VOL. 15 NO. 6 PAGES 60 www.expresspharma.in

EXPRESS PHARMA

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16-31 JANUARY 2020, ₹40

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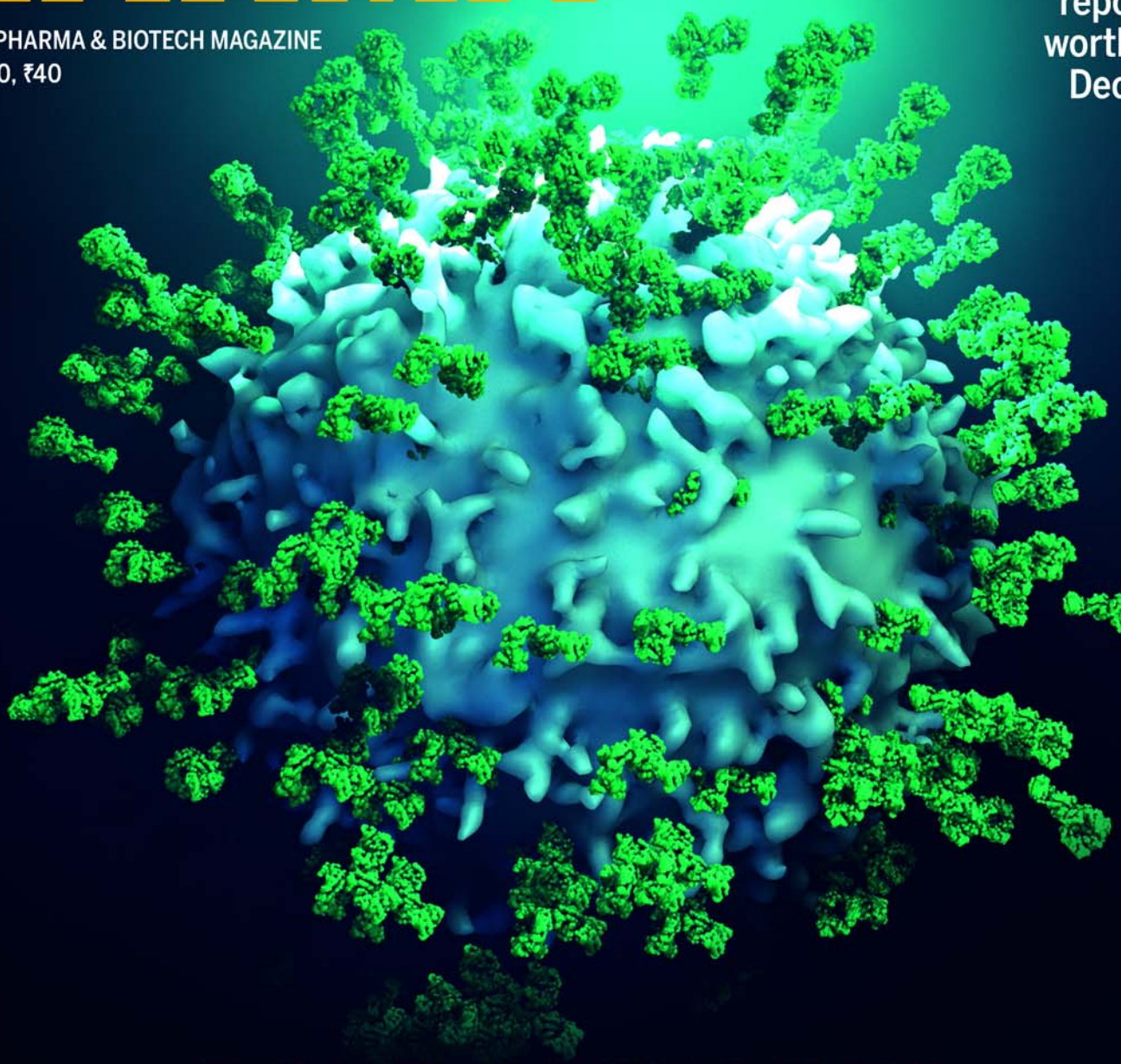
Policy

Budget 2020: What does the industry want?

Deals

Healthcare industry reports 58 deals worth $12.4 bn in December 2019



RARE DISEASES AWAITING RENEWED FOCUS

India needs a multi-pronged and multi-sectoral approach with significant investments in R&D, policy reforms, and measures to enable affordability and accessibility of medicines and healthcare to manage the burden posed by rare diseases

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BUDGET 2020: WHAT DOES THE INDUSTRY WANT?

Last year in July, Finance Minister Nirmala Sitharaman presented the first Budget of Modi Government 2.0. Since the pharmaceutical industry did not get much attention from the government last year, they have strongly voiced their concerns and expectations about the upcoming financial budget, especially amidst rising concerns about the economy | P20

PRE EVENT

DEAL

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Regd. With RNI No.MAHENG/2005/21398. Postal Regd.No.MCS/164/2019-21. Printed and Published by Vaidehi Thakar on behalf of The Indian Express (P) Limited and Printed at The Indian Express Press, Plot No.EL-208, TTC Industrial Area, Mahape, Navi Mumbai-400710 and Published at Express Towers, Nariman Point, Mumbai 400021.
Editor: Viveka Roychowdhury.* (Editorial & Administrative Offices: Express Towers, 1st floor, Nariman Point, Mumbai 400021)
* Responsible for selection of news under the PRB Act.

Will Budget 2020 be a salve or a sting for India Pharma Inc?

As Finance Minister Nirmala Seetharaman prepares to walk the economic tight rope in her second budget on February 1, there seems to be a renewed hope in the pharmaceutical sector that this time, there will be mercy shown.

Many industry groups have lobbied for an increase in the weighted tax deduction from the present 150 per cent to 200 per cent, with an extension for another five years. This, they affirm, is vital for nurturing R&D and innovation in the industry. The groups have also suggested that the government expand the definition of R&D to include R&D-related work done outside the premises of the company's R&D centre, for instance, work like clinical trials outsourced to CROs.

This weighted tax deduction on R&D expenses has in fact been progressively reduced, from 200 per cent in the 2010 budget, to 150 per cent on 2017, and it is due to reduce to 100 per cent in 2020 if the FM does not relook the case. This does seem counterproductive when you consider the hype about India being a hub of innovation. Unless there is sufficient incentive to invest in R&D, businesses will slowly wind up their R&D programmes.

The 2020 budget could also see some incentives for the setting up of API facilities, with many presentations underlining India's dependence on imports, especially from China, for key medicines. The SME and MSME segment has also renewed its long-standing plea that a separate fund needs to be set up for upgrading systems to global norms. In fact, leaders have suggested that the SME/MSME sector could be incentivised to focus on API manufacture to reduce dependence on imports as well as earn export revenues. Unfortunately, even if the 2020 budget does allocate funds for such schemes, it will be a few years till they show impact.

While the pharma sector has so far played a 'wait and watch' game with Ayushman Bharat (AB), there are signs that they might be willing to align with the scheme; but again, only if there are carrots like a weighted deduction of 200 per cent of the amount spent on specified activities. For instance, the building of healthcare infrastructure in rural/ semi-urban areas – there have been suggestions that pharma companies would be willing to sponsor health and wellness centres, a vital cog in the AB scheme. While this might sound altruistic, it is clearly a market expansion strategy for the pharma sector, with solid gains in brand visibility. But if it does solve the affordability and access issue, maybe this is an idea worth pursuing.

Will the sector get their shocks post-budget, via a revamped UCPMP, further pricing woes, etc?

On the pricing front, industry associations have pointed out that data has shown that while the number of essential drugs in the National List of Essential Medicines (NLEM) has increased, there has been no corresponding increase in patient-use, if sales volume is considered as one indicator. The NLEM has expanded to 870 drugs, from the initial 530 essential drugs. This represents a 64 per cent increase. But as per AIOCD data, sales value and volume percentages have not grown in sync, both moving up just one per cent, from 14 per cent and 24 per cent to 15 per cent and 25 per cent, respectively in this five year period.

In contrast, the associations point out that the non-NLEM products have seen modest price hikes of 3.5 per cent over the last three years, far less than the 10 per cent allowed under DPCO 2013. This is a clear indication that policy-driven regulation is not as successful as market forces, which keep process competitive.

Disruption in the pharma sector, or any sector, for that matter, is not linked just to the Budget. For instance, with the Uniform Code of Pharmaceutical Marketing Practices for Indian Pharmaceutical Industry (UCPMP) being revamped by the Department of Pharmaceuticals (DoP), associations have also asked for clear definitions of which expense would be considered 'ethical' and which 'unethical'. This is especially required because the pharma sector has issues like samples given to doctors, doctors being hosted at medical conferences, etc.

While it is learnt that the DoP has included some part of these suggestions to the finance ministry, we will have to wait for February 1 to see how far the FM will go to accommodate the pharma sector.

VIVEKA ROYCHOWDHURY *Editor*
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ICT-Mumbai to host 3rd Biosimilar Workshop in February

ICT-Mumbai will be hosting this workshop as a Biopharmaceutical Skill Development Program, supported by the National Biopharma Mission, BIRAC, Government of India

Institute of Chemical Technology (ICT), Mumbai, is conducting the 3rd Biosimilar Workshop from February 3-8, 2020. The workshop will be conducted at ICT, Mumbai. The workshop was initiated as an annual endeavour to bring together academicians and industry professionals and create awareness on recent technologies developed in various sectors of the biopharmaceutical industry. The Biosimilar Workshop 2020 will include the following sub-programs:

1. Hands-on training program on Biopharmaceutical Product Development sponsored by National Biopharma Mission, BCIL and BIRAC (Feb 3-7, 2020)

2. One Hour with Leaders and Biopharma Job Mela (February 7, 2020)

3. Biopharma Exhibition (February 4-6, 2020)

4. Leadership Conclave (February 8, 2020)

ICT-Mumbai will be hosting this workshop as a Biopharmaceutical Skill Development Program, supported by the National Biopharma Mission, BIRAC, Government of India. A biopharma exhibition will be organised concurrently where the latest technologies developed for the biopharma industry will be put on display for all participants to visit. The skill development programs will be followed by a Biopharma Job Mela, where participants will have the opportunity to interact with human resource delegates from several leading biopharma companies in India. Following, a Leadership Conclave will be held which will witness active participation from prominent organizations and government initiatives including IAVI, Wellcome Trust, Ayushman Bharat, Insurance Players, and leaders of Indian and Global Biopharmaceutical Industry.

The Conclave will consist of the following sequential panels and will include talks from distinguished members of the industry and government:

1) Global Policy Initiative for Affordable Biotherapeutics

2) Indian policy perspective/Health program for affordable Biotherapeutics

3) Advances in Biomanufacturing/Services/Innovations

4) Regulatory and Clinical innovations towards affordable antibody production

The last date for registration is 14th January 2020. Participants will be selected by the NBM partner, BCIL.

BioAsia to promote innovations in healthcare through 'Start-up Stage'

BioAsia 2020 will showcase about 75 promising start-ups with cutting edge solutions to transform healthcare and give them an opportunity to interact with global industry leaders

BIOASIA WILL organise the 17th edition of Start-up Stage in Hyderabad from February 17th to February 19th. The Start-up Stage at BioAsia 2020 will provide a unique opportunity to the most promising start-ups across India to interact with global industry leaders. Start-up Stage will enable entrepreneurs to showcase their innovative solutions in the pharma, biotech, life sciences, health-tech, and med-tech sectors.

The event is designed to encourage innovative collaborations and partnerships between entrepreneurs and industry leaders/investors. Top five start-ups from these 75 short-listed start-ups will get an opportunity to present their solution to the leaders from over 50 Nations in attendance at BioAsia in addition to the cash prize. The start-ups will also get an unmatched opportunity to request exclusive one-to-one meetings with the participating delegates and be a part of the overall deliberations at the event. These opportunities would help them to get insights and guidance on several emerging healthcare challenges and technologies. They will get access to be a part of all the conferences and sessions at BioAsia 2020.

Government of Telangana and BioAsia have partnered with Tech Mahindra as the lead sponsor for the Start-up stage. Commenting on the Start-up Stage, Jayesh Ranjan IAS, Principal Secretary, Industries & Commerce and Information Technology, Government of Telangana said, "BioAsia has emerged as one of the highly regarded life sciences conventions with the participation of top leaders of the life sciences sector. The vision of the Telangana Government has been to promote innovation and in line. We have been encouraging innovative solutions in life sciences and healthcare by start-ups to be showcased as part of this biggest gathering of life sciences. In the last five years of the Start-up Stage at BioAsia, we have constantly worked to encourage and showcase the promising start-ups, and this platform has received an enthusiastic response from the stakeholders, investor community, etc."

In the last two editions of BioAsia's Start-Up stage, some of the high potential start-ups recognised and awarded have been continuously moving up in the value chain creating a niche positioning. Caredose which was awarded in 2019 edition and offers a proprietary technology aiding chronic patients in medicine adherence by providing pre-packaged medication, reminders to consume medication, ability to reorder, alert a caregiver and relay the adherence data to providers for better diagnosis has successfully raised a total of USD 300,000 in 2019 itself and partnered with Abbott Pharmaceuticals to help them with their patient adherence program.

Similarly, Next Big Innovation Lab which developed India's first customisable 3D Bioprinter (TRIVIMA), was not only successful in raising funds from global major MERCK but has also set-up TRIVIMA within Merck's R&D lab in Darmstadt, Germany for collaborative R&D. It is also invited at World Economic Forum to be part of Expert Network in 3D printing and offer inputs in the area of 3D Bioprinting.

Another start-up, Dozee which is a contactless, non-wearable health-monitoring solution provider has been selected by the Government of India to represent Indian start-ups at Estonia its solution achieved accuracy to track heart valve movements, thereby, helping flag cases of heart failure in advance.

Docturnal Private Limited which is a point of care screening and diagnostics provider of non-invasive and proactive detection of diseases as also raised funds from Mumbai Angels.

Testright which developed high performance and portable Spectrophotometers was also adjudged the National winner at 'Get in the Ring event' and further represented India in Berlin. The start-up also received the Patent for its Holofy technology which is stickerless hologram technology to protect Pharma and FMCG products from counterfeiting. It is now working with eminent brands to protect them from fake products.

To provide an understanding of the growth drivers and motivating the start-up founders, Shakthi Nagappan, CEO, BioAsia, said "Start-up Stage has become one of the highlight components of BioAsia and the platform helps start-ups get unparalleled access to the who's who of the global life sciences and healthcare industry. We are overwhelmed with the response from the Start-up community for the event and more than 300 applications have already been received so far. We are also thrilled with the enthusiastic response from the Life Sciences Industry leaders, Venture capital & Angel investor community and the corporate M&A teams of leading pharma & biotech companies."

Some of the biggest and influential organizations in the have come joined together for the Start-up Stage includes Tech Mahindra, Swissnex India, Department of Biotechnology, BIRAC, Telangana State Innovation Cell, NASSCOM, T-Hub, Research and Innovation Circle of Hyderabad, Ernst and Young, Endiya Partners, Mumbai Angels, IKP, AIC_CCMB, Light House Canton, Life Sciences and Healthcare Innovation Forum, YourStory, xpomet (Germany), among others.

BioAsia 2020 is set to host eminent global leaders from the life sciences industry including Vas Narasimhan, CEO, Novartis; Dr Carl June, CAR-T Expert; Dr Peter Piot, Director, London School of Hygiene and Tropical Medicine and Co-Discoverer of Ebola; Ajay Piramal, Chairman, Piramal; Dilip Sanghvi, Chairman, Sun Pharma; Kiran Mazumdar Shaw, CMD, Biocon; and Satish Reddy, Chairman, Dr Reddy's), among others.

Inventicon to conduct 3rd Annual Anti-Counterfeiting & Brand Protection Summit

The summit will be held in Mumbai from January 21-22, 2020

INVENTICON WILL conduct the 3rd Annual Anti-Counterfeiting & Brand Protection Summit in Mumbai from January 21-22, 2020. The summit will focus on discussing latest trends in anti-counterfeiting, challenges, issues, recent legal developments, understanding how to carry out risk profiling, role of effective packaging, supply chain authentication and latest technologies and solutions.

Leading brand protection leaders, legal, IP and packaging heads will congregate under one roof to present case studies, presentations and engage in interactive panel discussions, open house forums and debates along with networking with solution providers. Over 500+ delegates across various industries have participated with key take-aways from the summit. The event has witnessed amalgamation of leading and renowned personalities in this domain present their case studies and views.

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DEAL TRACKER

Healthcare industry reports 58 deals worth $12.4 bn in Dec'19

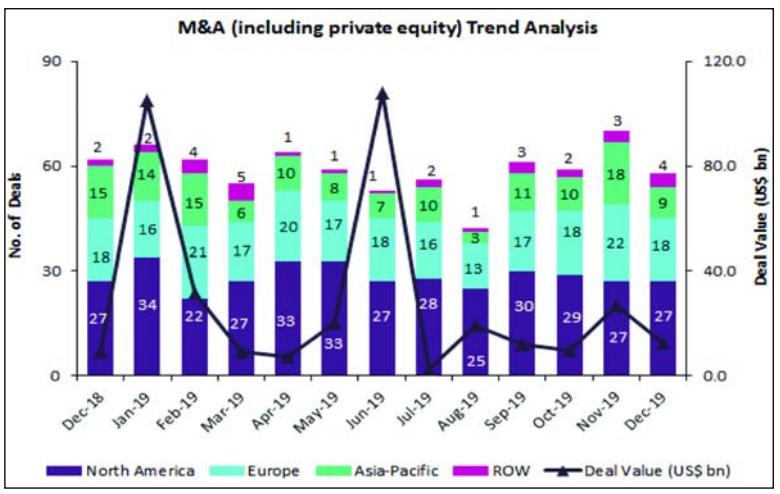
According to GlobalData, three big ticket deals together contributed 63 per cent to the total deal value in the month

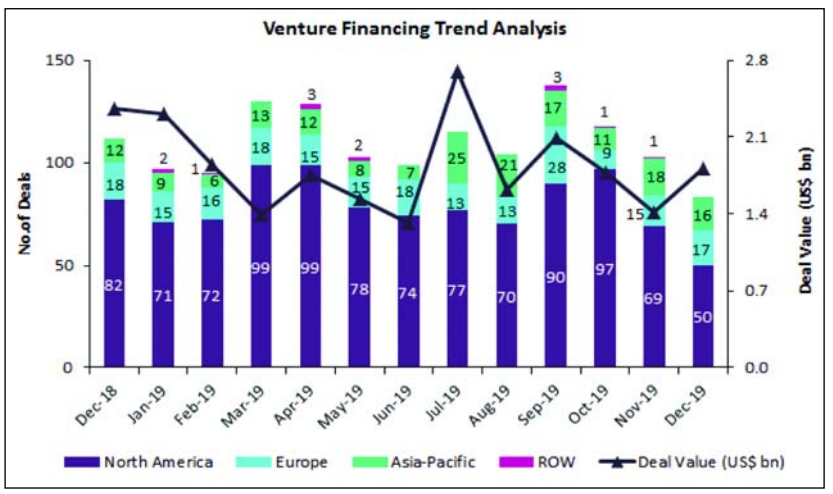
In December 2019, the healthcare industry reported 58 deals worth US$12.4 billion as compared to the last 12-month average (December 2018 to November 2019) of 59 de als worth US$30 billion. Three big ticket deals — Astellas Pharma announcing to acquire Audentes Therapeutics, a clinical-stage AAV-based gene therapy company focusing on rare neuromuscular diseases, for US$2.7 billion; Merck, through its subsidiaries Merck Sharp & Dohme Corp. and Argon Merger Sub, announcing to acquire ArQule for US$2.7 billion; and Sanofi, entering into an agreement to acquire all of the outstanding shares of Synthorx, Inc., a clinical-stage biotechnology company focusing on prolonging and improving the lives of people suffering from cancer and autoimmune disorders, for US$2.5 billion — together contributed 63 per cent to the total deal value in December 2019.

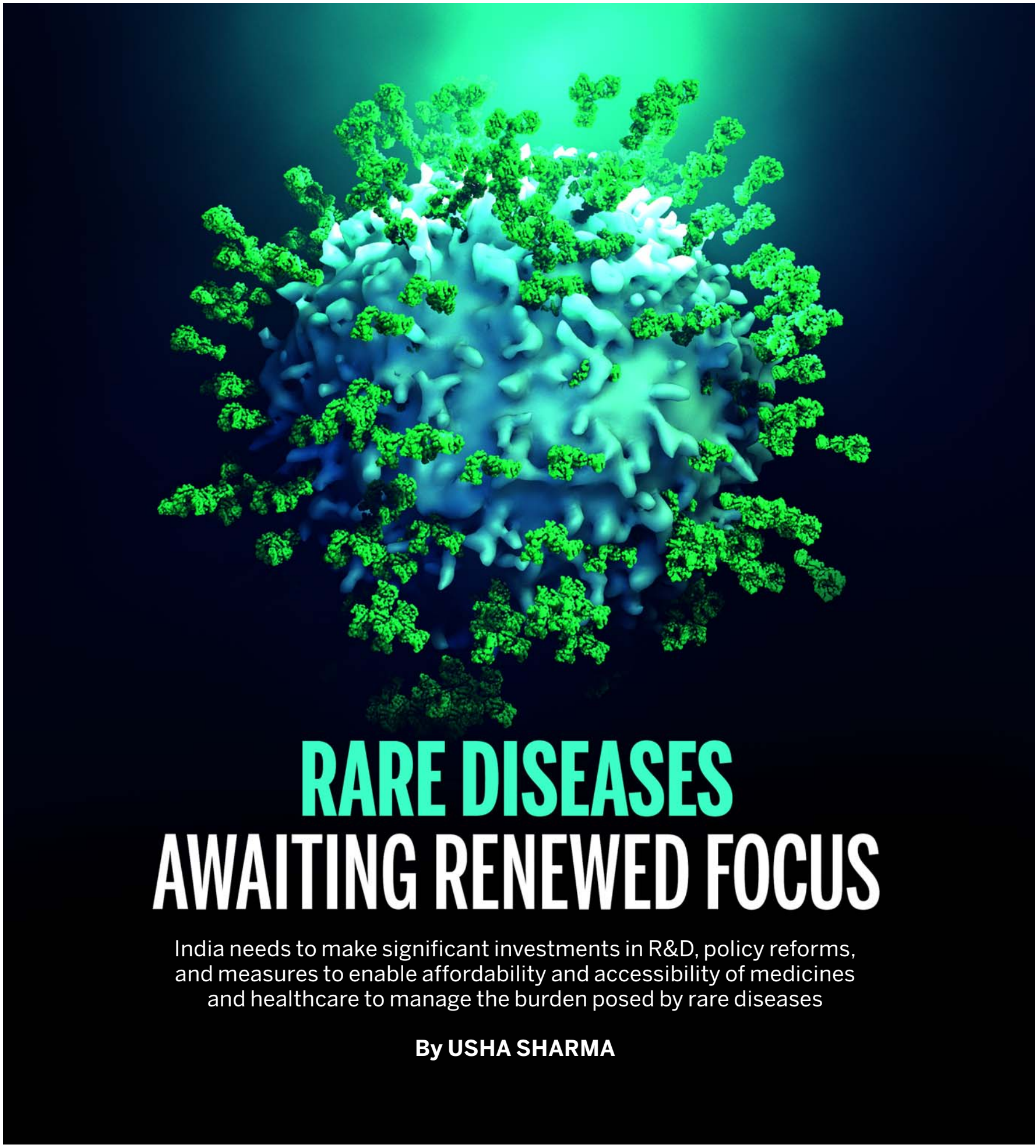
The healthcare industry reported 87 venture capital (VC) deals worth US$1.8 billion in December 2019, compared to the last 12-month average (December 2018 to November 2019) of 112 deals worth US$1.8 billion. FORMA Therapeutics raising US$100 million in series D financing; Elpiscience Biopharma raising US$100 million in series B financing; and Black Diamond Therapeutics raising US$85 million in series C financing are some of the major VC deals reported in December 2019.

Deal Date	Acquirer (s)	Target	Deal Value (US$ m)
2-Dec-19	Astellas Pharma Inc (Japan)	Audentes Therapeutics Inc (US)	2,700.0
6-Dec-19	Merck Sharp & Dohme Corp (US)	ArQule Inc (US)	2,700.0
9-Dec-19	Sanofi (France)	Synthorx Inc (US)	2,500.0
26-Dec-19	Astellas Pharma Inc (Japan)	Xyphos Biosciences Inc (US)	665.0
12-Dec-19	Altaris Capital Partners, LLC (US)	Drug Delivery Business (US)	650.0

Deal Date	Acquirer (s)	Target	Deal Value (US$ m)
19-Dec-19	Janus Henderson Group Plc; Wellington Management Company LLP; Undisclosed Investor; RA Capital Management LLC; Cormorant Asset Management LLC; Samsara BioCapital LLC	Forma Therapeutics Inc (US)	100.0
28-Dec-19	CDH Investments; Tencent Holdings Ltd; Lilly Asia Ventures; Hillhouse Capital Group; Shenzhen GTJA Investment Group Co Ltd; Oriza Holdings Co Ltd; DYEE Capital; Hyfinity Investments; Ming Bioventures; Undisclosed Investor(s)	Elpiscience Biopharmaceutical Ltd (China)	100.0
5-Dec-19	Wellington Management Company LLP; City Hill Ventures LLC; Roche Venture Fund; Nextech Invest Ltd; RA Capital Management LLC; Invus Group LLC; Deerfield Management Company LP; Versant Venture Management LLC; New Enterprise Associates Inc; Perceptive Advisors LLC; Boxer Capital LLC; Casdin Capital LLC; BVF Partners LP; Janus Henderson Investors; Logos Global Management LLC	Black Diamond Therapeutics Inc (US)	85.0
9-Dec-19	Matrix Capital Management Company, LLC; Viking Global Investors LP; Farallon Capital Management LLC; Redmile Group LLC; Perceptive Advisors LLC; Eventide Asset Management, LLC; Surveyor Capital Ltd	Zentalis Pharmaceuticals LLC (US)	85.0
18-Dec-19	Longitude Capital Management Co LLC; Adams Street Partners LLC; ARCH Venture Partners LP; The Longevity Fund; Vertex Ventures HC; Bluebird Partners LLP	Epirium Bio Inc (US)	85.0







RARE DISEASES AWAITING RENEWED FOCUS

India needs to make significant investments in R&D, policy reforms, and measures to enable affordability and accessibility of medicines and healthcare to manage the burden posed by rare diseases

By USHA SHARMA

The global rare disease drug market is expected to touch $242 billion by 2024 with a Compound annual growth rate (CAGR) of 12.3 per cent between 2019-2024. Globally, the definition of rare disease (RD) is at nascent stage although it is evolving constantly. It is assumed that there are approximately 8,000 different types of RDs, with more being discovered each day. Particularly in India, nearly 450 RDs have been enlisted. Due to its poor diagnosis mechanism, low prevalence and limited treatment options, often it is addressed as an 'orphan' disease.

Rare diseases in India

The Ministry of Health and Family Welfare, Government of India announced that so far only about 450 rare diseases have been recorded in India from tertiary care hospitals. The most common rare diseases include haemophilia, thalassemia, sickle-cell anaemia, primary immunodeficiency in children, auto-immune diseases, lysosomal storage disorders such as Pompe disease, Hirschsprung disease, Gaucher's disease, cystic fibrosis, hemangiomas and certain forms of muscular dystrophies.

Dr Prashanth L K,Consultant Movement Disorders Specialist, Vikram Hospital informs, " According to the definition, a rare movement disorder is one whose prevalence is less than 50 per 100,000 population. India constitutes 1/5th of this global scenario. Many of these disorders require dedicated healthcare services and some of them have dramatic medical care. Because of the rarity of these disorders, most of them are usually misdiagnosed and do not get proper interventions."

Dr Sudheendra Rao,NR Scientific Advisor, Organisation for Rare Diseases India (ORDI) gives more update as he elaborates, "Due to lack of comprehensive national registry for RD or genetic disorders there is no exact data available in India. But, the clinical consensus is that apart from rare cancers, Duchenne Muscular Dystrophy, Limb Girdle Muscular Dystrophy, Spinal Muscular Atrophy, Primary Immunodeficiency disorders, Inborn errors of metabolism, Lysosomal Storage Disorders, Cystic Fibrosis, Hirschsprung's Disease, Haemangiomas and Genetically Determined Epilepsies certainly top the chart in the non-oncological orphan diseases. They have varied onset, high mortality depending on the underlying cause whereas, some such as muscular dystrophies are chronic in nature causing a loss in quality of life for one or two decades. It is essential to remember that each of the diseases mentioned above have multiple subtypes as well as genotypes."

US FDA has designated orphan drug status to nearly 5198 drugs since 1983. There has been a six-fold increase in the orphan drug designations by US FDA in the last decade. This includes drugs developed for 363 different health conditions including some rare genetic diseases. However, the striking feature is that nearly 81 per cent of filing (4208) for orphan drug designation came from the US.

The rising number of rare disease profile indicates that it needs more research and development focus. Since India has a large population, it needs to give this subject considerable attention, especially in terms of research.

Significance of research

India is 21st in the line of drugs developement of rare disease and between 2003-2019, it has filed 10 drugs for orphan drug designation covering 13 different conditions. The US has had the first-mover advantage with well laid regulatory processes, sufficiently funded R&D centres in both academia and industry and with the insurance industry bearing the cost of the treatments. All these factors have ensured that any investment in developing newer drugs remained lucrative. Therefore, what is apparent is that the focus for developing new drugs for rare diseases is very sharp in the US, however, the rest of the world is yet to catch up. Some of the countries for e.g., the UK, Switzerland, Canada, France, Israel, Sweden, Italy, South Korea and China are increasingly focusing on this growing need.

Rao comments, "Indians need to remember that even though we did not have the privilege of a stable and powerful economy like the US, within 60 years, we have captured 30 per cent (by volume) of the generic market of the US. Together these suggest that R&D funding and patents and licenses majorly guard the focus on developing newer drugs for rare disease portfolio. Purchase power parity and incomplete health insurance coverage are the other two factors dissuading novel formulation research in India."

To overcome the rare disease burden in India, besides pharma companies, research institutes are also engaging themselves.

Research projects initiatives in India

Indian Council for Medical Research (ICMR) has been working on a national registry for a while now that is reported to include lysosomal storage disorders, neuromuscular disorders, skeletal dysplasia, haematological disorders, inborn errors of metabolism and primary immunodeficiency disorders.

Rao highlights that knowing the fact that around 70 per cent of rare disorders are due to genetic mutations. Therefore, if we talk about rare genetic disorders, then one of the rarest is genetically documented ribose-5-phosphate isomerase (RPIA) deficiency caused by mutations in RPIA gene. He further elaborates, "RPIA mutations lead to developmental delays, psychomotor regression by seven years, seizures and abnormalities in the nervous system including white matter changes in the brain. There have been only four reported cases worldwide. Apart from symptomatic, rehabilitative and supportive care, there is no specific treatment for this disorder even today. However, for research purposes, genetically modified mice having mutations in RPIA gene have been developed and archived."

Recently, an official circular issued by the ICMR states that the research body among other things has proposed forming the task force to explore gene editing based therapeutic approaches to treat illnesses. ICMR has narrowed down on genetic diseases affecting the brain and muscles, eye disorders affecting the retina and cornea, heart diseases and blood disorders like thalassemia, sickle cell disease and haemophilia. It has also stressed on diseases like cancer, diabetes and lung diseases. The strategies proposed should have a possibility of translation into future human trials. While the western world has made considerable strides with regards to gene therapy over the past 30 years, ICMR stated that drugs like Luxuturna for Retinitis Pigmentosa, a condition which leads to breakdown of retinal cells in the eye, and leads to low vision, or Yescarta which is a cell therapy for cancer, are currently in clinical trial phase.

Besides ICMR, other research bodies like Council of Scientific and Industrial Research (CSIR) are also working aggressively tracking down the gene sequencing. Recently, CSIR announced the launched of an ambitious project, IndiGen, to sequence whole genomes of diverse ethnic Indian population to develop public health technology applications. It has mentioned that sequencing of 1,008 Indian genomes as part of the project. It aims to complete sequencing of at least 10,000 Indian genomes over the next three years.

Many countries around the world have developed rules and guidelines to regulate gene therapy trials. Taking cognizance of situation, it was felt necessary to frame national guidelines and regulations to direct scientists and clinicians including industry regarding the procedures and requirements to be followed for performing gene therapy in India.

These is an indication of developing disease model systems, stem cell products to cheaper and reliable diagnostic methodologies. Rao emphasises, "The onus always falls on the orphan drug sponsor who has to sift through literature or available patient registries to justify the designation. Hence some of the well-kept disease-specific patient registries are with pharma companies and not with governments."

Market trend

According to Evaluate Pharma-Worldwide Orphan Drug Report, the top 10 multinational pharma companies by 2020 would be Celgen, Novartis, BMS, Roche, Alexion Pharma, Pfizer, Vetex Pharma, Merck AbbVie and J&J. To beat the hit of the market competition, Indian origin companies like Sun Pharma, Biocon, ReGrow Bioscience, Piramal, Natco and Cadila Pharma have at least one designated orphan drug by US FDA. There are several other pharma companies from domestic as well as from the international market who are involved in different profile of rare disease. In addition, there are at least 14 different orphan drug related organisations in India developing therapeutic products or working towards diagnostics.

Rare diseases provide an opportunity to pharma companies for innovation because in contrast to lifestyle diseases, majority of them have discernible elements such as genetic mutations. This leads to an enormous room for novel targets, formulations, dosage all providing opportunities for intellectual property generation. "There are thousands of rare diseases and to tackle some of the rare diseases therapeutically, pharma companies had to resort to advanced therapies, including cell therapy, gene therapy, gene editing, RNA therapy etc., suggests Rao". However, these newer therapy modalities provide unique advantages to pharma in terms of novelty, efficacy and achieving success and miracles in hard to tackle healthcare

problems, thus positively affecting company finances.

While making a comparison of global scenario with Indian context, particularly in research and development of rare disease, it indicates that pharma companies in the US, Europe and Japan have been investing more on the rare disease portfolio. Analysing the possible reason for the thrust there could be the support from government/regulatory agencies!

To name a few, a move of US FDA granting a research grant for rare disease research is an example!

Dr Sudheendra Rao
NR Scientific Advisor, Organisation for Rare Diseases India

Dr Ketan R Patel
Chairman and Managing Director, Troikaa Pharmaceuticals

Anil Khanna
Partner, Wisdomsmith Advisors

Dr Prashanth L. K
Consultant Movement Disorders Specialist, Vikram Hospital

Research grants for rare disease

Recently, the US Food and Drug Administration (US FDA) has awarded 12 new clinical trial research grants totalling more than $15 million over the next four years to enhance the development of medical products for patients with rare diseases. The FDA awarded the grants through the Orphan Products Clinical Trials Grants Programme, funded by Congress to encourage clinical development of drugs, biologics, medical devices and medical foods for the treatment of rare diseases. The grants are intended to substantially contribute to marketing approval of products to treat rare diseases or provide essential data needed for development of such products. The grants awarded are focused on supporting product development to meet the needs of patients impacted by a variety of rare diseases, mainly those affecting children and cancers.

"For more than 35 years, the FDA has been providing much-needed financial support for clinical trials of potentially life-changing treatments for patients with rare diseases. To date, the Orphan Products Clinical Trials Grants Program's grants have supported research that led to the marketing approval of more than 60 treatments for rare diseases," informs Amy Abernethy, FDA Principal Deputy Commissioner.

Besides this, there is also a provision for developing orphan drug (OD) which has been financially incentivised through US law via the Orphan Drug Act (ODA) on 4 January, 1983. The enactment of ODA in the US and EU emerged as ground breaking and provided the necessary support to guide research focused on RDs worldwide. The orphan designated drugs (ORD) are granted important incentives which include market exclusivity and fee reduction. Prior to the 1983 Act, only 38 ODs were approved. The success of the original ODA in the US led to its being adopted in other key markets, most notably in Japan in 1993 and in the European Union in 2000. Currently, Singapore, South Korea, Canada, and New Zealand also have their own country specific ODA. India launched Organization for Rare Diseases India (ORDI) on 18 Feb 2014.

Clinical Trial Advantage

Increasing traction of private capital towards rare diseases and unmet medical needs has also been influencing the focus spectrum of pharma companies. Coupled to R&D ecosystem and regulatory help, pharma companies from US, Europe and Japan have been investing on rare disease portfolio. Naturally, compared to non-orphan drugs, orphan drugs incur substantially less cost in clinical trials.

The advantage of conducing clinical trials on rare disease drugs or orphan drugs, against conditional disease profile are varied as it requires fewer patient against other chronic disease profile, expediting the regulatory approval process of US FDA as well as assisting in providing grants to conduct the clinical trials. Does the situation remain similar in India as well?

The Ministry of Chemicals and Fertilizers (Department of Pharmaceuticals) has notified an order amending the Drugs (Prices Control) Order 2013. Effective January 3, 2019, Drugs for treating orphan diseases as determined by the Ministry of Health and Family Welfare will be exempted from price control. The five-year window starts from the date when the manufacturer starts commercial marketing in India.

The orphan drug exemption is expected to encourage domestic companies to develop drugs for orphan diseases and to foreign pharma companies to market their drugs in India. There are about 8,000 rare diseases across the globe, of which 450 have been reported in India and India itself has about 70 million patients of rare diseases. This indicates that there is a dire need for research and development in this arena. Are there any policy or guideline in place for the development of research molecule?

Indian regulatory scenario

In 2016, Stempeutics Research, in a joint venture with Cipla Group granted limited approval for manufacturing and marketing of stem cell based biological product Stempeucel for the treatment of Buerger's Disease (a rare and severe disease affecting the blood vessels of the legs), by the Drugs Controller General of India (DCGI). If such programmes and initiatives are in place, then why the Indian pharma companies are hesitant in conducting the researches?

Anil Khanna, Partner, Wisdomsmith Advisors, informs. "Effective research in ODs is not widespread in India. Currently, drug developers in India receives no formal incentives from the government and hence they are more focused on developing affordable drugs for more common diseases. Only few Indian companies like Cipla, Natco Pharma and Troikaa pharmaceuticals are doing research in ODs."

Dr Ketan R Patel, Chairman and Managing Director, Troikaa Pharmaceuticals too agrees to his industry colleagues views and comments, "As of now, there is no definite list of rare diseases and hence there is no policy in place to help quick approval of medicines for such diseases. A fast track approval would bring down costs and make the treatments of such diseases available. A low or negative return on investment is not a deterrent if a proactive policy in place when it's a question of alleviating the suffering of such patients."

Rao points out that no special financial incentives are available for orphan drug developers looking to develop a treatment in India. He suggests, "There is a growing demand that the government of India should focus heavily on local R&D for orphan drugs. The outcomes and the effectiveness of government intervention in R&D can be measured by the number of patents filed. Incentives such as tax credit on R&D costs or access to national research infrastructure

or facilities to aid industrial R&D, phase I and II clinical trial grants or tax credits, market exclusivity and subsidies on orphan drugs market value will certainly help local development of orphan drugs. Since a huge chunk of orphan drugs getting developed now are biologics, incentivising, supporting and strengthening the industry infrastructure to support biologics manufacturing is the need of the hour. This will also align with growing focus on reaping benefits from the $240 billion biosimilar market, in which a large number of patents are set to expire. In addition, the government needs to come up with a policy on drug repurposing R&D, incentivising it with funds for national and international industry-academia collaborations. There is also a need for a clear directive as to how to proceed if a repurposed drug is found to be beneficial as an orphan drug, but the original manufacturer refuses to enter a required regulatory process in India."

Pointing out the regulatory challenges, Khanna says, "Though there are not much-documented differences in approval criteria for ODs and non-orphan drugs, sponsors have to prove substantial evidence of the effectiveness of the drug using adequate and well-controlled investigations. Nevertheless, FDA has publicly expressed sensitivity for applying flexibility in its approval standards to new therapies for RDs. Although ODs may qualify for fast-track regulatory review and smaller safety data set requirements, regulatory approval may also come with a laborious risk evaluation and mitigation strategies requirements. The regulatory complexity in determining what evidence is sufficient to support FDA approval of ODs is due, in part, to the lack of clinical trial precedents and limited scientific understanding of RD processes."

He further elaborates that ODs have a significant competitive advantage being first in the market. The additional market exclusivity provides long term benefits to the sponsor/ manufacturer. The time from phase II to market is often shorter for ODs due to shorter and smaller clinical trials and FDA fast track designation. Timelines for FDA approval for OD is 10 months v/s 13 months for non-orphan drugs. And, expected return on investment of phase III/ filed ODs is 1.89 times greater than the non-orphan drug."

Khanna informs the steps taken by the Indian regulators and says "Drug Control General India (DCGI) has given waive off in conducting clinical trial for approval of ODs and drugs indicated for conditions/diseases for which there is no therapy. This condition is applicable only if the OD is already approved in the US and Europe. If the drug is a new molecular entity (NME), it has to undergo clinical trials."

Highlighting the advantage of conducting clinical trials for rare diseases, Khanna emphasises, "Developmental drivers such as government incentives, shorter development timelines and high rates of regulatory approval are making OD development as economically viable as non-orphan drug development, even though there is a small patient pool."

Majority of rare disease cases are diagnosed at a chronic stage which, requires long term treatment procedures and it turns out to be a huge financial and psychological burden not only for patients but also for their family members. Do they get financial assistance?

Patient assistance programme

In India, a National Policy for the treatment of rare diseases (NPTRD) was formulated in 2017 by Ministry of Health and Family Welfare, Government of India, which earmarked as a corpus of Rs 100 crores for the scheme. Additionally, another corpus was to be maintained by the state governments under the ratio of 60:40. However, it was withdrawn suddenly, by the government, without assigning any reason.

The withdrawal of the amount became huge hue and cry. Not only the Indian pharma industry, but many multinational pharma companies also felt offended. To take a remedial step on the earlier decision of withdrawal of fund, last year (2019) in November end, the Modi government made an announcement of providing a one-time payment of Rs 15 lakh to economically backward patients suffering from rare diseases, which will affect an estimated 70 million people in India. An expert committee is currently devising a new policy and the expert committee [working on the proposal] is likely to finalise its draft report soon. Thereafter, consultations with state governments and other stakeholders will be held.

> GoI has also launched UMMID (Unique Methods of Management and Treatment of Inherited Disorders) initiative and inaugurated NIDAN (National Inherited Diseases Administration) Kendras

Rao informs, "A rare disease patient below the poverty line is eligible for one-time assistance of up to 25 lakhs under Rashtriya Arogya Nidhi (RAN). This type of monetary support is really helpful for surgeries or organ or bone marrow transplant procedures. Whether this can also be used for cell and gene therapy products needs to be clarified."

GoI has also launched UMMID (Unique Methods of Management and Treatment of Inherited Disorders) initiative and inaugurated NIDAN (National Inherited Diseases Administration) Kendras with the help of Department of Biotechnology, GoI. This initiative should enable a rough prevalence estimation through the genetic screening of 10000 pregnant women and 5000 new-borns. However, practical issues of sampling bias, handling error, testing methodologies etc will determine the integrity of the generated data.

According to the IRDAI guidelines, internal congenital disorders and genetic diseases, or diseases to which a definite cause is not known, cannot be exclusions in a health insurance policy. Hence, covering the pre-existing conditions themselves is the biggest help as of now because denial will have huge repercussions on the care provided to rare disease patients. Pre-approval access to investigational drugs developed outside India could be one way to assist therapy ultra-rare genetic disorder patients in India, though this might require a waiver of compensation in clinical trials.

Some of the governments (Punjab, Haryana, Karnataka, Kerala) also engaging in subsidising or reimbursing some rare disease medicines such as IVIG for primary immunodeficiency disorders, Enzyme Replacement Therapy for lysosomal storage disorders. However, funding crunches, administration changes have often plagued a continuous supply of these life-saving medicines. Having a stable reimbursement scheme, expanding coverage of reimbursement scheme to other rare disease medicines and uninterrupted reimbursement of life-saving rare disease medicines will certainly help. Supportive therapies related to few rare diseases (e.g., Hirschsprung's disease) are covered under package schemes of PM-JAY and state schemes such as Arogya-Karnataka.

Expressing the concern on some of the work carried at the government level and its impact on patients, Khanna explains, "Government has announced the formation of a committee. Among the four terms of reference of the committee, one is to define 'rare diseases' for India! This is absolutely criminal, as one expert pointed out. People are dying due to lack of medicines and you say you are looking for definitions."

The key problem is the availability of drugs, which the government policy itself underscored. "Wherever the drugs are available, they are prohibitively expensive, placing immense strain on resources of families, health systems and donor agencies alike. It is estimated that for a child weighing 10 kg, the annual cost of treatment for some rare diseases may vary from Rs 18 Lakh to 70 lakh," states the NPTRD document.

Khanna says, "Since the healthcare system in India is mostly self-funded, price becomes a significant challenge, and so does the patients' need for financial assistance. For this purpose, they usually look for support from patient foundations, other non-governmental organisations and charitable access programs offered by certain pharma companies to cover these costs. Recently, the Bangalore based Vikram Hospital opened the state-of-the-art 'Center of Excellence' for Huntington Disease. In the coming time, the hospital is also planning to open up new exclusive clinics for various other rare disorders and aiming to fill the void of care in the health sectors.

Conclusion

Presently, there is a lack of diagnosis methods and facilities for rare diseases and the treatment for such them is quite expensive. To overcome these challenges, a lot of effort needs to be made by the government bodies as well the pharma companies. People also need to take measures like self-examination and healthy lifestyle adoptions. Even insurance players need to understand the severity of the disease and their financial burden on the patient, and they should consider incorporating rare disease profile in the insurance coverage as well.

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E-pharmacies – what lies ahead?

Dr Vikram A Munshi, Founder, WhiteSpace, Consulting and Capability Building discusses how e-pharmacies are faring in current times, their growth potential, and what their future beholds

A pharmacy, or an online pharmacy, is one that basically takes an order of medicines over the Internet and then delivers medicine to a patient through mail or dedicated delivery companies. From the first pioneering steps in 2015, the e-pharmacy industry has crossed Rs 3500 Cr in 2018 and is estimated to touch Rs 25000 Cr in 2022 as per a Frost and Sullivan Report.

This rapid growth of the pharmacy business speaks of a gap that exists in the market. For four years, the e-pharmacies have operated in a grey area while the government is yet to formulate concrete regulations for them.

In September 2018, the All India Organisation of Chemists and Druggists (AIOCD), who represent the 8 lakh plus brick and mortar retail chemists, observed a day-long strike. It triggered the Indian Government to issue a set of draft rules for the working of e-pharmacies in India, stating that no person will

distribute, sell, stock, exhibit or offer for sale of drugs through an e-pharmacy unless registered.

These draft rules ended the debate against e-pharmacies then. But even after a year, there has been no update on these rules by the Government.

In a November 2019 order, the drugs controller general of India (DCGI) directed all states and union territories to prohibit the sale of medicines through unlicensed online platforms till the draft rules for regulating e-pharmacies are put in place.

There are two challenges that the e-pharmacies need to navigate. One is the regulatory challenge and the other being the challenge in providing a meaningful value proposition to the population segment it aims to serve.

Regulatory Challenge: In India, pharmacy law broadly states that medicines should be sold only through a valid prescription and dispensed through a registered pharmacist. However, a patient can purchase medicines without a prescription from a retail chemist. Even if the purchase is made with a prescription there is no record maintained of the prescription at the chemist end. Moreover, while the pharmacy may have a registered pharmacist on paper, the person manning the counter and dispensing medicines is rarely the registered pharmacist. The e-pharmacy scores over the retail chemist in these two critical areas.

The prescriptions have to be loaded on the portal. After the loading of the prescription, they are verified by a registered pharmacist and then finally the medicine is dispensed and mailed to the patient along with the full invoice of batch number and expiry date. This also helps to safeguard against the patient receiving counterfeit or spurious drugs. This meticulous record-keeping of prescriptions and invoices is also an insurance for the e-pharmacy in case of any consequences of claims of incorrect medicines dispensed. Thus, while the AIOCD is crying itself hoarse protesting against the e-pharmacies, it may find itself in a spot if the government inspects the adherence to pharmacy laws across the 8 lakh plus

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the brick and mortar retail chemists pan India.

Value Proposition Challenge: What is this gap which the e-pharmacies are filling? Every online business in the e-commerce space is built on the philosophy of 'traction before transaction'. This means that profits are sacrificed to ensure customers switch to these companies. For the cost-conscious Indian customer, discounting is the easiest lure. The e-pharmacies, especially the bigger ones are heavily funded and hence the value proposition offered by most of them is more focused on savings on medicine cost, ranging from 10 to 25 per cent. Most of the communication in the advertisements focuses on savings. The funding behind the e-pharmacies makes this discounting easy to bear. This discounting changed the perception for the Indian customers that even medicines could be available on discounts.

The dual convenience of discounts and home delivery is now offered by many of the neighbourhood retail chemists. Some retail pharmacy chains offer loyalty programs rather than discounting but in the end, they are delivering the dual advantages of cost savings and the convenience of home delivery.

In addition to this, the neighbourhood retail chemist offers two more advantages that the pharmacy cannot – one personal touch, experience and immediate delivery. The 'friendly' neighbourhood chemist interacts with the customer personally and is known to respond to home delivery on an immediate need within the neighbourhood. The best of e-pharmacies may have a highly user-friendly technological interface but are unable to deliver medicines on the same day. Hence, they get more suitable for chronic care medications which are long term whereas they cannot make the urgent requirement for say a pain killer or a prescribed antibiotic.

Keeping in mind the above scenario, I believe that e-pharmacies need to explore other hidden needs rather than just price discounting. The need may be to get reliable medicines for a loved one from long distance, or ensuring the patient is never out of dose for the regular medication. Moreover, e-pharmacies can offer other related value-added services like customised diagnostics, counselling services, etc. to that patient apart from the medicines to impact the outcome.

E-pharmacies are here to stay. While we await a set of formal regulations governing them, they will exist side by side with the retail chemist, each fulfilling specific needs of different patient segments.

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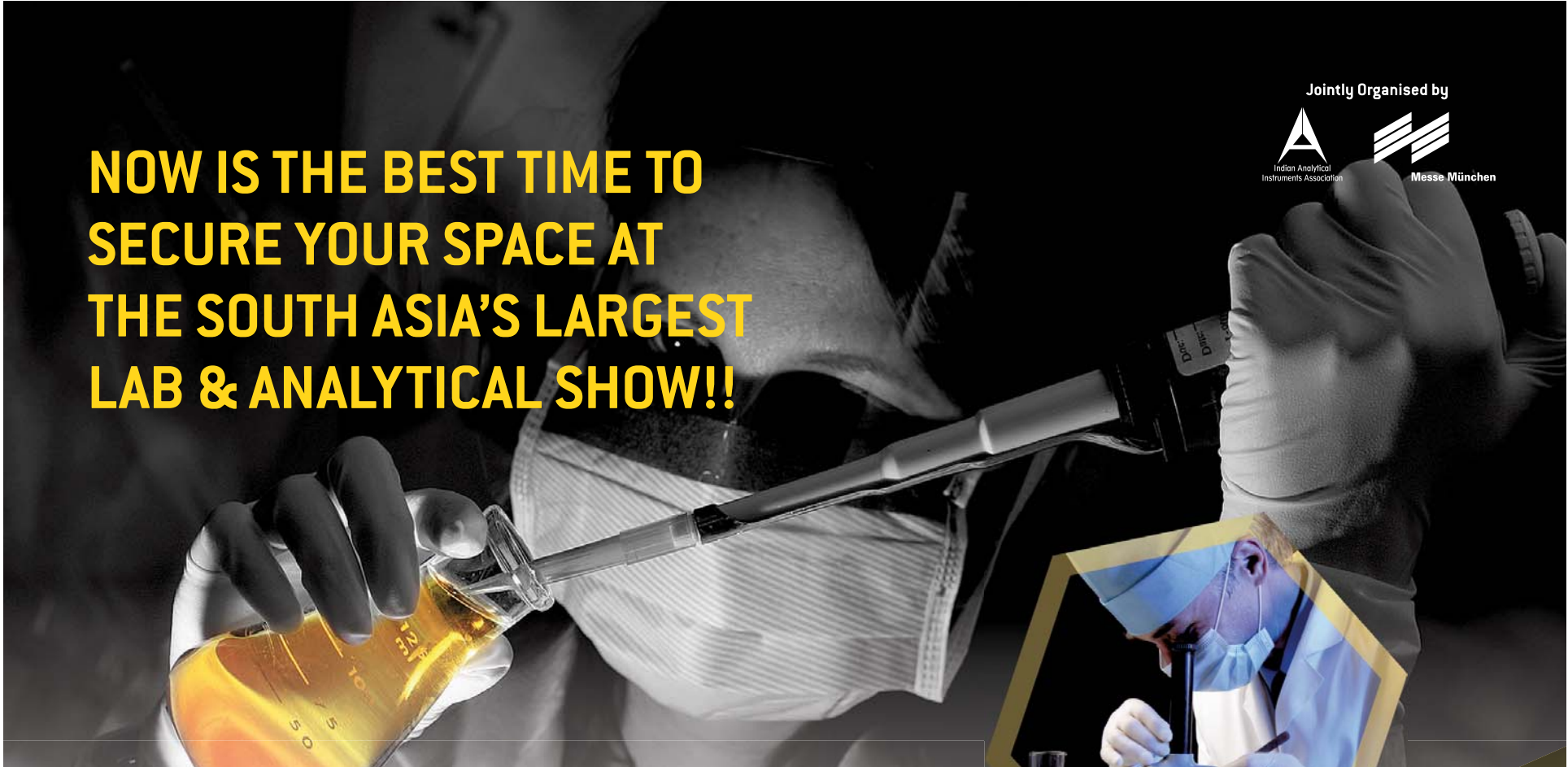

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Budget 2020: What does the industry want?

Last year in July, Finance Minister Nirmala Sitharaman presented the first Budget of Modi Government 2.0. Since the pharmaceutical industry did not get much attention from the government last year, they have strongly voiced their concerns and expectations about the upcoming financial budget, especially amidst rising concerns about the economy

BY **USHA SHARMA**

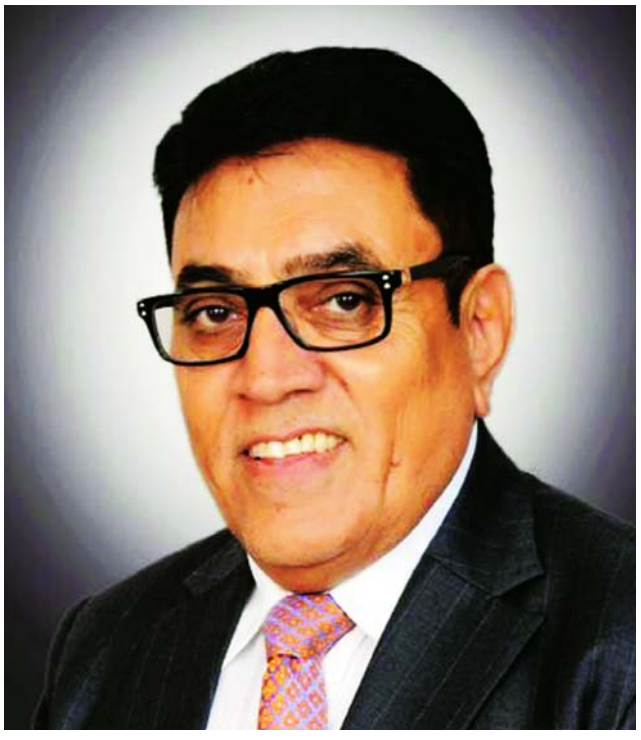
We expect the government to give strong support particularly to the API sector

The pharmaceutical industry had a lot of hope during the last budget but the government disappointed the life sciences sector. Since the Finance Minister was new to this portfolio, there was hardly any time for the government to prepare an exhaustive budget.

We took it in a sportsman spirit and accepted whatever they gave. This year the industry is hoping for strong support from the government as in the recent past, the industry has suffered many setbacks due to frequent regulatory interventions and huge investment by MSME category of units.

Our expectation from the government in the coming years is to have strong support, particularly in the API sector. In the last five years, the government has talked about APIs, but nothing much constructive happened, although many forums and meetings were held at ministry and NITI Aayog level.

Dependability on China is becoming a big threat to the nation's security and it is high time for the government to focus on to reduce 50 per cent dependability on China. Formulators who use API of domestic source with 100 per cent locally manufactured intermediates, should be exempted from price control.



BR Sikri, Chairman, Federation of Pharma Entrepreneurs (FOPE)

Similarly, R&D and process development activities both in the finished dosage form and API needs special incentive and we recommend the government to make it a 200 per cent incentive from existing 150 per cent.

The government expects more quality products from MSME and wants this sector to compete with international standards. If that is the case, the government has to come forward with massive financial help to the small scale sector without any burden to pay a higher rate of interest. Such help should be free of interest and that too with sufficient time of moratorium.

Academia is capable enough to produce new technologies and industry is keen to accept such new technologies. But, the government has to take a serious lead in arranging tie-ups between industry and academia. This will reduce dependability on China over a period of few years to come. The government has to take up this matter on priority and seriously.

There is a gap between SLA and CLA understanding the Rules and Act. This needs deliberation between State Governments, Central Government and the Industry. Existing infrastructure within the pharma industry needs further improvement as old industrial townships have outlived their life and need further upgradation. BA/BE is another additional burden on the industry particularly on MSME as each product need to undergo this test. MSME does not have sufficient funds to invest in this head. Moreover, different CROs are charging different rates for such studies and it is a big financial burden. Government of India has to come forward with streamlining the system and give financial support to small scale without any rate of interest burden, that too the rate of study should be reasonable and affordable.

Changing lifestyle with a spurt in population has led to a rise in geriatric population in India, rising healthcare spending by individuals etc. Government of India, a couple of years back, announced a new health policy, which led to the introduction of Jan Aushadhi Scheme, free distribution of medicines through wellness centres.

There is a huge potential for the pharma sector in days to come. With the government's initiative, not only can the industry support the government in providing affordable and efficacious medicines it will also help to mark its presence in the global markets. The present growth projection for the pharma sector is from 10 to 12 per cent which can certainly be more than 15 per cent.There is a saying "Relationship always work when trust is bigger than doubt". Therefore, the government has to work on trust with the industry to bring in phenomenal change, constructive and positive result in the overall interest of the nation.

Policy and financial initiatives are long over due

Harish Jain, Secretary, Karnataka Drugs & Pharmaceuticals Manufacturer's Association

Pharmaceutical industry is the major contributor to the India's economy. In hard times, pharma stands out with double digit growth. Pharma sector would like to be major contributor in terms of employment, knowledge, turnover and spreading soft power of India across the globe. However, there is a huge potential to accelerate growth and with right therapeutic dose of support from the Government, achieving more than 12 per cent year on year growth is distinct possibility. Area of focus should be end to end indigenous manufacture of APIs and speciality excipients, R&D specially innovative dosage forms (rather than NCEs), API process development, biologics and biosimilars, upgradation of MSMEs, ease of doing business.

Self sufficiency in API and speciality excipients remains a dream on paper. One cannot have a robust global formulation industry dependent largely on imported inputs. It is also a strategic risk in terms of health of more than 1300 million Indians. There has to be end to end (Not n-1 or n-2) indigenous manufacturing. Policy and financial initiatives are long over due. Industry is in crying need of rationalisation in environmental norms and compliance procedures for API Industry without compromising on effluent standards. There is a Bulk Drug Cluster scheme of Department of Pharmaceuticals with grants upto Rs 100 Crore for each cluster. However, this scheme can be availed only by State Implementing Agency (SIA). India requires a minimum of 15-20 clusters immediately. In addition to SIA, the scheme should be extended to SPVs floated by reputed industry associations and maximum extent budget allocation is expected. To encourage R&D including process development, clinical, BA/BE studies etc there is a long standing demand of the Industry to restore 200 per cent weighted deductions.

Also, currently API attracts GST of 18 per cent whereas, formulation attract sGST of 12 per cent which means there is inverted duty structure. This needs to be corrected by reducing API GST to 12 per cent to avoid accumulation of GST credit and clogging of precious working capital.

Upgradation of MSME to WHO-GMP norms by way of interest subvention on capital goods investment as well as investment on upgrading quality assurance systems is long overdue. Target should be to upgrade at least 1000 MSMEs within the next three years with interest subvention assistance of at least Rs 3 crores per MSME. Budgetary allocation needs to be done without any further delay.

Industry-academic partnership is long overdue. All the public sector institutions like NIPER should have industry academic department headed by senior professor to facilitate partnership and create opportunity for industry, students and institutes. This has been global practice and all major research projects are incubated and commercialised by this partnership.

We recommend restoration of 200 per cent depreciation for R&D expenses

S V Veerramani, Immediate Past President, IDMA, Chairman & Managing Director, Fourrts (India) Laboratories

We strongly recommend for restoration of 200 per cent depreciation for R&D expenses. At present, it has been reduced to 150 per cent and the pharma industry requires to roll back to 200 per cent considering the need for increased investments in R&D. We feel that if the government gives proper financial support to SMEs from technology upgradation fund for Pharma SMEs, then the pharma SMEs in India can graduate to the next level and can become exporters. Special package for bulk drug sector is required to reduce dependence on Chinese imports.

We also need stable pricing policy and simplification of drug regulations.

Increased outlay for registration of product dossiers in export markets as well as reimbursement of expenses on bio equivalence studies and clinical trials for Exports. We are also looking grants for Industry-Academia tie up for technology development.

Particularly for income tax we request the government to remove conditions for availing the revised income tax rate of 22 per cent to avoid double taxation on dividend payment by companies as well as individual shareholders.

As an industry, we feel the need for a separate Ministry for Pharmaceuticals considering the enormous growth potential both in domestic and international markets.

We would like an enhancement of weighted tax deduction from 150 to 200 per cent for R&D

Dr Dinesh Dua, Chairman,Pharmexcil

It's for the first time post independence that a political party think tank has reached out to the industry to create a White Paper on revving up the sagging economy for GOI to create a Union Budget which addresses these issues. Dr Vinod Paul Member, NITI AYOG who robustly participated in deliberations and wholeheartedly supported the industry. On behalf of the Indian pharmaceutical industry and all stakeholders we have presented a detailed note on inverted duty structure which is achilles heel for the pharma industry currently valued at US $40 bio equally divide in US $20 billion each for Exports and domestic currently growing at 11 per cent YoY.

1. Enhancement of weighted tax deduction from 150 to 200 per cent and extension for another five years for the development research and development in the pharmaceutical industry enabling innovation. To also include lab work, process research, pre-clinical, clinical & CRO

2. To give strong support and level playing field to Indian API industry to be more self-dependence than China. Cluster development budget allocation to the maximum extent possible.

3. The contribution from large scale pharma companies is significant for our exports and most of the ANDA and DMFS are filed by the large scale companies. Any proposal for downsizing the product registration reimbursement under MAI for large companies would impact the export growth in the long run and will also discourage product registrations abroad.

4. It is a fact that 55 per cent of our exports are to highly regulated markets and the condition under the MAI scheme restricting the financial assistance for the delegate participation in RBSMs from developed markets would hamper exports in the long run, which may please be relaxed.

5. Establishment/Development of the common Effluent treatment plants(CETP) at pharma clusters or alternatively providing grant for individual companies for establishing the ETPs would improve the efficiency of the pharma industry functioning.

6. Clarification may please be provided on the inclusion of the current benefit for the manufacturers under excise for operating from the excise free manufacturing zones. The pharmaceutical industry is also asking for more information on the implementation of GST on the MRP of pharmaceutical products

7. To incentivise value added exports to semi and high regulated markets, three years of moratorium for all pharma manufacturing units from taxes / allowing DTA sales from SEZ units / regulatory compliance licenses except safety issues / interest / repayment of loans.

8. Alternatively grant should be given to MSME units who get approval by PICS/ EU/US/MCA approvals for plants. Which should be at least a Rs 1 Cr per plant and it should be only a one time grant to company. Grant may not be allowed if any other plant of company is already approved as on date.

9. After starting up, units need to qualify machines and validate there process and then wait for six months stability.

10. Then wait for international inspections and certifications. In all if we see any new manufacturing unit targeting overseas supply does not operate above break even before two to three years.

11. FastTrack procedure in CDSCO with FastTrack fee as this will help products to be commercialised at faster pace than today which will result in increase in pharma production in country both for domestic as well as exports.

12. Virtual vendor platform on information highway for B2B pharma Business.

13. Financial support to Indian R&D based companies for BA BE and clinical studies to get their products registered in Europe and US. As there are of products in India having much better technology with easy Availability but units in MSME are unable to complete registration requirements due to funds.

14. Fund for skill development program for all functions in pharma sector for Quality Management Systems, warehouse, distribution, management of supply chain, manufacturing, QC , QA, Marketing & Regulatory Compliances.

15. Biggest issue as far as budgeting is Inverted Duty structure in Pharma wherein there is mismatch of GST on APIs (18 percent) and finished formulations (12 percent) .Industry working capital gets severely stuck with the govt as GST refund almost takes a year to get back money.

16. Situation is further aggravated by some rule which doesn't allow refund on GST /to ITC on services received. This leads to huge accumulation of ITC without any recourse for refund.

17. Revision in definition of Small and Medium Scale industries. This was proposed to be revised based on GST turnover in 2015. But that proposal never got passed in parliament and has lapsed. Old definition on basis of investment in plant and machinery still continues which is too low.

18. ITC on capital goods purchased - under inverted duty structure, there is no recourse to utilise or seek refund of ITC on capital goods purchased. For new projects or units undergoing modernization and/or expansion, amount of ITC on capital goods can be substantial which gets locked / accumulated.

19. Ease up in issue of Pollution Consents for new units or units undergoing expansion for Pharmaceutical Formulations as well as bulk Drug units.

20. The Government needs to work on a radical policy implementation by converting NPPA into EMMA (Essential Medicines Monitoring Authority) that focuses on quality, availability, affordability and accessibility of essential medicines.

21. DPCO 2013 brought a select list of 530 essential drugs in the NLEM under price control that accounted for 14% in sales value and 24 per centin sales volume of the Indian pharmaceutical market. Five years later, NLEM has increased the list by 64% to include 870 drugs. What is most startling is that despite this increase, there is no significant change in either the sales value or volumes as a percentage of the market. In fact, the sales value and volume percentages remain at 15% and 25% respectively which reflects very poorly on our health regulators. This begs the question that has the sales volume of many of the drugs brought under price control fallen over time lending serious doubts on its availability to the patients.

22. No price control on Non NLEM products since market forces a very potent factor in keeping prices down. As per AIOCD, the pharma industry has seen a price increase of only 3.5% over the last 3 years. In FY18, approximately 90% of the non-NLEM drugs witnessed a price hike of less than 5% as against the 10% allowable under DPCO 2013. Patients could benefit from the government's vision of minimum government, maximum governance if implemented in the pharma industry. Instead of trying to control the prices of all drugs, the government should regulate the prices of only the essential or scheduled drugs being sold.

23. Too much price control has negative impact for the very patients they are trying to help as availability of price controlled products is diminished.

24. Companies promote next generation molecules, whose rampant use leads to creating immunity across population and also increases cost of medication as more expensive medicines are promoted and prescribed.

25. MSME- to encourage by way of financial help so that they can upgrade to WHO approval standards

26. Industry academia tie up for technology development.

27. Reduction in multiplicity of regulatory interventions.

28. Environmental problems & complications of API industry to be resolved on priority.

29. Improvement in existing infrastructure

30. Reforms in Patent Law.

31. To expedite final notification on E pharmacy.

32. Innovation & biologics funds as well as infrastructure to be created to maintain India's leadership in Lifesciences.

CBDT could constitute a panel with adequate representation from the Departments of Revenue, Pharmaceuticals and Trade

The Central Board of Direct Taxes (CBDT) may consider to constitute a panel with adequate representation from the Departments of Revenue, Pharmaceuticals and Trade to define which expenses would be considered as 'ethical'/ 'unethical' (eg, samples, conferences, etc) and guidelines for implementation.

Notwithstanding the above, the provisions of the Circular should be prospective in nature and not effective from the date of the Regulations (i.e. December 10, 2009). Further, the Circular should be linked to violations of Uniform Code of Pharmaceutical Marketing Practices for Indian Pharmaceutical Industry (UCPMP) as and when it becomes mandatory. Till such time Circular should be kept in abeyance. The UCPMP is a voluntary code of marketing practices for pharmaceutical companies in India and it was introduced in March 2012 by the Department of Pharmaceuticals (DoP). Further, DoP is now in process to re-draft the UCPMP code and is engaged in discussions with the stakeholders from the pharma and medical device industry for their comments.

A weighted deduction of 200 per cent of the amount spent on specified activities like investment in in rural/ semi-urban healthcare infrastructure. Even donations to institutions carrying out building of such an infrastructure should be qualified for weighted deduction. With special focus of the Government on scheme like Aayushman Bharat, such provisions will give big boost to the pharma players to contribute to success of the scheme.

Daara B Patel, Secretary General, IDMA

Currently, active pharmaceutical ingredients ('APIs') (raw material used to make bulk drugs) are majorly imported from China. India imports around 80 per cent - 90 per cent of its raw material from China. Thus, India runs the risk of a severe shortage of medicines because of it's over dependence on China for sourcing raw material for drugs. From a tax point of view, investment based tax incentives can be declared to boost API manufacturing in India. Special zones may be notified for manufacture and export of APIs. Special package schemes, similar to Modified Special Incentive Package Scheme ('M-SIPS') or Electronics Manufacturing Cluster Scheme could also be considered for this purpose with ongoing trade war between USA and China, there is a big opportunity for India.

Under the section 35(2AB) of the ITA provides for weighted deduction of 150 per cent on the expenditure incurred on scientific research on in-house R&D facility approved by the prescribed authority – DSIR. Further, DSIR has issued guidelines dated May 2014 which provides for approval of the R&D facility subject to fulfilment of certain conditions. It is suggested that the existing provisions should be specifically clarified to allow weighted deduction in respect of expenditure incurred outside the R&D facility which are sometimes necessitated by the industry's business needs. Additionally, it could also be provided that where the risk of doing research is assumed by a company, the entire cost of R&D activities (whether outsourced or undertaken in-house) is eligible for weighted deduction in the hands of company undertaking the risk. Our recommendation is that DSIR guidelines should not deal with the allowability or disallowability of any expenditure incurred on in-house R&D facility. There are sufficient provisions within the Act which provides powers to the Assessing Officer (AO) to examine the same. Further in case of doubt about the usage of asset for or activity constituting scientific research, the AO can always refer the question to CBDT under Section 35(3) of the Act, which in turn will refer the question to DSIR. Based on these feedback the AO should decide the quantum of R&D expenditure entitled to weighted deduction under Section 35(2AB) of the Act. In other words, DSIR should not decide the quantum of R&D expenditure entitled to weighted deduction under Section 35(2AB) of the Act. The AO should decide the quantum of R&D expenditure entitled to weighted deduction under Section 35(2AB) of the Act. Accordingly, the provisions of Section 35(2AB), Rule 6 (including relevant forms) and DSIR guidelines should be amended.

With a view to achieve a growth rate of eight per cent and put India on the growth trajectory and to ensure having a robust R&D database, it is suggested that the weighted deduction under Section 35(2AB) of the Act should be extended for a further period of 10 years. This would enable the country to be on par with the developed nations which have robust R&D centres fuelling growth in the economy.

INTERVIEW

‘We may look at scaling to 50 per cent growth in the next financial year’

Manish Jain, Managing Director of Cilicant Chem, a company that provides solutions to protect highly moisture-sensitive products from the harmful effects of moisture or humidity for the desiccant market, discusses the company's growth strategy with **Akanki Sharma**

What was the need to come up with Cilicant Chem?
Medicine spending in India is projected to grow nine to 12 per cent over the next five years, leading India to become one of the top 10 countries in terms of medicine spending. Pharma is amongst few industries which understand the criticality of having the right active packaging in the formulation of the product’s shelf life. Selection of active packaging is thus based upon many stability studies and trials.

Given this scenario, the active packaging in India, primarily has been coming from multi-national players, when India is definitely poised to manufacture the same international standard and quality indigenously.

Cilicant Chem was born out of that passion - the need for an indigenous source which will manufacture the right quality of active packaging to protect the products from degrading effects of moisture and oxygen.

Tell us about the solutions you offer to the pharma industry and other stakeholders.
Our products CILICANTFG desiccants sachets and canisters, and CILICANT oxygen absorbers have been specially designed for usage in primary packaging of pharmaceutical products, medical devices, diagnostic kits and food products. It adheres to the international quality standard and meets the requirement of US Food and Drug Administration (USFDA)standards with respect to Type III DMF (Drug Master File). Hence, it is completely safe for direct food contact in accordance with the Federal Food, Drug and Cosmetic Act requirement of 21 CFR. We have an array of desiccant solutions which ensures protection from the harmful effects of moisture and oxygen and provides the much required extended shelf life. The other industries include nutraceutical, medical devices, processed food, electronic equipments, etc.

> We have partnered with over 150 pharma companies to provide right and active quality packaging. Nutraceuticals and medical devices companies are others

How do you ensure the affordability and cost-efficiency of your solutions?
Quality is the prerequisite to many of our customers and they have been willing to pay for the right active packaging product that is available in the market anywhere today. Therefore, at Cilicant, we adhere to strict quality control to provide the right product which makes our active packaging solutions cost-effective. We never compromise on the stringent measures that we have upheld for the safety of our customers, which in turn, safeguard the health of the end consumer.

What is the growth rate of desiccant markets in India as compared to other countries?
Indian companies received 304 Abbreviated New Drug Application (ANDA) approvals from USFDA in 2017. The country accounts for around 30 per cent (by volume) and about 10 per cent (value) in the $70-80 billion US generics market.

The desiccant market has been playing a significant role in extending the shelf life of many life-saving drugs and medical devices. The market today is largely unorganised, but is moving towards the organised sector. The Indian government has also taken many steps to reduce costs and bring down healthcare expenses. Speedy introduction of generic drugs into the market has remained in focus and is expected to benefit the Indian pharmaceutical companies. In addition, the thrust on rural health programmes, life-saving drugs and preventive vaccines also augurs well for the pharmaceutical companies.

Going forward, better growth in domestic pharmaceutical sales would also depend on the ability of companies to align their product portfolio towards chronic therapies for diseases like cardiovascular, anti-diabetes, anti-depressants and anti-cancers that are on the rise.

With the increase in demand for pharmaceuticals and medical devices, there is a definite need to improve not just the quality, but provide for a safe extended shelf life sans preservatives. This calls for a safe reliable desiccant that cannot only enhance the shelf life, but provides for a safer consumption for the end consumer. These have been significant growth drivers for the desiccant market and the sector is growing at a healthy

rate of 18 per cent.

In what ways do healthcare products get affected due to moisture? How is a moisture absorber different from an oxygen absorber? Kindly elaborate in terms of their applications.

Moisture can hamper and shorten the shelf life of pharmaceutical products by leading to degradation, inferior efficacy, physical and chemical instability of the formulation. Desiccant absorbs only moisture and stabilises the formulation and ensures an extended shelf life of the product. Oxygen causes the formulation to oxidise resulting in rancidity, mould growth, degradation, odour, etc. ultimately shortening the shelf life of the product. The oxygen absorber, on the other hand, absorbs and reduces the oxygen content within the packed products to 0.01 per cent, which helps to extend the shelf life of the product. Therefore, desiccant is to moisture and oxygen absorber is to oxygen, both have different purpose and abilities.

Who all do you sell your products to, and what is your current business scale?

We have partnered with over 150 pharma companies to provide right and active quality packaging. Nutraceuticals and medical devices companies are others. Our current scale of business is at 30 per cent year on year. We may look at scaling to 50 per cent growth in the next financial year.

How does your manufacturing facility in Pune function? What are your growth plans for the next five years?

The quality checks that go into the manufacturing and packaging of the desiccant follow a strict regimen. Every stage of production is stringently monitored and controlled to warrant the highest quality and most efficient performance of the product. The various elements right from temperature and RH control to the quality of sachets to the medical grade ink that's used to print, and the area of storage to transport, have all been analysed threadbare to ensure the highest safety standard. The steps are followed stringently to provide for a safe use of the desiccant product both by the manufacturer and the end-user.

Some of the other significant features include: made in India by indigenous company (amongst the ruling multinational/ foreign companies); a dedicated cGMP & ISO 15378:2017 certified manufacturing facility for manufacturing; assurance that a robust quality management system is in place so that the quality of the products manufactured is not compromised in any way; emphasis on product safety and quality in every step of the process to ensure the right quality of desiccants to keep the pharmaceutical shelf life extended. With the growing population, and with the growing demand in the desiccant industry for quality products that adhere to international safety, we are confident to be the number one active packaging manufacturer in India with international presence in the next five years.

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ANDA approvals in 2019: Trends for the generics industry

Meenu Grover Sharma, Scholar Delhi Pharmaceutical Sciences & Research University, Principal Consultant, BusinessAssociar Consultants, New Delhi and **Dr (Prof) Harvinder Popli**, Dean & Principal, School of Pharmaceutical Sciences, Delhi Pharmaceutical Sciences & Research University, New Delhi write about the ANDA trends seen by the generics industry in 2019

US-FDA continued with its momentum of previous years and granted 833 final ANDA approvals in the year 2019, slightly higher than the 813 final approvals in 2018. Additionally, 146 Tentative Approvals were also granted during the calendar year 2019.

Momentum maintained despite strong headwinds in the US generics industry

US Generics space has been under tremendous pressure for the last few years manifested in the form of significant pricing pressure, eroding profit margins, shrinking number of first-to-file windfalls, consolidation of buyers flexing their buying power, some big players like Sandoz, Teva divesting parts of and reorganizing their portfolio exiting pure generics spaces and continuing woes with negative outcomes of FDA-inspection for several players, especially in India and China.

Despite all these hurdles, the US generics market continues to attract a large number of ANDA filings and approvals, as also evidenced this year. Especially after some of the big players started divesting large parts of their generics portfolio, one might have anticipated a slowdown in numbers as these players with deep pockets were prolific filers in the past. However, this year's approval numbers do not show the expected dip as several other smaller and newer players, including some from China, started on the ambitious US-market dream. Another plausible reason could be that the companies that had already invested in development completed and filed the running projects, so the impact on number of approvals is not evident yet and will be seen over the next couple years, the lag being the time taken by companies to respond in terms of adjusting their business models and pipelines. Another hypothesis could be that having invested in the infrastructure, manpower and capacities, there is still no other option as lucrative as the US market, and hence companies that do not have the capability or resources to shift to specialty business are continuing to invest in commodity generics and adapting to the expectation of much reduced returns. Lastly, of course, the analyst prophesies of rebound to better times in terms of easing pricing pressures is keeping the wheel moving at the same speed, at least thus far.

Regional trend: Indian companies continue to dominate, China registering presence

In terms of regional trends, Indian companies continued to dominate with 374 or around 44 per cent of final approvals, followed by US, EU and then China. While India has remained at the forefront of US generics market for several years, Chinese companies, traditionally considered a strong force in API space, are now steadily forward-integrating into the formulation space as well. In the year 2019, Chinese companies garnered 56 ANDA approvals which is 7 per cent of total final approvals. This number includes the approvals obtained by respective subsidiaries such as Nesher for Zydus or Watson and Actavis for Teva, but does not include the companies in other regions with significant Chinese investment (such as Gland Pharma of India with 74 per cent stake of Fosun from China).

In addition to global ambition of the Chinese companies, another reason for increasing participation in the US ANDA space is the domestic policies favoring high-quality products with overseas approval. A generic product that shares the same manufacturing line as the one approved by US FDA can qualify for priority review in the domestic market in China and thus becomes eligible for certain exemptions such as bioequivalence and can receive a much faster approval. Hence, a significant attractiveness for Chinese companies is getting access to domestic market simultaneous with the US market, through a US ANDA targeted development. Although Chinese companies still have a long way to go to come closer to the level of ANDA filing activity in India, the dual benefits are a strong indication that Chinese companies will continue to steadily keep building this capability.

Expectedly, oral solids hold major share of approvals, but high value products in complex forms such inhalation and vaginal ring also make a long-awaited appearance

60 per cent of ANDA approvals in 2019 were for oral solid dosage forms, of which 20 per cent were for extended release or delayed release formulations. Additionally, 20 per cent of total approvals were for injectable products. For Indian companies, 66 per cent of approvals were for oral solid dosage forms and this number is as high as 78 per cent for Chinese companies. The highlight among dosage forms is the approval for generic for Advair diskus inhaler for Mylan and Nuvaring vaginal ring generic for Amneal. Inhalers were one form where development of generics has remained complicated by need for similarity of device confounded by

Fig 1: ANDA Approvals in 2019 by Month

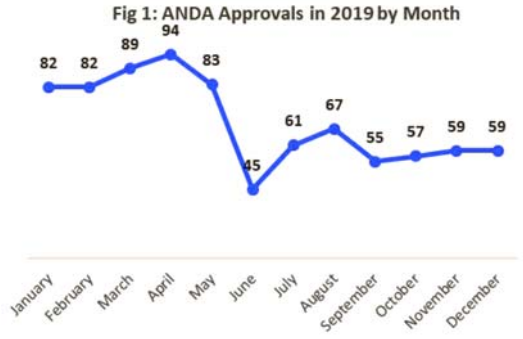


Fig 2: ANDA Approvals in 2019 - Regional Breakdown

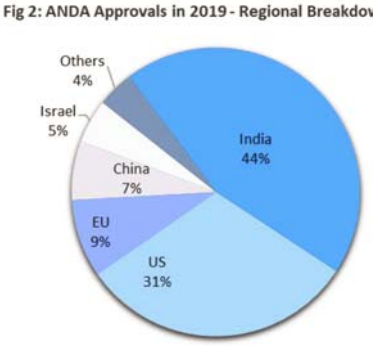
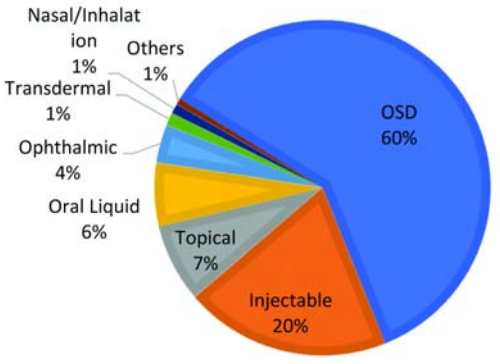


Fig 3: ANDA Approvals in 2019, Dosage Forms



the complex IP scenario. This approval paves the way for similar approvals for more such products and more companies acquiring such capability in the near future. Another area in dosage forms which has traditionally remained lower activity segment has been the oral liquid forms – not because of technical difficulties but mostly because of logistics and cost-efficiency of transportation from distant geographies. This year witnessed over 50 ANDAs approvals for oral liquid products, majority of which were obviously from local US firms, but then again 13 approvals were also garnered by Indian companies, supported by their local manufacturing plants in the US.

Crowded markets becoming a norm, Indian companies have higher exposure to extremely-competitive products

A sizeable 29 per cent of total approvals are for the products where there are 10 or more active ANDAs approved (without considering the discontinued ones, if any), pointing to companies continuing to invest in spaces erstwhile ignored for being very crowded. The proportion is even larger for Indian companies, with 35 per cent of approvals being for products with 10 or more active ANDAs. As the industry evolves and the talent-knowledge pool migrates between companies, a larger number of companies are developing technical competence to develop and file even those products that were earlier considered relatively difficult. While some of these products may be large enough to attract more players, for others the continued filing could either be due to belief of these new entrants in their own cost-efficiency or other technological capabilities that they feel would support their quest for market share or it could just be a miss in their portfolio selection and review process, discovered far too late.

Conversely, there were 21 per cent approvals for products with three or less active approved ANDAs listed. A large proportion of these were contributed by non-oral solid dosage forms. Injectable and topical preparations still contribute a large proportion of these products, followed by Oral Liquids and Ophthalmic as the other significant contributors to the numbers. However, for Indian companies, only 14 per cent of approvals were for products in this low competition space, where also the larger companies dominate, indicating that while in overall numbers Indian companies command a lion's share, the quality of product portfolio that they are going after needs to improve for better return on investment.

Fig 4: Competition/Market Size Attractiveness Matrix

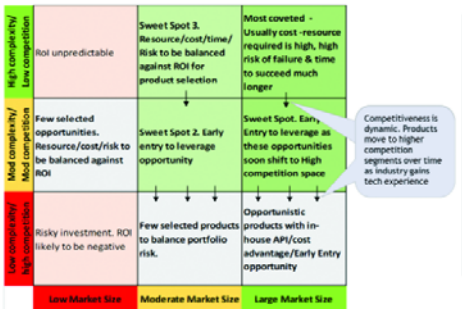


Fig 5: ANDA Approvals 2019 – Market Competition

Dosage Form	% of Total Approvals		% of Approvals for Indian Co.	
	3 or less Active ANDAs	10 or More Active ANDAs	3 or less Active ANDAs	10 or More Active ANDAs
OSD	16%	36%	13%	39%
Injectable	24%	24%	15%	38%
Topical	38%	22%	14%	11%
Oral Liquid	33%	8%	15%	15%
Ophthalmic	32%	6%	25%	40%
Transdermal	20%	-	-	-
Nasal	25%	-	-	-
Inhalation	50%	-	-	-
Vaginal	100%	-	-	-
Total	**21%**	**29%**	**14%**	**35%**

Fig 6: First Time Generic ANDA Approvals in 2019

Dosage Form	% of Total Approvals		% of Approvals for Indian Co.	
	First Time Generic	First Time Generic with a Single Active ANDA	First Time Generic	First Time Generic with a Single Active ANDA
OSD	13%	3%	10%	0%
Injectable	8%	5%	8%	8%
Topical	13%	13%	11%	0%
Oral Liquid	20%	12%	15%	15%
Ophthalmic	19%	16%	-	15%
Transdermal	-	-	-	-
Nasal	25%	-	-	-
Inhalation	75%	50%	-	-
Vaginal	100%	100%	-	-
Total	**13%**	**9%**	**9%**	**3%**

Going after associated exclusivity, Indian companies Lag vs. International Peers

There were 108 First-time-Generics approved in 2019. Quite a few of these were for products that had patent expiry due in 2019 and multiple ANDAs got approved simultaneously and all got listed as First-time-generic. The most notable one here were, Pregabalin with 10 approvals listed as First-time-generic, followed by Bosentan with 8. Lurasidone, Ambrisentan, Febuxostat and Deferasirox are some of the other such products with First-time-generic approval in 2019. Interestingly generics for products such as Apixaban and Ticagrelor also saw first-time-generics approvals, however, it is widely anticipated that these products would not launch anytime soon despite final approval due to unresolved IP concerns.

On the other hand, 48 First-Time-Generics approvals were for products with only one Active approved ANDA, of these only 11 were from the Indian Companies. A substantial proportion of these were for products that are listed by FDA under the Complex Generics Therapy (CGT) Initiative - as Off-patent - Off-exclusivity Products with no generic available. These are usually either products with small market size but requiring investment/effort intensive development or are those with highly complex regulatory path which the industry and the FDA are collaborating to find the best option for. Since this initiative offers 180-day exclusivity to first generic, even a relatively smaller market size products are being perceived as sufficiently attractive for companies to invest in development, which is the whole objective of this program. However, a significant proportion of the CGT list comprises products that are still too small to invest in generics development. In 2018, only five products received exclusivity under this initiative which has increased to 12 products that have already been reported having received exclusivity and another 5-6 approved in later months that are likely to also get CGT related exclusivity.

Significant number of ANDAs discontinued in the approval year itself, raising questions on portfolio investment decision processes

A striking observation, not quantified in earlier analyses summarizing ANDA trends, is the number of discontinued ANDAs, right in the approval year. A neat 10 per cent of approvals in 2019 are already listed as discontinued. Since there will always be lag in approval and active status update, if we consider approvals only in the first six months of the year and the discontinuations in the same period, approx. 15-16 per cent of ANDAs were discontinued already before the close of 2019. This is a significantly high number considering the expense-effort invested on each ANDA and considering that currently the lag between ANDA filing and approval is quite short, so market conditions do not change drastically between filing and approval. Quite interestingly, the list of discontinued ANDAs also includes 17 ANDAs which were listed as First-time generics. A plethora of reasons could be behind these discontinuations, the major one being the questionable commercial viability, with a few also falling prey to technical hurdles in manufacturing on commercial scale. If the analysis is extended to include products that are successfully marketed and were able to get at least reasonable return, the numbers would be overwhelmingly large with some experts indicating that over half of ANDAs approved in 2018 were not even launched, again pointing to a significant need to adjust business strategy and portfolio to minimise wasteful investment.

Program fee has not been a big deterrent, lukewarm response to companies offering ANDA 'Parking Lot'

In addition to the significant filing fee for each ANDA, FDA stipulates annual program fee from each ANDA applicant based on the number of ANDAs approved (including those discontinued). A company with five or less approved ANDAs is considered small and charged a nominal fee at 10 per cent of full program fee, while that with six to 19 approved ANDAs pays 40 per cent and those with 20 or more approved ANDAs pay full programme fee of $1.6 million every year, irrespective of marketing status of the ANDAs. For small and mid-size companies, especially those dependent on licensing their products to partners for commercialisation, this is a huge expense especially when they migrate from lower slabs

to the higher slabs. Hence, the industry saw emergence of companies offering 'parking lots' where they could rest their ANDAs till they find a suitable commercialisation opportunity. However, trends indicate that even small to mid-size companies are holding on to ANDAs in their own name as they see an advantage being visible with their own name in terms of finding a licensing partner and for their company valuation vs. the tradeoff of saving programme fee and losing visibility but paying the parking lot fee. One such company ANDA Repository LLC has only 57 ANDAs transferred in its name thus far, most being very old approvals. Among the 2019 approvals, only 6 are in the name of ANDA Repository.

Fig 7: Top 20 Companies, Dosage Form Breakdown of ANDAs Approved in 2019

	Company	Total	OSD	Injectables	Topical	Oral Liquid	Ophthalmic	Inhalation
1	ZYDUS	35	27	3	4	0	0	0
2	MYLAN	34	22	6	2	0	2	1
3	AMNEAL	32	18	3	0	6	0	0
4	SUN PHARM	30	22	7	0	0	0	1
5	TEVA	27	20	2	1	1	0	1
6	ALEMBIC	27	15	0	4	0	8	0
7	AUROBINDO	21	12	5	0	2	2	0
8	ALKEM	21	16	0	0	5	0	0
9	LUPIN	20	14	2	2	0	1	0
10	CIPLA	15	10	4	1	0	0	0
11	GLENMARK	15	9	1	5	0	0	0
12	MICRO LABS	14	7	1	0	1	4	0
13	PAR PHARM	14	12	1	0	1	0	0
14	APOTEX	14	7	3	1	2	1	0
15	DR REDDYS	14	7	6	0	0	0	0
16	GLAND PHARMA	13	0	11	0	0	2	0
17	TARO	13	3	0	8	2	0	0
18	NOVITIUM	12	6	0	1	5	0	0
19	NOVAST	11	10	1	0	0	0	0
20	ACCORD	11	6	4	1	0	0	0
	Total for Top 20 Players	393	243	60	30	25	20	3
	% of Total	47%	49%	36%	48%	49%	65%	75%

**Company Names Shaded in Yellow are from India*

Fig 8: Top 20 Companies, Market Competition for ANDAs Approved in 2019

	Company	Total	# with ≤3 Active Approved ANDAs	# with ≥10 Active Approved ANDAs	# First Time Generics (FTG)	# FTG with only 1 Approved ANDA	# Discontinued
1	ZYDUS	35	6	7	3	0	5
2	MYLAN	34	7	6	9	3	6
3	AMNEAL	32	11	6	7	3	7
4	SUN PHARM	30	5	11	5	1	2
5	TEVA	27	10	5	15	6	3
6	ALEMBIC	27	2	7	3	0	0
7	AUROBINDO	21	2	4	1	1	0
8	ALKEM	21	2	11	2	1	0
9	LUPIN	20	4	3	2	1	3
10	CIPLA	15	2	6	2	0	3
11	GLENMARK	15	2	4	1	1	0
12	MICRO LABS	14	3	4	3	2	0
13	PAR PHARM	14	7	1	6	3	3
14	APOTEX	14	5	3	1	1	3
15	DR REDDYS	14	4	5	3	2	0
16	GLAND PHARMA	13	4	6	1	1	0
17	TARO	13	7	0	3	2	6
18	NOVITIUM	12	6	0	4	2	0
19	NOVAST	11	0	1	0	0	3
20	ACCORD	11	3	5	2	1	2
	Total for Top 20 Players	393	92	95	73	31	46
	% of Total	47%	52%	40%	68%	65%	54%

**Company Names Shaded in Yellow are from India*

Key Highlights:

- 833 Final ANDA Approvals granted in 2019 by US-FDA, up from 813 in 2018
- Additionally, 146 Tentative Approvals
- Indian Companies account for 44% of total approvals, Chinese companies for 7%
- 60% ANDA approvals for Oral solid dosage forms, proportion higher for Indian (66%) and Chinese companies (78%)
- Advair Diskus (Inhaler) and Nuvaring (Vaginal Ring) generics from Mylan and Amneal respectively most notable approvals in terms of new dosage forms
- Competition further intensifying in most products, 29% total approvals for products with ≥10 active approved ANDAs. 21% approvals where ≤3 active ANDAs listed, with a larger proportion of these seen in non-oral solid dosage forms.
- Indian companies, despite lion's share of overall number of approvals, fare worse in quality of approvals, with higher proportion (35%) in products with ≥10 active ANDAs and lower proportion (14%) in products with ≤3 active ANDAs.
- 108 First Time Generics approved in 2019, of which just 48 have only one active ANDA approved. Just 11 of these single ANDA First Time Generics were from Indian Companies.

12 of the top 20 companies are from India; Sandoz is conspicuous by its absence in the Top 20, consistent with its strategy of exiting generics business

Zydus with 35 approvals topped the overall list of companies (including their subsidiaries) getting final ANDA approvals in 2019. However, very few of the approved products from Zydus this year are in very low competition space, Carbamazepine XL Tablets and Phytonadione tablets being a couple such products. On the other hand, Mylan with 34 Approvals is second in terms of numbers but with several high value opportunities captured, the most notable of its approvals being Wilexa Inhaler, the generic version of Advair Diskus. In addition to this, Mylan got first-time generic approval for another 8 ANDAs, making a total of nine First-time-generic approvals, second only to Teva that got 15 first time generic approvals among a total of 27 approvals that it garnered during the year. The other important approvals for Mylan were Everolimus Tablets and Mesalamine ER Capsules (Apriso Generic), each representing significant market opportunity. Amneal with 32 approvals was the third ranked player in terms of number of approvals. For Amneal, the most notable approval was Eluring, the generic version of Nuvaring where Amneal pipped Dr Reddys Labs in getting the first approval. Among Indian companies, Zydus obviously gained the highest number of approvals in 2019, followed by Sun Pharma, Alembic, Aurobindo and Alkem. Novast Labs is the only Chinese company in the Top 20.

Cumulatively, Top 20 companies garnered 48 per cent of total final approvals. In terms of portfolio breakdown, the approvals for top 20 companies spanned all dosage forms, but these companies represented a larger share of the more complex, lower-competition dosage forms such as Inhalations, ophthalmics and oral liquids. Also, in terms of quality of portfolio, Top 20 companies fare better than the rest, as evidenced in their disproportionately larger share of first-time-generic approvals as well as lower competition products. However, these companies also discontinued approved ANDAs within the approval year at almost the same rate as the overall set of approvals.

Thus, the year 2019 concluded with positive outlook at least in terms of number of ANDA approvals, with numbers remaining steady and approval of some of the most complex of products. However, competition continues to intensify even further with each passing year, in not only commodity generics, but also several products considered difficult earlier. Pricing pressure remains intense in general, though the entire industry is hoping for getting some respite soon enough. Discontinuations after investing and taking ANDAs right upto approval stage and then finding commercial unviability is a serious concern that will eventually impact the resources and intent to continue to file at the same pace, if not addressed through a thought-through portfolio investment strategy. While large players and those with willingness to invest have moved towards opportunities in complex generics, attracted by exclusivity granted through CGT initiative, or towards specialty generics, all companies do not have the wherewithal to tread into this territory and thus continue to explore their sweet spots in the traditional generics space.

INTERVIEW

Lonza India plans to double its turnover by 2024

Lonza is a global integrated solutions provider for pharma, consumer healthcare and nutrition segments. **Deepak Sood**, MD, Lonza India talks about the company's plans for the Indian market, its strategic focus areas, and more in an exclusive interview with ***Express Pharma***

How large and important is Lonza's focus on the Indian market? What are your revenue and growth targets for India's pharma business?
Lonza India is a wholly-owned subsidiary of Switzerland-based and world's leading, integrated solutions provider for pharma and consumer healthcare. Lonza started its operations in India in 1997 as a liaison office. The office was involved mainly into sourcing advanced intermediates from India. Lonza came in as a full-fledged sales and commercial organisation with the acquisition of Cambrex Bio Products in 2007 and was renamed as Lonza India in 2008.

As India is a strategic market for the company, Lonza India has set the target of doubling its turnover by 2024 with an estimated growth of over 14 per cent. Therefore, Lonza India, recently opened its Corporate Office in Gurugram (Delhi-NCR). The new office was inaugurated by Andreas Baum, Ambassador of Switzerland to India who emphasised on India and Switzerland's full-fledged partnership with each side benefiting from the strength of the other.

Tell us about Lonza India's product offerings and strategic focus?
The offerings consist of products for cell discovery, molecular biology, rapid testing tools, fine chemical intermediates and pharma and intermediates for agrochemicals, consumer health and nutrition, biocides for industrial application, disinfectants for hospitals and various performance chemicals. Lonza India is now focusing on achieving the strategic vision of being a leading, integrated solutions provider for its pharma, consumer healthcare and nutrition customers all along the healthcare continuum in India.

You have made some significant acquisitions in the past few years, Capsugel for instance. How have they helped you expand your capabilities for the pharma sector?
Capsugel is known to be a leader in capsule manufacturing, but has also been an important player in the entire overall dosage form solutions. It offers integrated, high-quality, highly customised solutions spanning from design to clinical and commercial manufacturing. In the meanwhile, Lonza has demonstrated great abilities in the manufacturing of small molecule APIs. There are thus a lot of synergies to be leveraged from combining the two entities. So, now Lonza is able to offer our existing and future customers services along the entire value chain from gene to patient.

In case of Capsugel, does a global presence give any advantage over competition?
As we have presence globally , our customers get flexibility in getting capsules across the globe like Japan, China, the US and Europe. Hence customers can get capsules wherever they need, the biggest advantage

over other manufacturers. Our manufacturing process and quality systems are harmonised across all sites, which means a stronger and uniform quality along all sites.

What are the market trends in oral dosage forms? And how does Capsugel plan to capitalise on the opportunities in this competitive environment?
The benefits of using oral therapies is influencing pharma companies to develop new and improved oral therapies to support patients who need accuracy of dose, convenience and ease of compliance to medication regimen. The demand is also due to increase in the incidence of chronic diseases and technological advancements. Novel technologies are being developed to deliver drugs via an oral route. The evolving treatment regimens are influencing a trend for innovative processes and technological advancement where major pharma companies are investing in new target-based therapies. Capsugel's high-quality, innovative dosage forms and solutions can help us capitalise on such emerging consumer trends as healthy ageing, sports nutrition and digestive health, while standing out in an increasingly competitive marketplace.

Capsugel continues to launch ground-breaking capsule designs and equipment technologies that are improving drug development and delivery. Whether you're looking to formulate new products or enhance an existing line, Capsugel has the right capsule to help you bring improved products to market faster. With a diverse portfolio including HPMC, liquid filled hard capsules, or specialised clinical capsules, we are a global leader in capsule development and manufacturing, bringing unmatched products and technical support to our worldwide customer base.

How does a global brand like Lonza offer continous value to its customers?
We have a large sales organisation who understands the needs of customers at local level. Also we have various global customers like Teva, Sandoz, Mylan who are present in India. We serve and meet their requirements as well. Moreover, now we are part of a larger family Lonza. Our activities include the sourcing of intermediates from strategic partners for our manufacturing plants worldwide. In India, we are catering to pharma giants such as Cipla, Sun, Aurobindo, DRL, Novartis. Our customers in Specialty Ingredients include HUL, Asian Paints, Berger, and P&G to mention a few. Life sciences are yet another core area for Lonza and we are catering to research institutes like IIT, JNU, IGIB, NII and medical device companies like Baxter, Brawn. We are also expanding our markets in nutraceuticals and petrochemicals segments.

What are your core priorities going forward?
We aspire to change the company and the relationship with our customers from being 'a' functional service provider to being the knowledge partner of choice for supplying the most innovative solutions. We seek to be truly transformational during these extremely exciting times that we live in today in which medical science is making huge breakthroughs.

Atul Kumar Nasa awarded 'Schroff Memorial National Award, 2019'

The award was given by the Indian Hospital Pharmacists' Association in recognition of his contribution in strengthening the regulatory services

ATUL KUMAR NASA, Head of Office/Controlling & Licensing Authority and Deputy Drugs Controller with Drugs Control Department, Government of NCT of Delhi has been awarded the 'Schroff Memorial National Award, 2019'. The award was given by the Indian Hospital Pharmacists' Association in recognition of his contribution in strengthening the regulatory services

Nasa is a member of Drugs Consultative Committee (DCC) and various other committees of Government of India constituted from time to time. He has more than 33 years professional experience including 27 years experience in the Enforcement of Drugs & Cosmetics Act, 1940 and Rules made thereunder, Drugs (Price Control) Order, 2013, Drugs & Magic Remedies (Objectionable Advertisements) Act, 1954 and Medical Devices Rules (MDR), 2017.

Nasa has been nominated a member of Central Council of PCI. Recently, in the month of August 2019, he was elected as an Executive Committee member of Pharmacy Council of India. Also, PCI has nominated him as a member of Appellant Committee for All India Council for Technical Education (AICTE) office at Delhi. Furthermore, Nasa is the member of Law Committee & other committees of PCI.

Nasa is the life member of IPGA, IPA, APTI, IHPA, AIDCOC, ISTE, IPS, and ISC. Mr. Nasa is also a member of FIP (International Pharmaceutical Federation). Nasa has spoken on various National and International Conferences including FIP 2013 at Dublin (Ireland), FIP 2018 at Glassgow (United Kingdom) and FIP 2019 at Abu Dhabi (UAE).

"We in the Indian Hospital Pharmacists' Association are immensely pleased to confer the Schroff Memorial National Award, 2019 to Nasa and wish him the best in his future endeavours," stated IHPA in a press release issued by the institution.

ERT Solutions Support 75 per cent of 2019 FDA Approvals

eClinical solutions deliver critical safety, efficacy, and patient experience data to meet sponsors' drug development goals

ERT, A global data and technology company that captures critical endpoint data while minimising uncertainty and risk in clinical trials, recently announced an ERT record: 75 per cent of the compounds approved by US FDA in 2019 were developed using one or more of ERT's eClinical solutions during the drug development process.

ERT delivers innovative imaging, cardiac safety, respiratory, and electronic Clinical Outcome Assessment (eCOA) solutions that help biopharmaceutical companies meet global regulators' strict guidelines for demonstrating the safety and efficacy of new medical compounds. ERT's eClinical solutions were involved in the clinical trials of 36 compounds that gained FDA approval during 2019. These compounds represent a wide spectrum of therapeutic areas, and now have the opportunity to make a big difference for patients diagnosed with various forms of cancer and rare disease, CNS and hematologic disorders, infections, and other diseases.

"We are honored that so many bio-pharmaceutical companies have relied on ERT to support their drug development efforts, and very proud of the important role our employees play in improving patient health," said Jim Corrigan, President and CEO of ERT.

"We look forward to strengthening our relationships with these global organizations and continuing to provide innovative solutions that help them develop novel treatments for patients in need," he further added.

VENDOR NEWS

Gandhi Automations awarded the WASME Award of Warehouse & Logistic Innovation Award

The company bagged the INNOVATION AWARD for advanced tech innovations

WORLD ASSOCIATION for Small and Medium Enterprises (WASME) is a global non-profit organisation, that has been spearheading the cause and development of Small and Medium Enterprises (SMEs) world over since its inception in 1980.

Warehousing and logistics are crucial factors for companies to gain a competitive edge. With the advent of modern manufacturing, which combines smart and effective products with advanced and innovative technologies, the very definition of warehousing and logistics has evolved to a much larger and integral concept.

Gandhi Automations range of Entrance Automation and Loading bay range of products have changed the evolution in traditional warehousing powered by advanced engineering technology that is not only impacting logistics but the supply chain as a whole. Thus, Gandhi Automations once again bags the INNOVATION AWARD for advanced tech innovation as the logistics and manufacturing sectors move beyond the rudimentary manual operations in the supply chain.

Gandhi Automations has successfully evolved into an innovative company catering to all kinds of needs. We have an extremely talented in-house research and development team which designs customized solutions for our customers. Our product engineering team uses the latest software in combination with technologically advanced machinery to provide our customers with an unmatched experience in entrance automation and loading bay equipment

We have made significant improvisations and innovations to our loading bay equipment range of products as well as high speed doors. Our new Forklift Roll-off Barrier lip Dock Leveler, Prime Cold Reset, High Speed Doors- Prime Reset, High Speed Doors- Prime Internal Doors, Industrial Sectional Overhead Doors, Dock Levelers, and Isotherm Rolling Shutters are some of the most fast moving innovations and products that have changed the landscape of logistics and warehousing automation.Quality is a key driver of progress for us and is an integral part of every process we undertake, from R&D to product delivery. Our quality policies are constantly upgraded to exceed our customer's requirements and expectations. Gandhi Automations is committed to delivering high-quality products and services to its customers and continuously strives to improve in all aspects. Our products and services are geared towards ensuring that every delivery to the client passes through our stringent quality measures. This policy has engendered a work culture that exhibits a no-compromise attitude towards quality.

Gandhi Automations is known for its research and development, quality and commitment towards customers. The material handling industry is responding with new equipment, technology, and systems that enable complete supply chain visibility, thus allowing customers to see how their investments are impacting their overall operation. The demand for material handling automation and equipment has increased exponentially over the past few years. It is because of the increasing production capacity, reducing man hours and meeting deadlines. Now with more and more companies streamlining their processes, use of material handling equipment for any industry is a must. Demand for such automation is the need for the hour; and also, to deliver faster, hassle free loading / unloading functions to reduce supply chain operating costs.

Ami Polymer signs master distribution agreement with Foxx Life Sciences

The Network allows full coverage of specialised Pharma Tubings (Platinum cured Silicone, TPE, FKM, and FEP tubings), O-rings, Manifolds, and Sanitary Gaskets for the markets such as Bio pharma, Medical and Lifesciences

AMI POLYMER, on November 18th, 2019 offered International Distribution Network by signing an exclusive master distribution agreement with Foxx Life Sciences offering services to customers in North America, Mexico and Canada by giving quick access to the company products.

"This Imperative addition will allow Foxx Life Sciences to become a key global supplier to the pharmaceutical and biotech markets and for that our strategic Partnership will help businesses to create business plans that provide profitable, sustainable results" said President and CEO of Foxx Life Sciences, Thomas Taylor.

Foxx Life Sciences is a global leader in single-use technology having a strong presence in the Bioprocess market. Through strategic planning and acquisition, commitment, and hard work, Foxx has developed an unparalleled reputation for technical expertise, quality and value.

Ami Polymer is leader in rubber product manufacturing for food, pharma, Medical, and heavy engineering industries. Ami is enjoying the business growth through offering products with excellence in quality, ultimate customer satisfaction and being in business with ethics.

Alpesh Gandhi, Managing Director – Ami Polymer said, "For the first time Ami is going to do long term business partnership. Ami is super excited to take a step forward with team Foxx and it will enhanced the wide business opportunities in pharma sector with technological advancement and customer satisfaction.

"An organisation that helps business to develop strong leaders while creating a culture where self-improvement is an intrinsic part of the organisation's value system" is the inspiration behind the partnership, according to a press release issued by Ami Polymer.

The Network allows full coverage of specialised Pharma Tubings (Platinum cured Silicone, TPE, FKM, and FEP tubings), O-rings, Manifolds, and Sanitary Gaskets for the markets such as Bio pharma, Medical and Lifesciences.

25th ANNIVERSARY SPECIAL ISSUE 1994-2019

Experience B&R's leadership in plastics at Plastivision 2020

The highlights of the B&R's exhibition at the event will be its state-of-the-art solutions for machine builders, end users and system integrators in the plastics industry

The Innovative automation technology for plastic industry

Plastivision 2020 will be held from January 16-20 at the Bombay Exhibition Centre in Mumbai. At this leading exhibition for plastic, B&R's entire product range will be on display in Hall 1 Booth C4-2. The highlights will be B&R's state-of-the-art solutions for machine builders, end users and system integrators in the plastics industry. These innovations from B&R are opening new opportunities for them to build and strengthen their competitive edge.

"In our opinion, India's plastics industry is always keen to try new technologies and appreciates the benefits of our completely integrated automation solution. With the extraordinary scalability of our products, machine builders can easily and cost-effectively tailor their solutions to meet their customers' demands," says Dharmendra Patel, plastics industry expert at B&R India. "From control and HMI to drives, motors and safety technology, B&R offers the entire spectrum of machine and factory automation solutions and is always leading the industry with innovation."

APROL to increase efficiency of entire plant

Faced with enormous cost and quality pressure, users are seeking solutions to reduce maintenance costs and downtime while optimizing availability and utilization. Production processes generate huge amounts of data, which helps generate valuable reports about equipment utilization, asset availability, productivity and energy efficiency. Real time data acquisition with APROL enables complete online performance monitoring and visual overviews that make it possible to track quality for the entire manufacturing process and plant. The ready-to-use solutions available with B&R's APROL process control system for energy monitoring, condition monitoring, advanced process control and process data acquisition provide higher benefits and strengthened core competencies.

Optimum quality with machine vision

B&R will also be exhibiting its machine vision solution, which is fully integrated into the automation land-scape. "In the plastics industry, our vision solution is best for quick qualitative analysis where processes are complex. In the production process, our integrated machine vision system can be deployed for applications such as calibration, measurement, orientation, inspection, barcode reading, locating, positioning, prepro-cessing and comparison. "Defective products can be immediately rejected, which saves raw materials and makes it possible to rectify problems at the same level – resulting in increased quality and productivity," says Patel.

All visitors to the B&R booth will also be able to experience ABB products and services for the plastics industry, which helps manufacturers achieve higher quality, comply with standards and become responsive to the challenges of global markets.

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NANO 16	16	42	500	2.24	1,200 x 800 x 1,100
ZSE 12 HP-PH	12	20	1,000	2	1,500 x 700 x 1,200
ZSE 18 HP-PH	18	71	1,200	7.1	2,290 x 700 x 1,270
ZSE 27 HP-PH	27	268	500 & 1,200	15	3,650 x 1,150 x 1,800
ZSE 40 HP-PH	40	830	400	37	4,000 x 1,400 x 2,100
ZSE 50 HP-PH	50	1,570	400	70	4,630 x 1,800 x 2,120

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