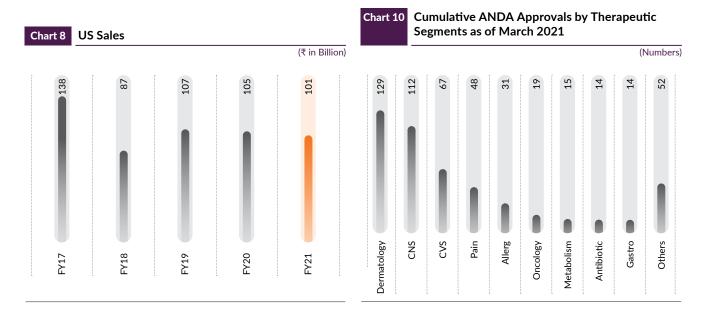
#### Table 9 Milestones in the US Business

Year	Major Initiatives
FY17	<ul> <li>Filed Tildrakizumab</li> <li>Acquired Ocular Technologies to receive access to Cequa – treatment for dry eyes</li> </ul>
	<ul> <li>Launched BromSite</li> <li>Acquired Odomzo – branded oncology product from Novartis</li> </ul>
FY16	Acquired InSite Vision to strengthen the ophthalmology portfolio
FY13	Acquired DUSA to enter the branded specialty market
FY10	Acquired Taro Pharma to enter the dermatology market
FY98	Entered the US market through Caraco acquisition

#### FY21 Highlights

- Revenues from US de-grew by 4.4% Y-o-Y to ₹100,839 Million
- Despite the significant challenges posed by the COVID-19 pandemic, the specialty branded business in the US witnessed positive growth, with Ilumya, Cequa, Yonsa and Odomzo being key contributors
- Following the end of FY21, the first generic for Absorica entered the market In April 2021
- The US generics market continues to witness Y-o-Y price erosion, driven by faster pace of generic approvals and customer consolidation, resulting in a competitive market



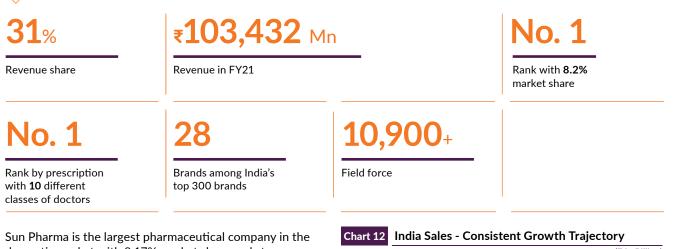


## 26

#### Roadmap

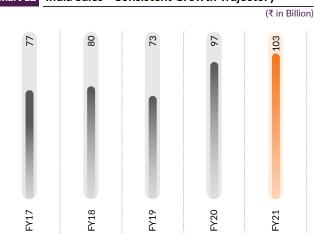
- Ramp-up prescriptions for specialty products
- Continue to focus on complex generics and high-entrybarrier products
- Focus on product robustness and supply-chain efficiencies to ensure high service standards for customers

### India Branded Generics Business: Largest Pharma Company in India<sup>5,6</sup>

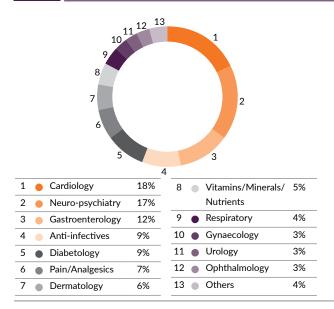


Sun Pharma is the largest pharmaceutical company in the domestic market with 8.17% market share and strong positioning in the high-growth chronic segments. It offers a complete therapy basket, with products in neuro-psychiatry, cardiology, diabetology, gastroenterology, pain/analgesics, gynaecology, ophthalmology, urology, dermatology, respiratory, anti-infectives, and other segments.

Over the years, the Company has built a strong sales force, which enables it to reach a large number of doctors in the country.







# Table 10India Prescription Ranking - Leadership in KeyTherapeutic Areas6

Specialist	February 2020	February 2021
Psychiatrists	1	1
Neurologists	1	1
Cardiologists	1	1
Orthopaedic specialists	1	1
Diabetologists	1	1
Gastroenterologists	1	1
Consultant physicians	1	1
Urologists	1	1
Dermatology	1	1
Chest physicians	2	1
ENT specialists	1	2
Nephrologists	1	2
Ophthalmologists	2	2
General surgeons	2	2
Gynaecologists	2	2

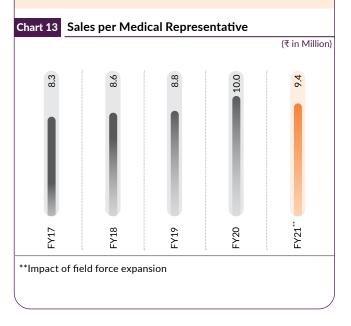
#### FY21 Highlights

- Revenue from the India Formulations business grew by 6.5% to ₹103,432 Million, driven mainly by chronic segments
- To contain the COVID-19 outbreak, the government announced a lockdown in the country in the first half of the year. This resulted in temporary closure of doctor clinics, reduction in patient consultations, postponement of non-critical treatments including elective surgeries and restrictions in the movement of the medical representatives. As per AIOCD AWACS data for the 12 months ended March-2021, average industry growth was 2.1% with acute and semi-chronic segments getting impacted due to lockdown restrictions
- Growth was driven by a combination of volume and price progressions
- The field force expansion project undertaken in Q4 of FY20, was completed during the year and the new medical representatives commenced their field work
- During the year, we launched 96 products in the domestic market, including the anti-epileptic Brevipil (Brivaracetam) and FluGuard (Favipiravir)
- The Company supplied drugs like Remdesivir, Itolizumab, Hydroxychloroquine (HCQS), Favipiravir and Liposomal Amphotericin B in the Indian market for treatment of COVID-19 and associated ailments
- In May 2021, Sun Pharma entered into a licencing agreement with Eli Lilly to expand access to Baricitinib, in helping alleviate the burden of COVID-19 in India

#### Best-in-Class Field Force Productivity

Sun Pharma has among the highest Sales per Medical Representative (MR) ratio in India's pharmaceutical market.

During the year, the Company completed the expansion of its sales force to enhance brand focus and improve geographic and doctor reach.



#### Roadmap

- Focus on productivity enhancement
- Maintain leadership position in a fiercely competitive market
- Innovate continuously to ensure high brand equity with doctors
- Continue to evaluate in-licencing opportunities for latest generation patented products, given the Company's strong brand equity and extensive distribution network

#### **Emerging Markets**



Sun Pharma is the one of the leading Indian pharmaceutical companies in the emerging markets. The Company sells its products in ~80 global markets, with a focus on Romania, Russia, South Africa, Brazil, Mexico and other complementary and affiliated markets. It has local manufacturing units across Bangladesh, South Africa, Malaysia, Romania, Egypt, Nigeria and Russia, which provides increased flexibility in servicing these markets.

#### FY21 Highlights

- Revenues from emerging markets grew by 5.1% to ₹57,834 Million
- Many emerging market currencies showed higher volatility, given the global impact of the pandemic in these markets. While the reported growth for Sun

Pharma's emerging markets revenues was 5.1%, the constant currency growth was higher, at 6.4%

• Sun Pharma entered into an exclusive licencing and distribution agreement for ILUMYA<sup>™</sup> with Hikma Pharmaceuticals PLC (Hikma) for the Middle East & North Africa (MENA) region. Under this agreement, Hikma will be responsible for the registration and commercialisation of ILUMYA in these markets.

#### Roadmap

Rest of the World (RoW): Western Europe, Canada, Japan, Australia, New Zealand (ANZ) and Other Markets

- Gain critical mass across key markets
- Enhance product basket in emerging markets
- Focus on profitable growth

Leading

Indian companies in RoW

**₹48,191** Mn

Revenue share

budget.

15%

Revenue in FY21

Sun Pharma is among the leading Indian pharmaceutical

characterised by an ageing population and an increasing

alongside government efforts to tighten the healthcare

incidence in chronic ailments and lifestyle diseases,

companies operating in Western Europe, Canada, Japan, as

well as Australia & New Zealand (ANZ). These markets are

In RoW markets, Sun Pharma offers an expanding products

suite, including injectables and hospital products as well

as products for the retail market. It has established local

manufacturing footprint in Canada, Japan, Australia, Israel and Hungary and follows a distribution-led growth model

focused on development and commercialisation of complex

generics and differentiated products to drive sustainable

Global Consumer Healthcare Business <sup>1,7,8</sup>

Sun Pharma is present in countries like Romania, Russia,

Belarus, Kazakhstan, Morocco, UAE and Oman. The

South Africa, Nigeria, Myanmar, Ukraine, Poland, Thailand,

Company enjoys strong brand equity in in India, Romania,

manufacturing footprint

Markets have local

- FY21 Highlights
   Revenue from RoW markets increased by 6.6% to ₹48,191 Million
  - Growth driven mainly by Western Europe, Canada and Australia markets
  - Sun Pharma launched ILUMYA in Japan for the treatment of plaque psoriasis in adult patients who have an inadequate response to conventional therapies. This is Sun Pharma's first innovative drug to be launched in the Japanese market

#### Roadmap

Brands

- Ramp-up ILUMYA prescriptions in Japan and Australia
- Evaluate newer markets in RoW for commercialising the specialty portfolio
- Launch differentiated generics in key markets

20+

Consumer healthcare companies in India, Romania, Nigeria and Myanmar

and profitable progress.

on

ZU+ Countries ~400,0

Retail outlets in India where Company's products are available

Nigeria and Myanmar, with a portfolio, including overthe-counter (OTC) brands in the Vitamins, Mineral & Supplements (VMS), Cold & Flu, Analgesics, Digestive and Dermatology categories.

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As per IQVIA, Sun Pharma's key consumer healthcare brands – Volini and Revital H – are ranked  $23^{rd}$  and  $63^{rd}$ , respectively in the Indian pharmaceutical market. The Indian distribution network spans 1,000+ cities and towns, supported by ~400,000 retail outlets. Globally, the Company has strong pharmacy reach in Russia, Romania, Nigeria and Myanmar for its OTC brands.

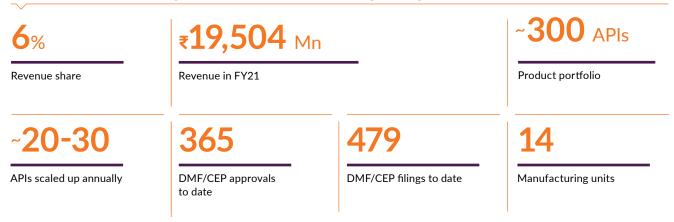
#### FY21 Highlights

- In India, the consumer business revenue recorded double-digit growth, driven mainly by higher sales of Revital-H, which was a result of increased consumption of vitamins, given the COVID-19 pandemic
- We expanded the launch of Volini Joint Xpert Gel to more locations in the country and introduced the Abzorb T Cream, which further expands the dermatology portfolio

#### Roadmap

- Sustained focus on key brands
- Maintain leadership in existing markets through focus on innovative solutions and brand extensions
- Enhance presence in high growth markets
- Increase retail connect programmes to ensure better availability of our products for end consumers

#### Active Pharmaceutical Ingredient (API) Business: Strategic Integration



The API business is strategically important for Sun Pharma, as it provides opportunities for strong backward integration and speed to market. These linkages, in turn, provide cost competitiveness and a reliable supply chain, thereby reducing dependence of third-party suppliers. With ~300 offerings in the product portfolio, it caters to large generic manufacturers and innovator companies, after meeting captive consumption requirements. The Company has 14 API manufacturing units across multiple countries and develops ~20-30 APIs annually.

#### FY21 Highlights

- Revenue from the API business increased by 1.8% to ₹19,504 Million
- Growth was muted mainly due to lower sales of opiates products

#### Roadmap

- Focus on development and commercialisation of strategic APIs for captive consumption
- Ensure consistent supplies and high service standards for customers

Research and Development (R&D): Creating Future Growth Engines

6.5%

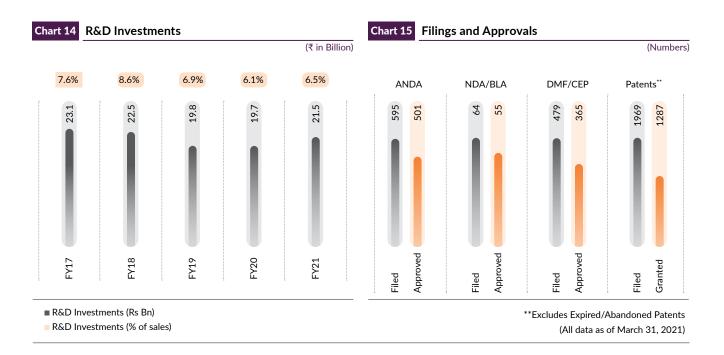
**₹193**+ Bn

R&D spend as percentage of sales in FY21 Cumulative R&D expenditure till date

At Sun Pharma, R&D is a key determinant of future success. The R&D team focuses on delivering innovative and affordable therapies to cater to the needs of patients. A critical catalyst to the business, R&D investments help build a strong pipeline of branded generics, pure generics and specialty products for India and international markets.

Sun Pharma's R&D capabilities include expertise in the development of products across dosage forms, such as injectables, orals, liquids, ointments, gels, sprays, hormones and oral products. The R&D team is actively supported by strong intellectual property capability.

The Company operates in a highly competitive industry and thus continues to fortify its R&D capabilities with focused investments to develop its long-term specialty and complex generics pipeline in the long run.



#### FY21 Highlights

- Commenced phase 3 trials for Ilumya (Tildrakizumab) for psoriatic arthritis indication
- Commenced phase 2 trials for:
  - SCD044 A S1P1 agonist for plaque psoriasis and atopic dermatitis
  - MMII Treatment of knee pain in patients with symptomatic knee osteoarthritis
- Commenced phase 1 trials for GL0034, a GLP-1R (Glucagon-Like Peptide-1 Receptor) agonist for treating diabetes

#### Roadmap

- Invest to build the specialty R&D pipeline
- Develop complex products for global markets
- Target products specifically for emerging markets and India
- Continue to work on developing APIs of strategic importance

#### Global Manufacturing Base: World-class Manufacturing Infrastructure

The Company has 44 state-of-the-art production units spanning India, the Americas, Asia, Africa, Australia and Europe. This enables Sun Pharma to produce highquality affordable products. With a vertically-integrated manufacturing network, the Company can produce diverse dosage forms, including hormones, peptides, controlled substances, orals, creams, ointments, injectables, sprays and liquids.

Many of Sun Pharma's manufacturing facilities are certified by global regulatory agencies like the United States Food and Drug Administration (USFDA), the European Medicines Evaluation Agency (EMEA); the UK Medicines and Healthcare Products Regulatory Agency (MHRA); Australia's Therapeutic Goods Administration (TGA); South Africa's Medicines Control Council (MCC); Germany's Federal Institute for Drugs and Medical Devices (BfArM); 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.

Sun Pharma has 30 finished dosage manufacturing facilities, while its 14 API facilities provide captive support.

#### Table 11 Finished Dosage Manufacturing Units

Country	Number of Finished Dosage Facility
India	15
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
Total	30

#### Table 12 API Manufacturing Units

Country	Number of API facility
India	9
Australia	2
Israel	1
US	1
Hungary	1
Total	14

#### People: Share One Purpose

Sun Pharma's global team has 37,000+ people from over 50 nationalities, collaborating across cultures and locations to develop, manufacture and distribute pharmaceutical products to patients/customers across over 100 geographical markets. The Company offers a congenial work environment that provides equal opportunities for growth, recognising and rewarding the merits of its people. Sun Pharma offers inclusive growth and knowledge-sharing to make its teams future-ready.

#### Quality: Commitment to Excellence

Sun Pharma has a robust quality management system. Its research centres, manufacturing units, testing labs and distribution facilities follow the highest global quality

standards. The Company has a global Quality Management team that oversees regulatory conformity of every product and manufacturing facility. It has cGMP certifications from global regulatory authorities like USFDA, EMEA, WHO and TGA, among others. The Company has a Corporate Quality Unit that supervises the implementation of latest cGMP updates and guidelines.

In December 2019, the USFDA inspected the Company's Halol facility and issued Form 483 with 8 observations. Following submission of the Company's response in January 2020, the USFDA classified the inspection status as Official Action Indicated (OAI). The Company was in continuous communication with the USFDA to resolve outstanding issues and is awaiting a re-inspection by USFDA to resolve the OAI status. However, due to the pandemic and travel restrictions, the re-inspection has been delayed. The Company continues to manufacture and distribute products to the US from this facility. However, the OAI status normally implies that the USFDA may put all new approvals from the Halol facility on hold till the OAI status is changed.

#### Roadmap

- Ensure 24x7 compliance to cGMP, which is imperative for a global pharmaceutical business
- Enhance systems, processes, human capabilities continuously to ensure compliance with global regulatory standards

Strengths	Opportunities	Threats and Weaknesses
<ul> <li>Strong global prominence</li> <li>4<sup>th</sup> largest global specialty generics company</li> <li>10<sup>th</sup> largest generics Company in the US</li> <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>No. 1 ranking with 10 different classes of doctors in India</li> <li>Among the largest Indian pharmaceutical companies in the emerging markets</li> <li>Largest Indian pharmaceutical company in Japan</li> </ul>	• The pandemic has resulted in increased healthcare awareness globally. This augurs well for companies like Sun Pharma, which can supply high-quality pharmaceutical products at affordable prices	• Fresh outbreaks of the pandemic across the world and subsequent disruption in economic activities may impact economic growth across countries and indirectly also impact pharmaceutical consumption
Robust R&D infrastructure and capabilities to develop technologically complex products in the generic and specialty segments	• The pandemic has also brought forward the need for therapeutic medicines for treating COVID-19 symptoms, extending an opportunity for pharmaceutical companies to service the urgent and vital needs of patients. However, the demand for such products keeps fluctuating depending on the number of viral infections	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
<ul> <li>Focus on driving growth and profitability through a pragmatic mix of organic and inorganic initiatives</li> </ul>	• Favourable macro-economic parameters for India and emerging markets are likely to ensure reasonable volume growth for pharmaceutical products across these markets in the long term	• 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

#### Table 13 SWOT Analysis<sup>1,4,5,6</sup>

Strengths	Opportunities	Threats and Weaknesses
• Strong balance sheet imparts ability to undertake inorganic initiatives without any significant leverage, allowing future growth headroom	• For many years, developed markets witnessed a consistent increase in contribution of specialty products in their overall pharmaceutical spending and this trend is expected to continue in future as well. Sun Pharma has already commercialised many of its specialty products in developed markets, and hence will be able to reap the benefits of this expanding opportunity	<ul> <li>Given the additional spending on battling the pandemic, governments across the world may try to control pricing of certain products, which may lead to government-mandated price controls on pharmaceutical products</li> </ul>
• Ability to supply affordable, high-quality products consistently across the world	• Growing penetration of generics in Japan and opening of the China market, present good long-term opportunities for Indian companies, including Sun Pharma	• Developing a specialty pipeline entails high upfront investments for long-term benefits, and may impact short-term profitability

## 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.

The 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,

## Bibliography

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#### Disclaimer

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