



**HEALTH MEETS HOPE**



**52nd Annual Report 2017-18**



# *#ThinkForHealth*

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# Executive Committee

## PRESIDENT

Annaswamy Vaidheesh

## VICE PRESIDENTS

Ambati Venu (up to Aug 10, 2018)

Sharad Tyagi

Sanjiv Navangul

Anand Nambiar (up to April 13, 2018)

S. Sridhar

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Gagan Singh Bedi (w.e.f. July 1, 2017)

Manoj Saxena

Jitendra Tyagi

Dr Sanjit Singh Lamba

Edgard A. Olaizola (up to Jan 31, 2018)

Luca Vicini (w.e.f. Feb 1, 2018)

G. Sathya Narayanan

Milind Thatte (w.e.f. April 13, 2018)

Vivek Kamath

Dr Ramesh Panchagnula

Ranjit Shahani (up to Sept 22, 2017)

Javed Zia (w.e.f. Sept 22, 2017 up to April 13, 2018)

Milan Paleja (w.e.f. April 13, 2018)

Melvin D'Souza

Maturin Tchoumi (up to Sept 22, 2017)

Lara Bezerra (w.e.f. Oct 12, 2017)

Dr Georges Jabre (w.e.f. Oct 1, 2017)

Dr Shailesh Ayyangar

Mr Ashok Bhattacharya (w.e.f. Sept 22, 2017)

## SECRETARIAT

### MUMBAI

Kanchana TK

Rajiv Shukla

Bhavna Singh

Ajit Bendre (up to April 5, 2018)

Shreyas Kale (w.e.f. March 7, 2018)

Nitika Garg

Cloti Baptista (up to June 30, 2018)

### NEW DELHI

Dr Ajaykumar Sharma

Prem Singh Rawat

GlaxoSmithKline Pharmaceuticals Ltd

Abbott India Ltd\*

Boehringer Ingelheim India Pvt Ltd

Johnson & Johnson Pvt Ltd

Merck Ltd

Pfizer Ltd

Allergan India Pvt Ltd

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AstraZeneca Pharma India Ltd

Bayer Pharmaceuticals Pvt Ltd

Bristol-Myers Squibb India Pvt Ltd

Eisai Pharmaceuticals India Pvt Ltd

Eli Lilly and Company (India) Pvt Ltd

Eli Lilly and Company (India) Pvt Ltd

Nestle Skin Health India Pvt Ltd

Merck Ltd

MSD Pharmaceuticals Pvt Ltd

Nektar Therapeutics (India) Pvt Ltd

Novartis India Ltd

Novartis India Ltd

Novartis India Ltd

Novo Nordisk India Pvt Ltd

Roche Products (India) Pvt Ltd

Roche Products (India) Pvt Ltd

Serdia Pharmaceuticals (India) Pvt Ltd

Sanofi India Ltd

Takeda Pharmaceuticals (India) Pvt Ltd

Director General

Director – Alliance Development

Director – Communications

Director – Finance, Admn & Association Secretary

Director – Finance, Admn & Association Secretary

Director – Research

Sr Executive Secretary

Director – Government Affairs

Manager – Government Affairs

\* Resigned

# Members

## ORDINARY MEMBERS:

## AFFILIATE MEMBERS:

				
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## ASSOCIATE MEMBERS:

		
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**A. VAIDHEESH**  
President, OPPI

As we go into print, India has just rolled out the ambitious National Health Protection Scheme (NHPS) with 28 states being signatories one of the most ambitious and largest health coverage scheme in the world that will have a far-reaching impact on the healthcare and insurance landscape of the country.

The government must be lauded for introducing the Ayushman Bharat initiative to upgrade primary healthcare centres significantly and substantially and provided the budgetary resources to kick-start the process. The larger NHPS is a huge step, both in intent and scale; and will help address India's large disease burden, particularly NCDs. OPPI will look forward to working with governments, both state and central, to support its on-ground implementation.

Access to healthcare, especially with the shift of the disease burden to NCDs – recall that nearly 60 per cent of all deaths in India can be attributed to just four NCDs – will require new and innovative medicines. The dominant conversation has been about affordability – which the NPBS will address in large part – which has meant price control.

*At OPPI we have been working with the government to change the terms of this conversation, from 'price control' to 'price reform'.* Pricing is a very large conversation in most countries, whether in the developed countries, or in those emerging economies like our own. With the discovery of new therapies, new treatments and a new mindset, it is time to press forward with a reform prism approach that creates more effective public policy and regulation.

Reform also brings in a broader discussion on quality and safety. We have been in dialogue with the Department of Pharmaceuticals and other regulators on the importance of this issue. In this endeavour, we look forward to working with the Quality Council of India on this critical issue. Quality also puts the patient first, and that has been the driving purpose for the pharmaceuticals industry. Most successful companies use flexible, and interactive approaches with their most important stakeholders; we should give patients better tools and more focused information about the medicines they are taking and how to manage their conditions.

Technology goes a long way to achieving successful patient engagement; think data analytics. For pharma companies, the volume and variety of available medical information has expanded, driven in large part by the large-scale utilization of electronic medical records, high-resolution medical imaging, and next-generation genomics. Companies have extracted benefits from this evolving data ecosystem, and rapidly acquire curate, analyse and visualise large data sets.

Analytics can help craft flexible, interactive approaches that gives patients better tools and more focused information about the drugs they are taking and how to manage their conditions. The insights that drug makers provide to patients drawing on this analytics capability can help substantially reduce potentially dangerous errors in taking medicines and cut out the stress in managing the disease.

Efficient technology-enabled care models, integrated delivery designs can be tailor made to meet the specific needs of the patient and is consistent with the emerging trends in patient care, from personalised medicine to genomic therapies. Let me reiterate: in all of this is the principle of patient centricity is the theme that runs through all activity.

In India, 2017-18 has been an eventful year. As we approach the national elections of 2019 with great expectations, we hope that as most experts suggest, India will find opportunities to grow faster.

In the coming year, let's continue to work on patient education and responsible self-medication for creating greater awareness of anti-microbial resistance (AMR) and appropriate regulation, through continued advocacy of raising public spending on health from 1 to 2.5 per cent of GDPO in the first phase, and higher to a level that is appropriate for India.

I thank all the OPPI members for your continued commitment and support to the agenda; together there is much we can do; when Health meets Hope.

**A. Vaidheesh**

President, OPPI

and Vice President, South Asia &  
Managing Director India,

GlaxoSmithKline Pharmaceuticals Ltd

September 2018

Mumbai



**HANCHANA TH**  
Director General, OPPI

The one thing that marks the year gone by has been 'momentum'. To get this momentum, it is critical that we focus on a specific set of goals. In 2017-18, OPPI has worked on a focused approach on three specific areas- innovation, access to healthcare and ethics. As momentum demands movement, through the year we demonstrated movement on these areas. This movement with relevant stakeholders has led us closer to our vision of building a *scientific and innovative India*.

While the contours of this New India are being re-drawn, science remains the fulcrum on which this New India will be firmly established. Science is a global endeavour which bridges national boundaries and requires international discussion and collaboration. As OPPI represents research-based pharma companies in India, our members continue to work tirelessly in their pursuit to use science for the benefit of humanity. One of the goals of OPPI and its members is to continue to develop a scientific temper in the country where science is recognized as the true crusader in transforming lives. To this end, OPPI continues to advocate for a strong innovation-friendly eco-system – one that encourages foreign direct investment (FDI), stimulates research and gives India a progressive healthcare system, with newer and better medicines. The momentum needs to be that of building an ecosystem that respects and rewards innovation in our country.

Patient-centricity is the driving force of all our endeavours. This year, the focus on this area was catalyzed with Government's announcement of the Ayushman Bharat. During the year, the OPPI goal of partnering with Government and strengthening the contours of an Ayushman, Swastha and Surakshit Bharat called for drawing a blue print to augment healthcare access to the millions of patients in India. OPPI has embarked on this journey and the Annual Summit 2018 themed #HealthMeetsHope is our first milestone in this continuous journey, wherein innovation, ethics, quality of medicines and access to medicines are to be integrated, in the interest of patients at large.

Responsible healthcare is synonymous with patient safety and adherence to accepted standards of quality in drug manufacturing. Given the changing landscape of Indian healthcare and the push towards generic manufacturing, the critical component of quality in medicines, emerged an important aspect of patient safety. The OPPI Quality Summit brought to fore the conversations around quality. OPPI led the all-industry associations collaborative effort to engage with Government, patient groups and the Quality Council of India to establish the need for quality in medicines. OPPI has engaged with policymakers and other key



stakeholders to strengthen the policy ecosystem around innovation, access to newer medicines and ethical practices, for the benefit of patients.

The most critical area of focus has been on co-creating an ethical ecosystem which promoted doing business in the right way. OPPI can proudly say that we have been championing with the Government and are self-regulated with the OPPI members adhering to the OPPI Code of Marketing Practices.

This year, OPPI engaged with relevant stakeholders with roundtables, opinion pieces, research papers and publications that have been published, all in the interest of patients. As an illustration, the paper that outlines the need for OTC drugs in the country, established the need for an urgent need for patient education around responsible self-medication and is also an important step in combating AMR.

While focusing on the present, OPPI and its members acknowledge the future. An age of promise fueled by the drive to discover and a dedication to a future without illness. Every day, OPPI members imagine, inspire and innovate for a patient-driven inclusive healthcare ecosystem, aided by technological advancements. As we move into a highly competitive and patient-centric pharma world, there are strong evidences of technology that has positively disrupted the way healthcare works.

Health Technology Assessment, a multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner; Blockchain Technology, a decentralized, distributed and public digital ledger used to record transactions across many computers so that the record cannot be altered retroactively and Artificial Intelligence that drives applications that analyze relationships between prevention or treatment techniques and patient outcomes, are some of these future drivers of patient well-being .

Though the future makes healthcare public in some respects, health continues to be a topic of extensive personal interest. Investments in health, therefore are decisions that remain personal. Starting with customised and personalised medicines to insurance and financing, and after care, decisions are made by patients. Patients are today becoming empowered to make wise decisions and make their choices. This has called for evolved communication with multiple stakeholders, including patients, health-tech companies, social entrepreneurs, media and patient groups.

To this end, OPPI's communication and advocacy efforts have also transformed. Throughout the year, OPPI has been connecting with the world through the digital medium and for the first time, OPPI has launched #ThinkForHealth, a nation-wide digital campaign, in collaboration with the Govt. of Telangana. The campaign calls for ideas on woman & child health, NCDs, mental health and health technology and provides a platform for the best ideas to be heard, rewarded and mentored.

Reviewing the outcomes of our work over the past year, it is our fervent belief that going forward, collaborative approaches to key issues will enable us to move the needle further. While the momentum is on, the future is now. And, we need to leverage this momentum to carve out a future that allows for innovation-led treatment, technology-led empowerment and care-led patient-centric approach to healthcare.

OPPI is committed in building an ecosystem of science and innovation and will continue to encourage curious minds in the quest for modern healthcare in India.

**Kanchana TK**  
Director General, OPPI  
September 2018  
Mumbai



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persist

commit

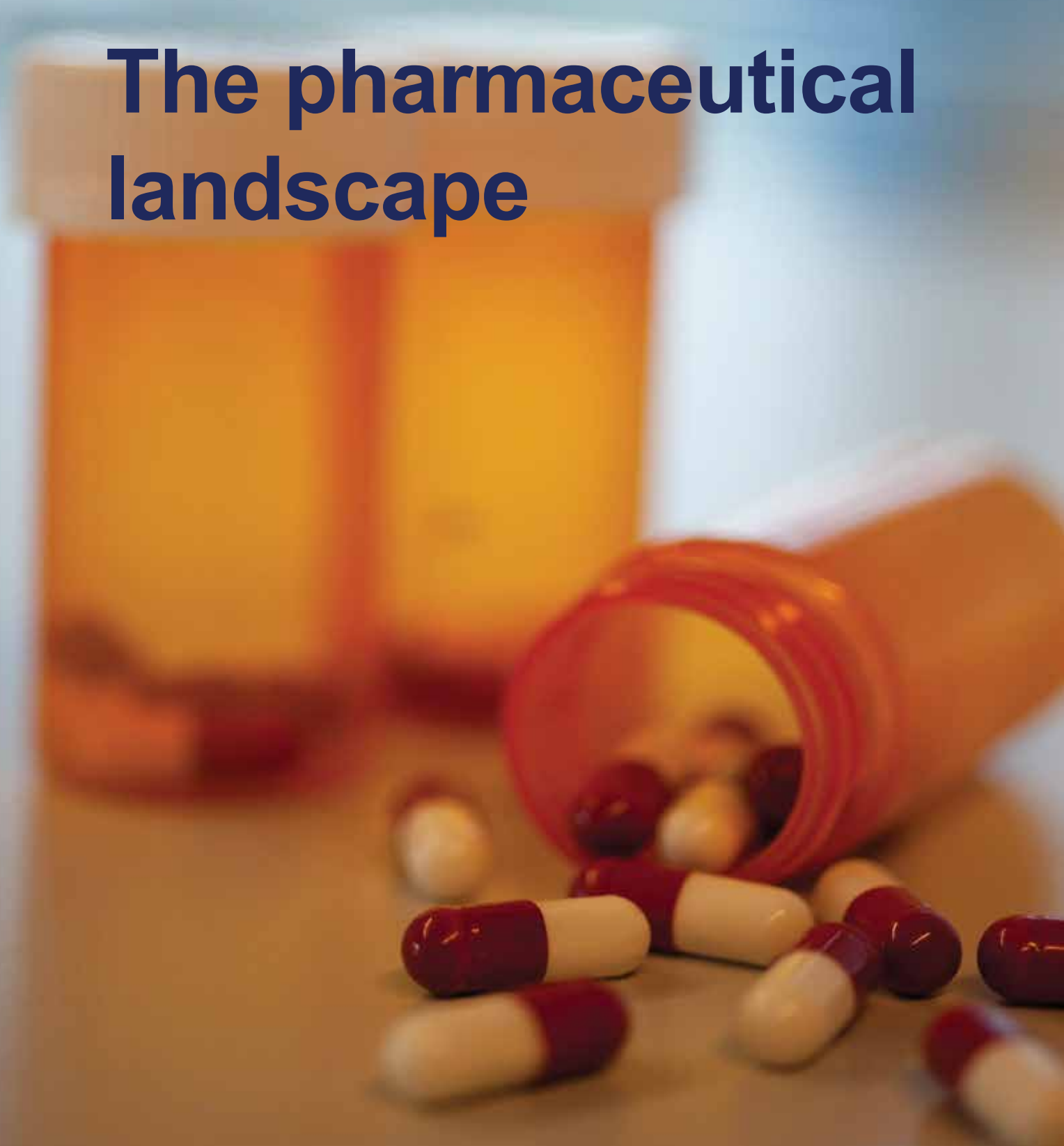
promise

trust





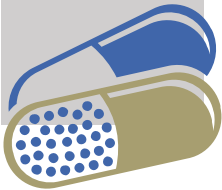
# The pharmaceutical landscape



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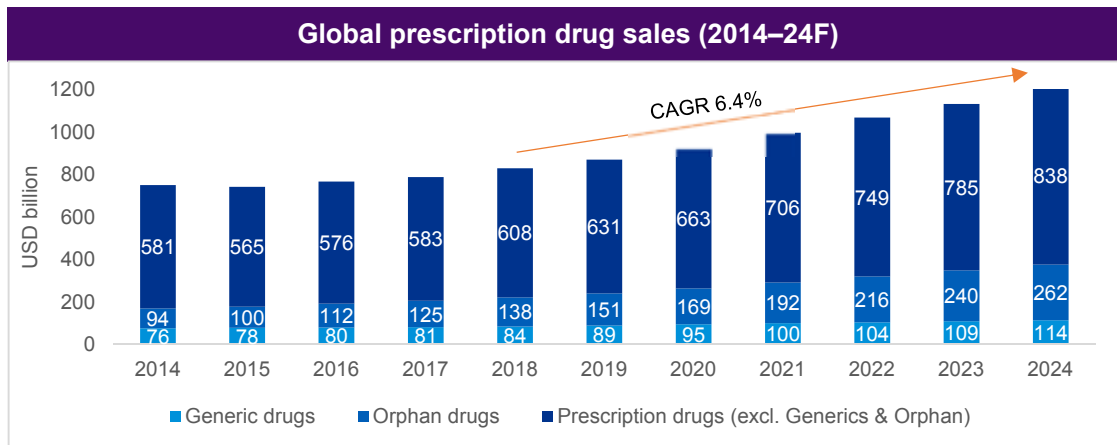
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## The pharmaceutical landscape

### The global pharmaceutical market

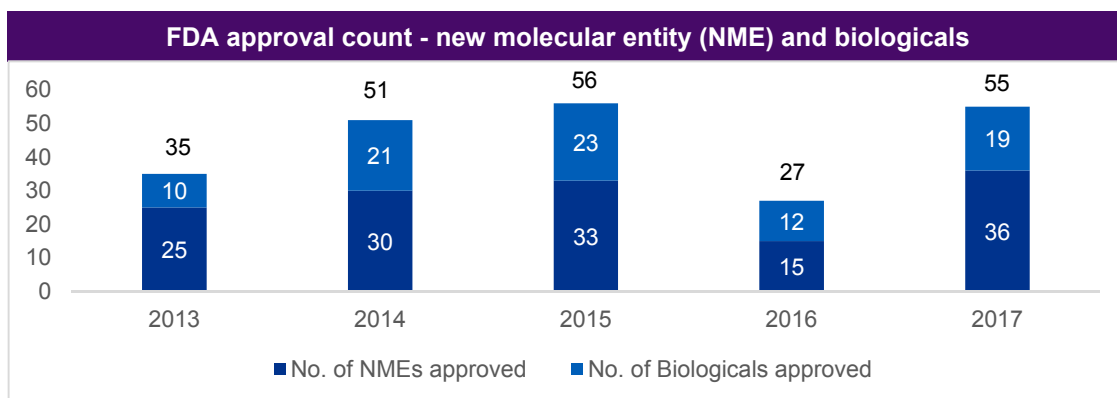
#### Market overview

- Global sales of prescription drugs are expected to grow at a compound annual growth rate (CAGR) of 6.4 per cent until 2024 to reach USD1.2 trillion.<sup>1</sup> Growth could be driven by the continued uptake and anticipated launch of novel therapies addressing key unmet needs, as well as increasing access to medicines globally
- U.S., China, and Japan are the worlds' largest pharmaceutical markets followed by the four biggest European markets: Germany, France, Spain, and Italy<sup>2</sup>



Source: World Preview 2018, Outlook to 2024, EvaluatePharma, June 2018

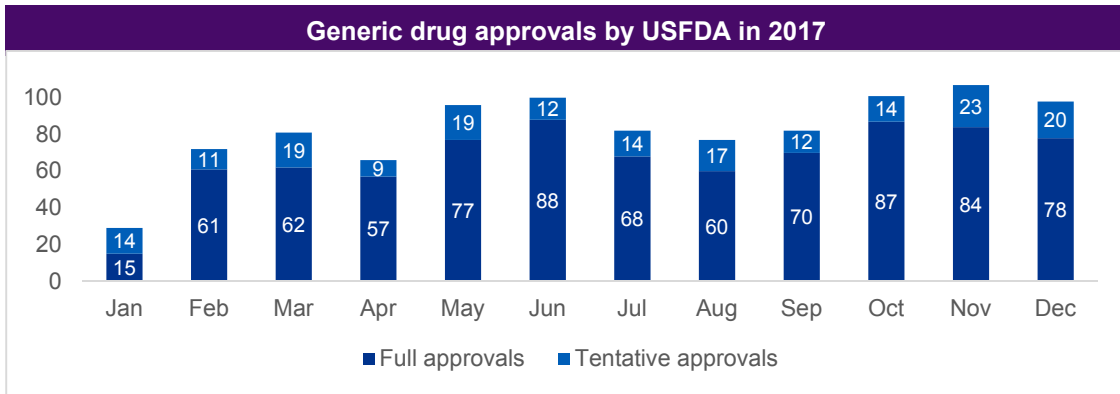
- Drug affordability and access continue to apply downward pressure on the market with payers, including those in the U.S., reevaluating use of prescription drugs that do not provide sufficient real-world value
- In 2017, the number of drugs approved by the United States Food and Drug Administration (US FDA) was more than double compared to the previous year. However, this number for 2017 was in line with the drugs approved in 2014 and 2015<sup>1</sup>
- The year 2017 also saw the approval of innovative gene and cell therapies<sup>3</sup> which are likely to pave the way for more advanced therapy approvals in the years to come



Source: World Preview 2018, Outlook to 2024, EvaluatePharma, June 2018

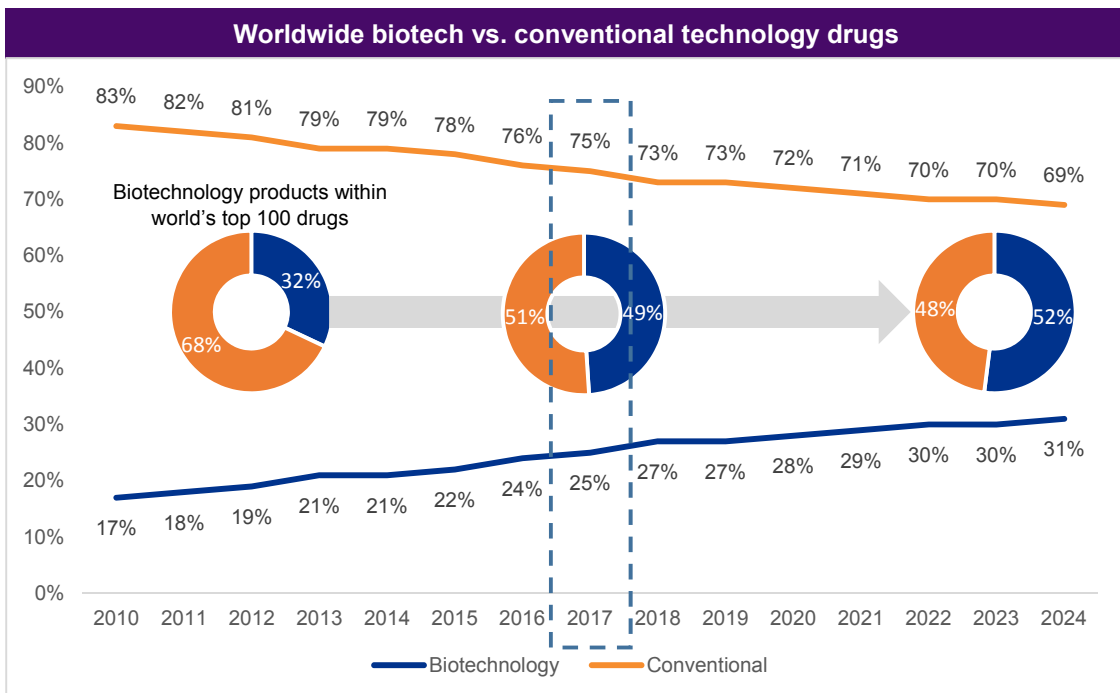
Source: 1 - World Preview 2018, Outlook to 2024, EvaluatePharma, June 2018; 2 - Global Pharmaceuticals, Marketline, June 2018 via ThomsonOne research database accessed July 2018; 3 - FDA approval brings first gene therapy to the United States, FDA, August 2017

- The FDA approved 1,027 abbreviated new drug applications (ANDA)<sup>4</sup> in 2017 as compared to 813 in 2016. The increasing number of product approvals indicate that competition is likely to remain high and continue to put pressure on pricing



Source: 2017 Was another Record-Setting Year for Generic Drugs, US Department of Health and Human Services, 7 February 2018

- Biotechnology drugs will represent 31 per cent of the total market in 2024 from 25 per cent in 2017.<sup>5</sup> Similarly, within the world's top 100 products, biotechnology products will account for 52 per cent of sales in 2024 from 49 per cent in 2017.<sup>5</sup> This trend indicates the increasing reliance on novel drugs accessible only through biotechnology. Innovation will be a key growth driver.



Source: World Preview 2018, Outlook to 2024, EvaluatePharma, June 2018

Source: 4 - 2017 Was Another Record-Setting Year for Generic Drugs, US Department of Health and Human Services, 7 February 2018; 5 - World Preview 2018, Outlook to 2024, EvaluatePharma, June 2018

## Key trends in the global pharmaceutical market



### Growing pricing pressure on generics

Apart from prescription drugs, pricing pressure has started trickling down to generic companies as well. The three largest U.S. drug wholesalers that warehouse and distribute ~USD400 billion<sup>6</sup> of pharmaceuticals annually have been competing aggressively to win business from independently owned pharmacies, largely by agreeing to cut prices on generics. Further, group-purchasing organisations are consolidating and thus commanding more negotiating power, representing a challenge for generics that comprise a large chunk of these purchases.



### Convergence of life sciences and technology

The increased adoption of healthcare apps and other digital innovation is boosting connectivity and engagement between players in the healthcare value chain. Apart from technology giants, smaller players are also investing in pharma, driven by growing demand for real-time monitoring of patients and real-world evidence not only of drug efficacy, but of overall effectiveness, including cost.



### Increase in mergers and acquisition (M&A) activity focusing on immunotherapies

The CAR-T cell therapy market is booming as it is expected to cure cancer in the future. This therapy goes a step further than immunotherapy by engineering the Tcells themselves to enhance response of the immune system against a specific tumor antigen. The top deals in 2017 were aimed to acquire novel therapies to treat cancer, especially immunotherapies such as CAR-T cell therapy and transformational medicine.<sup>7</sup>



### Divestment of non-core assets to focus on core therapeutic areas

Many pharmaceutical companies are considering strategies to trim their portfolio to achieve leadership and drive scale in a few core therapeutic areas. They are initiating targeted divestments to reduce their exposure to underperforming and non-core business assets.



### Tax reforms in the U.S.

The pharmaceutical industry is expected to see both favourable and unfavourable consequences from the U.S. tax reforms passed by President Donald Trump and Republican lawmakers in December 2017. The reform<sup>8</sup> included lowering of corporate taxes (15 per cent from the previous 35 per cent); moving to a territorial tax system (tax only on income earned within a country's borders); and offering incentives to encourage U.S.-based manufacturing. This could be a boon for all, cash-flow positive businesses, but may have some negative impact on development-stage businesses. Influx of repatriated cash could be used to repay company debt, fuel new business development activities, and/or reinvest in U.S.-based projects.

It is recommended that pharmaceutical companies re-evaluate and potentially restructure their supply chain to enhance benefits from the reforms.



### Disruption in the pharma supply chain

The entry of the largest online retail chain in pharma supply in the U.S. is expected to challenge pharmacy retail chains worldwide, and trigger a price war, putting immense pressure on store-brand profit margins. This online retail giant has recently acquired an online pharmacy to create its foothold in the regulated pharmacy business, signaling disruption in prescription drug distribution.

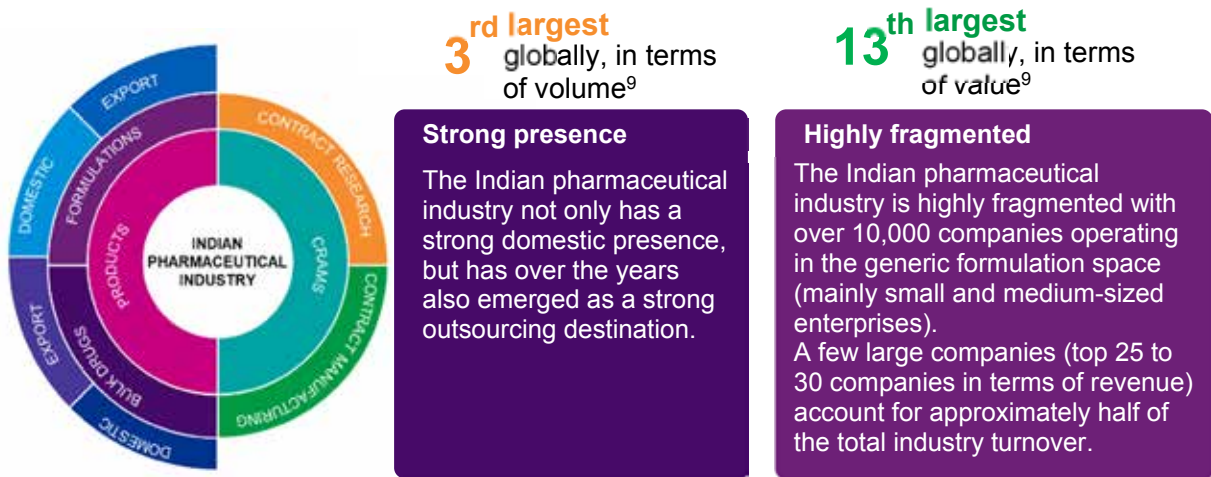
Source: 6 - Falling U.S. Generic Drug Prices Hurt Manufacturers, Wholesalers, The Wall Street Journal, 4 August 2017; 7 - World Preview 2018, Outlook to 2024, EvaluatePharma, June 2018; 8 - Corporate tax reform negotiators aim above Trump's 15 percent pledge, Reuters, July 2017



## The Indian pharmaceutical market

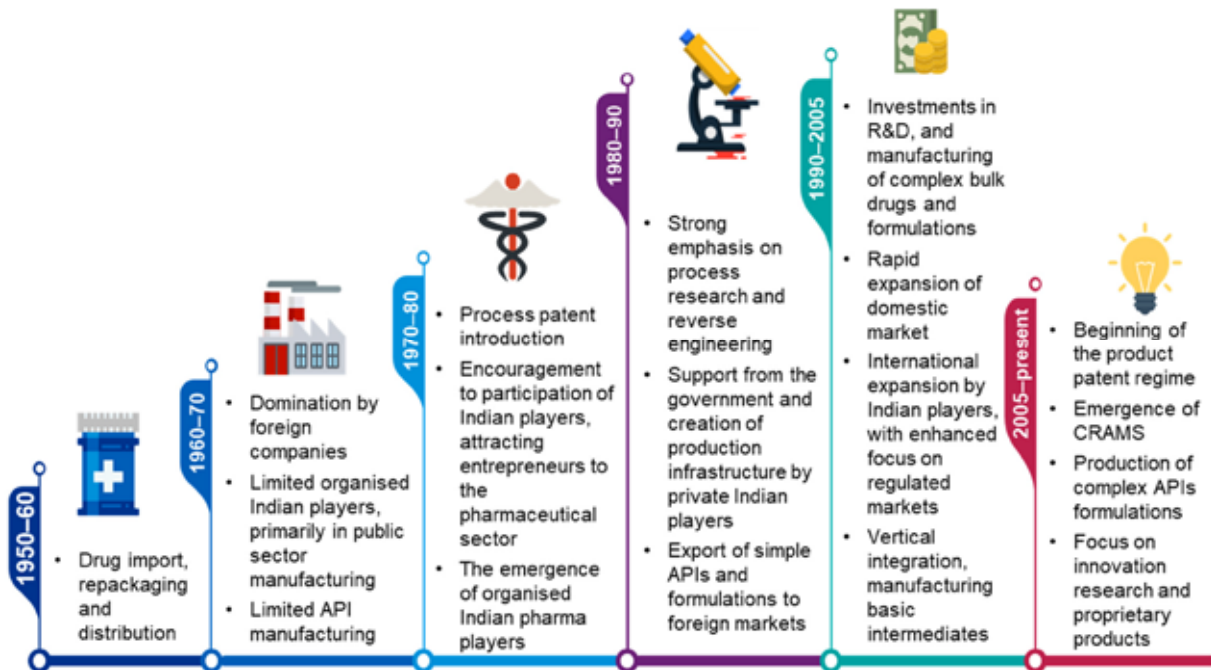
### Market overview

- The pharmaceutical industry can be primarily divided into two verticals: products (formulations and bulk drug) and contract research and contract manufacturing activities (CRAMS)



Source: Sectoral risk outlook – Pharmaceuticals, Dun & Bradstreet, June 2018

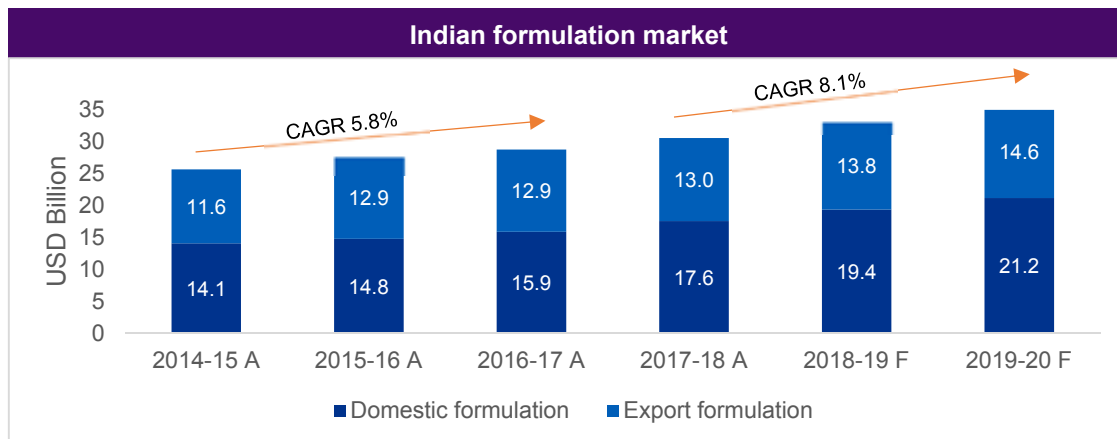
- Indian pharma companies have actively transformed themselves from being pure active pharmaceutical ingredient (API) manufacturers to finished dosage suppliers post the 2005 product patent regime



Source: KPMG in India analysis 2018

Source: 9 - Indian Bulk drug industry – Regaining the lost glory, KPMG in India, December 2017

— India’s domestic pharmaceutical market has been pegged at USD17.6 billion in 2017–18.<sup>10</sup>The market is estimated to grow to USD21.2 billion by 2019–20.<sup>10</sup> A key driver for this growth is the country's large population and a sizeable, growing segment of elderly citizens.



Source: Pharmaceuticals industry dashboard, Crisil research database, accessed July 2018

— The Indian pharmaceutical industry has come a long way — from being a relatively small player to emerging as one of the prominent drug producers in the world.

- Largest exporter of generic drugs:**  
 India is the largest exporter of generic drugs, and accounts for ~20 per cent of global exports by volume<sup>11</sup>
- Leading player in vaccines:**  
 Indian manufacturers accounted for 60 per cent of supplies made to United Nations Children's Fund (UNICEF)<sup>12</sup>
- U.S. among the biggest importers:**  
 The U.S. and North America contribute to over 30 per cent of the country's outbound shipments<sup>13</sup>
- Highest number of U.S. FDA-approved plants outside the U.S.**  
 India has over 600, U.S. FDA-approved plants — highest outside the U.S.<sup>14</sup>

Source: 10 - Pharmaceuticals industry dashboard, Crisil research database, accessed July 2018; 11 - Pharma sector bats for quality medicine, The Hindu, 8 December 2017; 12 - Indian manufacturers account for 60% of vaccine supplies made to UNICEF, BioSpectrum, August 2017; 13 - Pharma exports can cross \$20 bn by 2020: Chief of Pharmexcil, Economic Times, May 2018; 14 - The voice of the national sector, IDMA website accessed July 2018

- Despite an 8 per cent decline (in value terms) to the U.S., pharmaceutical export from India grew by 2.91 per cent, year-on-year (YoY) to reach USD17.27 billion in 2017–18.<sup>15</sup> This low growth is a consequence of increasing product price erosion largely due to the consolidation of distribution channels and increasing competition in the U.S.
- Indian companies received a record number of 304 ANDA approvals from the USFDA in 2017 as compared to 201 ANDA approvals in 2016.<sup>16</sup> With enhanced research and development (R&D) investments in the last few years, Indian companies secured around 36 per cent of total approvals by the US FDA<sup>16</sup>
- India is also one of the major exporters of bulk drugs, supplying high-quality bulk drugs to both regulated and semi-regulated markets.<sup>17</sup>



### Major supplier of bulk drugs

The Indian bulk drug industry, currently ranks third globally, next only to China and Italy<sup>18</sup>



### Key strengths of the bulk drug industry

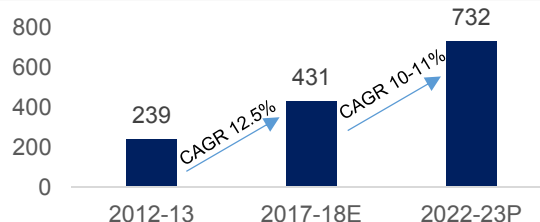
High competency in chemistry skills, understanding of global regulatory norms, large number of FDA approved manufacturing facilities, and skilled manpower



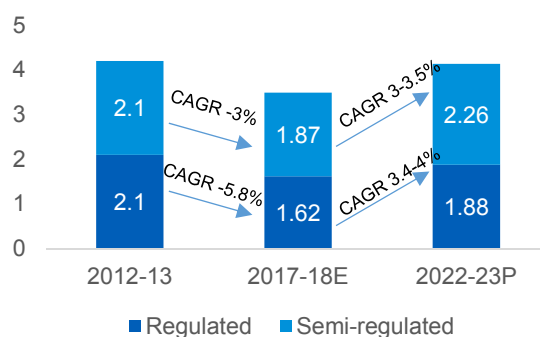
### Exports

Bulk drug exports declined during 2012–13 to 2017–18 owing to competition<sup>19</sup> from China and other Asian countries. Growth is expected to recover as players focus on niche molecules and specialty segments

### Domestic bulk drug market (INR billion)



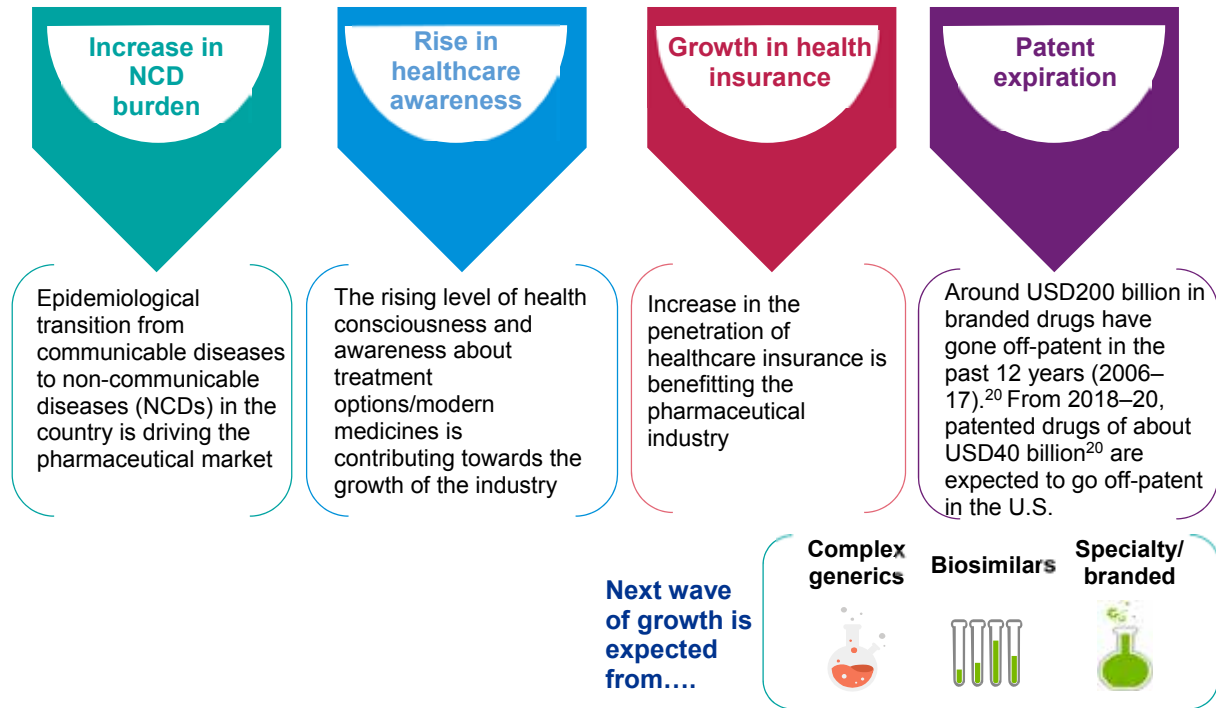
### Export bulk drug market (USD billion)



Source: Bulk drugs – Industry information, Crisil research database, accessed April 2018

Source: 15 - Pharma exports see double digit growth after a gap of three years, Business Standard, 3 July 2018; 16 - Record ANDAs from US FDA, Pharmabiz, 7 February 2018; 17 – Bulk Drug industry overview, Crisil research database, accessed July 2018; 18 – Indian Bulk drug industry – Regaining the lost glory, KPMG in India, December 2017; 19 - Bulk drugs – Industry information, Crisil research database, accessed April 2018

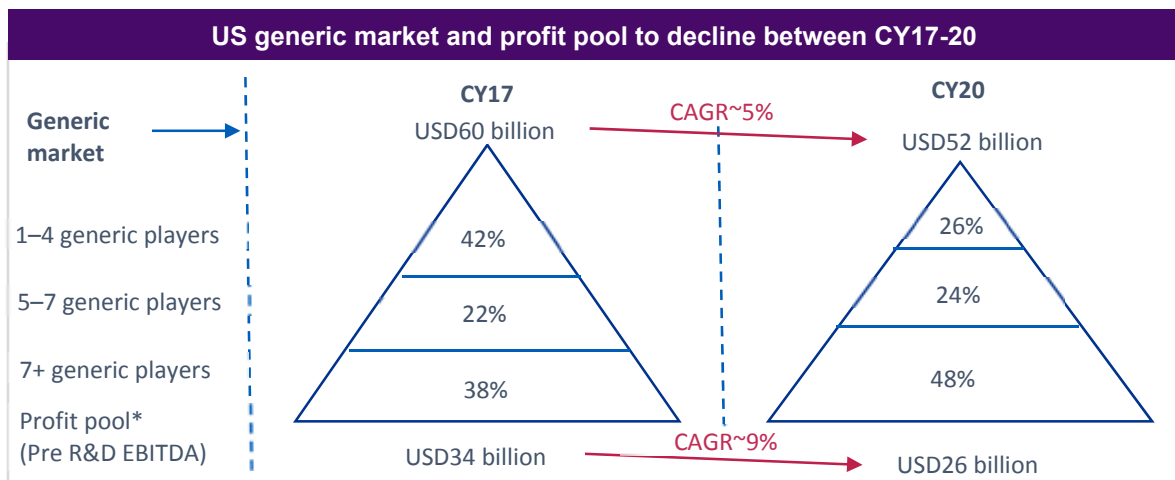
## Key growth drivers



## Key challenges

### Decline in the generics market in the U.S.

- The U.S. generics market declined in 2017, and is further expected to decline at a CAGR of 4–5 per cent over the next three years<sup>21</sup>
- The value of exports to the U.S. declined by 8.35 per cent to reach<sup>21</sup> USD5.1 billion in 2017–18 owing to intense competition, higher rate of ANDA approvals by the FDA, and consolidation of the supply chain



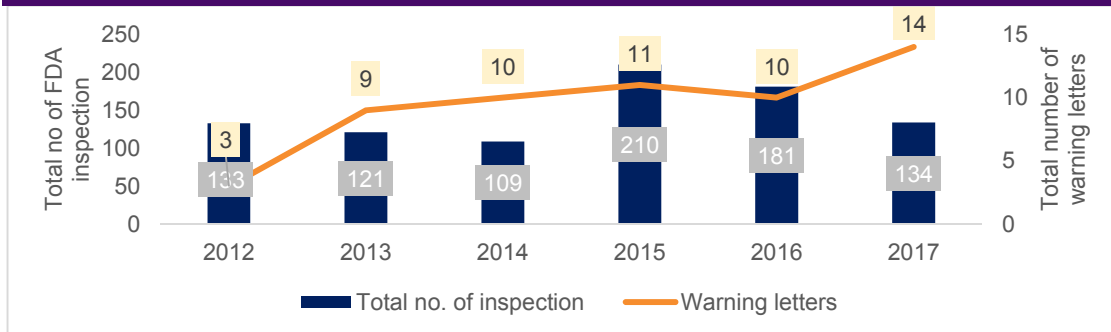
\*Profit pool includes channel margin; Source: India Pharma Sector, Credit Suisse, 9 January 2018, via ThomsonONE database, accessed Feb 2018

Source: 20 - India Pharma: 10 Years in a Snapshot, Morgan Stanley, 11 Dec 2017 via ThomsonONE database, accessed Feb 2018; 21 - India Pharma Sector, Credit Suisse, 9 January 2018, via ThomsonONE database, accessed Feb 2018

### Regulatory scrutiny by the USFDA

- The USFDA has tightened its global regulatory scrutiny, and Indian manufacturing plants have witnessed relatively higher inspection over the past three years. The number of warning letters and import alerts have also increased in the last few years. However, this increase has to be seen in the context of India also having the largest number of USFDA plants outside the U.S.

### USFDA inspection and warning letters to Indian manufacturing facilities

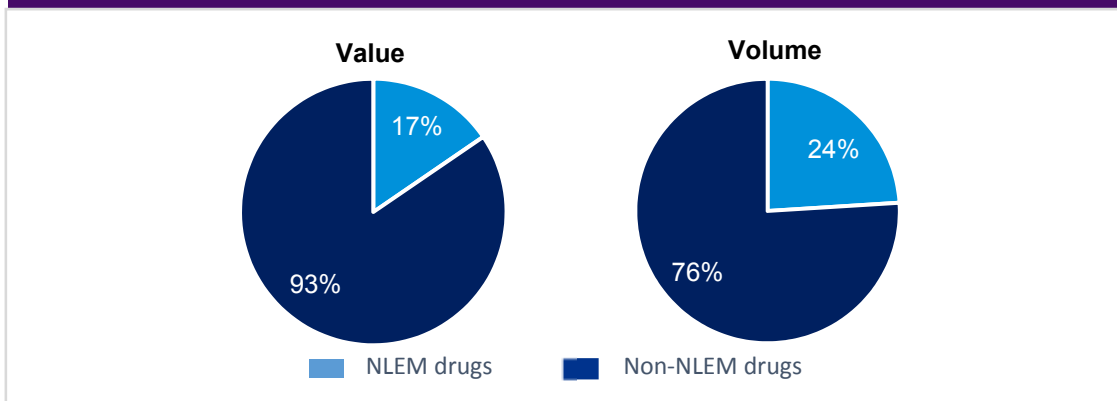


Source: Pharmaceuticals industry outlook, Crisil research database, accessed July 2018

### The price control regime

- In 2013, the Department of Pharmaceuticals (DoP) published the Drug Price Control Order (DPCO) 2013, which increased the number of medicines on the National List of Essential Medicine (NLEM) from 74 to 348, and imposed price ceilings on 652 formulations.<sup>22</sup> Currently, there are 376 drugs in NLEM 2015, and price ceiling applies to nearly 850 formulations.<sup>23</sup> This price control is adversely impacting the pharmaceutical industry as it does not allow an increase in selling price linked to the rising cost of production. The Government is further planning to link drug prices, even those that are not under price control, to wholesale inflation or to a special index for medicines

### Share of NLEM drugs (price controlled) in India

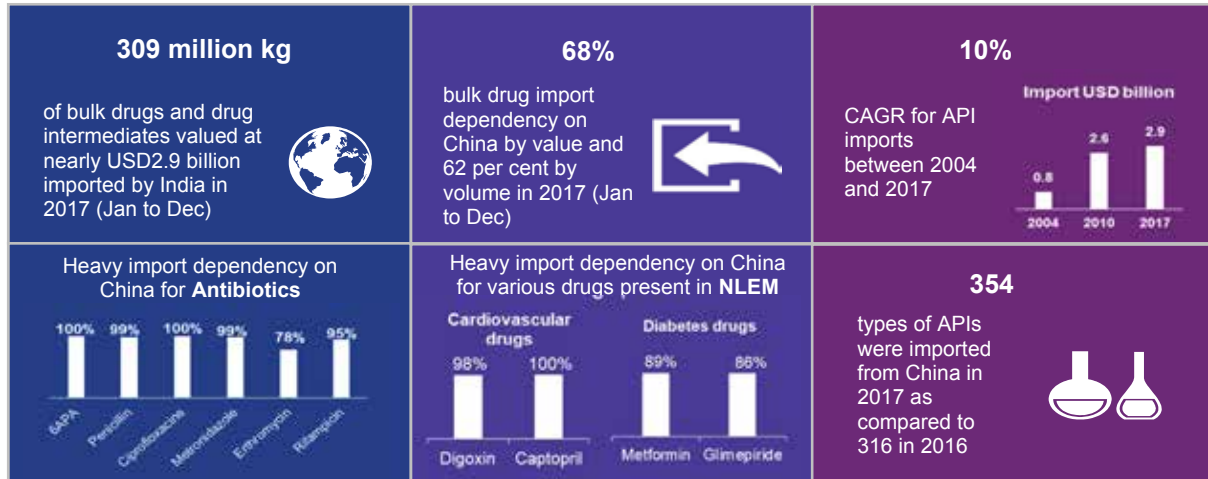


Source: Determination of Ceiling Prices of Drugs – Regarding, Press Information Bureau, Government of India, Ministry of Chemicals and Fertilizers, 20 October 2017; Government mulls new mechanism to monitor drug prices, Chemical weekly, 12 June 2018

Source: 22- Rise in Price of Drugs, Press Information Bureau, Government of India, Ministry of Chemicals and Fertilizers, August 2013; 23 - Determination of Ceiling Prices of Drugs – Regarding, Press Information Bureau, Government of India, Ministry of Chemicals and Fertilizers, 20 October 2017

### High bulk drug import dependency

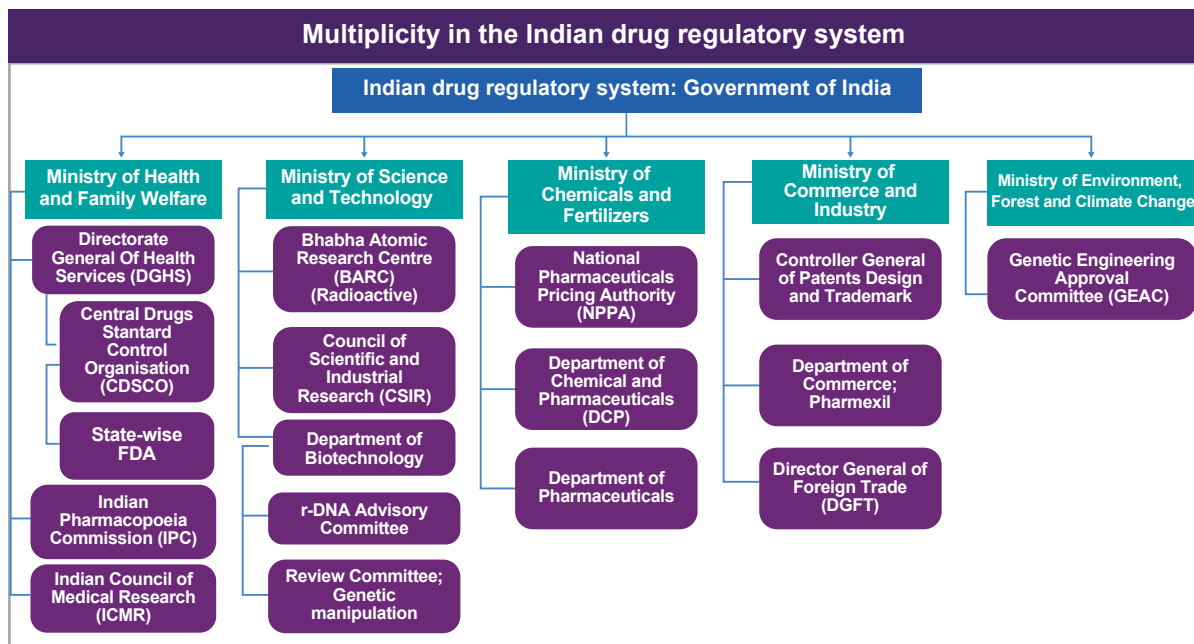
- Currently, the Indian pharmaceutical industry is heavily dependent on imports for many key intermediates and bulk drugs from a single, low-cost outsourcing nation, China. Overdependence on any one country creates significant risk for India's domestic supply of essential drugs



Source: Indian Bulk drug industry – Regaining the lost glory, KPMG in India, December 2017; Bulk Drug industry outlook, Crisil research database, accessed July 2018; Drugs imported from China, Lok Sabha unstarred question number 3131, Ministry of Health and Family Welfare, January 2018

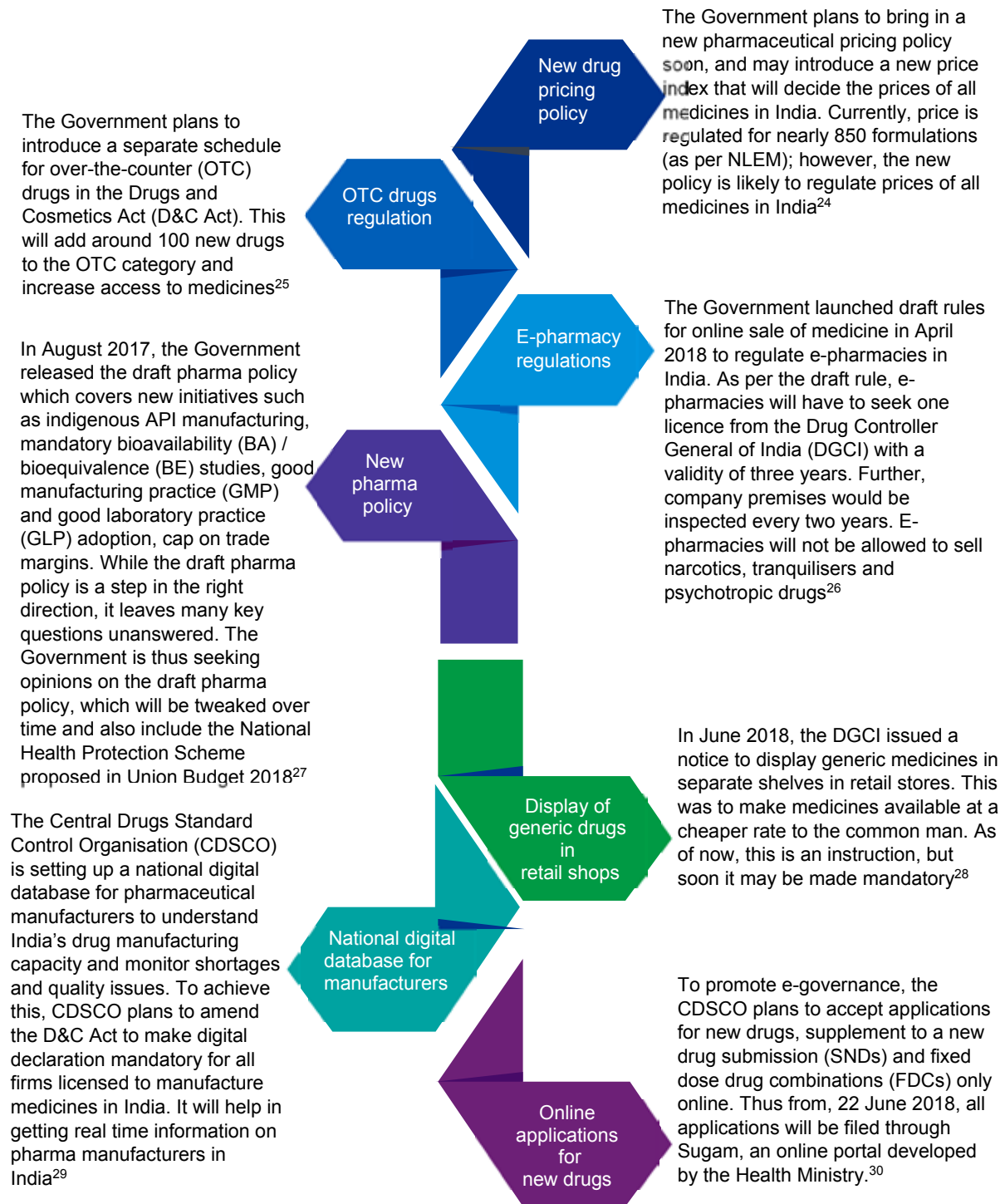
### Complex and uncertain regulatory regime

- The pharmaceutical industry is facing challenges around the complex drug approval process, lengthy approval timelines for setting up a manufacturing plant, stringent clinical trial guidelines and an unpredictable price control policy. The multiplicity of regulatory bodies with divided responsibilities leads to delays in decision making and implementation of policies



Source: KPMG in India analysis 2017

## Recent policy and regulatory developments



Sources: 24 - Govt may bring in new curbs on drug prices this month, Times of India, June 2018; 25 - India may soon give OTC drugs definition, The Economic Times, 20 September 2017; 26 - Purchase genuine medicines online as new ePharmacy draft moots single registry, Economic Times, 21 April 2018; 27 - Medicare to be part of India's new pharma policy, Live mint, 16 Feb 2018; 28 - Now, a rack for generic drugs in private chemist shops, The Hindu Business Line, 13 June 2018; 29 - Drug regulator plans national digital database of pharma manufacturers, 2 April 2018; 30 - CDSCO to accept only online applications for new drugs, SNDs and FDCs from June 22, Pharmabiz, 18 June 2018

To improve ease of doing business, a no objection-certificate (NoC) from CDSCO is no longer required for pharmaceutical exports. This new rule encourages hassle-free export of pharmaceutical products<sup>31</sup>

NoC not required for exports

The Government is planning a new FDC policy to streamline regulatory pathways for approvals. A panel is reviewing 349 banned FDC drugs, and is expected to submit its report in July 2018. The panel is reviewing the safety, efficacy and therapeutic justification for banning these drugs<sup>32</sup>

New FDC policy

The Government has made it mandatory for pharmaceutical companies to print generic names in a font size two times larger than the brand name. The rule will be implemented from 13 September 2018 to promote sale of generic drugs in the country<sup>33</sup>

New labelling rules

The Government may cap trade margins for pharmaceutical products to control drug prices in the country. The DoP recommended to the Ministry of Chemicals and Fertilizers to fix trade margins on all medicines with MRP above INR2 per unit while retaining it at the current level of 30 per cent for those priced below INR2 per unit. This is to curb profiteering by traders<sup>34</sup>

Trade margin cap

The Government is planning to amend the D&C Act to bring stem cells and cell-based products under legal regulations. Stem cells will be treated as drugs and will require regulatory approval to launch in the market<sup>35</sup>

Regulations for stem cells

In February 2018, the CDSCO issued the draft Clinical Trials Rules, 2018. The new rules aim to shorten the approval time for review of applications to 30–60 days<sup>36</sup> from the current average approval timeline of six to seven months<sup>36</sup>. The new regulations clearly define academic study, role of central licensing authority, trial protocol, biomedical and health research.

New clinical trial rules

Sources: 31 - CDSCO nod not mandatory to make unapproved drugs for export, DTAB clears proposal to empower state authorities, pharmabiz, 25 June 2018; 32- Panel reviewing safety of banned FDC drugs to submit report in July, Live mint, 25 May 2018; 33 - New labelling norms: Drug companies to have larger fonts for generic names, Moneycontrol, 20 March 2018; 34 - Govt may cap trade margins to control drug prices, Live Mint, 14 Feb 2018; 35 - Government of India seeks to define stem cells as drug, regulate use in therapy; scientists term move 'long overdue, Firstpost, 18 April 2018; 36 - India drug regulator expects to finalise new clinical trial rules in 2 months, 20 May 2018; 37 - Regulatory environment for clinical research: Recent past and expected future, Perspectives in Clinical Research, Volume 8, 2017



The Health Ministry is planning to amend the D&C Act to increase accountability on quality by marketing companies engaged in merchandising pharmaceutical products either as agents of licensed manufacturing companies or procurers from third party manufacturers<sup>39</sup>

BA/BE studies

The CDSCO launched a comprehensive draft guidance document in March 2018 to streamline the approval process for conducting BE and BA studies with human participants in India for export purposes<sup>38</sup>

Amendment in the D&C Act

WHO GMP certificate validity

The CDSCO increased the validity of the World Health Organisation (WHO) GMP certificate from two to three years to enable ease of doing business in the sector<sup>40</sup>

The CDSCO is planning to bring all implantable medical devices and other critical medical equipment under the D&C Act. These devices will be defined as drugs to control price and quality and will be regulated under the Medical Device Rules 2017<sup>41</sup>

Medical devices under the D&C Act

Track and trace mechanism

The CDSCO is planning a track and trace mechanism for the top 300 drug brands in the country to weed out counterfeit drugs from the Indian market. The plan is to print a 14-digit number on the label along with a mobile number of the manufacturer so that patients can easily check genuineness of the drug, if required<sup>42</sup>

The Government is planning to introduce a law to ensure doctors prescribe medicines by their generic names only. The Medical Council of India has already directed doctors to prescribe medicines by generic names in place of brand names<sup>43</sup>

Generic drug policy

Draft UCPMP

In December 2017, the DoP revised the Uniform Code of Pharmaceutical Marketing Practices (UCPMP). The Law Ministry, however, rejected the idea of putting it under the Essential Commodity Act, and has now referred it to the Niti Aayog<sup>44</sup>

Sources: 38 - CDSCO issues guidance document to streamline approval process for conducting BA/BE studies for export, 12 March 2018; 39 - Health ministry to amend D&C Rules to make marketing companies also accountable for quality of medicines, Pharmabiz, 10 July 2018; 40 - CDSCO increases WHO GMP certificate to three years for ease of doing business, The Economic Times, 8 May 2018; 41 - CDSCO to bring all implantable medical devices & other high end equipment under the category of 'drug' to ensure quality & reliability, Pharmabiz, 27 June 2018; 42 - CDSCO identifies 300 top brands for 'trace and track' mechanism, to meet firms on June 25 to discuss implementation, Pharmabiz, 19 June 2018; 43 - 'This scheme is a lifesaver': India's drive to provide cheap drugs, The Guardian, 25 June 2018; 44 - 4 years on, code to punish pharma firms for bribing doctors still in works, Times of India, 26 April 2018

## Government support to the pharmaceutical sector

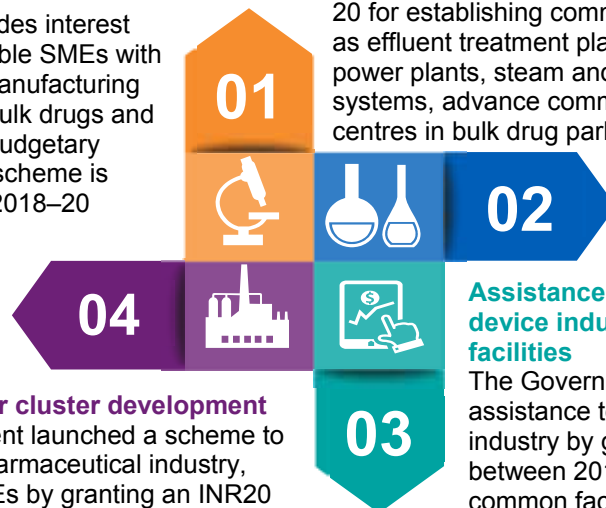
The Government has allocated over INR460 crore to help reduce cost of bulk drugs and medical devices by setting up common facilities centres, and help small and medium enterprises (SMEs) upgrade technology.<sup>45</sup>

### Pharmaceutical technology upgradation assistance scheme

The scheme provides interest subvention to eligible SMEs with GMP-compliant manufacturing facilities both for bulk drugs and formulation. The budgetary allocation for this scheme is INR144 crore for 2018–20

### Assistance to the bulk drug industry for common facilities

The Government is providing assistance to the bulk drug industry through an INR200 crore assistance between 2018–20 for establishing common facilities such as effluent treatment plants, captive power plants, steam and cooling systems, advance common testing centres in bulk drug parks



### Assistance for cluster development

The Government launched a scheme to support the pharmaceutical industry, especially SMEs by granting an INR20 crore assistance between 2018 and 2020 for setting up common facilities for testing, training, R&D, effluent treatment, logistics in a pharma cluster

### Assistance to the medical device industry for common facilities

The Government has planned assistance to the medical device industry by granting INR100 crore between 2018 and 2020 to set up common facilities for component testing, electro-magnetic interference laboratory, biomaterial testing, cabinet moulding, injection moulding for upcoming medical device parks

Source: Guidelines for implementation of sub-schemes under Scheme for development of Pharmaceuticals Industry, Department of Pharmaceuticals, June 2018

### Other notable Government schemes

**Pharmaceutical promotion and development scheme (PPDS):** to promote growth, development and export promotion in the pharmaceutical sector by extending financial support to conduct seminars, conferences, exhibitions, and so on

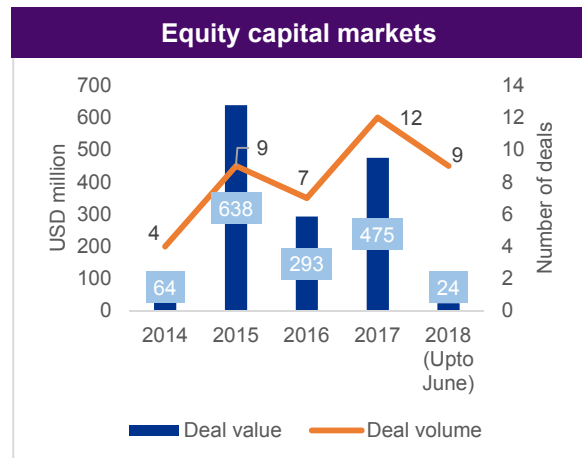
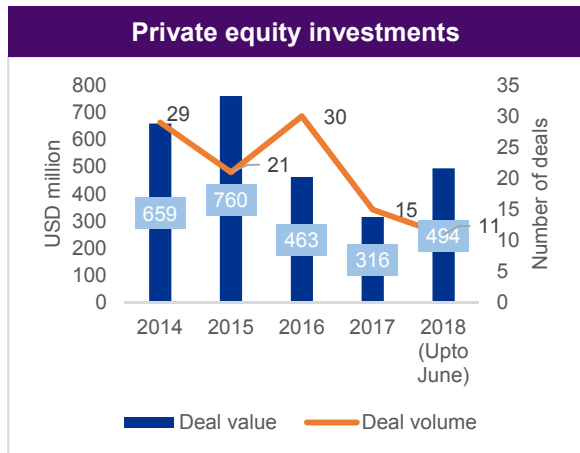
**Pradhan Mantri Bhartiya Janaushadhi Kendras:** to enable easy access to quality generic medicines at affordable rates and thus reduce out of pocket expenses in healthcare. As of June 2018, there were more than 3,600 Jan Aushadhi stores across the country

**Ayushman Bharat — National Health Protection Scheme:** This insurance scheme will cover over 10 crore poor and vulnerable families (approximately 50 crore beneficiaries) by providing coverage up to INR5 lakh per family per year for secondary and tertiary care hospitalization; the scheme is expected to boost demand for pharmaceutical products in the country.

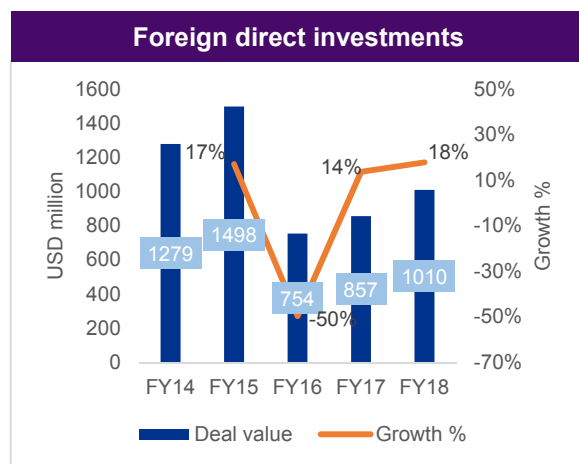
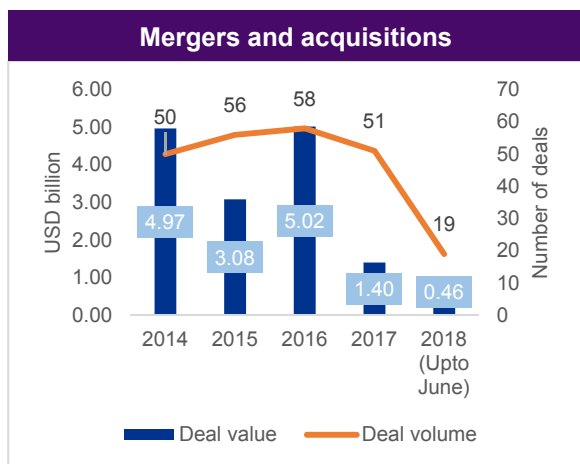
Source: Annual report 2017-18, Department of Pharmaceuticals, 2018; Govt to boost supply chain of Jan Aushadhi stores by setting up warehouses, Business Standard, 10 June 2018; Ayushman Bharat scheme will make India largest pharma manufacturer, The Week, February 2018

Source: 45 - Govt proposes over Rs 460 crore support for development of pharma sector, The Times of India, 25 June 2018

## Key investments in the life sciences sector



Source: Sector analysis – Pharmaceutical, Biotechnology, Life sciences tool & services, VCC edge database accessed July 2018



Sources: Sector analysis – Pharmaceutical, Biotechnology, Life Sciences tool & services, VCC edge database accessed July 2018; Fact sheet on Foreign Direct Investment in Drugs and Pharmaceutical, Department of Industrial Policy and Promotion, March 2018

## Future outlook

The pharmaceutical industry is transforming globally across all major parameters such as payment models, operating models, and business models. Regulatory structures are being revamped and evolving demographics are redefining demand.

Industry convergence and M&A are altering the value chain and creating new opportunities. As pressure mounts to reduce cost of healthcare, pharmaceutical companies are being challenged to prove their value against higher expectations.

With healthcare transforming rapidly, the pharmaceutical industry is also expected to deliver at both ends of the spectrum: generate scientific breakthroughs to meet evolving patient needs; and create innovative, efficient operating models to ensure that the most effective treatment reaches everyone.

The search for value is likely to drive pharmaceutical, medical device and diagnostics companies into new technologies, new business models and valuable partnerships that could lead to the next wave of transformation.

Following are the key trends impacting the pharmaceutical industry –

**01** Digitalisation to automation  
From drug development and manufacturing, to sales force management and compliance, digitalisation and automation are likely to drive and transform the pharmaceutical sector

**02** Technology for regulatory compliance  
Over the past decade, regulatory changes, growing compliance requirements and tax adjustments have been both catalysts and barriers to transformation in the pharmaceutical industry. As technology starts to play a greater role, many pharma companies are finding significant improvements in both cost and compliance, while uncovering new opportunities to drive growth

**03** Consumer commercialisation  
Consumers are more empowered than ever, and are demanding information in new ways. This is driving significant change not only in the way pharmaceutical companies detail and market their products, but is also redefining the relationship among patients, healthcare professionals and pharmaceutical companies

**04** Analytics integration  
By expanding the use of data; analytics; and technology, pharmaceutical companies are identifying opportunities to make significant improvements in decision making (particularly related to patient care and new product development), back-office operations, regulatory compliance reporting and drug discovery and development

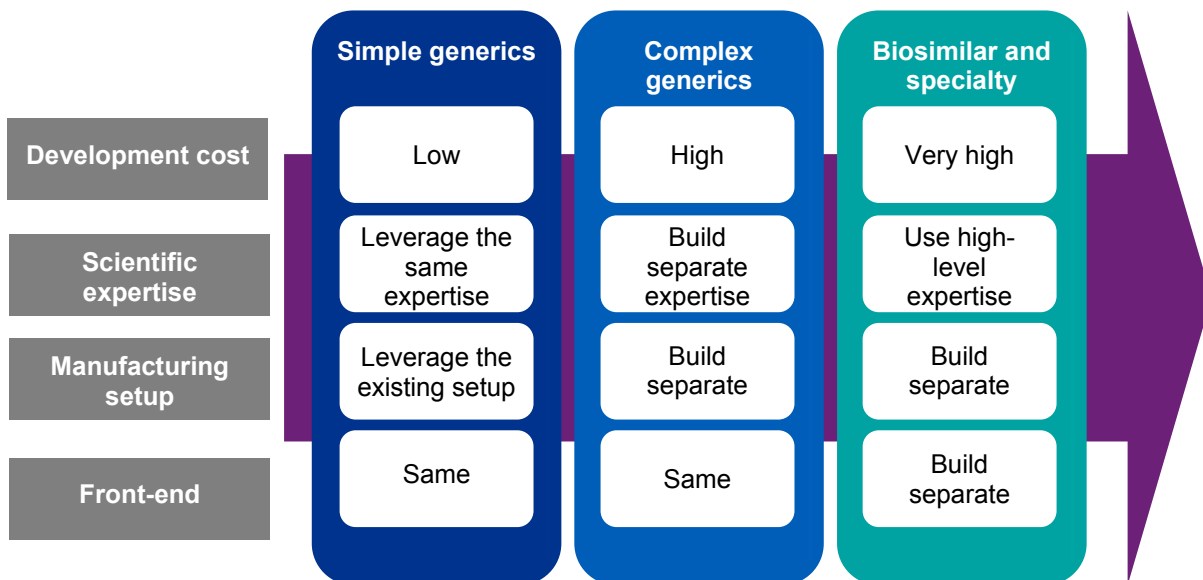
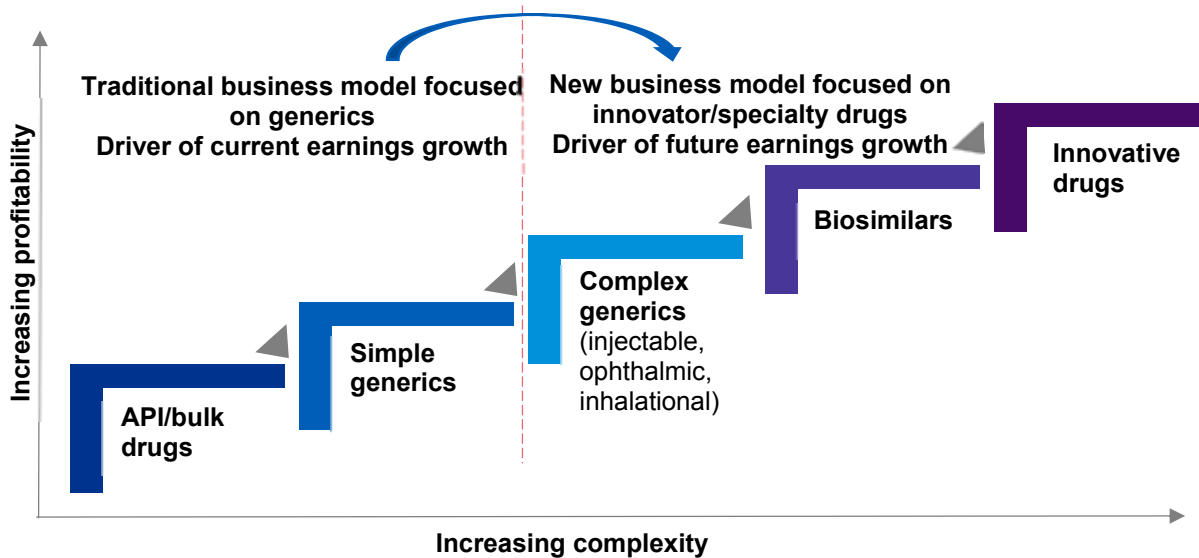
**05** Shift towards biosimilars  
Several countries are adopting biosimilars to provide affordable care and better access to drugs. The regulatory pathways are evolving towards establishing more rigorous standards for safety and efficacy of biosimilars. Patent expiries on major biologic products are also expected to push the growth of biosimilars globally.

Source: Thriving in an uncertain environment - the pharmaceutical industry refocuses, KPMG in U.S., 2017; KPMG in India analysis 2018

The Indian pharmaceuticals sector which has seen robust growth over the past decades is witnessing several headwinds such as continuous addition of drugs to the price control list, Government push towards generic-generic drugs, complex regulatory structure, price erosion in the U.S. generic market, and stricter FDA scrutiny. The typical generics business model is undergoing a sharp deterioration in returns as a result of these challenges.

The sector is currently transitioning from plain generics to high entry-barrier segments such as complex generics, biosimilars and specialty drugs which will not only increase the size of the opportunity in exports and domestic sales, but also insulate players from volume and price erosion in plain generics.

### Indian pharma — Business model transformation



Source: Indian Pharma - The new business model, UBS, August 2017 and Where is Indian Pharma Headed, Motilal Oswal, September 2017

Indian pharma companies are investing in capabilities across R&D, talent and also building capacity to facilitate their transition through this global change; companies are also investing in new-age technology and innovative business models.

While the environment poses several challenges for the industry, only time will tell whether some companies are able to turn these challenges into opportunities and present innovative breakthroughs that will change the face of this industry.

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The analysis of the global and Indian pharmaceutical landscape trends is attributed to KPMG in India.

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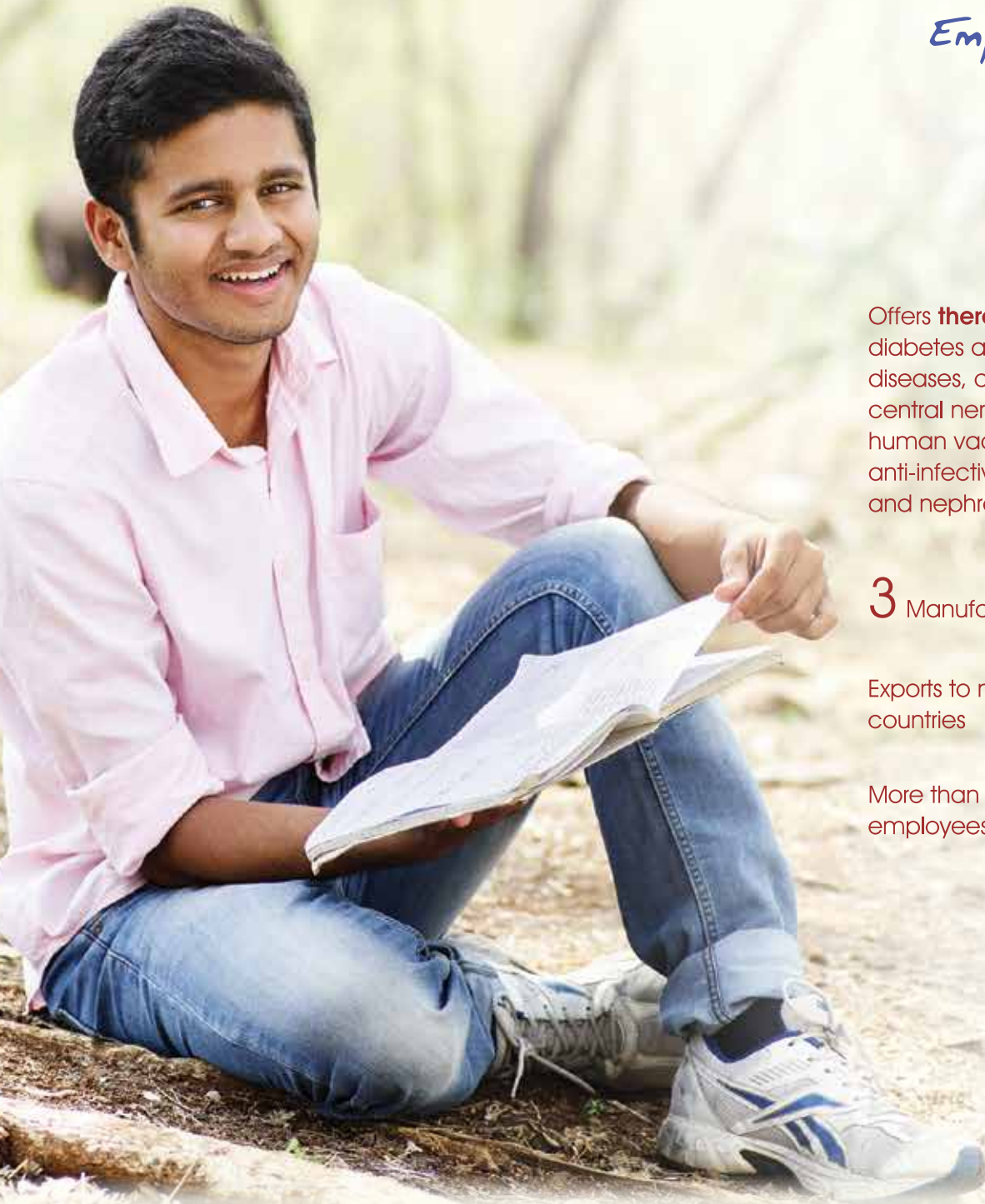
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Photo: 19-year-old Eshaan Shevate from India - the youngest member of an international team of people with Type 1 Diabetes, who participated in the Sanofi and World Diabetes Tour's 'Type 1 Diabetes Challenge' to Machu Picchu, Peru in 2014.

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**A**

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**M**

**Mineral Oil**

Slows skin function<sup>3</sup>

**A**

**Alcohol**

Can cause drying and skin irritation<sup>4</sup>

**S**

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1. Fernandes JD, Machado MC, Oliveira ZN. Children and newborn skin care and prevention. An Bras Dermatol. 2011 Jan-Feb;86(1):102-10. 2. Taylor JS & Amado A. Contact Dermatitis and Related Conditions. Cited 2017 December 28. Available from: <http://www.clevelandclinicmed.com/medicalpubs/disease/management/dermatology/contact-dermatitis-and-related-conditions/> 3. Crawford QD. Knowledge For Tomorrow: A Summarized Commentary Of World History, Nature, Health, Religion, Organized Crime, And Inspiration For The Youth. iUniverse, Inc. New York. 2005:pp:52. 4. U.S. Food and Drug Administration. "Alcohol Free". Updated 2014 October; Cited 2017 December 28. Available from: <http://www.fda.gov/Cosmetics/Labeling/Claims/ucm2005201.htm>



# Work Groups (WG)

## Access & Affordability

Initiatives	Advocacy
A clear charter of the Work Group was drawn to identify its scope	Approach of the Work Group was through communication by showcasing the various access initiatives of our members in India
To build a platform that will showcase the collective work of our members	Augmented the role of OPPI as a committed partner for improving access in India
A focused panel discussion on the role of insurance in driving access to healthcare at the OPPI Annual Summit 2018 themed Health Meets Hope	Collaborated with several organisations including CHAI, GIC, J & J Inc, Medanta and National Health Agency
OPPI's digital campaign #ThinkForHealth, in collaboration with Govt. of Telangana to promote access in four identified areas including woman & child health, mental health, NCDs and Health technology. The campaign calls for ideas to progress healthcare access with the winning ideas getting an opportunity to be heard, rewarded and funded	Partnered with a state Government in a first-of-its-kind digital campaign

### Impact

Health Meets Hope, a comprehensive microsite on the OPPI website showcases the collective initiatives of member companies, especially in the area of woman & child health, mental health, NCDs and Health technology. The microsite endeavours to establish the role of member companies as committed partners in the healthcare journey of the country.

#ThinkForHealth, a nation-wide digital campaign calls for ideas to progress access. Aimed at inspiring and innovating young minds, social entrepreneurs and health tech experts to think of fresh ideas in the four identified areas, the campaign will allow for the winning ideas to be mentored and commercialized by the Govt. of Telangana.

**CHAIRPERSON:** Anand Nambiar\* (Merck)

**CO-CHAIRPERSON:** Vivek Kamath (MSD Pharmaceuticals)

**OPPI LEADS:** Rajiv Shukla • Nitika Garg

**MEMBERS:** Rajaram Sankaran (Abbott)\* • Pusphak Khare (Abbott)\* • Anup Godbole (Allergan) • Sonika Shah\*(Amgen) • Devendra Mehta (Astellas) • Atul Tandon (AstraZeneca) • Gopal Agrawal (Baxalta Biosciences) • Deepak Chopra (Bayer) • Pradeep Sharma (Bayer) • Jagpreet Duggal (Boehringer Ingelheim) • Raghavendra Agarwal (Bristol-Myers Squibb) • Viral Mehta (Bristol-Myers Squibb) • Saumil Mody (Eisai) • Inderpal Singh (Eli Lilly) • Hema Srinivasan (Gilead) • Annapurna Das (GSK Pharmaceuticals) • Mahesh Kalsekar (GSK Pharmaceuticals) • Sarthak Ranade (Johnson & Johnson) • Aditya Berlia (Martin & Harris) • Nitesh Sharma (Merck) • Ruchita Mehra (Merck) • Anjan Sen (MSD Pharmaceuticals) • Sudheendra Kulkarni (MSD Pharmaceuticals) • Madhusudhan HK (Nestle Skin Health) • Rajni Abhijit (Novartis) • Sanchit Nanda (Novartis) • Vinay Ransiwal (Novo Nordisk) • Shashank Shanbhag\* (Pfizer) • V.Simpson (Roche) • Nakul Verma (Sanofi) • Sangita Topiwala (Sanofi) • Geeta Karnik (Serdia) • S. Raja Reddy (Serdia) • Sudip Chakraborty (UCB)

\*Resigned

## Compliance & Governance

Initiatives	Advocacy
Revised IFPMA Code	OPPI members have agreed to adopt the new global Code
Gamification of the OPPI Code of Pharmaceutical Practices	Work-in-progress: An internet-based game on the revised OPPI Code effective January 2019
A focused panel discussion on Ethics and Business Integrity at the OPPI Annual Summit	Collaborated with Patients Engage, PhRMA, TLEX Institute, CLG, IAPO & PointBlank to establish the importance of ethical marketing practices for responsible patient care.
Need for UCPMP	Advocated with Department of Pharmaceuticals for a standard UCPMP

### Impact

OPPI member companies endeavour to bring new treatments and cures for the benefit of patients. Pharmaceutical companies discover, develop, promote, sell and distribute their products in an ethical manner and in accordance with all the rules and regulations for medicines and healthcare. The overarching values of trust, care, fairness, respect and honesty guide their actions.

OPPI Compliance & Governance Work Group championed the adherence of core values and principles governing interactions with healthcare professionals and the broader health community, with the single-minded approach of patient safety.

**CHAIRPERSON:** Jitendra Tyagi (Bristol-Myers Squibb)

**CO-CHAIRPERSON:** Sridhar Ranganathan (Allergan)

**OPPI LEAD:** Rajiv Shukla

**MEMBERS:** Arun Kasat (Abbott)\* • D. Vijaya Prakash (Abbott)\* • Prem Kumar (Allergan) • Priya Rawal (Astellas) • Ramesh Varadarajan (AstraZeneca) • Mehnaz Qureshi (Baxalta Biosciences) • Neha Kshirsagar (Bayer) • Raelene Antao (Bayer) • Shreedhar Tantri (Bilcare) • Delvin Mathews (Boehringer Ingelheim) • Dr Viraj Suvarna\* (Boehringer Ingelheim) • Siddhartha Devani (Bristol-Myers Squibb) • Shubhangi Naik (Eisai) • Dr Gunjan Kaul Singh (Eli Lilly) • Varun Jain (Gilead) • Ashish Vohra\* (GSK Pharmaceuticals) • Jayashree Shetty (Johnson & Johnson) • Sachin Salian (Johnson & Johnson) • Dr Rajesh Chitre (Merck) • Muralidhar Karanam (MSD Pharmaceuticals) • Navaneetha Kumar (Novartis) • Nitesh Bakshi (Novo Nordisk) • Sandeep Seth (Pfizer) • Pankaj Dahibhate\* (Roche) • Arjun Thakkar (Sanofi) • Bratin Bag (Sanofi) • Dr Anita Bhat (Serdia) • Sofi Joseph (Serdia) • Jasmina Bisht (UCB)

\*Resigned



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We are on a quest to cure and to help people go on, unburdened, to experience, create and live their best lives.

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MSD in India currently operates in various therapeutic areas in human health, including Metabolics, Vaccines, Critical Care, Oncology, Women's Health, Dermatology, Respiratory, and Primary Care, and offers a strong and diversified product portfolio of over 35 brands.

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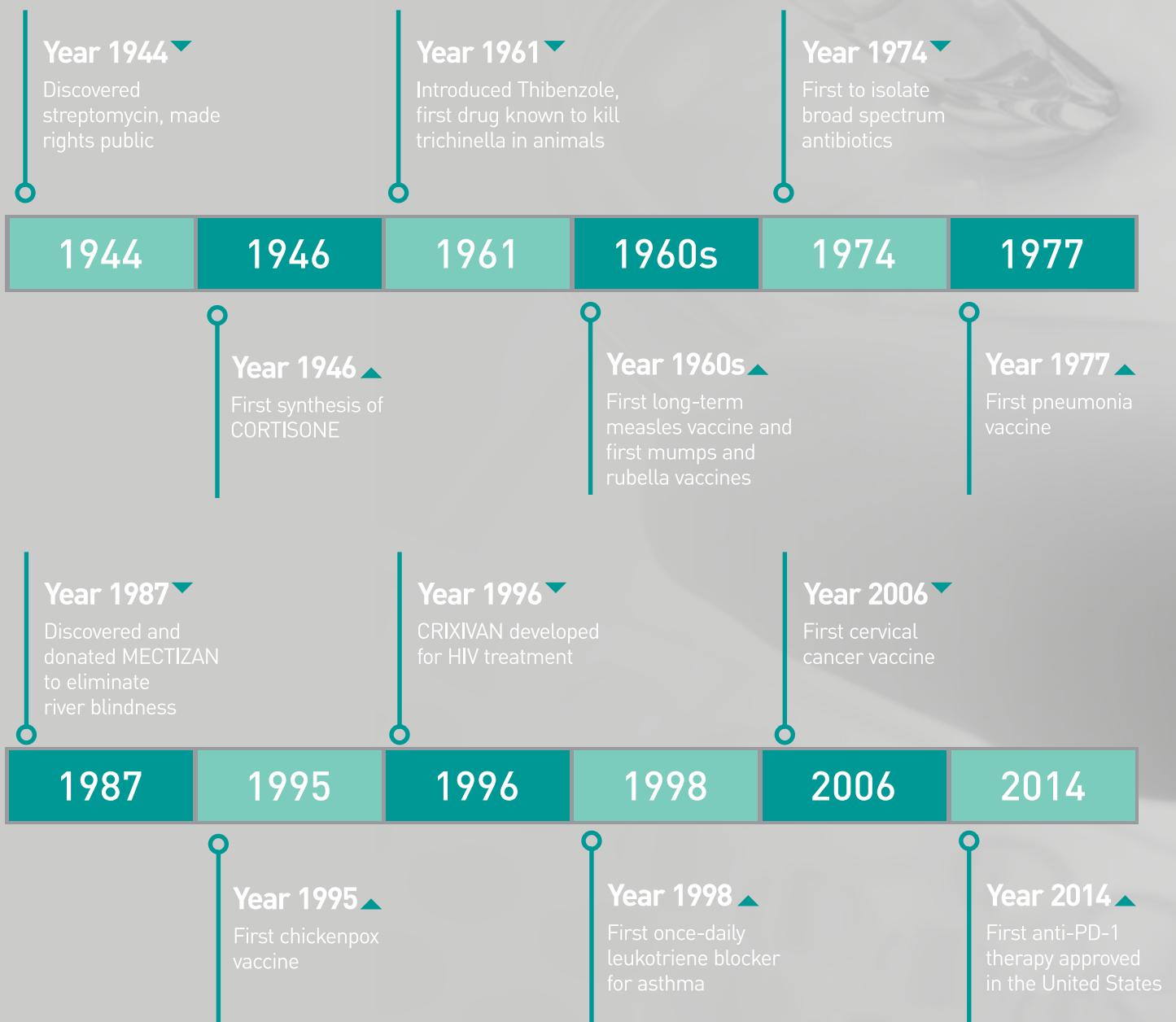
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## Finance and Taxation

Initiatives	Advocacy
Issues related to GST: input credit for date expired goods, consent for physicians' samples to be allowed as these expenses are in furtherance of business, need for place of supply for R & D services to be made recipient- based and ease of Compliance burden of Job-Work (Loan Licence manufacture)	Industry-wide issues were represented through multiple dialogues the Ministry of Finance and GST council and other relevant stakeholders
Issues related to NPPA: delink of Form I and IV applications from IPDMS and other requirements, delay in implementing Review orders etc, issue of immediate price implementation	Collaborated with relevant associations through representations on the need to allow time for the necessary change in labels. Disseminated information to members on ReviewOrders, and Judgment on DPCO
Worked on the change in labels due to inclusion of Tramadol under NDPS Act	Partnered with relevant associations and Ministry of Finance & CDSCO office to obtain an extension for including the necessary labelling changes
Ongoing advocacy on the draft DPCO Amendments 2018	Participated in several rounds of consultation with Government representatives and other relevant industry bodies
Recommendations on Union Budget 2018	Submitted pre and post budget representations

### Impact

The continuous efforts of the Finance & Taxation Work Group have led to delink of Form I and Form IV from IPDMS and other requirements; issuance of WPI notification for 2018-19 and grant for extension of 120 days for labelling of Tramadol.

The submissions by the Work Group on the DPCO Amendment 2018 was well received. The Work Group conducted seminars on the Union Budget 2018 which were well attended by the OPPI members.

**CHAIRPERSON:** S. Sridhar (Pfizer)

**OPPI LEADS:** Dr Ajay Sharma • M.K. Narayanaswamy

**MEMBERS:** Vishal Maheshwari (Abbott)\* • Rajesh Sharma (Allergan) • Rajesh Marwaha (AstraZeneca) • Vishvajeet Singh (Baxalta Biosciences) • Radha Khatu (Bayer) • Sachin Sule (Bayer) • Sandip Agrawal (Boehringer Ingelheim) • Harsh Mehta (Bristol-Myers Squibb) • Govind Jaiswar (Eisai) • Vishal Dhoot (Eli Lilly) • Andrew Arisidou\* (GSK Pharmaceuticals) • Puja S. Thakur (GSK Pharmaceuticals) • Veena Menda (Johnson & Johnson) • Kalpana Umakanth (Martin & Harris) • Amit Gupta (Merck) • Rajesh Tendolkar (MSD Pharmaceuticals) • Nimit Sanghvi (Nestle Skin Health) • Jaideep Gadgil (Novartis) • Sudhir Ghatge (Novartis) • Suhas R. Karambelkar (Novo Nordisk) • Nisha Mer (Pfizer) • Ravi Prakash Bhagavathula\* (Pfizer) • Sharad Goswami (Pfizer) • Daniel Pluess (Roche) • Vikas Aggarwal (Roche) • Charles Billard (Sanofi) • Lionel Guerin\* (Sanofi) • Vaibhav Karandikar (Sanofi) • Geeta Karnik (Serdia) • Vinay Potdar (Takeda) • Banibrata Lahiry (UCB) • Vaishali Paradkar (UCB)

\*Resigned

## Intellectual Property Rights (IPR) & Legal

Initiatives	Advocacy
Conducted a brainstorming session on IPR advocacy: <i>why innovation is critical for patients and the economy</i>	Discussions included: <ol style="list-style-type: none"> <li>Defining the IP ecosystem for pharma in India</li> <li>Defining the value of innovation</li> <li>Understanding policy makers' position on the IP policy for Pharma</li> <li>Defining stakeholder engagement</li> <li>Collaboration with industries and other stakeholders who add value to the ecosystem through innovation</li> </ol>
Convened a roundtable on the <i>Future of biopharmaceutical innovation in India</i> in collaboration with Department of Industrial Policy and Promotion AND Invest India	Discussed the need for policies that promote biopharmaceutical innovation in the country. Identified key drivers of biopharmaceutical Innovation – Research & Development and Artificial Intelligence
Advocacy for the need of a database of all approvals granted by State FDA's and Centre to be made public by CDSCO	Represented for simple notifications system to be adopted by CDSCO under its ongoing SUGAM initiative for streamlining the drug approval process
Continued advocacy on some of the challenges related to IPR that are faced by innovator pharmaceutical companies in the country	Representations and continued engagement with stakeholders on the current IPR challenges
Collaborated with global sister associations on <i>Working of Patents, Trade Marks and Design</i>	A joint approach and statement was made on the subject

### Impact

OPPI believes that there is a need to build and strengthen a positive IP environment for both patients and manufacturers that recognises and rewards innovation.

The roundtable established the need to address regulatory and policy hurdles that hinder future innovation in biopharmaceuticals in India. The sustained efforts of the IPR Work Group has led to the creation of a database of all marketing approvals granted by Centre and State FDA's.

The Work Group collaborated with the international associations in developing a joint representation that was made to the Controller General of CGPD TM office.

**CHAIRPERSON:** Sharad Tyagi (Boehringer Ingelheim)

**CO-CHAIRPERSON:** Manoj Saxena (Bayer) • Jawed Zia\* (Novartis)

**OPPI LEADS:** Dr Ajay Sharma • Nitika Garg

**MEMBERS:** Ghanashyam Hegde (Abbott)\* • Kaiyomarz Marfatia (Abbott)\* • Prem Kumar (Allergan) • Anuja Kadian (AstraZeneca) • Pankaj Jain (AstraZeneca) • Aparna Jetly (Baxalta Biosciences) • Gunjan Malhotra (Baxalta Biosciences) • Ashish Gawde (Bayer) • Neha Kshirsagar (Bayer) • Rajiv Wani (Bayer) • Rahul Bharadia (Bilcare) • Delvin Mathews (Boehringer Ingelheim) • Kedar Suvarnapathaki (Boehringer Ingelheim) • Shubhangi Naik (Eisai) • Dibakar Bhattacharya (Eli Lilly) • Varun Jain (Gilead) • Kaizad Hazari\* (GSK Pharmaceuticals) • Nischal Hindia (GSK Pharmaceuticals) • Tapan Pati (Johnson & Johnson) • Nishant Berlia (Martin & Harris) • Vikas Gupta (Merck) • Jyotsna Ghoshal (MSD Pharmaceuticals) • Muralidhar Karanam (MSD Pharmaceuticals) • Atul Bade (Novartis) • Sanjeev Shrivastav (Novartis) • Nitesh Bakshi (Novo Nordisk) • Masood Alam (Pfizer) • Samir Kazi (Pfizer) • Sharad Goswami (Pfizer) • Rahul Vartak\* (Roche) • Shivprasad Laud (Roche) • Dr Vivek Kashyap (Roche) • Abhijit Yadav (Sanofi) • Yasmin Cama (Sanofi) • Geeta Karnik (Serdia) • Sofi Joseph (Serdia) • Banibrata Lahiry (UCB)

\*Resigned

## Medical and Regulatory

Initiatives	Advocacy
Organised OPPI Medical Forum 2018	With over 200 participants from the industry, the event in the consecutive second year of existence provided regulatory and technology updates that impact work across different functions such as Medical Affairs, Clinical Research, Regulatory and Pharmacovigilance
Representation on the draft Clinical Trials Rules 2018	Identified key advocacy messages to communicate to relevant stakeholders
Abolishment of the mandatory NIB testing of all imported insulin batches since 2012	Representations and consistent consultations with stakeholders led to discontinuation of this practice
Mandatory Ethics committee registration	Worked with stakeholders to obtain an extension to the mandatory registration
Worked on addressing the challenges on the SUGAM portal	In dialogue with CDAC, CDSCO
Inclusion of the OPPI Medical Excellence Award as part of OPPI Annual Awards 2018	The Award recognises the impact of Medical Affairs on commercial operations of products and services

### Impact

The continued efforts of the Work Group have helped to discontinue the mandatory insulin testing by NIB and led to greater ease of doing business for OPPI members.

The Work Group continued to advocate for separate rules for Clinical trials in the country.

**CHAIRPERSON:** Sanjiv Navangul (Johnson & Johnson)

**CO-CHAIRPERSONS:** Dr Suresh Menon (Novartis) • Suneela Thatte (IQVIA)

**OPPI LEADS:** Dr Ajay Sharma • Prem Singh

**MEMBERS:** Dr Balagopal Nair (Abbott)\* • Shiraz Kandawalla (Abbott)\* • Dr Ammar Raza (Allergan) • Dr Thirumalai Velu (Allergan) • Sonika Shah (Amgen) • Arun Mishra (Astellas) • Dr Pratik Shah\* (Astellas) • Himani Shah\* (Astellas) • Dr Anilda D'Souza (AstraZeneca) • Dr Nagaraj Bannur (AstraZeneca) • Mamta Singh (Baxalta Biosciences) • Rohit Arora\* (Baxalta Biosciences) • Ashish Gawde (Bayer) • Manali Agrawal (Bayer) • Dr Shraddha Bhure (Boehringer Ingelheim) • Dr Viraj Suvarna\* (Boehringer Ingelheim) • Kedar Suvarnapathaki (Boehringer Ingelheim) • Poonam Rohira (Bristol-Myers Squibb) • Pradeep Shetty (Bristol-Myers Squibb) • Dr Mangesh Kamle (Eisai) • Lipi Chakhaiyar (Eli Lilly) • Parveen Jain\* (Eli Lilly) • Rajeev Sharan Shrivastava (Eli Lilly) • Rohit Arora (Eli Lilly) • Tarun Puri \*(Eli Lilly) • Dr Rahul Bargaje (Gilead) • Dr Bhavesh Kotak (GSK Pharmaceuticals) • Sukanya Choudhury (GSK Pharmaceuticals)



- Dr Prasanna Bangale (Johnson & Johnson) • Dr Prashant Desai (Johnson & Johnson) • Dr Vikram Singh\* (Johnson & Johnson) • Nishant Berlia (Martin & Harris) • Dr Nitin Mulgaonkar (Merck) • Dr Swashraya Shah\* (MSD Pharmaceuticals)
- Dr Viraj Salgaonkar (MSD Pharmaceuticals) • Rahul Luthra (MSD Pharmaceuticals) • Amanjit Kaur Ahluwalia (Nestle Skin Health) • Amita Bhave (Novartis) • Dr Anil Shinde (Novo Nordisk) • Dr Guruprasad Thimmaiah (Novo Nordisk)
- Anurita Majumdar (Pfizer) • Manish Paliwal (Pfizer) • Shashwati Devsharma (Pfizer) • Dr Anil Kukreja (Roche)
- Seema Shimpi (Roche) • Dr Mubarak Naqvi\* (Sanofi) • Dr Shalini Menon (Sanofi) • Yasmin Shenoy (Sanofi)
- Dr Preeti Nikam (Serdia) • Sofi Joseph (Serdia) • Naveen Kumar Nagaraja (Takeda) • Prashant Agrawal (Takeda)
- Dr Prashant Dongre (UCB) • Meenu Batolar (UCB)

\*Resigned



# Advancing Therapeutics. Improving Lives.

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. Gilead's portfolio of products and pipeline of investigational drugs includes treatments for HIV/AIDS, liver diseases, cancer, inflammatory and respiratory diseases, and cardiovascular conditions.

We believe that everyone in need should have access to our medicines, regardless of where they live or what resources they have. Gilead's dedicated Access Operations & Emerging Markets business unit is focused on enabling sustainable access to high-quality, low-cost therapies for viral hepatitis, HIV and visceral leishmaniasis for millions of people in more than 135 countries worldwide.

2018 marks 15 years since Gilead began treatment access initiatives in developing countries including India. We recognize that each country faces its own set of barriers to health and access to medicines and pursue innovative approaches in order to close treatment gaps.



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# Committees

## Human Resources Management

Initiatives	Advocacy
Collaboration with other Industry Associations / Forums on topics related to industrial relations	Collaborated with relevant industry bodies such as IDMA, EFI and AIOE on messages
Study on Workforce of future by Accenture	Developed a white paper on the job/role specific work skills for the industry
Enhancement of skills <ul style="list-style-type: none"> <li>Continued support to the initiatives of the Life Sciences Sector Skill Development Council (LSSSDC)</li> <li>Managed knowledge dissemination programmes throughout the year</li> </ul>	Supported LSSSDC in their ongoing initiatives  Conducted several programmes during the committee meetings

### Impact

The rapid digital transformation, evolving regulatory landscape and most importantly the rising wave of consumerism have necessitated the need to re-design people strategies at the workplace. To this end, OPPI along with Accenture prepared a whitepaper that captures the broad themes that will become relevant to the future workforce of the pharmaceutical industry.

Besides this, the Human Resource Management Committee addressed the current HR challenges faced by the industry and collaborated with relevant industry bodies and aligned with common messages and themes.

**CHAIRPERSON:** G. Sathya Narayanan (Nestle Skin Health)

**CO-CHAIRPERSON:** Ashok Bhattacharya (Takeda)

**OPPI LEAD:** Rajiv Shukla

**MEMBERS:** Deepshikha Mukherjee (Abbott)\* • Debashish Chatterjee\* (Allergan) • Natasha Tiwary (Allergan) • Smita Saha (AstraZeneca) • Priyank Parakh (Baxalta Biosciences) • K.S. Harish (Bayer) • Kumar Amitabh (Bayer) • Sanjay Srivastava (Boehringer Ingelheim) • Abhijit Naik (Eisai) • Anant Garg (Eli Lilly) • Meenakshi Priyam (GSK Pharmaceuticals) • Cecilia Azavedo (Johnson & Johnson) • Vikram Patki (Merck) • Sameer Tamhane (MSD Pharmaceuticals) • Abhigyan Ghosh (Nestle Skin Health) • Savitha Shivsankar (Novartis) • Ravi Subramanian\* (Pfizer) • Shilpi Singh (Pfizer) • Swati Yadav (Roche) • Gaurav Bahadur (Sanofi) • Vinod Shetty (Sanofi) • Jui Dabir (Serdia) • Grishma Patel (UCB)

\*Resigned

## Technical & Supply Chain

Initiatives	Advocacy
Created awareness on Quality Standards- Industry perspective	Employed digital media and conducted knowledge sessions
Organised the OPPI Quality Summit 2018	Collaborated with Department of Pharmaceuticals (DoP), Quality Council of India (QCI), Indian Pharmaceutical Alliance (IPA), Indian Drug Manufacturers Association (IDMA) and patient groups: Indian Alliance of Patient Groups and Partnership for Safe Medicines (PSM)
Conducted a focused panel discussion on the need for accepted quality standards in the Annual Summit 2018 themed Health Meets Hope	Engaged in discussions with DCGI, THSTI, QCI, PSM
Worked on the challenge of Counterfeits	Worked on the OPPI Proposal on Track and Trace
Collaborated with industry associations on industry initiatives to upgrade Schedule M to WHO GMP standards	Supported the DoP – IDMA Seminar

### Impact

The Committee worked on several initiatives that highlighted the need for accepted quality standards that ensured patient safety. To this end, awareness was created by a well-attended webinar of the Chair of the Committee on ET Healthworld, as a precursor to the OPPI Quality Summit 2018.

The proceedings of the Quality Summit were put together in a white paper titled *Journey towards Quality Excellence* with knowledge partner- McKinsey & Company. A dedicated column on quality titled Know Your Pill (KYP) has been initiated in Express Pharma, the leading pharma vertical magazine from the Indian Express Group. This column will cover six separate subjects that makes a pill more than just a pill.

**CHAIRPERSON:** Dr Sanjit Singh Lamba (Eisai)

**CO-CHAIRPERSON:** Dr Ramesh Panchagnula (Nektar)

**OPPI LEAD:** Rajiv Shukla

**MEMBERS:** Akkaraju Rajasekhar (Abbott)\* • Atul Kanyalkar (Abbott)\* • Shailendra Bobhate (Abbott)\* • K.T. Rajan\* (Allergan) • Himanshu Saxena (AstraZeneca) • Sanjay Manjrekar (Bayer) • Vinay Phatak (Bayer) • Ankush Gade (Bristol-Myers Squibb) • Lokesh Sharma (Eisai) • Ashwani Kumar Wadhwa (Eli Lilly) • Varun Jain (Gilead) • Raju Krishnaswamy (GSK Pharmaceuticals) • Himanshu Maloo (Johnson & Johnson) • Bipin Deshpande (Merck) • Dharmesh Kharwar\* (MSD Pharmaceuticals) • Pradeep Kumar (MSD Pharmaceuticals) • Sanjay Bhatkhande (MSD Pharmaceuticals) • Anand Dixit (Nestle Skin Health) • Keyur Parikh (Nestle Skin Health) • Dr Firdosh Gardin (Novartis) • Suhas R Karambelkar (Novo Nordisk) • Aninda Shome (Pfizer) • Vivek Dhariwal (Pfizer) • Arun Manjeshwar (Roche) • Seema Shimpi (Roche) • Ashwani Sood (Sanofi) • Krishna Parab (Sanofi) • Santhosh Menon (Serdia) • Sachin Gaonkar (UCB)

\*Resigned



## It begins with a Promise

Lilly unites caring with discovery to make life better for people around the world. With heritage of more than 140 years, approximately 41,000 employees worldwide, products marketed in 120 countries and clinical research being conducted in more than 55 countries, we work tirelessly to develop and deliver trusted medicines for some of the most stubborn and devastating diseases. In **India**, we are a team of around 700 committed, diverse and talented people, who aspire to make a meaningful impact on people and communities in **India**.

**Eli Lilly and Company (India) Pvt. Ltd.**

Plot No. 92, Sector 32, Institutional Area, Gurgaon - 122 001, Haryana-(INDIA)

*Lilly*

# PATIENT SUPPORT PROGRAM

Holistic disease management through patient-centric service offerings

MEDICATION ADHERENCE AND COMPLIANCE 

PATIENT ENGAGEMENT 

BRAND LOYALTY 

ACCESS TO MEDICATION 

QUALITY OF LIFE 

# INTEGRATED RURAL HEALTH

A collaborative healthcare platform for the patients in the hinterland

 AWARENESS

 DIAGNOSIS

 TREATMENT

 ACCESS



## About us

Tech Mahindra represents the connected world, offering innovative and customer-centric information technology experiences, enabling Enterprises, Associates and the Society to Rise™. We are a USD 4.9 billion company with 113,550+ professionals across 90 countries, helping over 926 global customers including Fortune 500 companies. Our convergent, digital, design experiences, innovation platforms and reusable assets connect across a number of technologies to deliver tangible business value and experiences to our stakeholders. Tech Mahindra is amongst the Fab 50 companies in Asia (Forbes 2016 list).

We are part of the USD 21 billion Mahindra Group that employs more than 200,000 people in over 100 countries. The Group operates in the key industries that drive economic growth, enjoying a leadership position in tractors, utility vehicles, after-market, information technology and vacation ownership. Learn more about Mahindra on [www.mahindra.com](http://www.mahindra.com) / Twitter and Facebook: @MahindraRise



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# Tech Mahindra

Connected World. Connected Experiences.

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# Task Force

## Over-the-counter (OTC) special task force

Initiatives	Advocacy
Prepared a white paper on the need for robust OTC guidelines for the country	Advocated the need for OTC guidelines for responsible self-medication for patients
Collaborated with Indian pharma companies	Collaborated with the Indian industry to collectively advocate for OTC guidelines
Conducted an OTC Policy Workshop at CDSCO, Hyderabad	A white paper was created which captured both the industry and Government perspectives.
Represented with various Government stakeholders, the importance of OTC in the roll-out of the Ayushman Bharat	As Ayushman Bharat sets out to improve access, a robust OTC guideline will accelerate the process

### Impact

OTC medicines have played a significant role in expanded access to safe and effective treatments in developing regions of the world. However, India lacks defined regulations over OTCs thereby compromising patient safety. The objective of the special OTC Task Force was to prepare a proposed set of OTC guidelines that will expand access of medicines in the country as well as educate patients on responsible self-medication.

The OTC taskforce continues to work together with the Government to build an inclusive patient-centric healthcare ecosystem with a robust OTC guideline that will enhance options for patients and help support the movement toward greater patient empowerment and self-care.

**CHAIRPERSON:** Ambati Venu (Abbott)\*

**CO-CHAIRPERSON:** G. Sathya Narayanan (Nestle Skin Health)

**OPPI LEAD:** Nitika Garg

**MEMBERS:** Ramakrishnan Sundaram (Abbott)\* • Mamata Kulkarni (Bayer) • Sophia Gonsalves (Bayer) • Anantha Nayak (Cipla Limited) • Nitin Jajodia (Cipla Limited) • Glenn Saldanha (Glenmark Pharmaceuticals) • Sujesh Vasudevan (Glenmark Pharmaceuticals) • Annaswamy Vaidheesh (GSK Pharmaceuticals) • Mahesh Kalsekar (GSK Pharmaceuticals) • Dr Prasanna Bangale (Johnson & Johnson) • Anil Kaushal (Lupin Limited) • Nilesh Gupta (Lupin Limited) • Brijesh Kapil (Merck) • Vivek Kamath\* (MSD Pharmaceuticals) • Vijaykumar Krishnamurthy (Nestle Skin Health) • Mayur Bhargava (Novartis) • Madhav Joshi (Pfizer) • Nikhilesh Kalra (Sanofi) • Kalyanasundaram Subramanian (Sun Pharmaceutical Industries Ltd) • Pranav Mehta (Torrent Pharmaceuticals Ltd) • Sudhir Mehta (Torrent Pharmaceuticals Ltd)

\*Resigned

# ANNUAL AWARDS

The OPPI Healthcare Access Awards recognises the highest contribution by an individual or Institution on Access to Healthcare with consideration for patient safety and adherence to quality.

## Congratulations to the winners of the 2018 OPPI Healthcare Access Awards!



Recognized for her contribution towards improving women's health - Dr Duru Shah, Scientific Director of Gynaecworld and the Gynaecworld Assisted Fertility Center



Recognized for her outstanding work in healthcare delivery - Meena Ganesh, CEO and MD Portea Medical



Recognized for her commitment towards improving healthcare access in India - Dr Daksha Shah, Deputy Executive Health Officer (TB) MCGM

## Well done Winners of the 2017 Awards!



Winner of OPPI Best Vendor Award - Anti-Counterfeiting Solution Provider- Bilocare Limited



Winner of OPPI Best Vendor Award - Packaging Material Supplier - Bilocare Limited





**Winner of Scientist Award - Dr D. Srinivasa Reddy, CSIR - National Chemical Laboratory, Pune**



**Winner of Woman Scientist Award - Dr Chitra Mandal, Indian Institute of Chemical Biology, Kolkata**



**Winner of Young Scientist Award - Dr Debabrata Maiti, Department of Chemistry, IIT Bombay**

OPPI has instituted Annual Awards for excellence in Research, Sales, Marketing and Supply Chain.

These awards have now become the gold standard of the pharmaceutical industry.



**Winner of OPPI HR - Diversity and Inclusion Award - MSD Pharmaceuticals Pvt. Ltd**



**Winner of OPPI HR Excellence Award - MSD Pharmaceuticals Pvt. Ltd**



**Winner of OPPI Marketing Excellence Award-Existing Product- Trajenta, Boehringer Ingelheim India Pvt. Ltd**



**Winner of OPPI Marketing Excellence Award-New Product- Qilib, Nestle Skin Health India Pvt. Ltd**



**Winner of OPPI Sales Force Excellence Award - Building of 'Quality of Voice' in Cardiovascular & Metabolics Team - MSD Pharmaceuticals Pvt. Ltd**



**Winner of OPPI Sales Force Excellence Award - Going for Gold in Customer Facing Excellence Project - Baxalta Biosciences India Pvt. Ltd**

# ARTWORK & PACK MANAGEMENT

Reduces product recalls due to packaging errors, at a lower cost.

It is estimated that losses due to product recall resulting from packaging errors can be up to **3%\*** of a company's revenue.

## IT'S TIME TO INNOVATE YOUR PRODUCT'S ARTWORK!

**50%**

Reduction in cost over 12 years of engagement

- Pack factory (global offshore delivery centers)
- Templates and reusable creative components

**100%**

Increase in productivity

- Consolidation of duplicate work activities
- Standard procedure for asset production across locations
- Centralized knowledge management
- Reusability of assets

**60%**

Reduction in Time to Market

- Shorter production SLAs
- Scalable staffing models for faster execution of projects
- Delivery models
- First time right quality

**50%**

Increase in efficiency

- 90% RFTs and 100% proofreading efficiency



VALUE DELIVERED  
ACROSS ARTWORK &  
LABEL MANAGEMENT

Zero product recalls due to incorrect labels since inception

Client saved €55 Mn over 12 years

ROI of 14X

### About us

Tech Mahindra represents the connected world, offering innovative and customer-centric information technology experiences, enabling Enterprises, Associates and the Society to Rise™. We are a USD 4.9 billion company with 113,550+ professionals across 90 countries, helping over 926 global customers including Fortune 500 companies. Our convergent, digital, design experiences, innovation platforms and reusable assets connect across a number of technologies to deliver tangible business value and experiences to our stakeholders. Tech Mahindra is amongst the Fab 50 companies in Asia (Forbes 2016 list).

We are part of the USD 21 billion Mahindra Group that employs more than 200,000 people in over 100 countries. The Group operates in the key industries that drive economic growth, enjoying a leadership position in tractors, utility vehicles, after-market, information technology and vacation ownership. Learn more about Mahindra on [www.mahindra.com](http://www.mahindra.com) / Twitter and Facebook: @MahindraRise



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## About the Company

Improving the health and quality of life of patients is the goal of the research-driven pharmaceutical company Boehringer Ingelheim. The focus in doing so is on diseases for which no satisfactory treatment option exists to date. The company therefore concentrates on developing innovative therapies that can extend patients' lives. In animal health, Boehringer Ingelheim stands for advanced prevention.

Family-owned since it was established in 1885, Boehringer Ingelheim is one of the pharmaceutical industry's top 20 companies. Close to 50,000 employees create value through innovation daily for the three business areas human pharmaceuticals, animal health and biopharmaceuticals.

As a family-owned company, Boehringer Ingelheim plans in generations and focuses on long-term success. The company therefore aims at organic growth from its own resources with simultaneous openness to partnerships and strategic alliances in research. In everything it does, Boehringer Ingelheim naturally adopts responsibility towards mankind and the environment.

Corporate Website: [www.boehringer-ingelheim.com](http://www.boehringer-ingelheim.com)

India Website: [www.boehringer-ingelheim.in](http://www.boehringer-ingelheim.in)



# Member Recognitions and Awards

This section showcases the achievements and recognitions received by our members in their pursuit of creating a responsible and collaborative healthcare ecosystem.

## Kudos to the winners!



Winner of the 'Unnatha Suraksha Puraskara Award 2017' from the Govt of Karnataka for 'Best Safety Performance & Management Systems'



Won the Mercer NDTV Employer Excellence Award for 'Excellence in Career Development'

Ranked among 100 Best Companies for Women in India - 2017

Ranked one of India's Best Employers winning Aon's 'Best Employer in India 2018' Award for the second consecutive year



Bayer Zydus Pharma Global Pharma receives the Best End to End Supply Chain Visibility at the Supply Chain Summit & NDTV Global Logistics Excellence Awards

Women in Compliance Awards, 2018, London: Compliance teams from India and the Middle East shortlisted in two categories



Recognized as one of the Top 20 Companies with Great Managers by People Business in partnership with Economic Times.



Recognized as 2017 Working Mother and AVTAR 100 Best Companies for women in India, for the second consecutive year



Winner of the Dr H R Nanji Memorial OPPI Award Marketing Excellence 2017



Awarded the AWACS Awards in Marketing Excellence 2017- Brand of the year: Jardiance



Winner of the AWACS Awards in Marketing Excellence 2017- Brand of the year: Trajenta



Winner of the CII SR EHS Excellence Award - EHS Practice



Certified as a Great Place to Work



Won the Outstanding Achievement Award in Healthcare-Social Cause at the Healthcare Leadership Awards 2017



Awarded the Prestigious Brand 2017 in Healthcare category by Goodwill Brands



Winner of the CII SR EHS Excellence Award - Manufacturing Process





Winner at the DigiPharmac: Digital Pioneer of the Year 2017



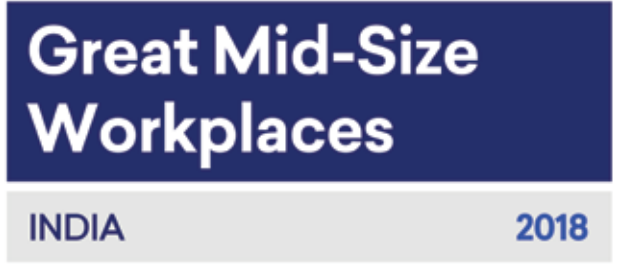
Winner at the DigiPharmac: Leveraging Technology for Better Patient Management



Recognized among Top 25 India's Great Mid-Size Workplaces 2018



Won Excellence in New Brand Launch for Cynamza at the the UBM India Pharma Awards 2017



Winner of the Great Mid-Size Workplaces



do more  
feel better  
live longer



Ranked among the 50 best companies in India as per People Capital Index (PCI)



Won 'Excellence in CSR' at the Pharma & Medical Devices Summit & Excellence Awards 2017



Won Gold at the Training Journal Awards for 'Best use of technology in learning'



Won the ABCI Silver Award in the features category for Infobytes- the in-house magazine



Winner of the Gold Award in the Sales Enablement Category at the Tata Institute of Social Sciences - CLO Summit



Recognized with an Excellence in CSR award at the UBM India Pharma Awards 2017



Winner of the prestigious Porter Prize 2018 award for Value Based Healthcare Delivery



Johnson & Johnson India was conferred the prestigious 'Employee Volunteer Program of the Year award' at the 2017 CSR Health Impact Awards.



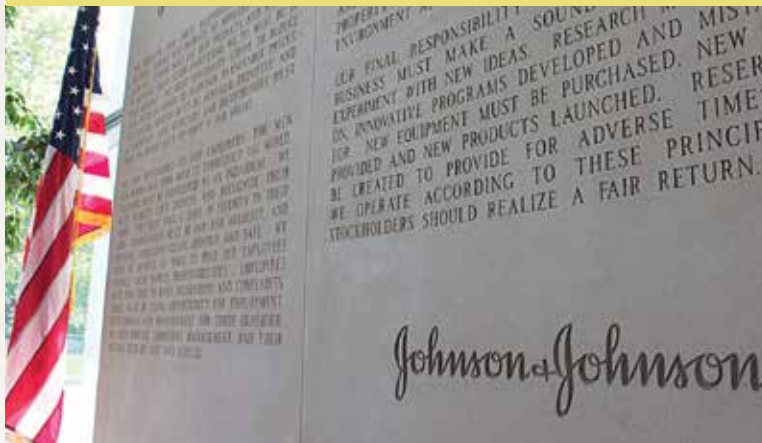
Johnson & Johnson India's 'Giving for Someone's Living' program awarded the Best Employee Volunteer Program at the 2017 ACEF Corporate Social Responsibility Awards



Johnson & Johnson India's leading-edge learning and development programs recognized at the 2017 Tata Institute of Social Sciences CLO Summit India



Awarded the 'Best Public Health Initiative' award at the ET Now MODI awards



Johnson & Johnson Named as 2018 Fortune World's Most Admired Company



Awarded the Best Marketing Campaign award & Best Digital Marketing in Healthcare at the World Health and Wellness Congress & Awards 2017



Vogue Beauty Awards 2017 & 2018 named Janssen India's RoC® Pro Sublime Eye Cream, the best Anti-Ageing Eye Cream

Winner of the AWACS Awards in Marketing Excellence 2017 - Unbroken Winning Streak Award: Ultracet and 'Brand of the Year – Gold' award



Winner at the DigiPharmax 2017: Digitally Visible Company of the Year & Leveraging Technology for Salesforce effectiveness

Winner of the Global MARCOM GOLD AWARD 2017 for its proof of concept for AI based Alexa Skill with Magic Mirror for healthcare professionals

Recognition to Sanjiv Navangul, Managing Director Janssen India by the Economic Times



Winner of the ABP Healthcare Leadership Awards- Best Healthcare & Social Care Support Campaign for Neurobion

Winner of the Global Logistics Excellence Awards in Partnership with CNBC: Best Pharma Supply Chain Team





**Winner of OPPI Award for Diversity and Inclusion 2017**



**Awarded the OPPI HR Excellence Award 2017**



**Won the OPPI Sales Force Excellence Award 2017**



**Winner of the Arogya World Healthy Workplace Platinum Award for the second time**



**Winner of the WILL Best Employer for Women Award for the fourth consecutive year**



**Awarded the Working Mother and Avtar's Award for Best Companies for Women in India.**



**Winner of the Great Indian Workplace Award 2018 for Pharma in the Established Companies category**



Awarded the CGP Health & Wellness Ranking 2017



Awarded the Dream Employer of the Year 2018



Winner of Excellence in HR Analytics 2017 from NHPL



Recognised as Best Employer Brand 2018



Arogya World - Healthy Workplace - Gold 2017



Named as one of Times Ascent Dream Companies to Work For 2018



Recognised as a Great Place to Work 2017 - 2018



Winner of Excellence in HR Analytics 2017 from NHPL



Recognised as one of the Best Companies for Women 2017



Named as one of Times Ascent Dream Companies to Work For 2018



Winner of the Swachhta Pharma Award, India Pharma 2018



Won the Future Ready Factory Award for the Goa plant at the India Manufacturing Excellence Awards



Winner of the Culture Champion Award 2017



Sanofi Genzyme awarded Certification of Excellence in the Public Affairs category at the 2018 South Asia Sabre Awards



Winner of the FDD Leadership award 2018 from Express Pharma: Dr Praveen Khullar, Senior Director - Goa Development Centre



Winner of the AWACS Awards in Marketing Excellence 2017 - Brand of the year Silver award in Acute category: Combiflam®



Winner of the AWACS Awards in Marketing Excellence 2017 - Unbroken Winning Streak Award: Lantus®



Recognised by the National Conference on Boiler & Steam Systems 2018: Certificate of appreciation to the Ankleshwar manufacturing site



Winner of the SECONA Shield Awards 2018 - Security professional of the year: Pramod Bhatt, Senior Director Security & Intelligence



Winner of the AWACS Awards in Marketing Excellence 2017 - Brand of the year Bronze award in Chronic & Sub Chronic category: Lantus®



Asia Pacific Integrity Award 2017 awarded to Ashok Bhattacharya at the Takeda Annual Conference



Ashok Bhattacharya honoured with the InnoPack Pharma Confex Jury Award 2018



Ashok Bhattacharya recognised in the Uttar Pradesh Investment Summit 2018





# driving change to defeat diabetes

Diabetes is one of the major health challenges of our time. Today, 72.9 million Indians are living with diabetes and by 2045 this number could rise to 134.3 million.<sup>1</sup>

Since Novo Nordisk became operational in India more than 25 years ago, we have been changing diabetes. Our key contribution is to make the best and widest portfolio of products accessible to people with diabetes throughout the country. However, it takes more than medicine to defeat diabetes.

We partner with patients, policymakers, and healthcare professionals to address diabetes risk factors in India, thus ensuring that people with diabetes are diagnosed earlier and that they have access to adequate care to be able to live their lives with as few limitations as possible.

For more details visit: [novonordisk.co.in](http://novonordisk.co.in)

**References:** 1. International Diabetes Federation. IDF Diabetes Atlas. 8th edn. Brussels, Belgium: International Diabetes Federation. 2017

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Novartis in India



# Changing the practice of medicine

At Novartis, we harness the innovation power of science to address some of society's most challenging healthcare issues. Our researchers work to push the boundaries of science, broaden our understanding of diseases and develop novel products in areas of great unmet medical need. We are passionate about discovering new ways to improve and extend people's lives.

 **NOVARTIS**

# Accolades for OPPI 2017-18



SABRE Asia Pacific Awards 2018



Winner of SABRE Asia Pacific Awards 2018 - CEO of the Year



Winner of Bronze ABCI Awards 2017 for Publications category



Winner of Bronze ABCI Awards 2017 for Web Communication - Online Campaign



Winner of Asia Pacific Communications Awards 2017 in the Publication Category for 'The Color of White'



Winner of Gold Hermes Creative Award 2018 for 'The Color of White'



Winner of Platinum Hermes Creative Award 2018 for 'The DNA of Care'



## Better Health, Brighter Future

There is more that we can do to help improve people's lives. Driven by passion to realize this goal, Takeda has been providing society with innovative medicines since our foundation in 1781.

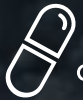
Today, we tackle diverse healthcare issues around the world, from prevention to care and cure, but our ambition remains the same to find new solutions that make a positive difference, and deliver better medicines that help as many people as we can, as soon as we can.

With our breadth of expertise and our collective wisdom and experience, Takeda will always be committed to improving the future of healthcare.

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# OPPI Knowledge Network

## OPPI events

	Date	Event	Venue
1	03.05.2018	OPPI Medical Forum 2018	Mumbai
2	06.06.2018	OPPI Quality Summit 2018	Mumbai
3	13.07.2018	OPPI Annual Summit 2018	New Delhi

## Knowledge-sharing sessions for Members

	Date	Topic	Speaker
1	17.11.2017	Presentation to the Human Resources Management Committee on HR opportunities and challenges	Ketaki Kadekar, Insights Learning & Development Ltd
2	08.12.2017	Legal perspective shared with the Over-the-counter (OTC) Task Force on OTC drugs in India	Riku Sarma, CLG
3	05.02.2018	Presentation to the Heads of member companies, Finance & Taxation and IPR & Legal Work Groups on Impact of Union Budget 2018-19	Ernst & Young Team
4	09.02.2018	Presentation to the Technical & Supply Chain Committee on E-Waste	Cerebra Integrated Technologies
5	27.02.2018	Presentation to the Human Resources Management Committee on Future of Workforce	Amit Mishra, Accenture
6	27.03.2018	Presentation to the Finance & Taxation Work Group on impact of e-Way Bill	Suresh Nair, Ernst & Young
7	17.04.2018	Special address to the Human Resources Management Committee on Diversity & Inclusion	Valerie Robert, Nestle Skin Health
8	11.05.2018	Special session on Story Telling with Human Resources Management Committee	Indranil Chakraborty, Story Works
9	14.05.2018	Presentation to the IPR & Legal Work Group on the Monsanto Vs Nuziveedu seeds case	Malathi Lakshmikumaran, Lakshmikumaran & Sridharan Attorneys
10	25.05.2018	Presentation to the Finance & Taxation Work Group on the mechanism of investigation and audits	Joshua Ebenezer, Lakshmikumaran & Sridharan Attorneys

	Date	Topic	Speaker
11	21.08.2018	HR Workshop by Cornucopia on Building Resilience	Anjali Sharma, Cornucopia
12	21.08.2018	Discussion with Human Resources Management Committee on the insights from the CEO's round table	Jagdish Kumar Audipudy, Boyden
13	30.08.2018	Brainstorming session with IPR & Legal Work Group on way forward on IPR advocacy	Krishna Sarma, CLG
14	30.08.2018	Presentation to the Over-the-counter (OTC) Task Force on 'Value of patient care through responsible self-medication guideline'	Susan Joshi, Cubex

## Events supported by OPPI

	Date	Programme	Venue
1	15-17, Feb	India Pharma 2018 - International Exhibition & Conference on Pharmaceutical Industry	Bangalore
2	23-24, Feb	Bio Asia 2018 - Global Life Sciences and Technology forum	Hyderabad



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# OPPI Past Presidents

Name	Company Name	Year
Late Dr H.R. Nanji	Pharmed	1966
Mr. Keith C. Roy	Merck Sharp & Dohme	1967-1969
Late Brig. B. S. Bhagat	Rallis	1970-1973
Mr. S.V. Pillai	Pfizer	1974-1975
Late Mr. Sisir Mitra	Cyanamid	1976-1978
Late Mr. H.N. Dutta Gupta	East India Pharmaceutical Works	1979
Late Dr S.K. Bhattacharya	Sandoz	1980-1981
Late Mr. George Daniel	Hoechst	1982-1984
Mr. R.N. Langrana	Abbott	1985
Mr. C.M. Hattangdi	Parke-Davis	1986-1987
Dr S. Agarwala	Rallis	1988-1990
Mr. D.K. Bose	Burroughs Wellcome	1990-1992
Mr. H. Dhanrajgir	Glaxo	1992-1994
Dr Anil S. Mehta	Wyeth	1994-1996
Mr. D. Bhadury	Hoechst Marion Roussel	1996-1998
Mr. H.R. Khusrokhan	Glaxo	1998-2000
Late Mr. P. Gupta	Infar	2000-2001
Mr. Tapan Ray	Abbott	Sept.-Nov. 2001
Mr. Ranjit Shahani	Novartis	2001 – 2007
Mr. Ranga Iyer	Wyeth	2007 – 2009
Mr. Ranjit Shahani	Novartis	2009 – 2013
Dr Shailesh Ayyangar	Sanofi	2013 - 2017



## Organisation of Pharmaceutical Producers of India

Mumbai: Peninsula Chambers, Ground Floor, Peninsula Corporate Park, Ganpatrao Kadam Marg  
Lower Parel, Mumbai 400 013. Tel: +91 22 2491 8123, +91 22 6662 7007

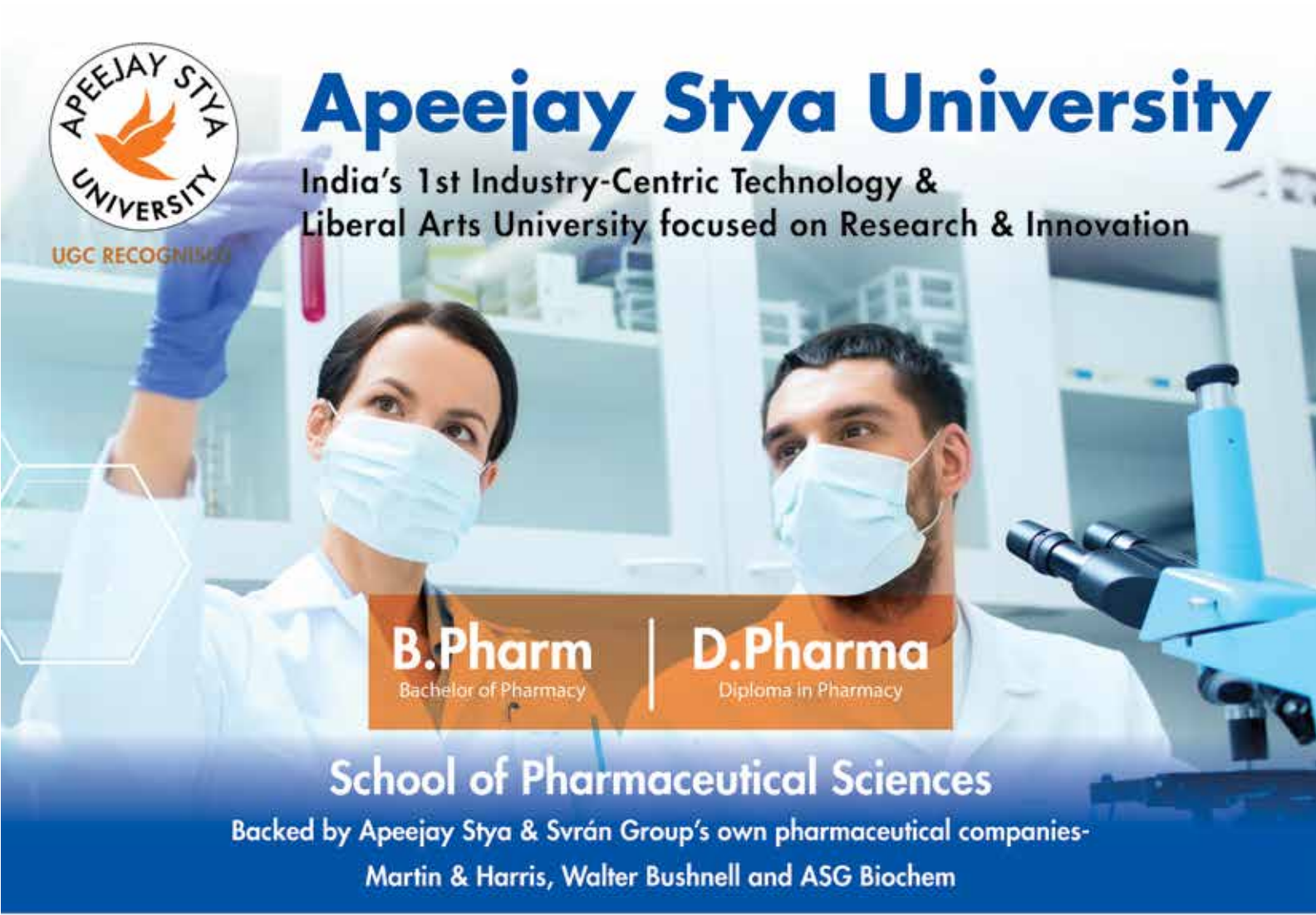
Delhi: First Floor, L-29, Outer Circle, Connaught Place, New Delhi - 110 001

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Pharmaceutical Sciences

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Therese Ntamvutsa, B.Pharmacy (III Year) | Rwanda

"The University has given me lots of exposure in terms of field exposure, industrial exposure, etc. It helps to bridge the gap between school atmosphere and Industry. We have proper updated laboratories for our course and we have all the privileges to use it any time. All in all, I'm very happy here and I really appreciate my faculty members for their great efforts for us."

Aayushma Karmacharya, B.Pharmacy (II Year) | Nepal

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