

SUN PHARMACEUTICAL INDUSTRIES LTD.



# NURTURING SPECIALTY GROWTH

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ANNUAL REPORT 2017-18

Reaching People. Touching Lives.





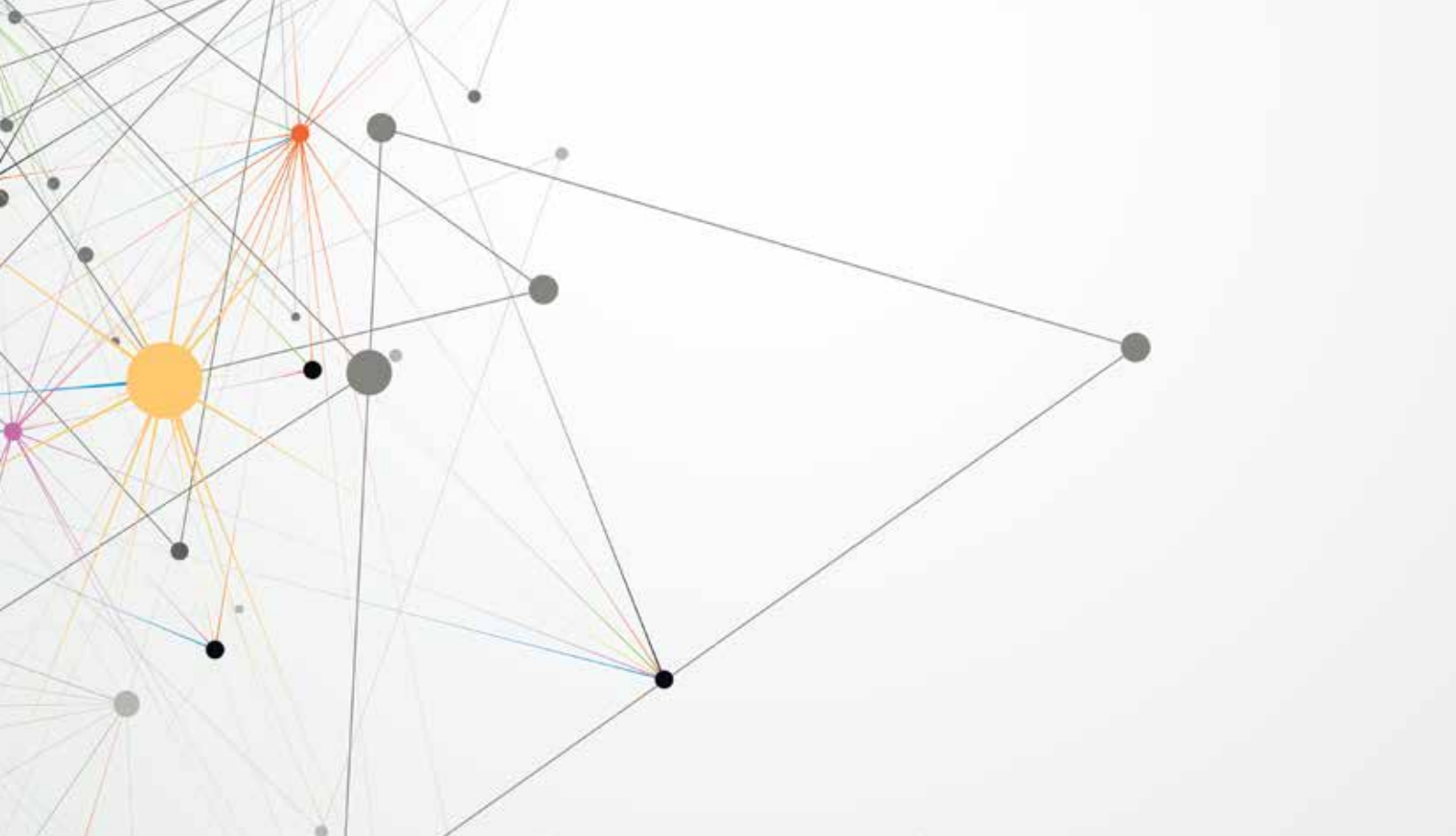
## Nurturing Specialty Growth

*Given the shifting dynamics of the global pharmaceutical market, progressive investments in innovative specialty products show the way forward for us.*

*At Sun Pharma, we have identified specialty as an additional growth engine; and a means to move up the pharmaceutical value chain through development and global commercialisation of branded patented products. We have invested significant resources in this initiative in the past; and will continue to invest in building the business further in the coming years.*

*We are meticulously nurturing the specialty business; and have built a portfolio of about 10 specialty products, of which five are already in the market, two more likely to be commercialised in the next few quarters; and two more awaiting USFDA approval.*

*The current financial year is likely to be a very important year in this journey with the potential launch of key specialty products in the US market. We are reinforcing our global specialty business with focused investments and strategies; and in the long-term, we expect the contribution of specialty products to increase substantially in our overall business.*



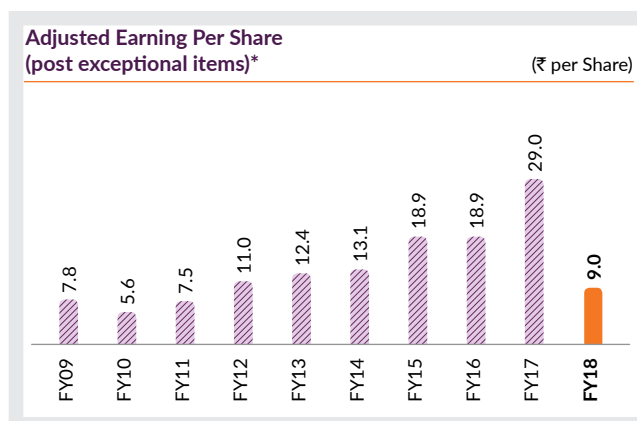
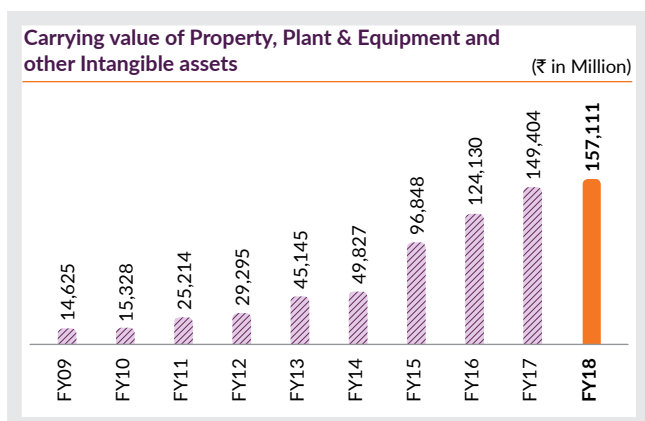
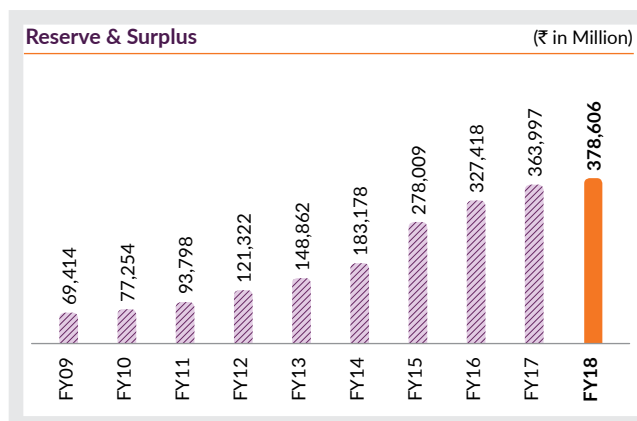
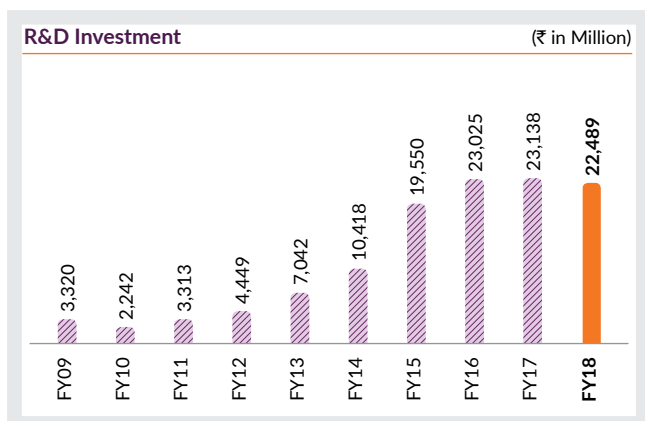
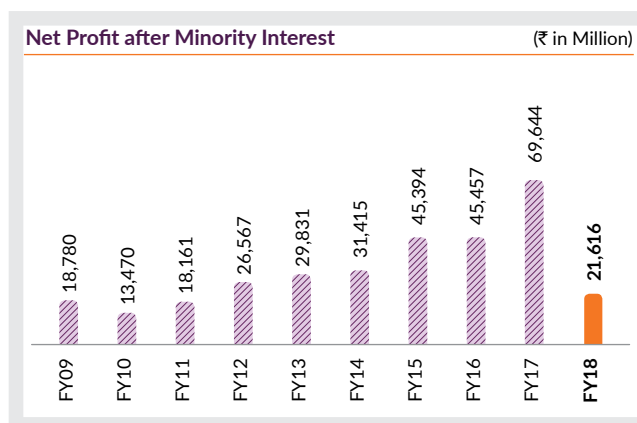
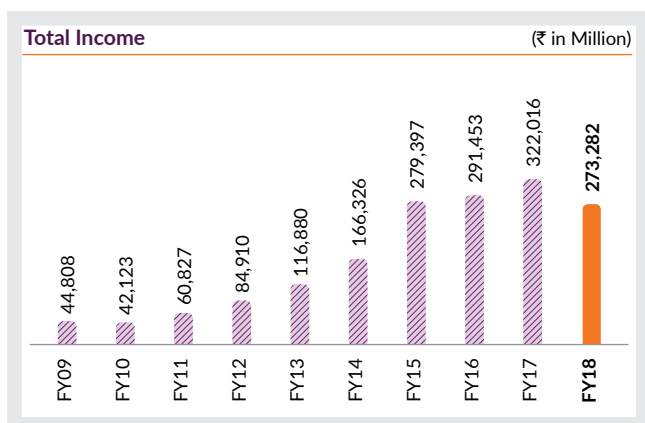
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The cover design of this year's annual report focuses on the theme of 'Nurturing Specialty Growth'. The visual treatment to help convey this sentiment has been developed around the idea of connectivity, direction, the sum of parts, particles, and science being the cornerstone of any development and future growth.

# Key Performance Indicators (Consolidated)



\* During FY11, each equity share of ₹5 was split into five equity shares of ₹1 each.

\* During FY14, the Company issued bonus shares in the ratio of one equity share of ₹1 for every share held.

\* During FY16, the Company's equity shares have increased to 2,407 Million due to the merger of erstwhile Ranbaxy Laboratories Ltd. (RLL) with the Company, wherein 0.80 equity share of ₹1 each of the Company have been allotted to the shareholders of RLL for every 1 share of ₹5 each held by them.

The Company has adopted Ind-AS accounting standards with effect from 01 April, 2015. Hence, FY16 onwards, the financials are reported as per Ind-AS and are not strictly comparable with previous years. For FY15, the balance sheet items are as per Ind-AS.

# Ten-Year Financial Highlights (Consolidated)

										(₹ in Million)
Particular	FY09	FY10	FY11	FY12	FY13	FY14	FY15	FY16	FY17	FY18
<b>Operating Performance</b>										
Revenue from Operations	43,751	38,086	57,279	80,195	112,999	160,804	273,920	284,870	315,784	264,895
Total Income	44,808	42,123	60,827	84,910	116,880	166,326	279,397	291,453	322,016	273,282
Net Profit for the year (after minority interest)	18,780	13,470	18,161	26,567	29,831	31,415	45,394	45,457	69,644	21,616
R&D Expenditure	3,320	2,242	3,313	4,449	7,042	10,418	19,550	23,025	23,138	22,489
a) Capital	222	159	236	362	427	556	1,178	783	1,679	1,819
b) Revenue (Excluding Depreciation)	3,098	2,083	3,077	4,088	6,616	9,862	18,373	22,242	21,459	20,669
c) % of Turnover	8.0%	6.0%	6.0%	5.6%	6.3%	6.5%	7.2%	8.3%	7.6%	8.6%
<b>Financial Position</b>										
Equity Share Capital	1,036	1,036	1,036	1,036	1,036	2,071	2,071	2,407	2,399	2,399
Reserve and Surplus	69,414	77,254	93,798	121,322	148,862	183,178	278,009	327,418	363,997	378,606
Property, Plant & Equipment and other Intangible assets (at cost/ deemed cost)	21,476	23,340	45,473	54,269	75,763	86,505	143,616	187,212	217,315	238,073
Carrying value of Property, Plant & Equipment and other Intangible assets	14,625	15,328	25,214	29,295	45,145	49,827	96,848	124,130	149,404	157,111
Investments	18,595	31,664	26,557	22,129	24,116	27,860	35,028	18,299	11,919	71,429
Net Current Assets	35,485	28,542	58,622	76,749	86,618	126,969	135,488	167,973	150,666	117,716
<b>Stock Information</b>										
Number of Shares (Million)	207	207	1,036	1,036	1,036	2,071	2,071	2,407	2,399	2,399
Adjusted Earning per Share (post exceptional items) (In ₹)*	7.8	5.6	7.5	11.0	12.4	13.1	18.9	18.9	29.0	9.0
Earnings per Share-Basic (In ₹)*	87.8	65.2	17.5	25.7	28.8	15.2	18.9	18.9	29.0	9.0
Earning per Share-Diluted (In ₹)*	87.8	65.2	17.5	25.7	28.8	15.2	18.9	18.9	29.0	9.0

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# Managing Director's Letter



## Dear Shareholders,

The global pharmaceutical industry offers significant opportunities to service the healthcare needs of a growing and ageing global population. The industry has witnessed major investments in developing innovative medicines like monoclonal anti-bodies, immunotherapy drugs and gene therapies. Many of these medicines have seen significant success as they are serving the unmet medical needs of patients, resulting in improved medical outcomes and thus changing the lives of patients. However, pricing in key markets like the US has come under severe pressure in the last two years. The industry will have to adapt to this changed scenario, although it also offers significant learning opportunities.

These changing dynamics are also likely to have an impact on competition since return ratios on investments in the US generics business are coming down and not every generics company will be able to remain economically viable at the current rate of price erosion. As a result, companies will have to optimise their future R&D investments.

The US generics market has been an important driver of growth and profitability for Indian pharmaceutical companies between 2005-15. However, now with the changed dynamics, the importance of other markets has increased. It has also become imperative for companies to identify new engines of growth and invest more in innovation. It is in this context, that Sun Pharma has been investing in building its global specialty business since the last few years. Through this initiative we are trying to gradually move up in the pharmaceutical value chain.

The other key focus area for us will be cost control and product rationalisation, with these efforts spread across R&D projects, manufacturing footprint and other areas. These steps will ensure that we continue to earn reasonable returns on our investments.

## Highlights of FY18

As guided at the start of the fiscal, FY18 was a tough year. While we witnessed a decline in our financial performance for the year, the challenges also offer us an opportunity to improve our processes and hence emerge as a much stronger company. Our FY18 revenues degrew by 14% to ₹261 Billion mainly due to decline in our US sales. We have recorded steady growth in all other markets except the US.

## Operational Performance

Revenues in the US declined 34% to US\$ 1.36 Billion due to higher base of FY17 wherein we had the benefit of 180-day exclusivity on generic Imatinib. Our subsidiary Taro recorded 25% decline in overall revenues for the year. This decline was mainly driven by more intense competition among manufacturers, new entrants to the market, buying consortium pressures, and a higher ANDA approval rate from the USFDA.

We recorded a 4% growth in our India formulations business. Overall growth for the domestic market was impacted by the temporary disruption in the trade channel due to the implementation of the Goods & Services Tax (GST) during the year. Adjusted for this impact, our India revenues have grown by about 9%.

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 20% for the year.

## R&D

R&D is the backbone of our business and a key determinant of our future growth and profitability. Our efforts to move up the pharmaceutical value chain mandate that we keep investing in R&D. Our R&D investments for the year were ₹22 Billion, targeted mainly at developing complex generics and specialty products. We continue to be disciplined in identifying future R&D projects for the generics market while simultaneously investing in developing a global specialty portfolio. We are also investing in enhancing our product pipeline for emerging markets and other non-US developed markets.

## Nurturing specialty growth

Our journey of building a global specialty business commenced a few years ago, and over the years, we have nurtured this evolving business through increased focus and investments. We have allocated significant resources in building the specialty business.

Our specialty initiatives are directed at achieving two main objectives – to build an additional engine of future growth and secondly to move up the pharmaceutical value chain through development and commercialisation of branded patented products. While we intend to target the global market with our specialty products, developed markets are likely to be key contributors to this strategy.

Our specialty portfolio targets Dermatology, Ophthalmic, Oncology and CNS segments. We are developing our specialty products pipeline with a focus on improving patient outcomes either by addressing unmet medical needs or by enhancing patient convenience through differentiated dosage forms.

Over the past two years, we have also focused on establishing the requisite front-end capabilities for our specialty business. This involves setting up a relevant sales force (for promoting these products to doctors), establishing the required regulatory and market access teams, along with support staff.

## Commercialisation of key specialty products

FY18 was a busy year for our specialty business and we crossed many important milestones. We filed two of our important products – Ilumya (Tildrakizumab) and OTX-101 with the USFDA and also received final

approval for Ilumya in the US. We also focused on building the relevant front-end presence in the US for marketing and promoting our specialty products. Some of the key highlights for the year were:

- The USFDA approved our Biologics Licence Application (BLA) for Ilumya in March 2018. Ilumya is an IL-23p19 inhibitor approved for the treatment of moderate-to-severe plaque psoriasis in the US. Launch preparations for Ilumya are ongoing for a potential commercialisation in the US in FY19. Ilumya was also filed with the European Medicines Agency (EMA) in March 2017. EMA's approval for Ilumya is awaited.
- Our New Drug Application (NDA) for OTX-101 was accepted by USFDA in December 2017. This is an important product for Sun Pharma's specialty ophthalmology portfolio. We are awaiting final approval for this product from the USFDA.
- Post the close of the year, we announced USFDA approval for Yonsa® (abiraterone acetate), a novel formulation in combination with methylprednisolone, for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC). Sun Pharma had acquired Yonsa® from Churchill Pharmaceuticals LLC. Churchill is eligible to receive upfront and sales-linked milestone payments, and royalties on sales from Sun Pharma. Yonsa® in combination with methylprednisolone was filed as a New Drug Application (NDA) under the 505(b)(2) regulatory pathway and will be promoted as a branded specialty product in the US. Sun Pharma has already commercialised Yonsa® in the US market.
- We also received approval from the USFDA for a new label for Odomzo® (sonidegib), an oral hedgehog inhibitor to treat patients with locally advanced basal cell carcinoma (laBCC) that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy. The new label incorporates long-term data from the 30-month analysis of BOLT trial, in which Odomzo® continued to show sustained durable tumour response of 26 months with no new safety concerns.
- We have recently initiated investments in the development of two new indications for Ilumya, viz., psoriatic arthritis and ankylosing spondylitis. Although the clinical trials for these new indications will require large front-ended investments, a successful outcome of the trials will significantly expand the addressable market for Ilumya globally.
- The clearance of the Halol facility by the USFDA paves the way for potential approvals for Elepsia XR (Levetiracetam Extended Release tablets) and Xelpros (Latanoprost BAK-free eye drops). These specialty products were in-licensed from Sun Pharma Advanced Research Company Ltd. (SPARC).

### Ranbaxy synergies

FY18 was the most important year in terms of accrual of the synergy benefits from the Ranbaxy acquisition. The targeted synergy benefits for FY18 was US\$ 300 Million and we are happy to have achieved this important milestone. As indicated before, we have utilised these synergy benefits to fund our evolving global specialty business.

### Global cGMP compliance

Worldwide, pharmaceutical regulatory agencies are focusing on improving the quality of products approved by them. This has mandated adherence to very stringent cGMP standards by pharmaceutical manufacturers with a need to focus on 24x7 compliance status. Ability to successfully adhere to these cGMP standards has become a key determinant of future for the pharmaceutical industry.

During the year, Sun Pharma made significant progress towards 24x7 cGMP compliance. Many of our facilities underwent successful audits by multiple regulatory agencies, including the USFDA. At the same time, remediation work continued at some of the facilities, which had been impacted by cGMP deviations.

Our Halol facility, which was impacted by cGMP deviations in FY15, underwent a re-inspection by the USFDA in February 2018. On completion of the re-inspection, the USFDA issued three observations for the facility. Subsequently in June 2018, the USFDA issued the establishment inspection report (EIR) for the facility, thus clearing the facility. With this clearance, new approvals from this facility for the US market are likely to start coming through gradually.

### Restructuring and rationalisation

Given the tough pricing conditions in the US generics market, we continue to make efforts towards optimising our costs. It mandates an unwavering focus on cost control across the organisation. We are trying to achieve better results with lower resources as we try to make the organisation more efficient.

Our efforts in this direction will cover multiple operational aspects. The focus will be on optimising our manufacturing footprint as well as generics R&D investments, to ensure a reasonable return on investment as well as overall cost management.

### Overall outlook

We are gradually ramping up our global specialty business. We plan to increase its contribution to our consolidated revenues in the long term. This will entail significant front-ended investments, with commensurate revenue streams accruing only over a period of time.

Some of our key specialty products are likely to be commercialised in the US in FY19 and hence we expect to incur significant pre-launch and branding costs along with increasing sales force costs.

The short-term outlook for the US generics market continues to be challenging given the pricing pressures. We expect normalisation of the India business in FY19 post the disruption in FY18 due to GST implementation. Favourable demographics will ensure reasonable volume growth in India. However, government-mandated price reductions/policy changes continue to be potential risks for this business. We are also expecting reasonable growth in our emerging markets business, however, as always, currency fluctuations continue to be a risk.

Given these factors, we expect a low double-digit topline growth in our consolidated revenues for FY19 over FY18. Our consolidated R&D investments for FY19 will be about 8-9% of revenues.

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

We are thankful for your support as a shareholder. You have continuously supported our endeavors over the past many years and we hope that you will continue to repose your confidence in us.

Warm regards,

**Dilip Shanghvi**  
Managing Director  
Sun Pharmaceutical Industries Ltd.

# Management Discussion and Analysis

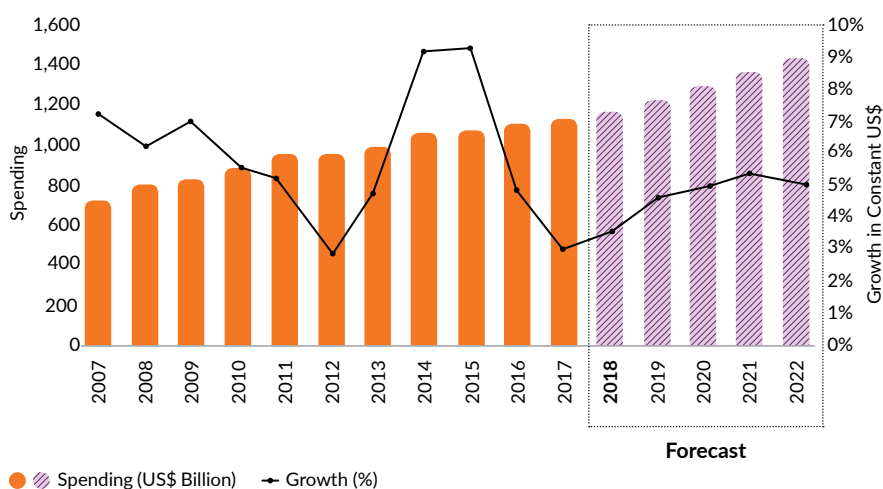
*The global spending on medicines is expected to reach over US\$ 1.4 Trillion by 2022, growing at an average CAGR of 3-6% from US\$ 1.13 Trillion in 2017.*

## Global pharmaceutical industry<sup>1</sup>

The global spending on medicines is expected to reach over US\$ 1.4 Trillion by 2022, growing at an average compound annual growth rate (CAGR) of 3-6% from US\$ 1.13 Trillion in 2017. Demographic changes in population and advances in medical treatments are expected to translate into a rise in spending. Innovation in medicines, along with economic progress, will result in a rise in volume for the pharmaceutical industry. Market growth is likely to occur concurrently with greater pharmaceutical cost controls, improving access and affordability.

In developed markets, ageing population and development of new specialty medicines will continue to drive pharmaceutical growth. In developing nations, growing population and rising disposable incomes among the middle-class, increasing aspirations for better healthcare and gradually increasing penetration of insurance coverage will drive the growth momentum.

**Chart 1** Global medicine spending and growth 2007-2022<sup>2</sup>

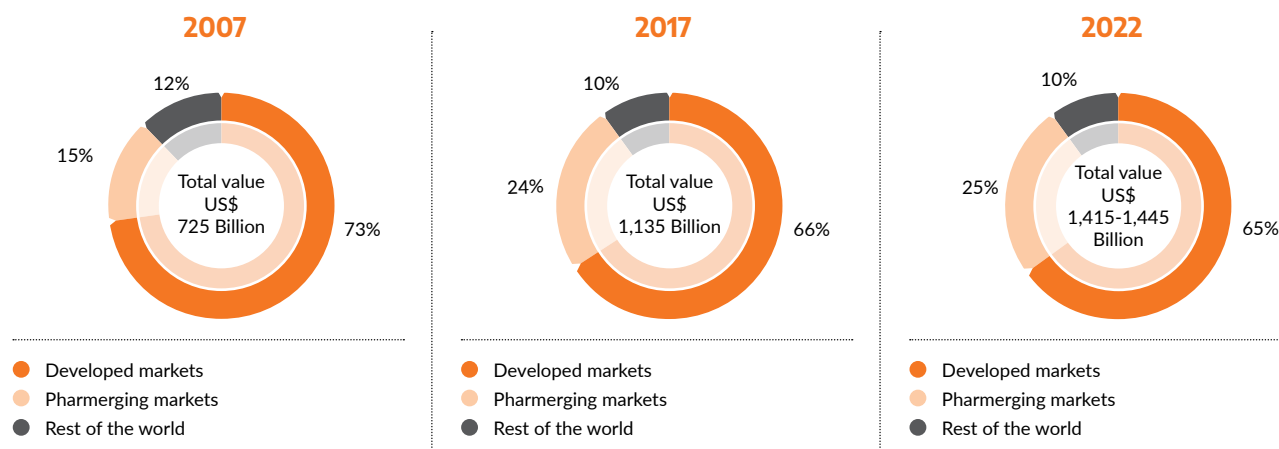


**Table 1** Global pharmaceutical spending and growth<sup>2</sup>

(US\$ Billion)

Regions	2017	2013-17 CAGR	2022	2018-22 CAGR
Developed Markets	753.2	5.8%	915-945	2-5%
Pharmerging Markets	269.6	9.7%	345-375	6-9%
Other Markets	112.3	2.0%	125-155	2-5%
<b>Global Pharmaceutical Market</b>	<b>1,135.1</b>	<b>6.2%</b>	<b>1,415-1,445</b>	<b>3-6%</b>



**Chart 2** Global spending by region<sup>2</sup>**Table 2** Leading therapy-wise spending and growth in selected developed and pharmerging markets<sup>2</sup>

(US\$ Billion)

Therapy areas	2017	2012-17 CAGR	2022	2017-22 CAGR
Oncology	81.1	11.8%	115-130	7-10%
Diabetes	72.2	16.9%	105-115	8-11%
Pain	76.1	5.7%	80-95	2-5%
Autoimmune	47.5	16.8%	65-75	7-10%
Respiratory	38.5	4.8%	40-50	2-5%
Antibiotics & vaccines	38.3	3.2%	40-48	1-4%
Cardiovascular	40.6	-1.8%	36-44	(-2)-1%
HIV	26.7	11.5%	32-40	5-8%
Mental health	36.1	-2.6%	32-38	(-2)-1%
Antivirals	23.8	25%	16-20	(-7)-(-4)%
All other therapies	368.3	5.1%	445-460	3-6%

Selected Developed and Pharmerging Markets: Includes 8 Developed and 6 Pharmerging countries of the US, France, Germany, Italy, Spain, UK, Japan, Canada, China, Brazil Russia, India, Turkey and Mexico

### Emerging trends for 2018-22<sup>1</sup>

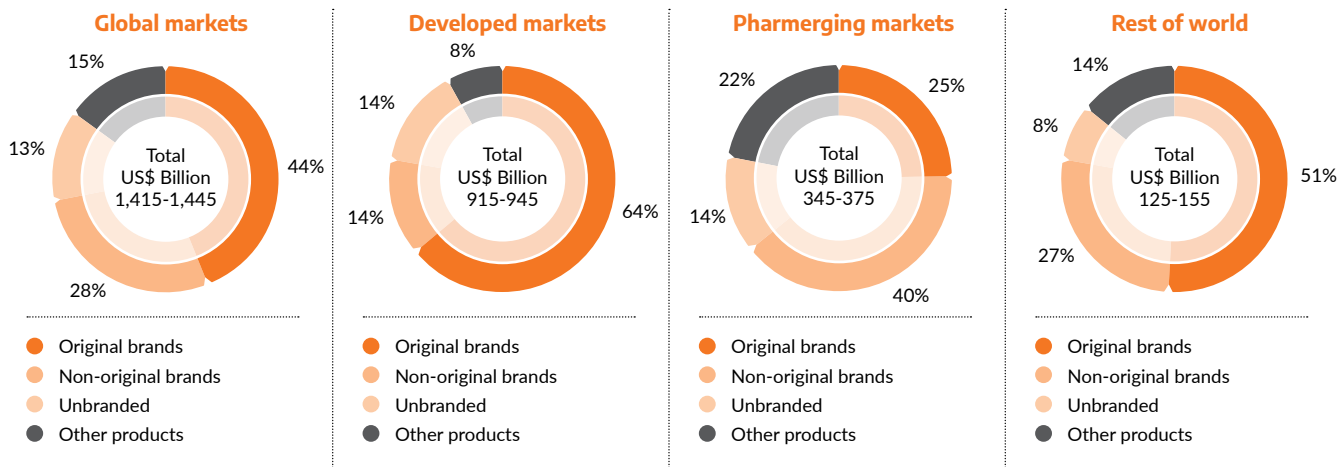
Pharmaceutical spending in developed markets is likely to grow at 2-5% CAGR between 2018-22 compared to 5.8% in the 2013-17 period. While launch of innovative products is likely to drive growth, is expected to be balanced by patent expiries of existing products.

- Specialty medicines will drive medicine spending in developed markets, partly offsetting the decline in spending on traditional medicines.
- The requirement to replenish product portfolios impacted by patent expiries will continue to drive acquisitions and in-licensing for the specialty segment.
- For pharmerging markets, policies designed to achieve universal healthcare will be an intricate formula that induces investment, while protecting affordability. However, sluggish economic conditions in these markets and relatively higher out-of-pocket costs for patients will offset some of the gains in access. Medicine spending in these markets is likely to grow at 6-9% CAGR for 2018-22 compared to nearly 10% for the 2013-17 period.

- Innovation in new drug development, immunotherapy, next generation biotherapeutics, including cell-based gene therapies and digital health tools will gain importance in the future of the global healthcare industry.

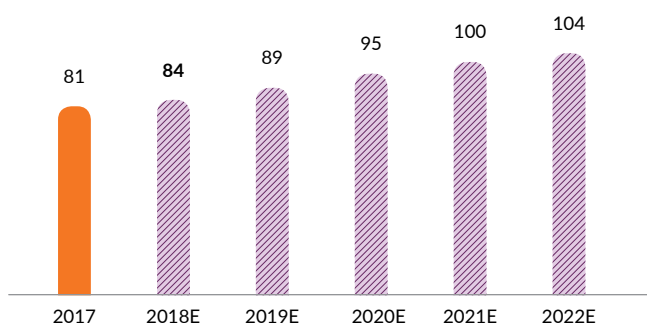
- Generic medicines will continue to be an important part of the efforts to reduce overall global healthcare costs.

*Innovation in new drug development, immunotherapy, next generation biotherapeutics, including cell-based gene therapies and digital health tools will gain importance in the future of the global healthcare industry.*

**Chart 3** Global medicine spending by product type in 2022<sup>2</sup>


### Global generics market<sup>3</sup>

The global generics market is estimated to grow at 5% CAGR for the 2017-22 period to reach US\$ 104 Billion by 2022. Governments worldwide are facing pressures of rising healthcare costs, thus emphasising on the importance of generics and their role in making pharmaceutical products affordable to those in need. Patent expiry for branded drugs in developed markets has a bearing on the potential of generics in those markets. In the emerging world, the branded generics markets will be driven primarily by rising per capita incomes, increasing healthcare awareness and enhanced incidence of chronic ailments.

**Chart 4** Global generics market growth<sup>3</sup> (US\$ Billion)


### Growth enablers of global pharmaceutical industry<sup>4</sup>

#### Ageing population

Global population is likely to cross 9.3 Billion by 2050 and the proportion of individuals aged 60 and above will account for 21% of it. The growing average life expectancy has been accompanied by a rise in different diseases, leading to the deployment of more resources for research and innovation to improve the quality of life for an ageing population.

#### Rising pollution

Rising air and water pollution is resulting in increased incidence of various diseases, leading to higher pharmaceutical consumption.

#### Changing lifestyles

Individual lifestyle choices are increasingly affected by stress, resulting in higher risk for obesity, hypertension, depression, diabetes and cardiovascular problems. Moreover, with rise in disposable incomes for global middle-class families, the demand for better healthcare is gradually increasing.

#### Cost controls

Governments, particularly in emerging economies, are shifting towards affordable, universal healthcare with reduced out-of-pocket spending for patients. Although they deepen market access, the cost-containment policies of governments will neutralise some of these gains for the pharmaceutical industry.

#### Technology

Empowered by technological advances such as mobile apps, wearable healthcare devices and greater awareness, patients are increasingly taking better and more well-informed healthcare choices.

#### Outlook

Changing lifestyles will increasingly make chronic diseases a global health issue. Developed markets growth will be driven by ageing population and adoption of emerging medical technologies.

In developing markets, besides growing populations, the pharmaceutical industry will benefit from higher incomes of consumers. The entry of wearables in the global market will facilitate access to accurate, real-world data. Subsequently, the quality of diagnostic services will improve thus leading to increased pharmaceutical consumption.