

Managing Director's Message



Dilip Shanghvi, Managing Director

Dear Shareholders,

The global pharmaceutical industry is at crossroads. The type of drugs being developed by the industry and the role played by technology are being juxtaposed against the value that healthcare delivers to patients. On one hand, the industry is developing new generation specialty drugs in gene therapy, monoclonal anti-bodies and immunotherapy categories, which have improved medical outcomes for patients; but on the other hand, the industry is facing increasing resistance from governments and payors over escalating drug prices, which impacts healthcare budgets. The need of the hour is for innovation and affordability to co-exist for the long-term benefit of all stakeholders.

The scenario for the generics industry is markedly different from its much larger branded counterpart. Generics pricing in the US, the largest and most important of all generics markets, has been under severe pressure over the last three years. The business profitability in the US generics market has suffered significantly over this period. Although there are early signs of price stabilisation for some products, the overall US generics pricing continues to be competitive.

The industry has started responding to these changes through a combination of multiple initiatives. These include a focus on developing innovative and differentiated products, withdrawal of non-remunerative products and persistent emphasis on cost control.

With business becoming more challenging, it has become imperative for companies to be more innovative and identify new engines of growth. Sun Pharma's significant investments in building a global specialty business is an important step in this direction. This initiative will enable us to build an additional engine of growth as well as move up the pharmaceutical value chain over the long term.

Our unwavering focus on cost control continues, with these efforts spread across generic R&D projects, rationalisation of manufacturing footprint and other areas. These steps will release resources which can be deployed in the specialty business.

FY19 highlights

We are back on the growth path with our FY19 revenues growing by 10% to ₹287 Billion. We have recorded steady growth in all the markets where we operate.

Operational performance

Revenues in the US increased 22% to ₹107 Billion and accounted for 37% of our consolidated revenues for FY19. The key growth drivers include increase in generics sales, incremental contribution from specialty product launches and a favourable foreign exchange rate. Our subsidiary, Taro recorded a marginal growth in overall revenues to US\$ 670 Million for the year. This was mainly the result of more intense competition among manufacturers, new entrants to the market, buying consortium pressures and a higher abbreviated new drug application (ANDA) approval rate from the United States Food and Drug Administration (USFDA).

We recorded 8% decline in our India formulations business, however, our adjusted growth, excluding one-offs, was 5%.

We grew by 11% in emerging markets for the year. This growth was broad based across various markets. Our sales in the rest of world (RoW) markets grew by 16% for the year, driven by increased sales in some Western European markets and partly driven by the Pola Pharma Inc. (Pola Pharma) acquisition in Japan.

R&D

R&D is the lifeline of our business as it enables us to develop and launch differentiated generics as well as innovative specialty products. It is a key determinant of our future growth and profitability. Our efforts to build a global specialty pipeline mandates that we keep investing in R&D.

Our R&D investments for the year were ~₹20 Billion, targeted mainly at developing complex generics and specialty products. Given the intensely competitive nature of the US generics market, we continue to be disciplined in identifying future R&D projects for the generics market. Investments for

developing the long-term specialty pipeline are expected to continue. We are also investing in developing specific products for emerging markets and other non-US developed markets.

Progress on specialty initiatives

We have further progressed in our global specialty initiatives, which commenced a few years ago. We view the specialty business as an additional engine of sustainable growth and cash flows over the long term. It is also an initiative to move up the pharmaceutical value chain and bring in more innovation to our business. We have allocated significant resources over the past few years in building this business for acquiring specialty products, funding their clinical trials and establishing the requisite front-end capabilities. We have now entered the commercialisation phase for most of our specialty products.

The focus areas for our specialty portfolio include segments like dermatology, ophthalmology and oncology.

Specialty products – Approvals and launches in FY19

We crossed many important milestones for our specialty business in FY19 with USFDA approvals for four specialty products and commercialisation of three specialty products. Some of the key highlights for the year were:

- We launched ILUMYA™ (tildrakizumab-asmn) 100 mg/mL in the US for treating moderate-to-severe psoriasis in October 2018. We have received a good initial response for the product and we expect ramp-up in ILUMYA™ sales in the US over the next few years. We have also commenced a direct-to-consumer advertising initiative for ILUMYA™ in the US.
- Our European partner, Ammirall, received approval for tildrakizumab from the European Commission (EC) under the ILUMETRI™ brand name. Ammirall has commenced commercialisation of ILUMETRI™ in Europe in a phased manner across different markets.
- Sun Pharma also received approval from the Australian Therapeutic Goods Administration (TGA) for ILUMYA™ during the year. The product has already been commercialised in Australia.
- During the year we received USFDA approvals for CEQUA™ (cyclosporine ophthalmic solution 0.09%). CEQUA™ increases tear production in patients with dry eyes. It is the first and only approved dry eye treatment to combine cyclosporine A with nanomicellar technology. CEQUA™ will be commercialised in the US in FY20.
- In May 2018, Sun Pharma received USFDA approval for YONSA® (abiraterone acetate), a novel formulation in

combination with methylprednisolone to treat patients with metastatic castration-resistant prostate cancer (mCRPC). This approval has further strengthened Sun Pharma's oncology portfolio in the US. The product was commercialised in the US in the first quarter of FY19.

- During the year, Sun Pharma also received USFDA approval for its New Drug Application (NDA) of XELPROS™ (latanoprost ophthalmic emulsion 0.005%) used for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. XELPROS™ is the first and only form of latanoprost that is not formulated with benzalkonium chloride (BAK), a commonly used preservative in topical ocular preparations. XELPROS™ was launched in the US in January 2019.
- In July 2018, Sun Pharma announced the USFDA approval for INFUGEM™ (gemcitabine in 0.9% sodium chloride injection), for intravenous use in a ready-to-administer (RTA) bag. INFUGEM™ uses a proprietary technology, which allows cytotoxic oncology products to be pre-mixed in a sterile environment and supplied to the prescribers in RTA infusion bags. These RTA bags will provide greater safety, by preventing problems of over-dosing or under-dosing and eliminating contamination risk. INFUGEM™ was commercialised in the US in April 2019.
- In August 2018, Sun Pharma launched KAPSPARGO SPRINKLE™ (metoprolol succinate) extended-release sprinkle formulation in the US. The product will help treat hypertension, angina pectoris (chest pain) and heart failure. These extended-release coated pellets can be sprinkled over soft food or administered via a nasogastric tube to facilitate long-term, once-daily administration for patients who experience difficulty while swallowing.
- We have also initiated investments in the development of new indications for ILUMYA™. Although the clinical trials for these new indications will require upfront investments, a successful outcome of the trials will significantly expand the addressable market for ILUMYA™ globally.

Enhancing presence in Japan

In January 2019, we announced the closure of the acquisition of Pola Pharma, a Japanese pharmaceutical company. Pola Pharma's portfolio primarily comprises dermatology products and it also has two manufacturing facilities in Japan with capabilities to manufacture topical products and injectables. This acquisition strengthens Sun Pharma's presence in Japan and accelerates its access to the Japanese dermatology market.

Regulatory compliance in pharmaceutical manufacturing

Regulatory standards for pharmaceutical facilities have been undergoing constant upgradation over the past many years, with regulatory agencies demanding the highest quality products. To adhere to these stringent standards, pharmaceutical companies need to have an unwavering focus on 24x7 compliance, which, in turn, raises compliance costs. 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, which was impacted by cGMP deviations in FY15, was cleared by the USFDA in June 2018. With this clearance, new approvals from this facility for the US market have started coming through gradually.

Restructuring and rationalisation

We also continue to focus on optimising our costs, given the tough phase that the global generics industry is passing through. We strive to optimally utilise our resources with greater involvement of people, to make the Company more efficient.

We continue to emphasise on optimising our manufacturing footprint, to strike a pragmatic balance between current costs and future capacity requirements. We are constantly evaluating our generics R&D investments, to ensure a reasonable return on investment.

Overall outlook

Our consistent focus is on growing each of our businesses faster than the market in which they operate. Our global specialty initiatives will supplement this objective as an additional growth engine.

Although the US generics industry continues to face pricing pressure, the industry has started responding to these challenges by rationalising product portfolios and discontinuing non-remunerative products. These steps have been taken to ensure that generics products are able to generate reasonable returns to manufacturers.

In US, generics account for more than 80% of overall pharmaceutical volumes. In Western Europe, generics account for a significant portion of volumes as well. In Japan, the government has been encouraging higher generics penetration to bring down healthcare costs. All emerging markets rely on branded generics and/or pure generics to service their healthcare needs, given the lower purchasing power of their population. Hence, generics will continue to be an integral part of the solution to control global healthcare costs and has an important role to play in overall healthcare management.

Sun Pharma continues to invest in the generics business, with a focus on developing differentiated complex generics and building a product pipeline across markets. Our strong

positioning in the global generics space will ensure that we remain an important player in the generics industry.

We are gradually ramping up our global specialty business. One of key ailments that we are targeting is psoriasis. As per a EvaluatePharma report, the size of the US psoriasis market was estimated at ~US\$ 10 Billion in 2018 and is expected to grow at 9% CAGR till 2024. The report also estimates the global market for psoriasis at ~US\$ 15 Billion in 2018, which is likely to grow at 9% CAGR to US\$ 24.6 Billion by 2024.

We have started commercialising ILUMYA™, useful for treating moderate-to-severe plaque psoriasis in various markets globally. It was launched in the US in October 2018 and in Australia in December 2018. Our partner in Europe has commenced a phased launch of the product, starting with Germany, under the ILUMETRI™ brand name. The product has received a good response from doctors in these markets. We continue to evaluate other potential markets for commercialising ILUMYA™.

We recently announced long-term clinical insights for ILUMYA™ at the 2019 American Academy of Dermatology conference. The data presented showed sustained skin clearance in some patients living with moderate-to-severe plaque psoriasis after three years of ongoing treatment with ILUMYA™. The product was also well tolerated with low rates of adverse events. We believe that these positive data points will enable the product to do well in the large US\$ 15 Billion global psoriasis market.

Our initiatives in the specialty ophthalmology segment are also gaining momentum. Our dry eye specialty product, CEQUA™, is expected to be commercialised in the US in FY20. We have recently launched XELPROS™ (latanoprost ophthalmic emulsion) 0.005% in the US for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.

Sun Pharma will continue to invest in branding and promotion of its various specialty products. R&D investments for funding clinical trials of some of the specialty products are also likely to continue in future.

For FY20, we expect our consolidated revenues to grow by low-to-mid teens, while R&D investments are estimated at ~8-9% of sales.

Our talented team of employees will be the key driver of all the above initiatives. We are grateful to our Board of Directors for their guidance and support.

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**

Whole-time 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

*Designation changed from Whole-time Director to Non-executive and Non-Independent Director w.e.f. May 29, 2019

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 -
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
Head - India and Emerging Markets



Kirti Ganorkar

Executive Vice-President, Head - Global Business Development Team

**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 Pharmaceuticals Industries Ltd.

**Sreenivas Rao**

Senior Vice-President, Head - Global Supply Chain

**Atanu Roy**

Senior Vice-President, Chief Information Officer



Management Discussion and Analysis



Global pharmaceutical industry¹

Global spending on medicines crossed US\$ 1.2 Trillion in 2018; and is projected to grow at a compound annual growth rate (CAGR) of 3-6% in the next five years, reaching over US\$ 1.5 Trillion by 2023. Growth in the global pharmaceutical market will continue to be led by the US and pharmerging markets.

While new product launches, especially specialty products, will be the key growth catalyst in developed markets, pharmerging market expansion will be driven by multiple factors. These factors comprise improving per capita income, increasing healthcare awareness, ageing population and rising incidence of chronic ailments. The product mix in the developed world will continue to shift towards specialty and orphan products. Emerging technologies are enabling healthcare providers to innovate and engage better with key stakeholders.

Chart 1 Global medicine spending and growth, 2016-23¹

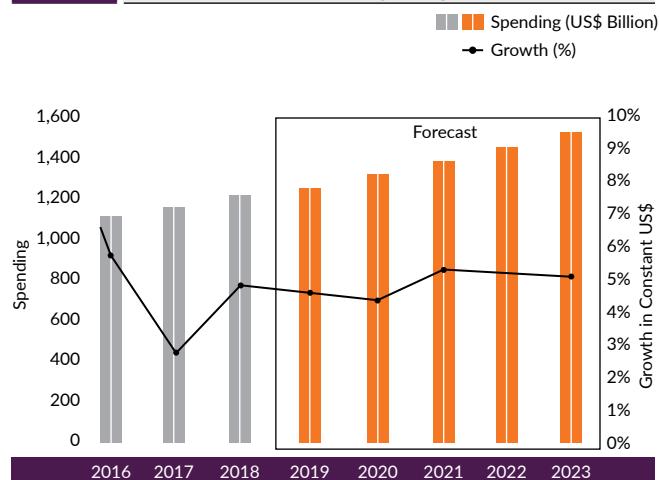


Table 1 Global pharmaceutical spending and growth¹

Regions	2018 (US\$ Billion)	2014-2018 CAGR (%)	2023 (US\$ Billion)	2019-2023 CAGR (%)
Developed markets	800	5.7	990-1,020	3-6
Pharmerging markets	286	9.3	355-385	5-8
Rest of the world	119	3.2	130-160	2-5
Global pharmaceutical market	1,205	6.3	1,505-1,535	3-6

Table 2 Global medicine spending by region and product types in 2023¹

Spending	Original brands	Non-original brands	Unbranded	Over-the-counter (OTC) and other products	Total (US\$ Billion)
Developed markets	76%	10%	8%	5%	990-1,020
Pharmerging markets	27%	40%	13%	20%	355-385
Rest of world	56%	26%	8%	10%	130-160
Global markets	61%	20%	9%	10%	1,505-1,535

Outlook and emerging trends^{1,2}

- US spending was at US\$ 486 Billion in 2018, while pharmerging markets spending was US\$ 286 Billion. These two regions will be key contributors to global pharmaceutical growth.
- Pharmaceutical spending in the top five western European markets (EU5) touched US\$ 178 Billion in 2018; and is likely to grow at a sluggish pace in the 2018-2023 period, as compared to that of the previous five years. Government-mandated price reductions and slower uptake of new specialty products will be key reasons of this sluggish growth.
- China's US\$ 137 Billion pharmaceutical market is expected to grow at 3-6% by 2023, driven by improving insurance access, modernisation of hospital systems and expansion of primary care services.
- Japan's medicine spending was at US\$ 86 Billion in 2018; and is expected to slow through 2023, on account of continued uptake of generics and government-mandated price reductions.
- Uptake of specialty medicines will continue to rise in developed markets, driven by advancement of new and innovative targeted medicines, using immunology, gene therapy, monoclonal anti-bodies and other contemporary technologies. Share of specialty medicines in overall pharmaceutical spending will cross 50% by 2023 in most developed markets.
- Healthcare providers are exploring technology investments in cloud computing, artificial intelligence and machine learning to ramp up productivity. This trend is expected to gain further momentum in the coming years.

Growth enablers for the global pharmaceutical market^{1,3,4,5}

Growing and ageing population: Global population is projected to exceed 9.3 Billion by 2050, of which 21% will be accounted for by those aged 60 and above.

Longer life expectancy: As individuals become increasingly health conscious and medical science continues to advance, life expectancy will increase. By 2040, Japan, Singapore, Spain and Switzerland are projected to have a life expectancy rate in excess of 85 years, while 59 countries, including China, are expected to surpass a life expectancy of 80 years during that period.

Improving purchasing power: The middle-class population as well as per capita income continues to expand, driving demand for pharmaceutical products. This expansion is likely to be broad based, but more pronounced in Asia, particularly in China and India.

Greater prevalence of chronic diseases: Chronic disease prevalence is expected to rise to 57% by 2020 – increasing the demand for healthcare products and services. Emerging markets will account for a majority share, as population growth is expected to be most significant in developing nations.

Research focus on orphan drugs: Growing research focus on rare disease therapies has resulted in a significant increase in new orphan drugs. The United States Food and Drug Administration (USFDA) approved 80 orphan indications in 2017 and 90 in 2018.

Developed markets¹

Growth in global pharmaceutical spending through 2023 will primarily be driven by developed markets and the accelerated adoption of new innovative products. Spending on medicines in developed markets is estimated to grow at 3-6% CAGR from US\$ 800 Billion in 2018 to US\$ 990-1,020 Billion in 2023. The US will continue to be an important contributor, with its medicine spending expected to remain higher than that of the top five European economies.

All developed countries will show moderation in growth through 2023, as compared to the 2014-18 period. Specifically in the US, the positive impact of new specialty launches will be partly moderated by loss of patent protection on older products.

Table 3 Pharmaceutical spending of developed markets (US\$ Billion)¹

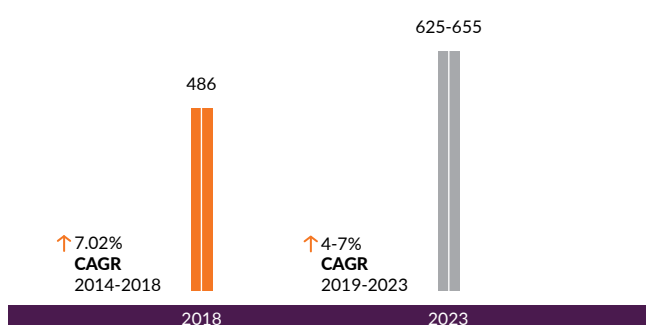
Region/Country	2018	2014-2018 CAGR	2023	2019-2023 CAGR
USA	486	7.2%	625-655	4-7%
EU5	177	4.7%	200-230	1-4%
Germany	53	5.0%	65-69	3-6%
France	37	1.5%	37-41	(-1)-2%
Italy	34	6.3%	40-44	2-5%
UK	28	6.2%	33-37	2-5%
Spain	25	5.4%	27-31	1-4%
Japan	86	1.0%	89-93	(-3)-0%
Canada	22	5.0%	27-31	2-5%
South Korea	16	4.7%	19-23	4-7%
Australia	13	4.3%	13-17	0-3%
Developed markets	800	5.7%	990-1,020	3-6%

USA

The US pharmaceutical market is set to exceed US\$ 600 Billion by 2023. The key driver of this trend will be launch of new specialty products which will be partly offset by patent expiries, growth of biosimilars and slower rate of rise in new launch prices. There has been significant attention given to the launch prices of recently introduced drugs, especially given the shift in innovation towards specialty, orphan and oncology areas (that are often costlier).

Chart 2 US pharmaceutical spending growth¹

(US\$ Billion)

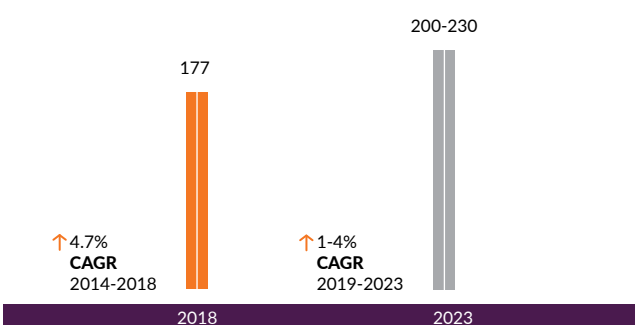


Western Europe

The CAGR for the top five developed markets in Western Europe is likely to reduce to 1-4%, with overall spending expected to cross US\$ 200 Billion in 2023. Government-led cost controls and decelerated growth in spend on new products will contribute to the slowing in pace vis-à-vis the 4.7% CAGR between 2014 and 2018, that was helped by spending on new products (especially oncology and viral hepatitis treatments).

Chart 3 Western Europe pharmaceutical spending growth¹

(US\$ Billion)



Japan

Spending in Japan amounted to US\$ 86 Billion in 2018, but over the next five years, spending on medicines is expected to continue to decline. This is largely due to the continued uptake of generics, despite higher spending on specialty products and an ageing population.

The government of Japan in 2014 set out a policy to achieve a rate of 80% of prescription volume of unbranded generics in the non-patented market by 2021. The resulting savings from generics is enabling a greater shift to specialty medicines without an overall increase in the country's healthcare budget. Share of specialty spending in Japan is expected to rise from approximately 30% in 2018 to 41% in 2023.

Growth in global pharmaceutical spending through 2023 will primarily be driven by developed markets and the accelerated adoption of new innovative products. Spending on medicines in developed markets is estimated to grow at 3-6% CAGR from US\$ 800 Billion in 2018 to US\$ 990-1,020 Billion in 2023.

Pharmerging markets¹

Spending on medicines in pharmerging markets was recorded at US\$ 286 Billion in 2018 and is projected to grow at 5-8% CAGR through 2023 to reach US\$ 355-385 Billion. A key driver to that end is increasing per capita uptake of medicines with a rise in patients' affordability.

Table 4 Pharmaceutical spending and region-wise growth for pharmerging markets (US\$ Billion)¹

Region/Country	2018	2014-2018 CAGR	2023	2019-2023 CAGR
China	132	7.6%	140-170	3-6%
Tier 2 markets	68	10.7%	91-95	7-10%
Brazil	32	10.8%	39-43	5-8%
India	20	11.2%	28-32	8-11%
Russia	16	9.9%	21-25	7-10%
Tier 3 markets	86	11.3%	105-135	7-10%
Pharmerging markets	286	9.3%	355-385	5-8%

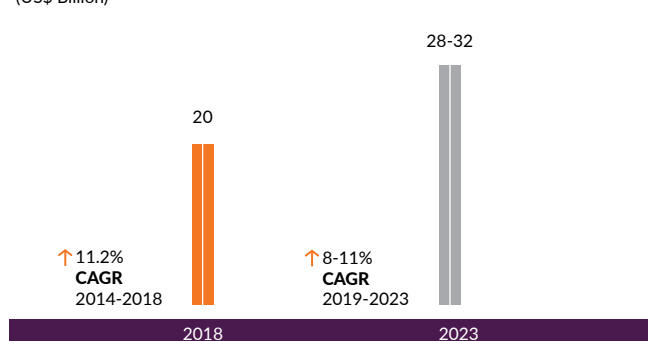
China is the largest pharmerging market registering pharmaceutical spending of US\$ 132 Billion in 2018; and is likely to reach US\$ 140-170 Billion by 2023. Spending is driven, in part, by reforms initiated by the Chinese central government to accelerate insurance access to rural and urban residents, as well as the expansion and modernisation of the hospital network and primary care services.

Indian pharmaceutical market^{1,2}

India enjoys a key position in the global pharmaceutical industry. The country is the world's largest supplier of generics, accounting for 20% of global exports. It supplies over 50% of global demand for various vaccines and 40% of the demand for generic products in the US. The domestic pharmaceutical market contributes to ~2% of the global industry in value and ~10% in volume terms. The domestic pharmaceutical industry has received foreign direct investment (FDI) worth ~US\$ 16 Billion on a cumulative basis, between April 2000 and June 2018.

India's pharmaceutical spending is predicted to grow at 8-11% CAGR in the 2019-23 period to reach a size of US\$ 28-32 Billion. A part of this growth will depend on the ability of companies to align their product portfolio towards therapies for chronic diseases that are on the rise.

Chart 4 India's pharmaceutical spending and growth¹
(US\$ Billion)



Growth enablers

- Increasing per capita income.
- Growing penetration of health insurance.
- Government thrust on improving penetration of modern medicines into rural areas and accelerating access of pharmaceutical products to the poor and low-income sections of the population.
- Increased incidence of chronic ailments.
- Changing lifestyle and consumption patterns.
- Improving healthcare awareness.

Specialty medicines¹

Specialty medicines refer to those used in the treatment of chronic, complex or rare diseases and that require advanced scientific research and innovation. Given their significantly higher purchasing power and strong healthcare insurance coverage, developed markets account for a significant share of global spending on specialty products. Specialty represents a small share in pharmerging markets, given the relatively lower purchasing power, and is expected to rise marginally from 13% in 2018 to 14% by 2023. Specialty is expected to represent more than half of newly launched medicines globally over the next five years. A larger use of biomarkers to segment and treat appropriate patients will characterise these launches.

Spending on medicines in pharmerging markets was recorded at US\$ 286 Billion in 2018 and is projected to grow at 5-8% CAGR through 2023 to reach US\$ 355-385 Billion. A key driver to that end is increasing per capita uptake of medicines with a rise in patients' affordability.

Spending on specialty medicines in developed markets accounted for US\$ 336 Billion in 2018 and is estimated to rise to US\$ 475-505 Billion in 2023. Specialty share of total spending across top 10 developed countries is likely to rise from 42% in 2018 to 50% in 2023. Almost 74% of this is expected to be led by the five largest specialty therapeutic classes: oncology, autoimmune, immunology, anti-virals and multiple sclerosis. In most developed markets, specialty spend continues to outpace that on other medicines.

Active Pharmaceutical Ingredients (API)⁷

APIs are chemicals and biologically active elements of drugs with a direct impact on cure, mitigation, treatment and prevention of diseases. The worldwide API market is likely to exceed US\$ 225 Billion by 2024 – a 6% CAGR for the forecast period.

The market has witnessed growth through the decades, due to an ever-increasing use of medication and biologics for disease management. Other drivers include increasing incidence of chronic ailments, growing volumes of generic drugs worldwide and rising technological advancements in API manufacturing.

Consumer healthcare⁸

Consumer healthcare providers deal with products in wellness, oral health, nutrition, skin health. These include over-the-counter (OTC) drugs. Globally, a large number of acquisitions, mergers and shutdowns has resulted in industry consolidation, with market share being concentrated within the top 10 firms. The Global OTC market was valued at \$135 Billion in 2018. Two top markets, the US (US\$34 Billion) and China (US\$25 Billion) accounted for ~44% of the global market. Vitamins, minerals & supplements and the cough, cold & allergy segments account for more than 50% sales of OTC products globally.

There is a global trend towards self-care, self-medication, awareness for wellness and preventive medicine, along with a rise in disposable income, demand for personalised products, acceptance of e-commerce retail and shift to OTC products. This trend is expected to drive the growth of the industry in future.

WORLD OF SUN PHARMA

Sun Pharmaceutical Industries Limited including its subsidiaries and associates (Sun Pharma) is the fourth largest global specialty generic company that is ranked No. 1 in India and No. 8 in the US. It is the largest Indian pharmaceutical company in the US and among the leading Indian pharmaceutical companies in emerging markets.

Sun Pharma enjoys a vertically integrated business, economies of scale and good talent management practices that enable it to deliver quality products at affordable prices. The Company is deepening its global footprint as a highly trusted manufacturer of specialty products, branded generics, complex and pure generics, OTC products, anti-retrovirals (ARVs) and APIs.

It is expanding its footprint among consumers and healthcare professionals in 100+ countries, and offers a portfolio of 2,000+ products, globally, in a full range of dosage forms. This includes tablets, capsules, injectables, ointments, creams and liquids, nasal sprays and hormones, among others.

Sun Pharma has 44 manufacturing sites approved by global health regulatory agencies—supported by a worldwide supply chain—and multiple research and development (R&D) facilities across the world, investing 6.9% of its sales in R&D. It has a diverse employee base of 32,000+ individuals across 50 nationalities worldwide.



Table 5 Major acquisitions and joint ventures (JVs)

Years	Acquisition/JV	Markets	Rationale
1997	Acquired Caraco	USA	Entry into the US generics market
2010	Acquired Taro Pharmaceutical Industries Ltd.	Israel	Enhance presence in the US generics market, especially in the dermatology segment
2012	Acquired DUSA Pharma, Inc.	USA	Access to branded dermatology product
2013	Acquired URL's generics business	USA	Addition to the US generics portfolio
2014	Acquired Pharmeducence	USA	Access to sterile injectable capacity in the US, supported by R&D capabilities
2014	In-licensing agreement with Merck for ILUMYA™, a biologic for psoriasis	Global	Strengthen the specialty product pipeline
2015	Sun Pharma–Ranbaxy merger	Global	Further strengthen position as the fifth largest global specialty generics pharmaceutical company and the No. 1 pharmaceutical company in India, with strong positioning in emerging markets
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	Acquisition of InSite Vision	USA	Strengthen branded ophthalmic portfolio in the US
2016	Distribution agreement with AstraZeneca	India	Distribution services agreement in India for brands Oxra and Oxramet® (brands of dapagliflozin; used for diabetes treatment)
2016	Acquired 14 brands from Novartis	Japan	Entry into Japan
2016	Licensing agreement with Almirall for ILUMYA™ for psoriasis	Europe	Strengthen the distribution of ILUMYA™ in Europe
2016	Acquired Biosintez	Russia	Access to local manufacturing capability to enhance presence in the Russian market
2016	Acquired global rights for Cequa and Odomzo	Global	Strengthen specialty pipeline in the ophthalmology and oncology space
2018	Acquired Pola Pharma in Japan	Japan	Access to the Japanese dermatology market



Sun Pharma enjoys a good track record of value-accretive M&A transactions.

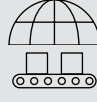
Sustainable value-creation model


US\$ 4.1 Bn

Global revenue as on March 31, 2019


100+

Global markets served


44

World-class manufacturing sites


2,000+

Products offered worldwide


32,000+

Global employee base

US business

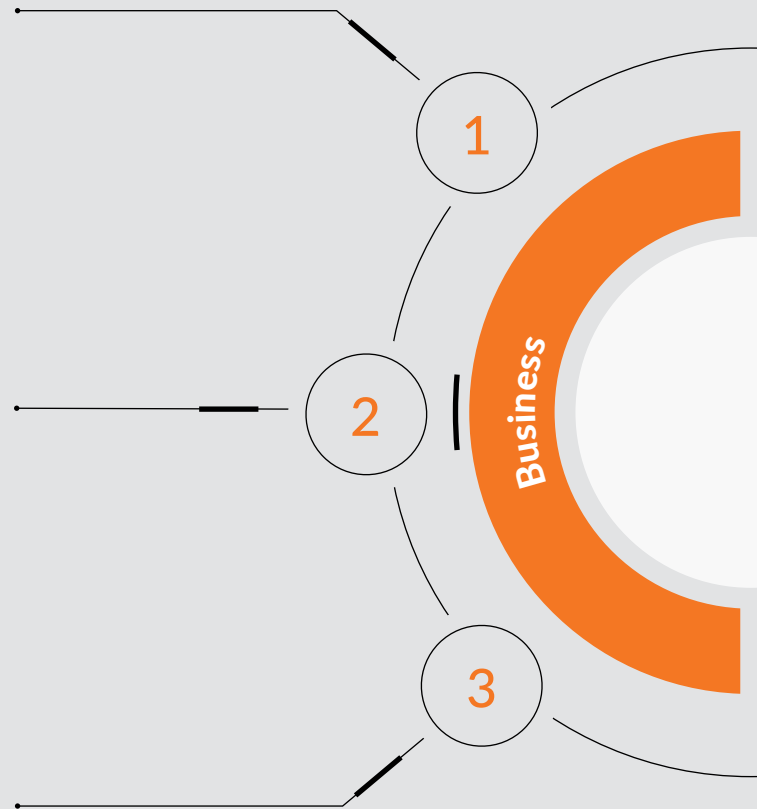
- 8th largest generics company in the US with a strong pipeline (118 ANDAs and 8 NDAs awaiting approval).
- Presence in generics, specialty and branded segments with 450+ approved products.
- FY19 sales: ₹106,713 Million.

Indian branded generics business

- Ranked No. 1 across 11 classes of doctors.
- Leading position in high growth chronic therapies.
- Specialises in technically complex products.
- FY19 sales: ₹73,483 Million.

Emerging markets

- Presence in ~100 countries across Africa, Americas, Asia and Eastern and Central Europe.
- Key focus geographies include Brazil, Mexico, Russia, Romania, South Africa and complementary and affiliated markets.
- FY19 sales: ₹53,624 Million.



Business features

Create sustainable revenue streams

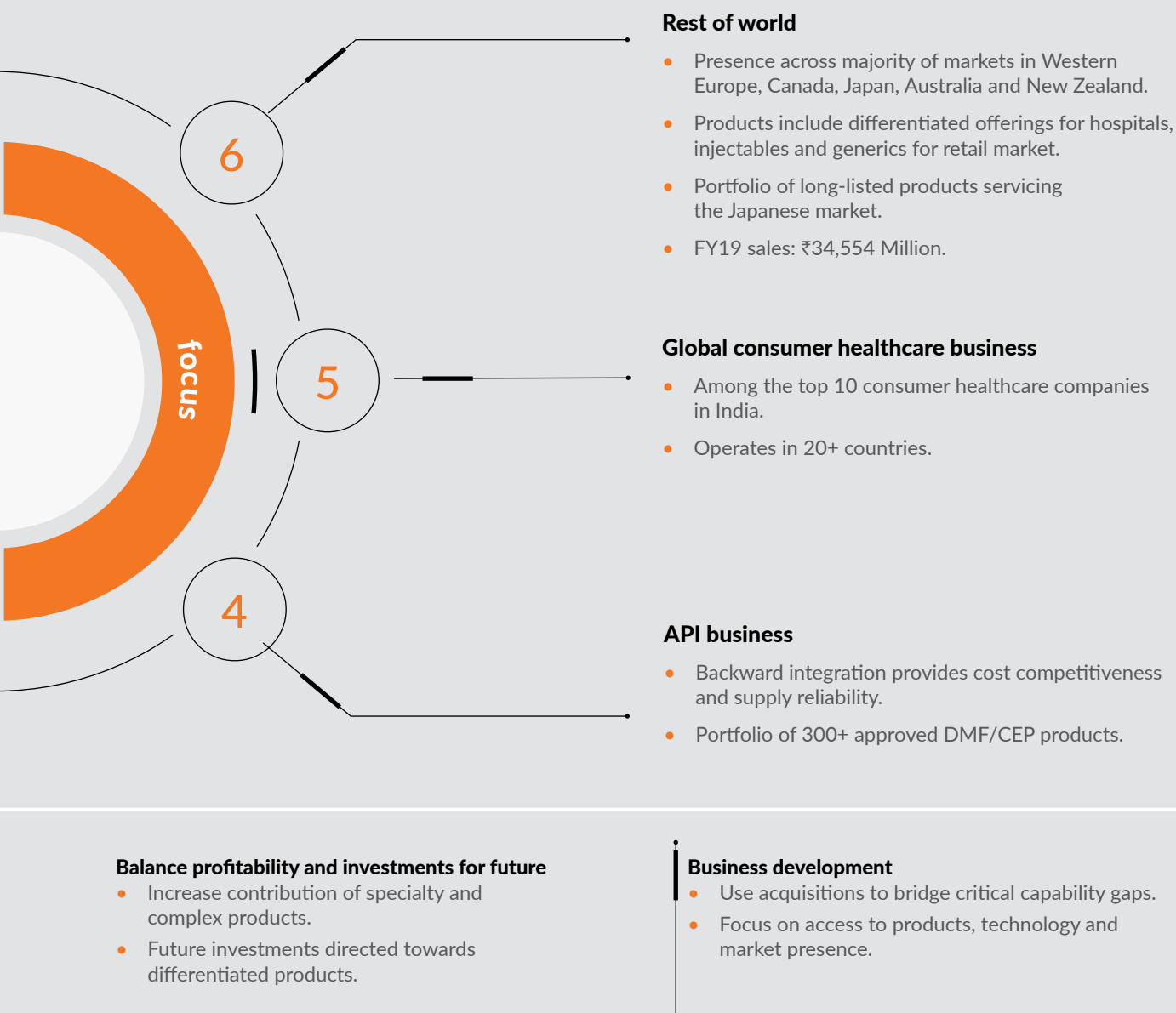
- Enhance share of specialty business globally.
- Achieve differentiation by focusing on technically complex products.
- Focus on key markets; achieve critical mass.
- Ensure sustained compliance with global regulatory standards.

Cost leadership

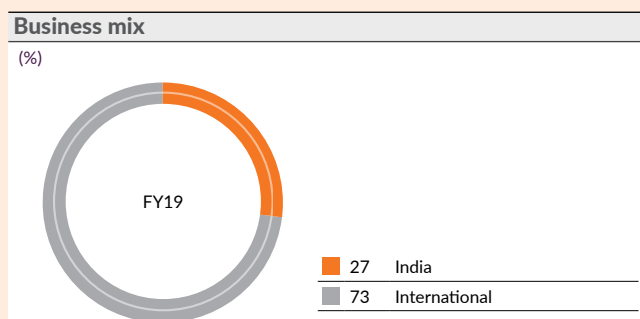
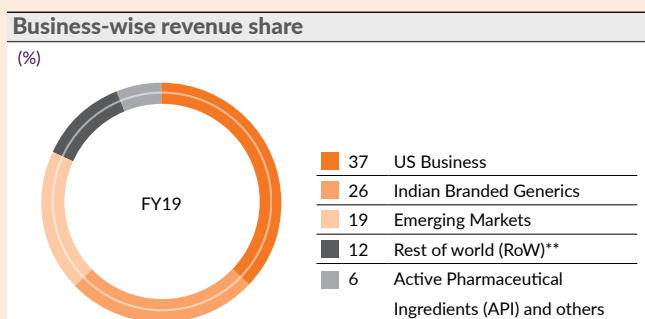
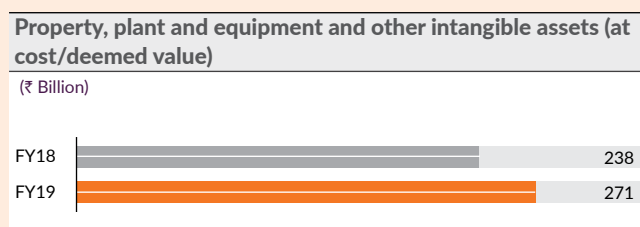
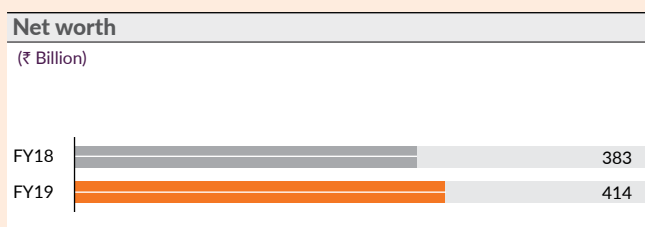
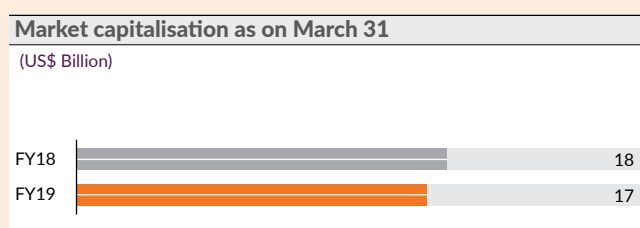
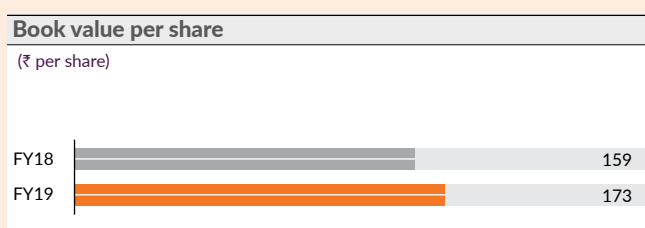
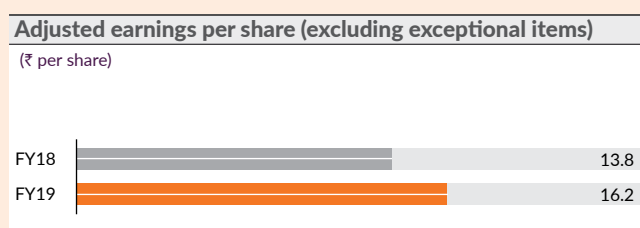
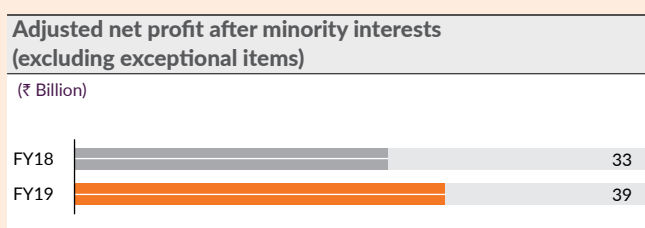
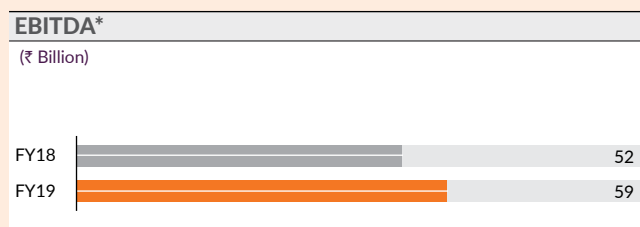
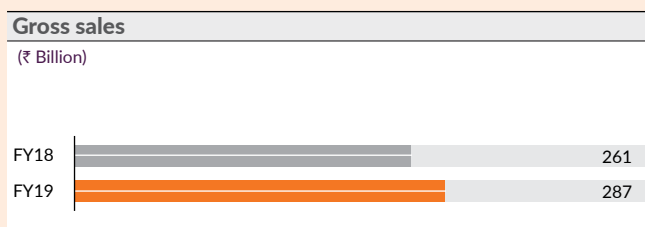
- Optimise operational costs.
- Rationalise vertically integrated operations.

ANDA: Abbreviated new drug application | NDA: New drug application | DMF: Drug master file | CEP: Certification of Suitability

Sun Pharma's business model comprises four crucial business features to help achieve higher efficiencies and drive sustainable growth. The Company is strategically poised to capitalise on the emerging opportunities in the global pharmaceutical sector, to deliver consistent long-term stakeholder value.



Key performance indicators



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

*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)

Financial ratios

Table 6 Consolidated

Ratios	Unit	FY19	FY18	Variance (%)
Return on net worth	%	6.4	5.5	18
Debtors turnover		3.2	3.3	-3
Inventory turnover (on cost of goods sold)		1.0	1.1	-8
Interest coverage ratio	times	10.0	9.6	5
Current ratio	times	1.8	1.6	13
Debt/Equity ratio	times	0.2	0.2	-4
Operating profit margin	%	20.7	19.9	4
Net profit margin	%	9.3	8.0	16

Table 7 Standalone

Ratios	Unit	FY19	FY18	Variance (%)	Reasons if variance is more than 25%
Return on net worth	%	3.6	1.4	161	Return on net worth is higher for the year ended March 31, 2019 due to higher profit after tax
Debtors turnover	times	1.9	1.7	17	
Inventory turnover (on cost of goods sold)	times	1.3	1.7	-21	
Interest coverage ratio	times	4.6	4.2	10	
Current ratio	times	0.8	0.8	10	
Debt/Equity ratio	times	0.3	0.3	-9	
Operating profit margin	%	12.6	8.5	49	On account of better revenue from contracts with customers which grew by 11%, along with cost containment
Net profit margin	%	8.3	3.5	140	On account of increased total revenue from operations by 14%, along with cost containment

FY19 operational highlights

- In April 2018, Sun Pharma entered the anti-fungal powder OTC category in India with ABZORB. The brand was co-promoted across prescription and OTC channels through a 360° marketing campaign comprising TV, print and digital, to expand consumer outreach and drive growth. ABZORB has a unique combination of talc and starch that ensures superior sweat absorption. It also contains clotrimazole—one of the best-in-class anti-fungals—to help treat infection and prevent its recurrence. The new packaging with an angular dispensing nozzle enhances consumer experience through targeted application.
- In May 2018, Sun Pharma received USFDA approval for YONSA® (abiraterone acetate), a novel formulation in combination with methylprednisolone to treat patients with metastatic castration-resistant prostate cancer (mCRPC). This approval has further strengthened the Company's oncology portfolio in the US.
- In June 2018, Sun Pharma received the Establishment Inspection Report (EIR) from the USFDA for the inspection conducted at its Halol facility in Gujarat (India) during the previous financial year. The receipt of the EIR implies that the issues contained in the Warning Letter dated December 2015 have been addressed. New ANDA approvals have commenced from the facility post the receipt of EIR.
- In July 2018, Sun Pharma announced Bollywood actor Akshay Kumar as its brand ambassador for Revital H. He is known for his high energy levels and was a natural fit for the product, which is India's leading and most trusted health supplement for over two decades. The Company launched a 360° marketing campaign featuring the actor and the brand that helps keep one's energy and stamina high throughout the day.
- In July 2018, Sun Pharma announced the USFDA approval for INFUGEM™ (gemcitabine in 0.9% sodium chloride injection) 10 mg/mL, for intravenous use in a ready-to-administer (RTA) bag. INFUGEM™ uses a proprietary technology, which allows cytotoxic oncology products to be premixed in a sterile environment and supplied to the prescribers in RTA infusion bags. It involves dose banding practice, whereby standardised doses of intravenous cytotoxic drugs are used for ranges (or 'bands') of doses calculated for individual patients. The RTA bags will provide greater safety by preventing problems of over-dosing or under-dosing, by eliminating contamination risk that can lead to infections, and by taking care of problems associated with and precautions to be taken while, handling cytotoxic drugs by healthcare providers.

- In July 2018, DUSA Pharmaceuticals, Inc., (DUSA) a wholly owned subsidiary of Sun Pharma, announced that it filed trade secret misappropriation and tortious interference claims in an ongoing patent infringement lawsuit against Biofrontera Inc. The patents-in-suit concerned an apparatus and method for photodynamic therapy (PDT) as well as an equipment for it. Pioneered by DUSA, PDT combines a drug with a light source to treat disease conditions. In December 2018, DUSA was granted preliminary injunctive relief by a federal district court prohibiting defendant Biofrontera (including Biofrontera Inc., Biofrontera Bioscience GmbH Biofrontera Pharma GmbH, and Biofrontera AG) from using DUSA's confidential and proprietary trade secret information.
- In August 2018, Sun Pharma received approval for CEQUA (cyclosporine ophthalmic solution) 0.09%, from the USFDA. CEQUA increases tear production in patients with dry eyes. It is the first and only approved dry eye treatment to combine cyclosporine A with nanomicellar technology.
- In August 2018, Sun Pharma launched a Kapsargo Sprinkle (metoprolol succinate) extended-release sprinkle formulation in the US. The product will help treat hypertension (high blood pressure), angina pectoris (chest pain) and heart failure. These extended-release coated pellets can be sprinkled over soft food or administered via a nasogastric tube to facilitate long-term once-daily administration for patients who experience difficulty while swallowing.
- In August 2018, the Company announced the launch of Volini Maxx, India's strongest pain relief spray. It also signed Virat Kohli, captain of Indian cricket team as Volini's brand ambassador.
- In September 2018, Sun Pharma announced USFDA approval for the NDA of XELPROS™ (latanoprost ophthalmic emulsion) 0.005%. The medicine is used for the reduction of elevated intraocular pressure (IOP or pressure inside the eye) in patients with open-angle glaucoma or ocular hypertension. XELPROS™ is the first and only form of latanoprost that is not formulated with benzalkonium chloride (BAK), a commonly used preservative in topical ocular preparations. It was in-licensed by Sun Pharma from Sun Pharma Advanced Research Company Ltd. (SPARC) in June 2015; and is developed using SPARC's proprietary swollen micelle microemulsion (SMM) technology.
- In September 2018, Sun Pharma announced that its European partner, Almirall, received the European Commission (EC) approval for ILUMETRI® (tildrakizumab) to treat adults with moderate-to-severe chronic plaque psoriasis, who are candidates for systemic therapy.
- In September 2018, Sun Pharma received the Australian Therapeutic Goods Administration (TGA) approval for its specialty product, ILUMYA™ (tildrakizumab) to treat adults with moderate-to-severe plaque psoriasis and are candidates for systemic therapy.
- In October 2018, Sun Pharma launched ILUMYA™ (tildrakizumab-asmn) 100 mg/mL in the US for treating moderate-to-severe psoriasis.
- In November 2018, Sun Pharma entered into a definitive agreement to acquire Pola Pharma Inc. (Pola Pharma), a Japanese pharmaceutical company. Pola Pharma is engaged in R&D, manufacture, sale and distribution of branded and generic products in Japan. Its portfolio primarily comprises dermatology products and it has two manufacturing facilities in Japan with capabilities to manufacture topical products and injectables, along with R&D capabilities to develop new technologies and formulations.
- Pola Pharma had annual revenues of approximately US\$ 108 Million and net loss of US\$ 7 Million for 12 months ended December, 2017 on a consolidated basis. This acquisition strengthens Sun Pharma's presence in Japan and accelerates access to the Japanese dermatology market.

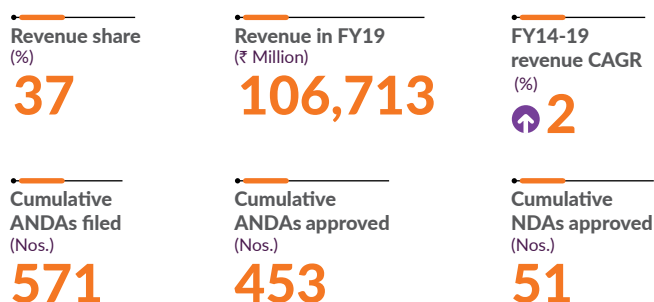
FY20 outlook

Sun Pharma's sustained focus is on growing each of its businesses faster than the market in which they operate. Its global specialty initiatives will supplement this objective as an additional growth engine. Although the US generics industry continues to face pricing pressure, the industry has started responding to these challenges by rationalising product portfolios and discontinuing non-remunerative products. Generics will continue to be an integral part of the solution to control global healthcare costs as well as play an important role in overall healthcare management.

Sun Pharma will continue to invest in the generic business with a focus on developing differentiated complex generics and building a product pipeline across markets. Its global specialty business is also expected to ramp up gradually. Investments in branding and promotion of specialty products and in funding clinical trials for specialty products will continue. For FY20, the Company expects its consolidated revenues to grow by low-to-mid teens, while R&D investments are estimated at ~8-9% of sales.

Business segment review

US BUSINESS



The Company's key focus areas encompass central nervous system (CNS), dermatology, cardiology, oncology and ophthalmic, among others. It has integrated USFDA-approved on-shore as well as off-shore manufacturing facilities that produce a variety of dosage forms, including liquids, creams, ointments, gels, sprays, injectables, tablets, capsules and drug-device combinations.

Strong product pipeline in the US

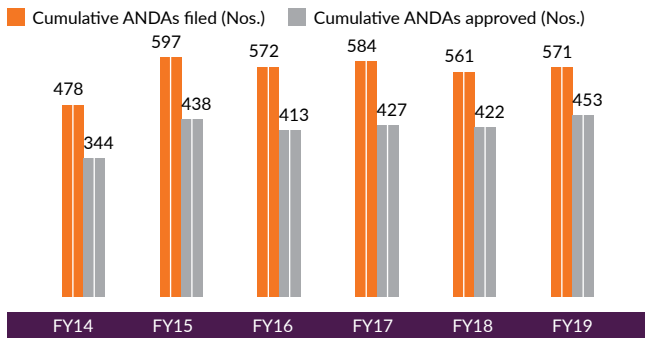
As on March 31, 2019, Sun Pharma had 118 ANDAs and 8 NDAs pending USFDA approval, including a combination of complex generics, patent challenge opportunities and pure generics.

Sun Pharma is the eighth largest generic pharmaceutical company in the US, with presence across generics, specialty, branded and OTC segments. It offers a comprehensive portfolio of 453 ANDAs and 51 NDAs approved across multiple therapies.

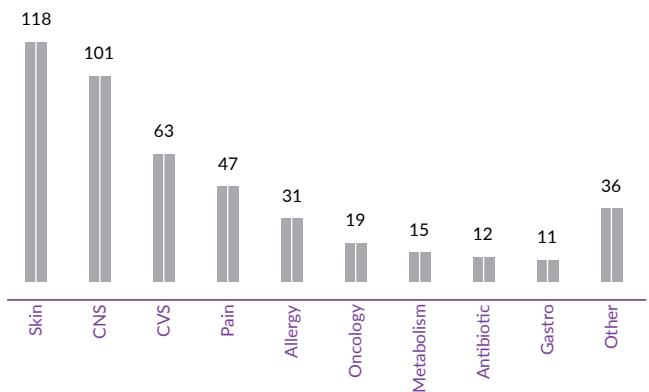
Table 8	Journey in the US - key milestones
Years	Events
FY98	<ul style="list-style-type: none"> Entered the US market through Caraco acquisition.
FY10	<ul style="list-style-type: none"> Acquired Taro Pharma to penetrate the US dermatology market.
FY13	<ul style="list-style-type: none"> Acquired DUSA to enter the branded specialty dermatology market.
FY15	<ul style="list-style-type: none"> In-licensed Ilumya (tildrakizumab)–strengthened specialty dermatology portfolio by gaining access to global rights including the US.
FY16	<ul style="list-style-type: none"> Strengthened specialty ophthalmic portfolio with the acquisition of InSite Vision.
FY17	<ul style="list-style-type: none"> Filed tildrakizumab in the US and Europe. Acquired Ocular Technologies–gaining access to Cequa—a product for treating dry eyes. Launched BromSite in the US ophthalmology segment. Acquired odomzo, a branded oncology product from Novartis.
FY18	<ul style="list-style-type: none"> Launched Odomzo in the US. Obtained USFDA approval for Ilumya.
FY19	<ul style="list-style-type: none"> Launched specialty products–Ilumya, Yonsa and Xelpros–in the US. Received USFDA approval for Cequa.

FY19 highlights

- Revenue from the US increased by 22% to ₹106,713 Million.
- Key growth drivers include increase in generic sales, incremental contribution from specialty product launches and a favourable foreign exchange rate.
- The US generic market continued to be highly competitive and witnessed price erosion, driven by higher bargaining power of customers and faster pace of generic approvals from the USFDA.

Chart 5 ANDAs filed and approved


(Cumulative numbers for FY16 are lower than FY15 due to Bryan facility divestment. Ranbaxy numbers added with effect from March 2015)

Chart 6 ANDA approvals by therapeutic area as of March 2019


Road ahead

Patent expiries and the US government's focus on reducing healthcare costs will continue to favour the growth of low-cost generics in the US market.

Going forward, the Company will focus on:

- Growing the share of specialty product revenues in its portfolio.

- Emphasising on complex generics and high-entry barrier segments.
- Ensuring a diversified offering to customers across multiple dosage forms.
- Sustaining and improving high service standards for customers.

INDIAN BRANDED GENERIC BUSINESS

Revenue share (%)

26

Revenue in FY19 (₹ Million)

73,483

FY14-19 revenue CAGR (%)

15

Market position with 8.2% market share⁹

No.1

Rank across prescriptions from 11 different classes of doctors¹⁰

No.1

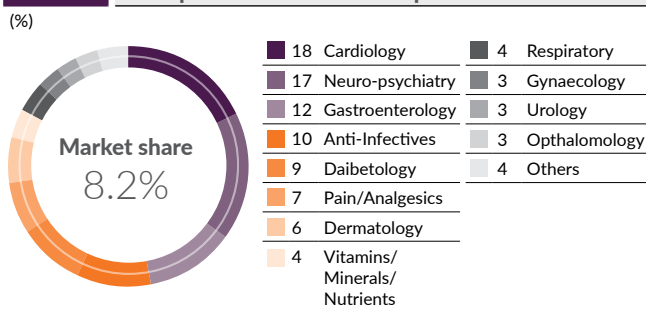
Sun Pharma continues to be the undisputed industry leader in India, enjoying 8.2% share of the market. The Company is also the market leader in the chronic segment. It specialises in technically complex products and offers a comprehensive therapy basket. It enjoys a strong brand positioning with 30 brands featuring in the country's top 300 pharmaceutical brands list.

Industry-leading productivity

The Company has a 9,500+ strong field force that ensures it reach to 4 lakh+ doctors across India. The Company's well-trained team of sales representatives, powered by scientific knowledge, has a strong performance track record with the highest productivity in the industry.

FY19 highlights

- Revenue from the Indian branded generic business declined by 8.5% to ₹73,483 Million.
- The Company has decided to transition its India formulations distribution business from a third-party distributor to the Company's wholly-owned subsidiary with effect from April 1, 2019. As a part of this strategy shift, the Company undertook a one-time adjustment relating to sales return from the distributor and lower invoicing to this distributor, totalling ~₹10,850 Million. This has led to the year-on-year decline in sales. Excluding this one-time impact, the India formulations revenues would have grown by about ~5% year on year.

Chart 7 Therapeutic revenue break-up⁹

Table 9 Leadership in prescription rankings¹⁰

Specialist	February 2018	February 2019
Psychiatrists	1	1
Neurologists	1	1
Cardiologists	1	1
Orthopaedic	1	1
Gastroenterologists	1	1
Nephrologists	1	1
Diabetologists	1	1
Ophthalmologists	1	1
Dermatologists	1	1
Urologists	1	1
Oncologists	1	2
Consulting physicians	1	1
Chest physicians	1	2

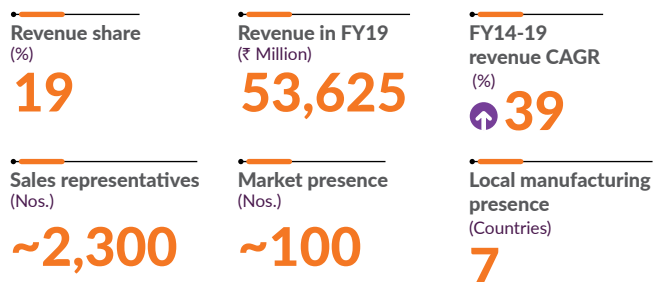
Road ahead

India's pharmaceutical market growth is expected to be driven by increasing per capita income, rising healthcare awareness, higher incidence of chronic ailments and gradually widening insurance coverage. Despite these tailwinds, the pharmaceutical companies face key challenges, which include government-mandated price controls, regulatory changes and intense competitiveness.

Sun Pharma's key priorities comprise:

- Consistent innovation as a definite roadmap to ensure high brand equity with doctors.
- Product basket enhanced developed through own development and in-licensing.
- Focus on improving productivity to maintain industry leadership.

EMERGING MARKETS



The focus markets for this segment include Brazil, Mexico, Russia, Romania, South Africa and complementary and affiliated markets.

The Company offers an extensive array of branded products and leverages its strong marketing infrastructure through its ~2,300-member strong sales force. This enables enduring relationships with doctors and medical practitioners.

The Company enjoys local manufacturing facilities, enabling reduction in logistics cost, across 7 countries.

FY19 highlights

- Revenue from emerging markets increased by 11% to ₹53,625 Million.
- Key markets, which contributed to the growth were Romania, South Africa, Brazil, Malaysia and Bangladesh, coupled with a favourable foreign exchange rate.

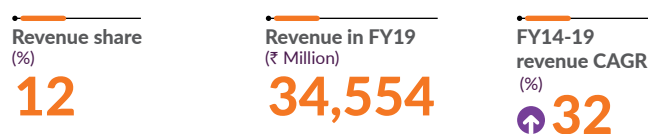
Road ahead

The favourable macroeconomic parameters of emerging markets offer encouraging long-term potential, which is expected to be partly offset by the various government efforts to make pharmaceutical products more affordable for all.

Going forward, the Company will:

- Focus on developing and commercialising more products across therapeutic segments to exploit growth opportunities.
- Explore organic and inorganic options to widen and deepen footprint in key markets.
- Strengthen business profitability by launching complex products and reducing presence in low profitable, non-core product segments.

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



Sun Pharma is among the leading Indian companies that has a presence across major markets of Western Europe, Canada, Australia, New Zealand and Japan, among others. Across these geographies, the Company offers a wide range of products, including injectable and hospital products, as well as products for retail market. It also has a portfolio of long-listed products in the Japanese market.

The Company primarily focuses on the development and commercialisation of complex generics and differentiated products for these markets. It has adopted a distribution-led business model to enhance its reach across these markets and caters to them through local manufacturing in Canada, Japan, Israel and Hungary, along with support from its India units.

Expanding presence in Japan

Sun Pharma had acquired 14 established prescription brands from Novartis in March 2016. During FY19, it acquired Pola Pharma in Japan, to strengthen its presence in the Japanese dermatology segment.

FY19 highlights

- Revenue from rest of the world increased by 16% to ₹34,554 Million.
- The growth was driven in part by contribution from the Pola Pharma acquisition in Japan, increase in sales in some of the western European markets and a favourable exchange rate.

Road ahead

With demographic changes across these markets, especially in Western Europe and Japan, enhanced drug demand for geriatric care and chronic diseases will drive pharmaceutical consumption. Additionally, the adoption of newer specialty products as well as government policies to promote low-cost generics will propel growth in these markets.

Sun Pharma will focus on:

- Ramping up its presence in Japan.
- Commercialising its specialty products, especially Ilumya, in key markets either on its own or through partnerships.

GLOBAL CONSUMER HEALTHCARE BUSINESS

Key brands (No.)	International presence (No. of markets)	Ranked amongst top 10 players (No. of markets)
20	20+	4

Sun Pharma ranks among India's top 10 consumer healthcare companies. Globally, it operates in 20+ countries, of which Romania, Russia, South Africa, Nigeria, Myanmar, Ukraine, Poland, Thailand, Belarus, Kazakhstan, Morocco and the UAE are the focus markets. The Company is also counted among the top 10 consumer healthcare companies in Romania, Nigeria and Myanmar.

Road ahead

India's consumer healthcare market will be driven by the emerging middle class and rising healthcare consumption. Emerging markets are expected to sustain growth steered by enhanced healthcare awareness.

Capitalising on these enablers, Sun Pharma will:

- Continue to invest in the accelerating OTC business across key markets through brand building.
- Focus on distribution expansion through brand extensions.
- Expand presence across OTC sub-categories in various markets.

Specialty in progress

- Sustain leadership in existing markets by offering innovative products and packaging.
- Evaluate new emerging markets for entry.

ACTIVE PHARMACEUTICAL INGREDIENTS (API) BUSINESS

Revenue share (%)	Revenue in FY19 (₹ Million)	FY14-19 revenue CAGR (%)
6	17,302	17
DMF/CEP filings* (Nos.)	DMF/CEP approvals* (Nos.)	Manufacturing units (Nos.)
413	305	14

*as on March 31, 2019

Sun Pharma started producing APIs in 1995 to strengthen backward integration to drive cost competitiveness and supply reliability.

The API business is of strategic importance for Sun Pharma, as a significant portion of the API production acts as inputs for its formulations business. Besides captive consumption, the Company also supplies APIs to external customers across many international markets.

FY19 highlights

- Revenue from Active Pharmaceutical Ingredients (API) business increased by 24% to ₹17,303 Million.
- Key growth drivers include new contracts, better realisations and a favourable foreign exchange rate.

Road ahead

Key focus areas for the future will be:

- Timely development and commercialisation of strategic APIs for captive consumption.
- Expansion in the scale and scope of API operations.
- Development and sustenance of enduring supply relationships with customers.

Research and development

R&D spend as % of FY19 sales (%)	Cumulative R&D spend till date (₹ in Billion)	Team of scientists worldwide (Nos.)
6.9	150+	~2,000

Sun Pharma has consistently invested in R&D for sustainable value creation. It services both regulated and emerging pharmaceutical markets with a diverse product range of branded and generics products. The Company's R&D capabilities enable it to develop technology-intensive products and deliver them at affordable prices across international markets.

Sun Pharma's R&D centres are equipped with cutting-edge technologies, where its scientists develop generics,

difficult-to-make technology-intensive products, APIs and novel drug delivery systems (NDDS). Additionally, the Company is focusing on the development of new chemical entities (NCEs) for global markets and has made significant investments in this domain. It also has a dedicated intellectual property rights (IPR) team, with internal and external lawyers, that supports its R&D efforts.

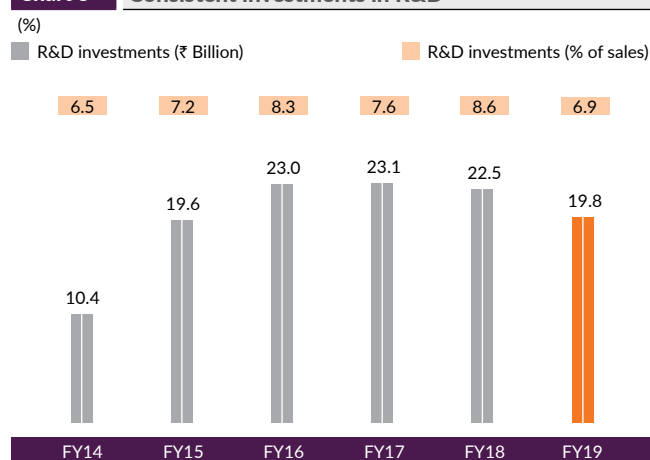
The Company has the capability to develop and commercialise a wide product range with successful offerings across different dosage forms such as gels, injectables, sprays, ointments, liquids and oral products, among others. Sun Pharma also manufactures liposomal products, auto-injectors, lyophilized injections, nasal sprays, and controlled release dosage forms.

Sun Pharma is focusing on the development of non-infringing formulations and expansion of the specialty/complex products portfolio. Its R&D spend is sustained by strong cashflows and large scale of the Company.

Going forward, the Company's R&D efforts will be focused at:

- Developing complex/differentiated generic products for global markets.
- Developing specialty products to enhance the specialty portfolio.

Chart 8 Consistent investments in R&D



Global manufacturing competence

Sun Pharma enjoys world-class production facilities spanning the five continents of Asia, Europe, Africa, North America and Australia. It owns 44 state-of-the-art manufacturing units that produce formulations and APIs. The Company enjoys vertically integrated operations that equip it to maintain a high-quality and low-cost value chain for timely market entry across geographies.

It has manufacturing units located in India, the US, Canada, Japan, Hungary, Israel, Russia, Egypt, Bangladesh, Nigeria, South Africa, Malaysia and Australia. These facilities are responsible for seamless production of oncology, hormones, peptides, controlled substances and steroidal drugs. They also manufacture generics, branded generics, specialty products, OTC products, ARVs and APIs, along with intermediates in the full range of dosage forms: tablets, capsules, injectables, ointments, creams and liquids.

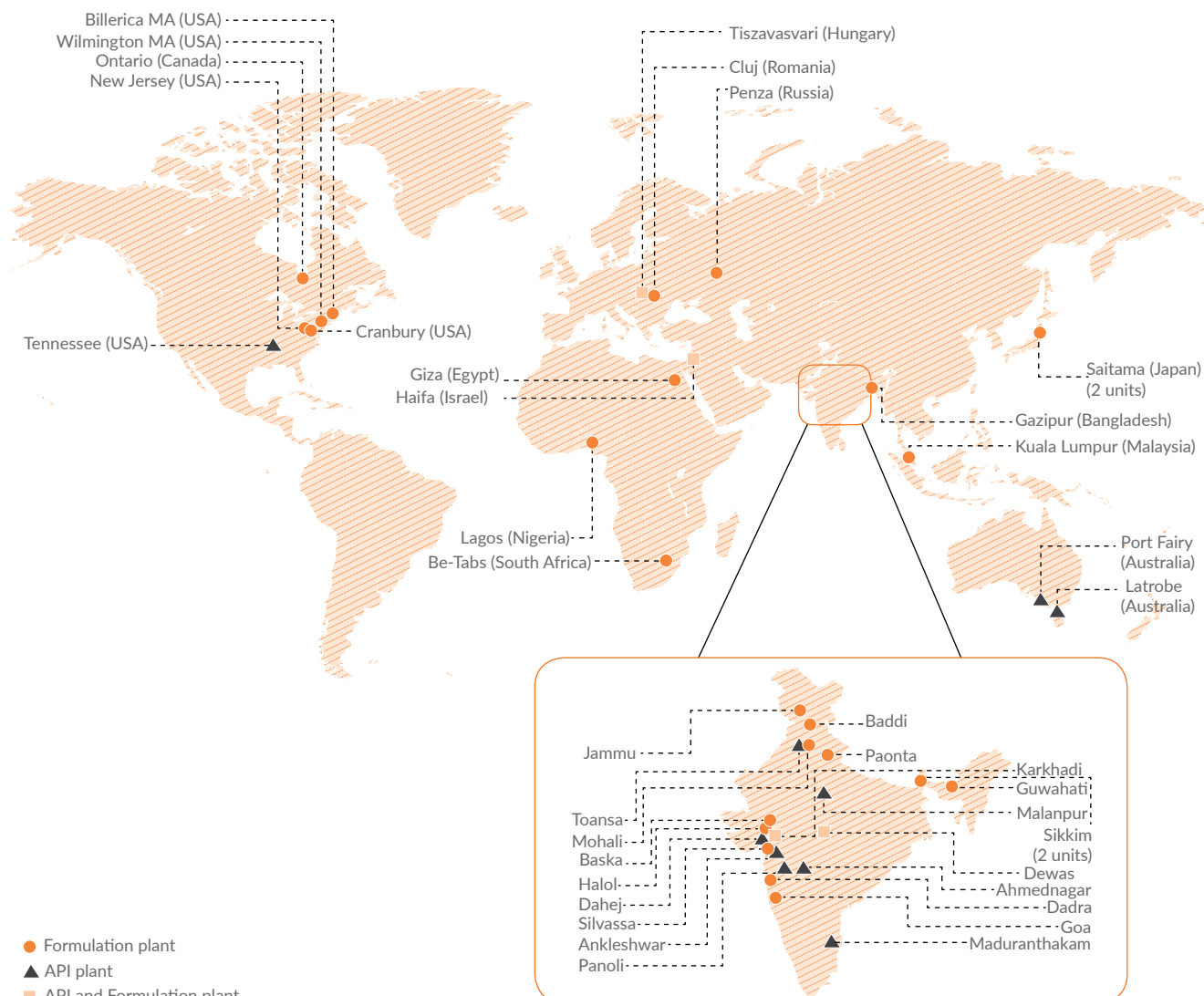
The Company has an expert team of regulatory affairs specialists, who are well-versed with the globally-relevant regulatory policies and procedures. They are experienced in timely filing of dossiers and concurrently managing the regulatory queries and timelines of regulatory authorities.

Sun Pharma meticulously follows global manufacturing standards and many of its manufacturing units are certified by regulatory authorities 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 also enjoys certifications by the Brazilian Health Regulatory Agency (ANVISA), the World Health Organization (WHO), South Korea's Ministry of Food and Drug Safety, and Japan's Pharmaceuticals and Medical Devices Agency. It emphasises on 24x7 compliance to Current Good Manufacturing Practice (cGMP) regulations, which is vital for a global business.

Table 10

Global Manufacturing Capability		
	Finished dosage manufacturing	API manufacturing
Total number of sites	30	14
Locations	India (14)	India (9)
	USA (4)	Australia (2)
	Japan (2)	Israel, USA and Hungary (1 each)
	Canada, Hungary, Israel, Bangladesh, South Africa, Malaysia, Romania, Egypt, Nigeria and Russia (1 each)	
Capability	<ul style="list-style-type: none"> • Orals: Tablets/Capsules, semisolids, liquids and suppository. 	<ul style="list-style-type: none"> • Controlled substances manufactured in Australia.
	<ul style="list-style-type: none"> • Injectables/Sterile: Vials, ampoules, pre-filled syringes, gels, lyophilized units, dry powder, eye drops and aerosols. 	<ul style="list-style-type: none"> • Standalone units for peptides, anti-cancer, steroids and sex hormones.
	<ul style="list-style-type: none"> • Topicals: Creams and ointments. 	

Global manufacturing footprint



Building an empowered team

Sun Pharma has a global strength of 32,000+ permanent team members across 50 different nationalities. It considers its people vital to its success and thus, endeavours to provide them with a congenial work culture that promotes work-life balance, provides growth opportunities and rewards and recognises talent.

The Company undertakes significant measures to help its people develop various skills through different training programmes. Sun Pharma promotes a culture of inclusive growth in the organisation to enrich knowledge and make its people future ready.

Quality adherence

Quality is sacrosanct at all Sun Pharma R&D centres, manufacturing units and testing and distribution facilities. The Company is committed to implementing a robust quality management system and sustains a culture of operational excellence and meeting and exceeding stakeholder expectations.

Sun Pharma believes in the motto of 'putting patients first' and its global Quality Management Team ensures every product complies with internationally accepted good practices and standards of quality, purity, efficacy and safety.

The Company has put stringent checks in place to conform to global quality standards and ensures compliance with the requirements of various regulators. It has cGMP certifications from various global regulatory authorities like USFDA, EMA, WHO and TGA, among others.

Sun Pharma has well-trained personnel for quality control at each site, who, along with a regulatory affairs department, ensure strict adherence to quality systems and procedures. The teams are guided by a Corporate Quality Unit, which oversees the translation of the latest GMP updates to guidelines, standard operating procedures (SOPs) and protocols. The Company's manufacturing plants are audited by an autonomous Corporate Compliance Department to set up 24x7 compliance and conformance.

Going ahead, Sun Pharma will continue to ensure 24x7 compliance to cGMP as an imperative for a global business. It will continue to enhance systems, processes

and human capabilities to ensure compliance with global regulatory standards.

During the year, the USFDA granted an EIR to the

Company's Halol facility, thus lifting the warning letter issued to the facility in 2015. Post the receipt of the EIR, the Company has started receiving new approvals from USFDA for the US market.

Table 11 SWOT analysis

Strengths	Opportunities	Threats and weaknesses
<ul style="list-style-type: none"> Global presence – 4th largest global specialty generic company. <ul style="list-style-type: none"> 8th largest generics company in the US. Largest company in India by market share. Among the largest Indian pharmaceutical company in emerging markets. Among the largest Indian pharmaceutical company in Japan. Strong R&D skillsets to develop technologically complex products in the generic and specialty space. Ability to drive growth and profitability through a pragmatic mix of organic and inorganic initiatives. Ability to supply high-quality products at affordable prices. 	<ul style="list-style-type: none"> Global efforts to reduce healthcare costs augur well for companies like Sun Pharma. Favourable macroeconomic variable for India and emerging markets are likely to ensure reasonable volume growth for pharmaceutical products in these markets. Contribution of specialty products is expected to increase in developed markets over the medium to long term. Sun Pharma forayed into this segment some years back; and is in the process of gradually ramping up this business as an additional growth engine. Growing penetration of generics in Japan and opening of the China market, present a good long-term opportunity for Indian companies including Sun Pharma. 	<ul style="list-style-type: none"> Challenging US generic pricing environment driven by customer consolidation and faster pace of generic drug approvals by the USFDA. Continuous upgradation of cGMP manufacturing standards by global regulatory agencies requires constant upgradation of facilities, resulting in higher compliance costs for the industry. Government-mandated price controls on pharmaceutical products. The specialty initiative entails high upfront investments for long-term benefits, thus impacting the short-term profitability. Significant volatility in the forex market, especially for emerging market currencies, may adversely impact growth reported for a particular period.

Internal control

The Company believes that internal control is a necessary prerequisite of governance and that freedom should be exercised within a framework of checks and balances. Sun Pharma 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 ensure 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 GIA at the corporate level carries out risk-focused audits across all businesses (both in India and overseas), to ensure that business process controls are adequate and are functioning effectively. These audits include reviewing finance, operations, safeguarding of assets and compliance related controls. Areas requiring specialised knowledge are reviewed in partnership with external subject matter experts.

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 audit, Internal Financial Controls (IFC) and Enterprise Risk Management (ERM) modules.

The Company's operating management closely monitors the internal control environment and ensures that the recommendations of GIA are effectively implemented. The Audit Committee of the Board monitors performance

of GIA, periodically reviews key findings and provides strategic guidance.

Disclaimer

Statements in this 'Management Discussion and Analysis' describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events are 'forward-looking statements' within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied. Important factors that could make a difference to the Company's operations include global and Indian demand supply conditions, finished goods prices, feedstock availability and prices, competitors' pricing in the Company's principal markets, changes in Government regulations, tax regimes, economic conditions within India and the countries within which the Company conducts businesses and other factors, such as litigation and labour unrest or other difficulties. The Company assumes no responsibility to publicly update, amend, modify or revise any forward-looking statements, based on any subsequent development, new information or future events or otherwise except as required by applicable law. Unless the context otherwise requires, all references in this document to 'we', 'us' or 'our' refers to Sun Pharmaceutical Industries Limited and consolidated subsidiaries.

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