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Good manufacturing practice (GMP) is a continuous journey: Dr. S Eswara Reddy

Mumbai, India: Good manufacturing practice (GMP) should be considered as a continuous journey, according to Dr S Eswara Reddy, Joint Drugs Controller of India, while delivering speech on "Revision of Schedule-M" on September 30, 2023 in Mumbai. Dr. Reddy also noted his cognizance and understanding of industry's challenges and offered guidance on how to navigate successfully in an evolving regulatory environment. He further described need for revision of Schedule-M, GMP requirements keeping in mind current changes in the concept of quality of drugs, convergence of Indian standards with global standards, and technological advancements in manufacturing and testing of drugs.

The Central Drugs Standard Control Organisation (CDSCO) in association with the Indian Drug Manufacturers' Association (IDMA) organised a workshop on "Revision of Schedule-M". The objective of the workshop was to make the participants aware of the proposed changes to the Schedule-M and prepare for implementation at the earliest. To create awareness amongst drug manufacturers about good manufacturing practices (GMP) requirements to ensure quality of medicines, workshops on Revision of Schedule-M were organised across India in Sep 2023 by CDSCO in partnership with IDMA.

Schedule-M prescribes requirements to the manufacturing plants of pharmaceutical companies for maintenance, manufacturing, control and safety testing, storage and transport material, written procedures and records, and traceability etc. The Government of India (GoI) has notified draft Schedule-M in October 2018 and had series of meetings with all drug manufacturers associations and other stakeholders. It is now under active consideration of the Ministry of Health and Family Welfare, Government of India. Larger companies with a turnover of over ₹ 250 crore have been asked to implement the changes within 6-months, while medium and small-scale enterprises with turnover of less than ₹ 250 crore have been asked to do so within 1-year. The new version of Schedule-M is designed to ensure compliance to standards of drugs, promote exports, promote innovation and to build trust and confidence on quality of drugs manufactured and sold.

Dr. Viranchi Shah, IDMA's National President, in his message extended gratitude to CDSCO and Dr. S Eswara Reddy. He added, "The Indian pharmaceutical industry welcomes Revised Schedule-M. IDMA member companies are committed for ensuring adoption and ongoing compliance with determination and discipline. The event was in continuation of momentum by IDMA in seeking greater collaboration and alignment between government, companies, regulators, and other stakeholders."

Mehul Shah, General Secretary of IDMA, reiterated the industry's positive response to Revised Schedule-M by stating that Indian pharmaceutical industry is committed in its endeavour to ensure manufacturing and supply of high-quality, safe, efficacious, innovative, and affordable medicines to patients and consumers in India and worldwide. Daara Patel, Secretary General of IDMA, and his team were lauded for excellent planning and execution of the event by dignitaries and participants. Daara added "Under Dr. Viranchi Shah's visionary leadership, IDMA has organised a series of events in last 2-years to advance cause of the nation and the Indian pharmaceutical industry especially MSME sector. We will continue to organize more such value-additive events in future."

Dr Mansukh Mandaviya launches National Policy on R & D and Innovation in Pharma-MedTech Sector in India

New Delhi, India: Dr. Mansukh Mandaviya, Union Minister of Chemicals and Fertilizers and Minister of Health & Family Welfare, Government of India announced the launch of National Policy on Research and Development and Innovation in Pharma-MedTech Sector in India. Dr V. K. Paul, Member, NITI Aayog, S Aparna, Secretary (Pharma), Ministry of Chemicals and Fertilizers and Dr Rajiv Bahl, Director General, ICMR were also present at the event. Dr Mansukh Mandaviya noted the scheme will focus on transforming India into a high-volume, high-value player in the global market of pharmaceuticals, meeting the quality, accessibility, and affordability goals. He further stated "The policy will help to create an ecosystem of skills and capacities including the academia and the private sectors, and give

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impetus to new talent among the youth through start-ups." This is a transformative stage in the Indian drugs and med-tech sector, he stressed where synergies are being created between various Government institutions and agencies such as Pharma Deptt., ICMR, DST, DBT, NIPER etc.

He elaborated that India prioritizes growth and innovation in brain power and manpower, wherein Covid is an example where we stood the testimony of the time. We need to do mass production of our pharmaceutical products and medical devices. For this, we have made three bulk drug parks in Himachal Pradesh, Vizag and Gujarat and four medical device parks in Himachal Pradesh, Uttar Pradesh, Madhya Pradesh and Tamil Nadu, which will help in strengthening this sector.

Emphasizing on the importance of the scheme, the Union Minister of Chemical and Fertilizer, Dr Mansukh Mandaviya said, "India can only achieve self-reliance in pharmaceuticals and medical devices by strengthening its research and development infrastructure that would drive the expansion of access to life-saving medicines and drugs and help India become a global pharmaceuticals and medical exports hub." We need to make policies, new products and new research according to the needs of our country and the world, in consultation with industries and academia. We should become so independent that we should not be dependent on anyone for our critical needs."

Dr V K Paul, Member (Health), NITI Aayog said that after learning lessons from the past, India is leading the world. These clusters of reforms will transform the Pharma MedTech Sector. We also need to focus on collaboration between academia, public and private institutions. This scheme and these initiatives will help in preparing us for the future challenges and ensuring national bio security. Senior officials from the Ministry of Health and Family Welfare and Chemicals and Fertilizers were also present at the event along with policymakers, experts from the healthcare and pharmaceutical sector, representatives from academia, think tanks, industry.

OPPI appoints Anil Matai as Director-General

Mumbai, India: The Organisation of Pharmaceutical Producers of India (OPPI), which represents global research-based pharmaceutical companies, has appointed Anil Matai as its Director General. Anil Matai, a seasoned general management professional, has extensive experience in the Life Sciences space having worked across MNCs including spearheading operations across Novartis India Ltd, GSK India, and Global Pharma, Dubai. After superannuating as Managing Director of Zydus Healthcare Ltd, Anil was engaged as Senior Advisor - Life Sciences at IQVIA Consulting and Information Services India Pvt. Ltd., and most recently as Operating Partner at Jashvik Capital - a mid-market Private Equity Fund focused on Healthcare & Consumer sector.


Anil Matai, Director General, OPPI

Anil has functioned on the boards of Zydus Healthcare Ltd., Bayer Zydus Pharma Private Ltd., Novartis Healthcare Private Ltd and Biochem Pharmaceutical Industries Ltd. As an influential leader, his proven skillsets in operations leadership, collaborative working, stakeholder management, have contributed towards market-leading results. He has championed multi-million-dollar businesses and is proficient in unlocking company value by successfully executing growth strategies, institutionalizing controls, and enhancing productivity.

Welcoming Anil as the Director General, Suresh Pattathil, President, OPPI said, "I welcome Anil on board and am confident that with his breadth of experience, we will be able to lead OPPI to achieve its objective of bringing innovative drugs and new therapies for unmet medical needs and drive key advocacy efforts on IP, Innovation, Quality and other areas. He has been a strong voice for healthcare transformation in the country and under his leadership we will be able to optimize patient outcomes by creating an environment conducive to innovation and growth, engaging productively with Government stakeholders."

Speaking on his appointment, Anil Matai said, "I am happy to say that OPPI's focus on importance of innovation, digitization and quality to drive impact in healthcare, aligns with the Government's vision for India@100. OPPI will continue to drive policy and advocacy discussions with the Government and endeavor to work together with various stakeholders on industry-related issues, to implement sustainable and patient centric solutions. I look forward to collaborating with the various stakeholders including the Government, Industry, Academia to make a positive impact on patient well-being; in alignment with OPPI's vision of "Bharat Ke Liye". I express my gratitude to the members of OPPI's Executive Committee for entrusting me with this responsibility."

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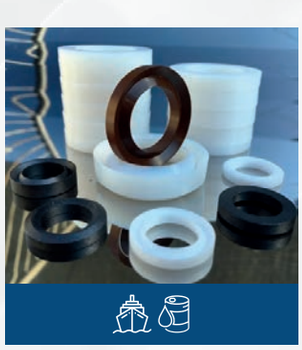

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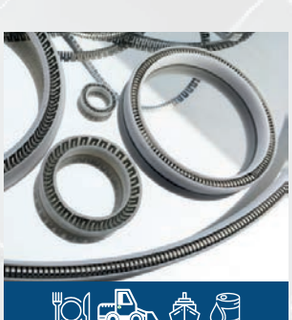

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Quality is paramount for the pharma industry: Sudarshan Jain


Sudarshan Jain, Secretary General, IPA

Mumbai, India: Quality is paramount for the pharma industry and Good Manufacturing practices ensure regulatory compliance and foster stakeholder relationships, stated Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance (IPA) while organizing 8th Advanced Good Manufacturing Practices Workshop. IPA is committed to sharing knowledge, embracing best practices, and encouraging collaboration – making India a global benchmark in quality, added Jain.

The workshop took place, with 20+ subject matter experts, industry leaders and global regulators from USFDA, MHRA, CDSCO. Over the years, the main purpose of the workshop has consistently been to facilitate the sharing of knowledge and the development of capabilities among Indian pharmaceutical companies, enabling them to embrace globally acknowledged manufacturing practices. The 8th edition of the Advanced GMP workshop served as a forum where manufacturers, regulators, and subject matter experts came together to engage in meaningful discussions and deliberate on strategies for advancing Manufacturing and Quality Excellence within the pharmaceutical industry.

In his inaugural address, Nilesh Gupta, Managing Director, Lupin and Chair of Quality Committee, IPA, highlighted the importance of fostering a culture of quality by all stakeholders in the industry. During her keynote address, S Aparna, Secretary, Department of Pharmaceuticals, Government of India emphasized that quality must be the hallmark of every newcomer in the pharmaceutical industry. The inaugural session also featured an address by Dr Sarah McMullen, Country Director, USFDA - India Office, who highlighted the importance of building a culture of quality across the functions from senior leadership to operator level. The event was covered with a broad spectrum of topics, including Quality Culture, Data Integrity within the context of Quality, Capacity Building, Next-Generation Operations, and India's journey towards quality leadership. Additionally, the workshop delved into the transformative potential of Generative AI in the pharmaceutical sector, offering insights into the future of quality practices.

Indian Pharmaceutical Industry sustained growth is here to stay: Dr. Manoranjan Sharma

Mumbai, India: Infomerics Ratings has released an industry outlook report - 'Indian Pharmaceutical Industry - Sustained Growth Is Here To Stay' by Dr. Manoranjan Sharma, Chief Economist, Infomerics Ratings.

According to the government data, the Indian pharmaceutical industry is worth approximately USD 50 billion with over USD 25 billion of the value coming from exports. India exports 20 per cent of the global demand for generic drugs. According to IQVIA, formerly known as Quintiles and IMS Health, Inc., the worldwide API market reached a valuation of around USD 210 billion in 2022, with the small molecule API sector accoun4ng for over USD 174 billion.

The worldwide consumption of APIs saw a compound annual growth rate (CAGR) of 5 per cent over the last five years and is projected to increase by 6 per cent over the next five years. Over the last two years, the Indian pharma sector has developed and supplied COVID-19 vaccines. The Indian vaccine industry created the COVID-19 vaccine utilizing indigenous technology in conjunction with the Indian Council of Medical Research (ICMR) and National Institute of Virology (NIV) in record time. Some of the major structural factors responsible for the steady growth are ageing of the population, rising lifestyle or chronic diseases, healthcare awareness and insurance penetra4on apart from increasing government spending under various schemes. The drugs & pharmaceuticals exports are expected to increase in FY 2023-24. The growth in exports will be supported by the drug shortages in the United States (US), trade agreements and the PLI scheme. According to the data from the University of Utah, while there are active shortages for more than 300 drugs in the US, Drug Information Service and Chemotherapy Drugs are among the most affected. This presents an opportunity for Indian pharma companies to meet the demand for generic drugs in this US$ 527 billion market and expand exports in the coming years. In the US, pharmaceutical companies faced persistent pricing pressures.

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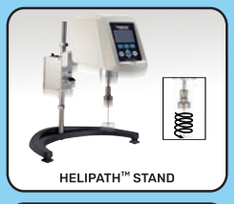
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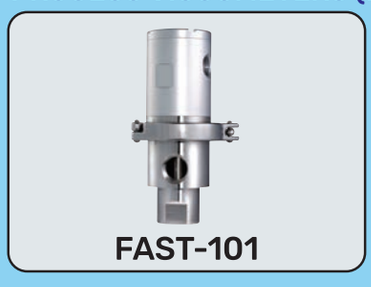
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Glenmark and Cosmo Pharma signs distribution and license agreements for Winlevi in Europe and South Africa

Dublin, Ireland and Mumbai, India: Cosmo Pharmaceuticals N.V. and Glenmark Specialty S.A., a subsidiary of Glenmark Pharmaceuticals Ltd. announced the signing of distribution and license agreements for Winlevi (clascoterone cream 1%) in Europe and South Africa. Under the terms of the agreements, Glenmark will receive from Cassiopea, a subsidiary of Cosmo, the exclusive right to commercialize Winlevi in 15 EU countries (Bulgaria, the Czech Republic, Denmark, Finland, France, Hungary, Iceland, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Spain and Sweden) as well as in South Africa and the UK. Cassiopea shall be responsible for the Centralized Marketing Authorization at the European Medicines Agency (EMA), and Glenmark will be responsible for the registration of the product in South Africa and in the UK. Cosmo will be the exclusive supplier of the product. Cassiopea will receive an upfront payment of USD 5 million, further double-digit regulatory and sales milestones and agreed double-digit royalties on net sales.

Alessandro Della Chà, CEO of Cosmo, said, "We are very pleased to partner with Glenmark. Their strong expertise in the commercialization of pharmaceutical compounds gives us great confidence in their ability to successfully market Winlevi. We look forward to eventually making Winlevi available to more patients around the globe." "We are delighted to have undertaken this exclusive licensing agreement with Cosmo Pharmaceuticals. Winlevi® is the perfect addition to our European dermatology portfolio and we look forward to leveraging our half-century long experience in dermatology to make this novel option available to patients and fill the current unmet medical need in treating acne," remarked Glenn Saldanha, Chairman & Managing Director Glenmark Pharmaceuticals Ltd.

Sun Pharma: CEQUA phase 4 data shows sustained improvement in dry eye disease signs and symptoms

Mumbai, India: Sun Pharmaceutical Industries Limited announced the presentation of Phase 4 data showing that CEQUA (cyclosporine ophthalmic solution) 0.09% induces sustained improvement in the signs and symptoms of dry eye disease (DED). CEQUA ophthalmic solution is a calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye). In a presentation at the American Academy of Optometry (AAOPT) 2023 annual meeting in New Orleans, La., researchers reported that CEQUA elicited significant improvement in corneal fluorescein staining (CFS, a test used to detect damage to the cornea) and in modified Symptom Assessment in Dry Eye (mSANDE) scores in patients with DED whose disease was uncontrolled on Restasis (cyclosporine ophthalmic emulsion) 0.05% therapy.

In the 12-week Phase 4 multicenter study, twice-daily administration of CEQUA improved CFS and mSANDE scores starting at Week 4 of treatment and maintained these improvements through Week 12. CEQUA offers a high concentration of cyclosporine for ophthalmic use and is the first and only U.S. Food and Drug Administration (FDA)-approved cyclosporine treatment delivered with nanomicellar NCELL® technology, which helps to improve the bioavailability of cyclosporine, resulting in improved ocular tissue penetration.

"We were greatly encouraged to observe significant improvements in dry eye signs and symptoms as early as four weeks into treatment with CEQUA, and to see even greater improvements at eight weeks and again at 12 weeks," said lead investigator Josh Johnston, OD, FAAO, of Georgia Eye Partners in Atlanta, Ga. "Moreover, by assessing corneal fluorescein staining in all five zones of the cornea, we were able to attain a more complete characterization of corneal health than in many dry eye disease trials, which typically assess only a few corneal areas."

The study enrolled adults with DED inadequately controlled (i.e., still symptomatic and/or exhibiting disease signs) on current Restasis® therapy for at least three months, and who had a history and clinical diagnosis of DED for at least three months before screening/baseline. Patients received one drop of CEQUA in each eye twice daily for 12 weeks. Investigators assessed CFS and mSANDE scores at baseline and at Weeks 4, 8, and 12, and/or upon early discontinuation from the study. CFS was scored on a 0-4 grading scale in 0.5-point increments, with a score of 0 indicating no stain (i.e., healthy cornea) and a score of 4 reflecting a severe stain; investigators calculated a total CFS score by summing all five corneal area scores. The mSANDE questionnaire ssessed frequency and severity of DED symptoms of dryness and irritation on a 0-100 scale, with 0 representing very low frequency/severity and 100 indicating very high frequency/severity.

Dr. Johnston and colleagues presented results from 124 patients in the modified intent-to-treat (mITT)

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population. The mean (standard deviation [SD]) age of the patients was 65.5 (11.6) years; 110 of the patients (88%) were female. The mean (SD) total CFS score was 5.7 (3.37) at baseline, and improved significantly (P <0.0001) to 4.0 (3.12) at Week 4, 2.9 (2.54) at Week 8, and 2.7 (2.36) at Week 12. Similarly, the mean (SD) mSANDE score was 67.1 (21.05) at baseline and improved significantly (P <0.0001) to 48.4 (23.31) at Week 4, 44.2 (24.28) at Week 8, and 38.3 (25.99) at Week 12.

CEQUA was generally well tolerated in the study, consistent with its established safety profile, and there were no new safety signals in the trial. Overall, 58 patients (43.3%) reported at least one treatment-emergent adverse event (AE); most AEs were mild in severity (73.8%). The most common treatment-related AEs were instillation site irritation and instillation site pain; all other treatment-related AEs occurred in fewer than 2% of patients. "In addition to the rapid and sustained symptomatic improvement in patients with dry eye disease treated with CEQUA, this study is notable for its design, which allows for use of artificial tears, thus replicating real-world conditions as closely as possible for a controlled clinical trial," noted Brittany Mitchell, OD, Head of Medical Affairs, Ophthalmics, at Sun Pharma. "The data presented at the American Academy of Optometry meeting represent the first of a series of assessments from this trial, with results thus far consistent with the efficacy, safety, and convenient dosing of CEQUA. We look forward to sharing additional information as we continue to analyze the data from this trial."

Strides announces "OneSource", an independent Specialty Pharma CDMO

Bangalore, India: Strides Pharma Science Limited announced "OneSource", an independent Specialty Pharma CDMO. The company is set to emerge among top 5 pure play CDMOs in the country. As part of the Proposed Scheme of Arrangement with an appointed Date of 1 st April 2024, Strides Pharma to demerge Oral Soft Gelatin business and Identified CDMO business (including investments held by Strides in Stelis) into Stelis. Upon demerger, the shares of Stelis held by Strides will be cancelled and shareholders of Strides will become shareholders of Stelis. SteriScience (promoter group company) to demerge Identified Sterile Injectables CDMO business into Stelis. Pursuant to the demerger, Stelis will issue equity shares to the shareholders of Strides and SteriScience on the recommended Share Entitlement Ratio determined by an independent valuer.

Pursuant to the approval of the Scheme, Stelis would be listed on NSE and BSE in next 12-15 months. OneSource is created by merging Strides Soft gel business and SteriScience CDMO injectables business into current Stelis. As part of the exercise a swap ratio of 1:2 has been finalized. Strides Pharma shareholders will receive one share of OneSource for every two shares of Strides Pharma with an Implied value of OneSource for Strides shareholders is ₹ 364/share. Strides Shareholders will own 44% of the economics of OneSource. On transfer of three businesses, "OneSource" will have revenue of ₹ 75501 million encompassing ₹ 24355 million of softgel business of Strides Pharma, ₹ 21958 million of Steriscience, ₹ 29208 million of Stelis.

Lupin acquires five Brands from Menarini

Nilesh Gupta, Managing Director, Lupin

Mumbai, September 22, 2023: Global pharma major Lupin Limited announced that it has signed an agreement to acquire five legacy brands in strategic therapy areas - Gastroenterology, Urology and Anti-infectives from Menarini (A. Menarini India Private Limited and A. Menarini AsiaPacific Holdings Pte. Ltd.), along with the associated trademark rights. The brands are Piclin (Picosulphate Sodium), Menoctyl (Otilonium Bromide), Sucramal O (Sucralfate + Oxetacaine), Pyridium (Phenazopyridine) and Distaclor (Cefaclor).Lupin has been exclusively marketing these brands in the Indian market since July 2021 under a distribution and promotion agreement with A. Menarini India Private Limited. This strategic acquisition for the Indian market marks a significant step forward for Lupin as it continues to expand its presence in India. These legacy brands help Lupin in further enhancing its diverse portfolio and solidifying its position as a leading pharmaceutical organization in India.

Commenting on the acquisition, Nilesh Gupta, Managing Director, Lupin said, "This acquisition aligns well with our strategic goal to broaden our presence in the Indian market. By offering a comprehensive range of products, our aim is to deliver even greater value to our stakeholders and the communities we serve." "Growing urbanization and dietary changes are driving

the demand for gastrointestinal and urology treatments in India," said Rajeev Sibal, President – India Region Formulations, Lupin. "This acquisition strengthens our presence in India and bolsters our therapy pipeline. At Lupin, we are committed to empowering healthcare professionals in managing the increasing disease burden and improving the lives of patients significantly."

"Lupin has been successfully marketing the scope brands for Menarini since 2021, which has been a testament to our evolved collaboration. I am happy that Lupin will now carry forward their legacy with full trademark ownership. For Menarini, this transaction further signals our continued commitment to nurture and expand our Dermatology and Aesthetics portfolio and business. Menarini is a top 10 multinational company in this therapeutic area in India and has witnessed strong organic and inorganic growth," said Girisan Kariangal, Managing Director – Menarini India.

The company has received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application for Apalutamide Tablets, 60 mg, to market a generic equivalent of Erleada Tablets, 60 mg of Janssen Biotech, Inc. This product will be manufactured at Lupin's Pithampur facility in India.

Syngene Q2 Revenue from operations up 18.5%

Jonathan Hunt, Managing Director and Chief Executive Officer, Syngene International Limited

Mumbai, India: Syngene International Limited announced its second quarter and half year financial results. The company reported revenue from operations for the quarter was up 18.5% year-on-year to ₹ 910 crores, around 15% at constant currency. The company's Profit after tax (before exceptional items) for the quarter increased 20% year-on-year to ₹ 122 crores. For the half year ended 30th September 2023, reported revenue from operations was up 22%, around 17% at constant currency, and profit after tax (before exceptional items) increased by 23% to ₹ 215 crores compared to the same period last year.

Commenting on the quarter, Jonathan Hunt, Managing Director and Chief Executive Officer, Syngene International Limited, said, "I am pleased to report a strong set of results for the second quarter and first half of the financial year, particularly in our Development and Manufacturing Services. In Development Services, we also added a new non-GMP capability center to meet market demand for agile, cost-efficient, early phase development and scale-up services. In Manufacturing, we made good progress on our long-term biologics partnership with Zoetis, as well as commissioning a state of the art, digitally-enabled Quality Control laboratory to support our growing biologics operations. The acquisition of a multi-modal facility from Stelis Biopharma Ltd, announced last quarter, is progressing. Within research services, our Dedicated Centers made a steady contribution to growth and in Discovery Services, while global demand remained generally healthy, we saw the US-based biotech segment showing signs of slowed growth year-on-year as companies adjust to a new funding environment.

Long term sector fundamentals remain strong and we expect continued growth but at a lower level in the second half of the year, this short-term slowing in the US biotech segment is reflected in our latest outlook. Overall, we reported a strong first half to the year and I am pleased with the good progress made on our strategic priorities in both our research services and our development and manufacturing divisions."

Sibaji Biswas, Chief Financial Officer, Syngene International Limited added, "We have reported strong second quarter and half year results with operating EBIT growth, tracking revenue growth. During the second half of the year, we will continue to invest in new science, technology and digitization, as well as building capacity to support future growth, while balancing discretionary expenditure in order to maintain margins."

"While the Company delivered strong performance in the first half, with the temporary slowdown in US biotech funding, we expect continued growth at a lower level in the second half of the year. Adjusting for this, against our previous guidance of high teens constant currency growth, we now expect the revenue to grow at mid-teens on constant currency basis," the company stated.

Granules India receives ANDA approval for Losartan and Hydrochlorothiazide tablets

Hyderabad, India: Granules India Limited announced that the US Food & Drug Administration (US FDA) has approved its Abbreviated New Drug Application (ANDA) for Losartan Potassium and Hydrochlorothiazide Tablets USP, 50 mg/12.5 mg, 100 mg/12.5 mg, and 100 mg/25 mg. It isbioequivalent and therapeutically equivalent to the reference listed drug (RLD), Hyzaar Tablets of Organon LLC. Losartan potassium and hydrochlorothiazide tablets are indicated for the treatment of hypertension to lower blood pressure and to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy. Granules now have a total of 60 ANDA approvals from US FDA (58 Final approvals and 2 tentative approvals). The current annual U.S. market for Losartan and Hydrochlorothiazide Tablets is approximately $73 Million, according to MAT Jul 2023, IQVIA/IMS Health.

Piramal Pharma's US manufacturing unit completes USFDA inspection

Mumbai, India: Piramal Pharma Ltd announced the closure of US FDA Inspection at the company's manufacturing facility located at Bethlehem, USA. The company stated that US FDA conducted a Good Manufacturing Practices (GMP) Inspection of Piramal Pharma Limited's Bethlehem facility from 18th September 2023 to 27th September 2023.

"On conclusion of the inspection, a Form-483 was issued with 2 observations. Both observations relate to system improvement only, and none are related to data integrity," the company stated. The Company is preparing a detailed response to said observations, which will be submitted to the US FDA within stipulated timelines. The Company remains committed to maintain the highest standards of compliance and will work closely with the agency to comprehensively address all observations.

Dr Reddy's Laboratories incorporates wholly-owned subsidiary in Jamaica

Hyderabad, India: Dr. Reddy's Laboratories SA, in Switzerland, a wholly-owned subsidiary of the Company, has incorporated a wholly-owned subsidiary in Jamaica, named "Dr. Reddy's Laboratories Jamaica Limited". Accordingly, Dr. Reddy's Laboratories Jamaica Limited is a step-down wholly-owned subsidiary of the Company. The NewCo. will be engaged in importation, warehousing, distribution and exportation of pharmaceuticals. Dr. Reddy's Laboratories SA will be paying cash consideration amounting to USD 3,000,000 to the proposed NewCo. towards subscription of 100% shareholding. The NewCo. will be engaged in importation, warehousing, distribution and exportation of pharmaceuticals.

Marksans Pharma gets USFDA approval for Esomeprazole Magnesium capsules

Mumbai, India: Marksans Pharma Limited has received final approval from US Food & Drugs Administration for its Abbreviated New' Drug Application (ANDA) fOi Esomeprazole Magnesium Delayed-Release Capsules USP, 20 mg (OTC). This product is bioequivalent to the reference listed drug (RLD), Nexium 24 HR DelayedRelease Capsules, 2.0mg (OTC), of AstraZeneca Pharmaceuticals LP. Esomeprazole is used to treat certain stomach and esophagus problems "'(such as acid reflux ane ulcer). It works by decreasing the amount of acid your stomach makes. It relieves symptoms such as heartburn, difficulty swallowing, and cough. This medication helps heal acid damage to the stomach and esophagus, helps prevent ulcers and is expected to help prevent cancer of the esophagus. Esomeprazole belongs to a class of drugs known as proton pump inhibitors (PPIs). The product will be manufactured at the Company's formulation manufacturing facility in Goa, India.

Alembic Pharmaceuticals receives 6 USFDA approvals during Q2FY24

Mumbai, India: Alembic Pharmaceuticals Limited has received US Food & Drug Administration (USFDA) approvals on six of its Abbreviated New Drug Application (ANDA) during Q2FY24. The Company has received six final approvals that includes Chlorpromazine Hydrochloride Tablets USP, 10 mg, 25 mg, 50 mg, 100 mg, and 200 mg, Brimonidine Tartrate Ophthalmic Solution, 0.1%, Guanfacine Extended-Release Tablets USP, 1 mg, 2 mg, 3 mg, and 4 mg, Erythromycin Tablets USP, 250 mg and 500 mg, Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%, Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules USP, 5 mg/2.5 mg.

Chlorpromazine Hydrochloride Tablets USP, 10 mg, 25 mg, 50 mg, 100 mg, and 200 mg of Upsher-Smith Laboratories, LLC., is to manage the symptoms of psychotic disorders and treatment of schizophrenia, control nausea and vomiting, relief of restlessness

and apprehension before surgery, acute intermittent porphyria, adjunct in the treatment of tetanus, to control the manifestations of the manic type of manic-depressive illness and for relief of intractable hiccups. Brimonidine Tartrate Ophthalmic Solution, 0.1% with the brand name Alphagan P Ophthalmic Solution is from the innovator AbbVie, Inc. The medication is indicated to lower elevated intraocular pressure (IOP) in patients suffering with open-angle glaucoma or ocular hypertension.

Guanfacine Extended-Release Tablets USP, 1 mg, 2 mg, 3 mg, and 4 mg by Takeda Pharmaceuticals U.S.A., Inc. and with brand name Intuniv Extended-Release Tablets is indicated for individuals suffering from Attention Deficit Hyperactivity Disorder (ADHD). The tablets can be used alone or alongside stimulant medications. Erythromycin Tablets USP, 250 mg and 500 mg by Azurity Pharmaceuticals, Inc. is for treatment of various infections caused by certain microorganisms.

Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5% by AbbVie,Inc. is an alpha-adrenergic receptor agonist with a beta-adrenergic receptor inhibitor indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP. The brand name for the product is Combigan Ophthalmic Solution. Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules USP, 5 mg/2.5 mg with the brand name Librax Capsules by Bausch Health US, LLC. are indicated to control emotional and physical factors that can cause gastrointestinal disorders. These capsules may also be used as additional treatments to help in peptic ulcer and in irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

Sai Life Sciences selects Dassault Systèmes' Solutions to accelerate Drug Discovery

New Delhi, India: Sai Life Sciences, India's fastest growing contract research, development, and manufacturing organization has selected Dassault Systèmes' solutions to enhance productivity, elevate data quality, and foster collaboration within Sai Life Sciences Research and Process Development laboratories leading to accelerated drug discovery. Sai Life Sciences is using Dassault Systèmes' industry solution experience "ONE Lab" based on the 3DEXPERIENCE platform. The solution, which leverages BIOVIA applications, helps optimise productivity, ensure data accuracy and data security, and enable seamless data accessibility and analysis.Sai Life Sciences is using Dassault Systèmes' industry solution experience "ONE Lab" based on the 3DEXPERIENCE platform. The solution, which leverages BIOVIA applications, helps optimise productivity, ensure data accuracy and data security, and enable seamless data accessibility and analysis.

Sai Life Sciences has implemented "ONE Lab" to bolster security measures, and facilitate effortless data access and analysis. Utilizing "ONE Lab," Sai Life Sciences is creating an integrated digital platform for its research and development (R&D) and chemistry, manufacturing and controls (CMC) laboratories, effectively tackling some of the most notable challenges ailing the research in this sector, specifically associated with project implementation. The primary objectives of this selection encompass error reduction, time-saving, the promotion of sustainability practices, and the establishment of a unified, reliable source of information to facilitate multi-stakeholder collaboration spanning research, development and commercial manufacturing.

"With Sai Life Sciences, we are attempting to build a brighter future for life sciences and health care research and development in the country. Our long-term vision is to redefine industry standards by combining transformative technology with unwavering commitment. This is not just about optimizing productivity and data quality; it is about setting a new benchmark for collaboration and efficiency in the industry. We are not simply innovating; we are shaping the future of research, one breakthrough at a time," said Deepak NG, Managing Director India, Dassault Systèmes. "With Dassault Systèmes' solutions, we are ushering in a new era of research and development excellence. The integration of Dassault Systèmes' 'ONE Lab' empowers us to drive productivity, enhance data quality, and fortify data security, revolutionizing our approach to research across the entire spectrum from early-stage development to commercial manufacturing," said Dr. Damodharen, Chief Quality Officer, Sai Life Sciences.

"ONE Lab" has played a pivotal role in empowering Sai Life Sciences to construct an all-encompassing digital platform for its R&D and CMC laboratories. This accomplishment involved surmounting common project implementation challenges, notably in the realm of change management. "ONE Lab" offers numerous benefits to the industry, including optimization of laboratories and knowledge utilization for accelerated time-to-market. Furthermore, it contributes to a substantial reduction in compliance risk through the

standardization of processes and enhanced data quality. Additionally, the solution delivers a remarkable boost in productivity and efficiency through streamlined processes and automation, leading to a reduction in cycle time, thereby enabling real-time project tracking and expediting decision-making.

Venus Remedies launches Elores in Ecuador


Saransh Chaudhary, CEO, Venus Medicine Research Centre

Mumbai, India: Venus Remedies Limited, a leading pharmaceutical company known for its commitment to innovation and healthcare excellence, announce the launch of Elores in Ecuador. This significant expansion follows the earlier launches of Elores in countries like Saudi Arabia, Myanmar, Oman, Tanzania, Ethiopia, and India, marking a momentous stride in the company's global growth. Additionally, the dossier has also been submitted in around 15 countries for getting the marketing authorisations.

Elores, a cutting-edge antibiotic formulation, has been developed to combat multi-drug-resistant infections, making it a ground breaking addition to Venus Remedies Limited's product portfolio. It is a novel patented Antibiotic Adjuvant Entity containing a beta-lactam antibiotic, a beta-lactamase inhibitor, and an Antibiotic Resistance Breaker (ARB) that work synergistically to rescue antibiotic activity and suppress the emergence of resistance against the antibiotic. With its proven efficacy against a wide range of bacteria, Elores is set to revolutionise the treatment of infections and enhance the quality of healthcare in Ecuador.

"We are redefining the scope of antibiotics through innovative R&D. Elores, a reliable carbapenem sparer, is the result of more than a decade of research wherein multiple studies were performed to elucidate the role of ARBs as one of the prospective solutions to save the life of existing antibiotics. Elores was our response to the problem of AMR, and it has been very satisfying to see the difference that it is making in the lives of patients," expressed Saransh Chaudhary, CEO, Venus Medicine Research Centre.

The eighth largest economy in Latin America, Ecuador witnessed a CAGR of 5.5% from 2015 to 2020, thereby becoming a US$1.6-billion pharmaceutical market. The Ecuador antibiotics market is majorly dependent on imports from India. Ecuador had imported antibiotics worth US $3.5 million in 2022. The launch of Elores in Ecuador is expected to open the doors for the entry of the novel antibiotic adjuvant entity in other important Latin American countries (LAC) as well.

Commenting on the launch, Aditi K Chaudhary, President, International Business, Venus Remedies, stated, "We are thrilled to introduce Elores to the people of Ecuador. We stand resolute in our commitment to developing innovative solutions to combat antibiotic resistance and improve patient outcomes. With Elores, we aim to provide a reliable and effective solution to healthcare professionals in Ecuador, enabling them to better serve their patients."

Elores has garnered widespread acclaim for its unique combination of antibiotics that work synergistically to combat even the most challenging infections. This launch is part of Venus Remedies Limited's ongoing mission to address the global health crisis of antibiotic resistance. Elores was declared the best innovation and received a gold medal under the India Innovation Growth Program in the year 2013.

Department of Science & Technology grants ₹ 13.69 crore to GITAM for Drug Discovery Centre

New Delhi, India: GITAM (Deemed to be University) has achieved a milestone in academic funding by securing an ₹ 13.69 Crore grant from the Department of Science & Technology (DST), Ministry of Science and Technology to establish a centre for drug discovery and marine biology research. The grant, conferred through the Promotion of University Research and Scientific Excellence (PURSE) program, will support the procurement of new equipment, research costs, manpower, conduct of workshops/summer schools etc. The university's five-year plan involves the establishment of a cutting-edge center for drug discovery research, with a focus on addressing pressing global health challenges.

"Studies have suggested the presence of bioactive compounds in marine organisms, such as astaxanthin found in zooplankton and fucoxanthin in brown algae and certain zooplankton, which may possess anti-inflammatory and anticancer properties. However,

further research is needed to validate these findings for human health," added Dr Hari Sharan Misra, Distinguished Professor from GITAM (Deemed to be University).

GITAM's marine biologists are at the forefront of exploring coastal marine ecosystems, hunting for bioactive compounds in aquatic zooplankton and bacteria. Once discovered, these valuable findings are handed over to biochemists and molecular biologists for isolation and characterization. These compounds could potentially combat cancer, reduce inflammation, and fight antibiotic-resistant diseases. Simultaneously, GITAM's chemists are busy developing various derivatives of these molecules with unique properties, while physicists are venturing into nanotechnology to create biocompatible nanoparticles that could transform drug delivery. As the project progresses, pharmacists will formulate these innovative drugs for animal testing, aiming to evaluate their effectiveness and safety.

Commenting on this significant achievement, Prof. Ravi Kumar Gurazada, a Distinguished Professor at GITAM (Deemed to be University), said, "This ambitious research project, valued at Rs 13.69 Crores, underscores the government's commitment to advancing scientific knowledge and tackling critical healthcare issues. This grant brings national recognition to GITAM and provides an opportunity to engage in pioneering research in the field of drug discovery. DST's recognition of our merit and trust in our institutional strengths and scientific capabilities is a moment of pride." GITAM's pioneering research, backed by DST's substantial funding, promises groundbreaking contributions to drug discovery, healthcare, and global sustainability.

Aurobindo Pharma's arm Eugia Pharma receives USFDA approval for Testosterone Cypionate Injection

Hyderabad, India: Aurobindo Pharma Limited announce that its wholly owned subsidiary company, Eugia Pharma Specialities Limited, has received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Testosterone Cypionate Injection USP 1,000 mg/10 mL (100 mg/mL) and 2,000 mg/10 mL (200 mg/mL) in Multi-Dose Vial and 200 mg/mL in Single-Dose Vial, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Depo-Testosterone Injection, 100 mg/mL and 200 mg/mL of Pfizer Inc. The product is expected to be launched in November 2023. The approved product has an estimated market size of US$ 226.8 million for the twelve months ending August 2023, according to IQVIA. This is the 169th ANDA approval (including 9 tentative approvals received) out of Eugia Pharma Speciality Group (EPSG) facilities, manufacturing both oral and sterile specialty products.Testosterone Cypionate Injection USP is indicated replacement therapy in the male in conditions associated with symptoms of deficiency or absence of endogenous testosterone, Primary hypogonadism (congenital or acquired) and Hypogonadotropic hypogonadism (congenital or acquired).

Blue Jet Healthcare IPO to open on October 25, 2023

Mumbai, India: Blue Jet Healthcare Limited, a specialty pharmaceutical and healthcare ingredient and intermediate company, offering niche products targeted towards innovator pharmaceutical companies and multi-national generic pharmaceutical companies, has fixed the price band at ₹329 to ₹346 per Equity Share for its maiden initial public offer. The Initial Public Offering ("IPO" or "Offer") of the Company will open on Wednesday, October 25, 2023, for subscription and close on Friday, October 27, 2023. Investors can bid for a minimum of 43 Equity Shares and in multiples of 43 Equity Shares thereafter. The Public Issue of face value of ₹2 per Equity Share is entirely an offer for sale of equity shares up to 2,42,85,160.

Incorporated in the year 1968 as Jet Chemicals Private Limited by the Late Shri B L Arora, Blue Jet Healthcare is promoted by its Executive Chairman; Akshay Bansarilal Arora. The company operates under the "Blue Jet" brand name and has competencies and manufacturing capabilities in contrast to media intermediates and high-intensity sweeteners, including saccharin and its

salts as well as active pharmaceutical ingredients. Its business model focuses on collaboration, development, and manufacturing of complex chemistry categories. Over the past 5 decades through its R&D center, it has developed over 100 products with over 40 products commercialised.

Over three years, the company has catered to more than 400 customers across 39 countries some of them being Colgate Palmolive (India) Ltd, Unilever, Prinova US LLC, and MMAG Co Ltd in the oral care and non-alcoholic beverage space; Hovione Farmaciência, Olon S.p.A., Esperion Therapeutics Inc., and Bial– Portela & CA, S.A for pharmaceutical intermediates, API and CDMO area and GE Healthcare AS, Guerbet Group, Bracco Imaging S.p.A, and Bayer AG, in the contrast media area.

As of June 30, 2023, it operates three manufacturing facilities, in Shahad, Ambernath, and Mahad in the state of Maharashtra, with an annual installed capacity of 200.60 KL, 607.30 KL, and 213.00 KL, respectively. In efforts of its capacity expansion in FY 21, it acquired a "greenfield" industrial facility on a leasehold basis in Ambernath. Its total annual production is expected to reach 1,513.6 KL.

Kotak Mahindra Capital Company Limited, ICICI Securities Limited and J.P. Morgan India Private Limited are the book running lead managers and Link Intime India Private Limited is the registrar to the offer. The equity shares are proposed to be listed on BSE and NSE.

Kedar Upadhye appointed as new CFO of Biocon Biologics

Bengaluru, Karnataka, India: Kedar Upadhye is appointed as the New CFO of Biocon Biologics. Current CFO, MB Chinappa will take on a Strategic Finance Role at Biocon Group. These leadership changes will be effective October 31, 2023. MB Chinappa has served as CFO of Biocon Biologics since his appointment in January 2020 and has played an integral role in developing business strategy and enabling profitable growth. He has helped secure over $500M in Private Equity investment and was instrumental in the Company's recent $3B+ acquisition of Viatris' global biosimilars business in 2022 and its strategic vaccines partnership with the Serum Institute of India.

A Biocon veteran, Chinappa joined the Biocon Group in 1999 as a key member of the Finance Leadership Team where he was part of several strategic initiatives including Biocon Limited's successful IPO in 2004. Subsequently, he moved to Biocon's research services subsidiary, Syngene, as the CFO in 2008 where he played a significant role in driving business strategy and growth and oversaw a successful public listing in 2015. He joined Biocon Biologics as the CFO in 2020 and has been instrumental in setting up the finance function and driving several strategic initiatives at the company. Given Chinappa's deep understanding and experience at each of the Group Companies' businesses during his 24-year tenure with Biocon Group, he will be moving to a strategic finance role and will work with Peter Bains, the recently appointed Group CEO, Biocon Limited.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics Ltd, said "I would like to thank Chinappa for his immense contribution to Biocon Biologics over the past 3 years and to the Biocon Group for more than two decades. He has successfully built a strong foundation of fiscal prudence, financial governance and risk management. Chinappa has played an invaluable role in the multi-billion-dollar acquisition of Viatris' global biosimilars business and set up the organization for success. I am delighted to welcome Kedar to Biocon Biologics. He joins us at an inflection point in our journey to become a leading global biosimilars company as we look to consolidate and unlock value in the acquired business. I am confident that he will build further on the strong foundation and with his expertise and experience work closely with all stakeholders to drive growth and deliver on our business goals."

Grundfos launches new iTruck initiative - the Grundfos iTruck Drive

From left: Burak Gürkan - Senior Regional Sales Director, IND - IMEA/Country Director Türkiye, Grundfos and Mr. Shankar Rajaram – Sales Director, IND – INDO, Grundfos

Chennai, India: In a world that's becoming increasingly conscious of environmental responsibility and technological advancement, Grundfos, a global leader in intelligent and energy-efficient pumping solutions, is driving change with its groundbreaking initiative - the Grundfos iTruck Drive. This unique campaign reflects

Grundfos' unyielding determination to sustainability and innovation, and it's poised to reshape the industry as we know it.

#GrundfosOnTheGo - A Green Parade: Imagine a journey that's not just about reaching a destination but about paving the way for a brighter future. The Grundfos iTruck aims to be a rolling testament to Grundfos' legacy, parading its cutting-edge solutions as it glides through cities and towns. When the iTruck is in your city, you might witness the captivating #SustainableInnovationDrive, a moving canvas of Grundfos' unwavering belief in blending technological progress with environmental stewardship.

The Carbon Crusader: The Grundfos iTruck isn't a run-of-the-mill innovation hub; it's a carbon crusader. By delivering the showcase to your doorstep, Grundfos envisions a staggering reduction of 33,500 Kg (Thirty-three thousand five hundred Kilogram) in potential carbon emissions and additionally covering three folds increase in target audience compared to conventional events. This highlights the company's steadfast dedication to fulfilling its Science-Based Target Initiative (SBTi) promises, charting a sustainable course for the future.

Grundfos' Bold Eco Odyssey: In the grand tapestry of sustainability, Grundfos has a crystal-clear mission: to unfurl the canvas of

energy-efficient marvels, unveiling their pocket-friendly prowess, and illuminating their excellence in curbing energy and water footprints. The brush strokes of this eco-tale is envisioned to lead to a net- zero horizon by 2050, with Grundfos already hoisting the flag of triumph, securing validation for its Science-based targets from the esteemed SBTi.

With resolute commitment, Grundfos marches to the front lines of greenhouse gas emissionreduction, confronting the notorious Scope 1, 2, and 3 emissions. Amidst this battle, it's the elusive Scope 3 emissions, the giants of carbon footprint, which steal the limelight, constituting a formidable 99% of Grundfos' emissions tableau. The near-term target: to carve Scope 1 and 2 emissions by 50% and chisel Scope 3 emissions by 25% by 2030.

Grundfos doesn't see this just as a mission; it envisages this as an odyssey towards crafting the world's most energy-efficient and digitally empowered product portfolio, where Grundfos' story of sustainability unfolds in every pump, every solution, and every drop of innovation.

Harnessing Global Participation: Global human involvement in this crusade will serve as the propelling force for Grundfos towards the realization of these sustainable dreams. Each droplet holds significance, every spark of innovation carries weight, and united, we have the power to etch an enduring transformation.

What waits for you in the iTruck? Showcase of Innovation.: Grundfos' iTruck introduces visitors, including industrial end customers and OEMs, to a range of Intelligent & Energy-Efficient Pumping Solutions tailored to meet diverse industrial needs.

Intriguing Insights: During each city stop, Grundfos' technical specialists will provide in-depth explanations of the purpose and science behind the products, allowing visitors to gain a deeper understanding of their benefits.

Impacts that Matter: The campaign showcases real case studies illustrating how Grundfos pumps have made a significant difference for businesses and OEMs, highlighting the practical applications of their solutions.

If you look out through your window, and you see a #GrundfosOnTheGo iTruck cruising through your city or town, you might be in for a delightful experience that involves innovation, responsibility, and sustainability. ■

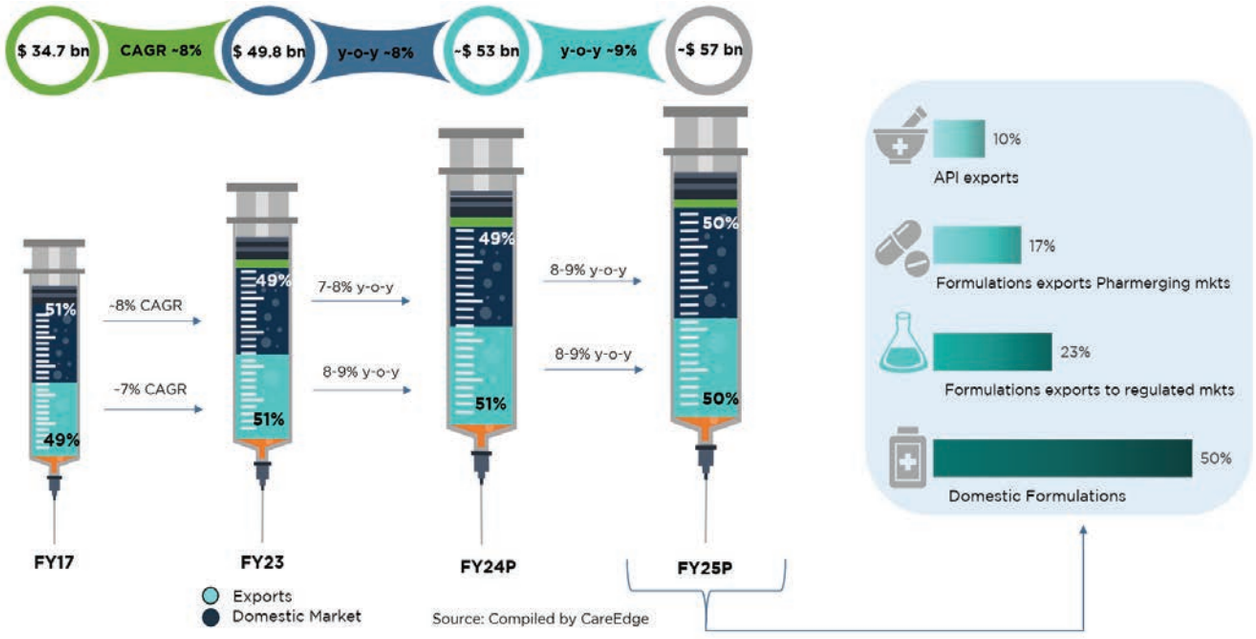
Pharma Exports to grow at CAGR of 8% for next 2 years

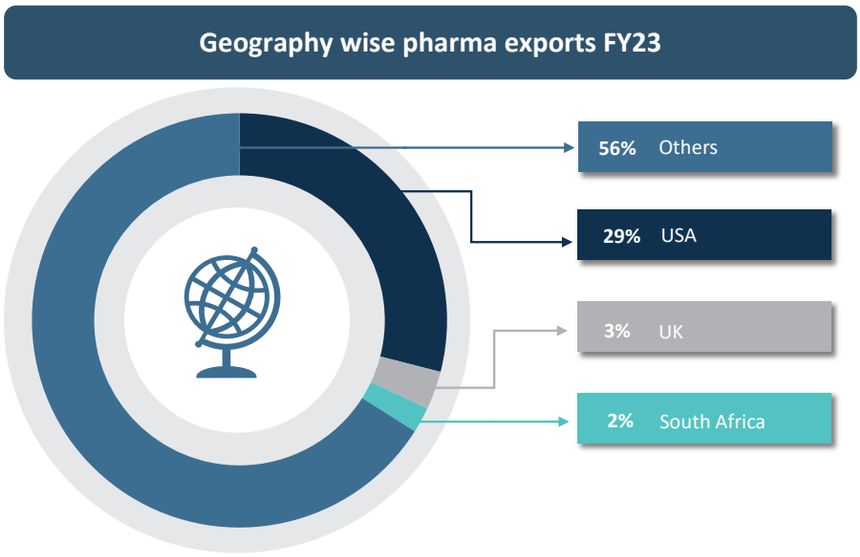
Overview of Indian Pharma Industry: The Indian pharmaceutical sector holds a prominent global position, particularly in the generic drugs market, ranking as the third largest by volume and thirteenth by value. Over the period spanning FY17 to FY23, the industry, encompassing both domestic and export markets, achieved a notable CAGR of 8%. This growth was driven by a 7% increase in exports and an 8% rise in the domestic market during the same timeframe.

Consequently, the Indian pharmaceutical industry expanded from approximately USD 34.7 billion in FY17 to reach approximately USD 50 billion in FY23; and is envisaged to further increase to USD 57 billion by FY25. Globally, the Indian pharmaceutical industry has established a robust presence in the generics segment, with pharma exports and the domestic market contributing equally to its overall stature.

Regarding exports, CareEdge expects that the industry's increasing emphasis on the synthesis segment, complex and specialty products, coupled with easing of pricing pressures in the US generics market, is expected to provide support for medium-term growth. Further improved access to healthcare services is poised to drive higher growth in emerging markets. Nevertheless, any adverse actions by regulatory authorities would remain key monitorable.

The United States accounts for approximately 40-45% of the global pharmaceutical market share, which underpins its significant prominence. Consequently, the presence of Indian pharmaceutical companies in the US market plays a pivotal role in their export strategies. This significance is underscored by the data illustrated in the righthand side pie chart, which reveals that nearly one-third of India's total exports originate from the US

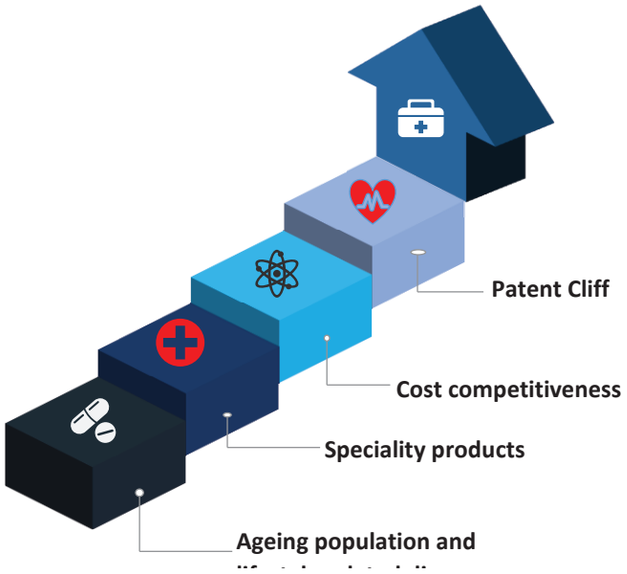




market, followed by the United Kingdom and South Africa.

The export of pharma products are expected to rise gradually. CareEdge expects India's pharma export to grow at around 8% during the next two years i.e. till FY25 with major contribution coming from the generic formulations. Indian pharma companies are one of the cost-effective producers of generic formulations. Changing world demography wherein it is observed that larger number i.e. about 30-35% of population is expected to fall in the age range of 50 – 80 years, combined with lifestyle related diseases would benefit the growth of industry.

Further, greater focus by top 20 pharma companies of India on R&D of complex and specialty generic and bio-similar products are expected to drive the export growth.



CareEdge expects the growth of formulations in regulated markets to be driven by 2 primary reasons:

New product launches in complex generics, specialty chemicals and products going off-patent

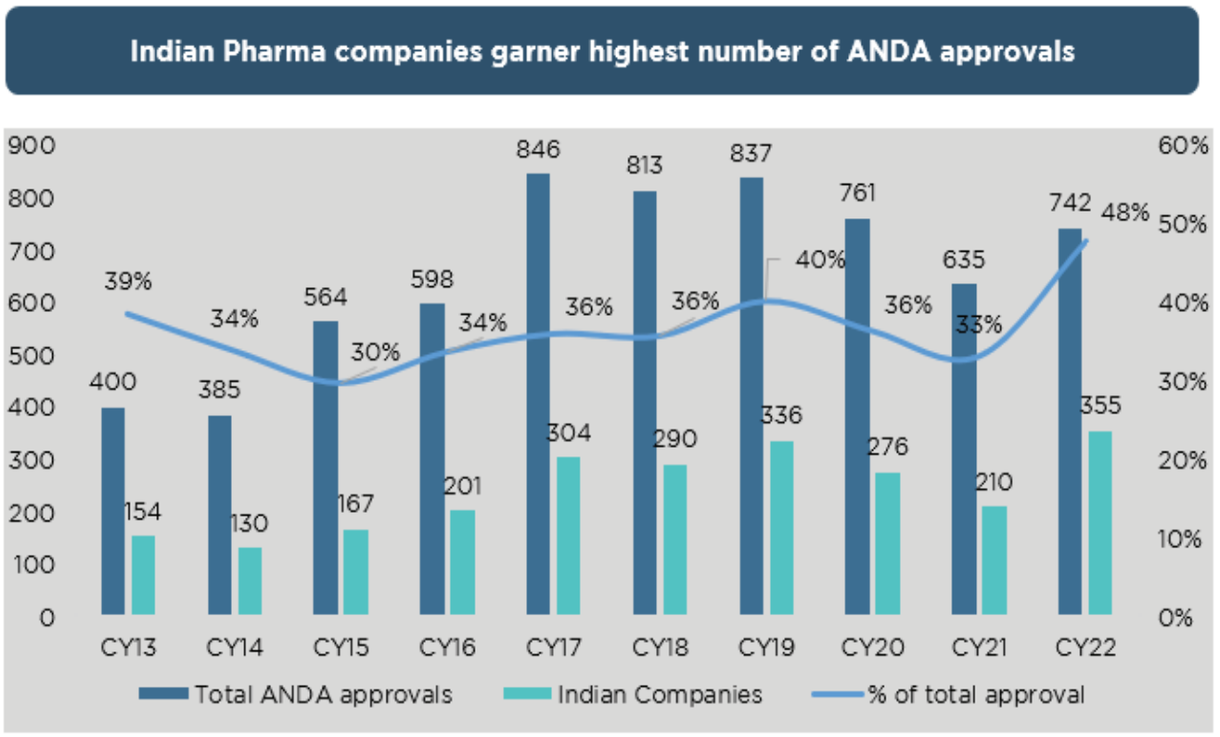
Abating of pricing pressure

While the growth in pharmerging formulations markets is expected on account of depreciating currency, however the growth prospects are also dependent upon availability of adequate forex reserves. Nevertheless, exploration of new markets or increase in generic penetration in existing markets is expected to drive the growth.penetration in existing markets is expected to penetration in existing markets is expected to drive growth grogthgrowgrowth growth. drive the growth.

The growth prospects will be bolstered by patent expirations in regulated markets, which pave the way for generic drug market entry. From CY2022 extending until CY2026, patented products with a cumulative value of USD 224 billion are set to lose their patent protection. This represents a substantial opportunity for Indian generic formulation companies, many of which are actively engaged in developing generic versions of these patented products to capitalize on this impending market opening. It is envisaged that Indian pharmaceutical firms may realize an opportunity in the range of USD 4-5 billion due to patent expirations within the next 3-4 years.

With promising opportunities emerging in developed markets, Indian generic formulation companies have been making strategic investments in their capabilities to develop complex and specialty drugs. Notably, the R&D expenses of the top 20 listed Indian pharmaceutical companies have consistently accounted for approximately 6% to 8% of their net sales over the past five years i.e. FY18-FY23. This trend is expected to persist at around 6.5% to 7% over the next two years as these companies maintain a robust product pipeline.

A significant portion of this product pipeline is geared towards the US and European markets, driven by the substantial opportunities in these regions. It is worth highlighting that India holds a prominent position in



the realm of ANDA approvals granted by USFDA. As illustrated in the chart on the left-hand side, Indian pharmaceutical companies dominate the landscape of ANDA approvals.

India has consistently commanded a share of around 35-40% of total ANDA approvals over the past 8-9 years. In CY22, product approvals reached their zenith in terms of percentage, with Indian firms securing 48% of the approvals. India boasts the distinction of housing the largest number of USFDA-compliant pharmaceutical plants outside of the US. With this substantial USFDA-compliant infrastructure in place, India is poised to lead the way in harnessing the opportunities presented by the patent cliff in the US.

CareEdge Ratings View

In light of the challenges that Indian pharmaceutical companies have encountered in their export endeavors, they are strategically allocating their resources and efforts in R&D and marketing, exercising discernment to safeguard their returns and sustain a seamless growth trajectory. Notably, a significant portion of their R&D expenditure is directed towards specialized and intricate pharmaceuticals. Additionally, these companies are identifying opportunities in semi-regulated and unregulated markets to capitalise on. CareEdge anticipates that the overall share of ANDA approvals in the current fiscal year may decrease, as companies opt to file for select products with relatively longer market presence and higher profit margins. In a broader context, CareEdge foresees that several factors will drive pharmaceutical exports, including the patent cliff, the compelling cost competitiveness of Indian players, a strategic shift toward specialised and complex drugs, a growing proportion of the population entering advanced age groups, the escalating prevalence of lifestyle-related diseases, and support from multilateral funding agencies, particularly in unregulated markets. All these factors will enable the Indian pharmaceutical exports to grow by approximately 8% over the next two years. ■

Authors

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"We will continue to leverage opportunities that lead us to organic growth and diversify into newer categories."

Nikhil Chopra
CEO & Whole Time Director
JB Pharma

Nikhil Chopra emphasizes about the JB Pharma's strategy for FY24 and outlook for contract manufacturing business. He also spoke about the company growth drivers, Research and Development initiatives and the company's financial performance.

What are the parameters driving growth for JB Pharma in India?

Our biggest bet is India market, as 50 per cent of our revenue comes from here. We will continue to leverage opportunities that lead us to organic growth and diversify into newer categories that can be in generic formulations, wellness etc. The company recorded a 35% year-on-year (YoY) increase in the company's net profit to ₹ 142 crore in Q1 FY24. The company's revenue from operations rose 14% YoY to stand at ₹896 crore. JB Pharma continues to be the fastest growing company amongst the Top 25 in the Indian Pharma Market, outperforming the market growing at 21% as against 11% (IQVIA MAT Jun'23 data)

The introduction of our Go-to-Market Model has been instrumental in driving growth and enhancing our performance in the domestic market during the quarter. On one hand, we have taken measures to drive therapy-wise and brand-focused expansion, especially within the domestic arena and on the other hand we are creating differentiation through sizeable opportunities. One of the pillars of strategy over the last 1-2 years has been acquisition led growth. Last year, we completed 4 major acquisitions (Sanzyme, Azmarda, Razel franchise and paediatric portfolio from DRL), thus foraying into the fast-growing probiotics, paediatric and the niche segment of heart failure. By placing a strong emphasis on bolstering our 'big brands,' we have introduced additional product variations within existing product lines, catering to diverse customer

needs and preferences.

In line with our expansion strategy, we have expanded our market reach by targeting tier-4 cities and rural areas. This deliberate expansion has increased accessibility to our current brands and allowed us to tap into previously untapped markets.

What is JB Pharma's strategy for FY24 and beyond?

From 1600 crore company in 2020, we are a 3200 crore company now. We launched our new identity 'Good People for Good Health' year ago and the culture we have been driving is centred towards simplicity, reliability, and agility. Presently, JB Pharma's India business is contributing about 54% to the overall revenue, and CDMO business contributes around 27% of total international business and we are looking forward to the domestic market contributing 80% to the overall revenue.

The current financial year, we aim to consistently outperform the domestic market through life cycle management and new launches, and cost optimization initiatives. We believe that the India and CDMO business should constitute in the near-term to around 75% - 80% of total revenue . The first quarter has been a robust performance both in terms of topline and operating profit, and we remain positive about delivering on our business objectives.

What growth have you seen in key chronic segments, especially in cardiology?

We now rank amongst the top 10 in the Cardiac therapy, as about 3 of our brands are among the top 25 in Cardiology segment. We have been actively directing our investments towards the chronic segment, with a specific emphasis on the cardiovascular segment. This strategic focus includes a combination of targeted acquisitions and the introduction of new products to bolster our presence in this critical therapeutic area. We also aim to enhance the contribution of this segment to their overall domestic formulation sales, to reach close to 60% in the short to mid-term. We have taken steps to establish and strengthen our acquired heart failure brand – Azmarda. At the beginning of 2023, we reduced the price of Azmarda by 50% to enhance its accessibility. We are focusing on growing our Razel brand which specifically targets lipid management. We have seen 24% growth in chronic therapies in the domestic formulations business as compared to the domestic market which reported a growth of 11%, according to IQVIA MAT March'23 vs MAT March'22).

What outlook do you see for contract manufacturing business?

Our contract development and manufacturing business plays a significant role in our overall growth strategy. This segment has scaled further during the quarter. Our contract development and manufacturing organization (CDMO) has consistently generated annual revenues of ₹400 crore, growing at 19%, this quarter it recorded a revenue of ₹ 119 crores.

We have established successful partnerships with international companies, focusing primarily on the production of medicated and herbal lozenges. These collaborations have been instrumental in driving our revenue and strengthening our presence

in the contract development and manufacturing space. Looking ahead, we are keen on forging additional partnerships to further enhance our operational efficiency and fuel our growth trajectory. By leveraging our expertise and manufacturing capabilities, we aim to attract more high-profile clients and expand our contract development and manufacturing portfolio. We believe that the CDMO business in India presents significant opportunities for growth, and we are committed to capitalizing on them to drive our business forward.

Amid a challenging environment, can you throw some light on your international operations?

Our international business contributes around 50 per cent of the total revenue, comprises three segments: export formulations, API and contract manufacturing. We operate using distinct operating models across multiple international businesses with a direct presence in Russia and South Africa as well as distributor relationships in the US and many markets across Asia, Africa and Latin America. Despite a challenging business environment, we experienced commendable growth in its international business, particularly in the US and Russian markets. For the first time in a quarter, revenue from international business crossed ₹ 400 crores mark.

The logistics and freight cost reduction has positively impacted operating margins for the business. We witnessed increased interest from existing and new clients in the CDMO business, specifically in the lozenges segment. JB Pharma aims to expand its international business pipeline for sustained growth. However, it acknowledges the presence of fierce competition and remains focused on executing well, optimizing costs, and improving operating margins. Our next priority is to scale up R&D and business development initiatives towards building a progressive portfolio for the US, Russia, South Africa, API and contract manufacturing businesses.

How was the performance of Cilacar, Rantac, Metrogyl and Nicardia brands in Q1 FY-24?

The domestic pharma market saw the after-effects of a delayed monsoon, which led to some impact on sales in acute therapies. However, the company's domestic business continued its growth trajectory through strong momentum in chronic portfolio and acquired assets. The big brands, namely Rantac, Cilacar, Cilacar-T, Metrogyl, Nicardia, continue to outpace the market and have reached new milestones.

As per IQVIA MAT Jun'23, Rantac gained 6 ranks to #35; Cilacar gained 9 ranks to #40; Metrogyl gained 20 ranks to #145; Nicardia gained 58 ranks to #162 and Cilacar-T gained 12 ranks to #178. Additionally, Azmarda ranks #270. Currently, there are 6 brands in IQVIA top 300 brands list with our recent expansion in the probiotic segment through Sporlac being the potential new entrant.

We recognized the importance of patient convenience and adapted the formulations accordingly. For instance, we introduced Metrogyl ER 600, which required only two tablets a day, compared to the previous formulation of three tablets at 400 mg each. Additionally, we offered Rantac OD 300 mg, a once-a-day dosage, as well as the traditional Ranitidine formulation. By incorporating these advancements and addressing patient needs for simplified dosing, JB Pharma improved patient compliance, resulting in its notable growth during the quarter. ■

INTERVIEW

"Artificial intelligence (AI) is poised to assume a larger role in the diagnostic landscape."

Raghavendra Goud Vaggu
Global CEO
Empe Diagnostics

Over the years, the diagnostic industry in India has transformed to better meet the needs of patients. It has become much easier for people to get the tests they need. There are more clinics and testing centers now and the technology used for testing has become more advanced. **Raghavendra Goud Vaggu** emphasizes about the innovations and changes taking place for the future of diagnostic Industry.

How has the diagnostic industry evolved with time and the need for patient care?

In the past, diagnostic tests were often time-consuming and sometimes less precise. However, with technological advancements, tests have become faster and more accurate. One major innovation in the diagnostic industry is the use of AI. AI has the ability to analyze large amounts of medical data with incredible speed and accuracy. This has been particularly useful in interpreting complex medical images, such as X-rays and MRIs. AI algorithms can identify subtle patterns or abnormalities that might be missed by human eyes, helping doctors make more precise diagnoses.

Moreover, AI is being used in predictive analytics, where it can analyze patient data to identify individuals at higher risk for certain diseases; enabling healthcare providers to intervene early and prevent health issues from progressing. In addition to AI, there has been a proliferation of advanced diagnostic tests. These tests go beyond basic blood work and include genetic testing, molecular diagnostics, and specialized assays for specific diseases. These advancements enable doctors to pinpoint the exact cause of a medical problem and tailor treatments accordingly. With the rise of telemedicine, one can even talk to a doctor and get the test results online. People are more aware of the importance of getting regular check-ups and tests.

What changes and developments are expected in the future diagnostic Industry?

We can anticipate a series of significant changes and advancements within India's diagnostic industry. Foremost among these is the prospect of even more advanced technology, promising faster and more precise diagnostic tests. This progress will equip doctors with superior tools for the accurate diagnosis and effective treatment of various medical conditions. Additionally, the growing prevalence of telemedicine

is a trend on the horizon. This mode of healthcare delivery allows individuals to consult with healthcare professionals and access their test results online, offering particular convenience when visiting a physical clinic proves challenging. Another notable development is the potential widespread adoption of personalized medicine, characterized by customized treatments and tests tailored to each individual's unique genetic makeup and healthcare requirements. Artificial intelligence (AI) is poised to assume a larger role in the diagnostic landscape. AI's capacity to swiftly and accurately analyze medical data and images will assist doctors in enhancing diagnostic precision. Home-based testing is expected to gain popularity, permitting individuals to conduct certain tests in the comfort of their homes and receive results electronically.

The continued emphasis on early disease detection is likely to persist, as detecting health issues at their inception can lead to better outcomes and less severe illness. Access to diagnostic services is set to improve, even in remote corners of India, ensuring that a broader segment of the population can avail themselves of essential tests. Furthermore, an increased awareness among people regarding the significance of regular check-ups and diagnostic tests is anticipated, contributing to overall population health. Finally, there may be a growing emphasis on sustainability within the diagnostic industry, with efforts directed toward ensuring that diagnostic processes are environmentally friendly and aligned with broader sustainability goals.

Brief us about the launch of EMPE's mfloDx MDR-TB rapid test kit?

EMPE's mfloDx MDR-TB is a unique product, which can accurately identify Mycobacterium Tuberculosis (MB) and determine its drug resistance profile within a quick 3-hour timeframe. Presently, we have the capability to produce 25 million kits annually at our ISO-certified facility located in Genome Valley. However, we have plans to expand this production capacity to 100 million kits.

Our collaboration extends to 14 different countries and involves 34 distinct laboratories worldwide. Our primary goal is to promote the "Make in India" initiative while simultaneously exporting our product globally. Our overarching mission is to combat TB on a global scale, and not just TB but also other diseases.

What are the support and developments needed in the R&D sector of the diagnostic industry?

The research and development (R&D) sector of the diagnostic industry in India requires support and specific developments to keep improving and meeting the healthcare needs of the people. Financial support is crucial. Research in the medical field can be expensive, so funding from the government and private sectors is necessary to conduct experiments, develop new tests, and improve existing ones. There is a need for skilled scientists and researchers as training programs and educational initiatives can help build a strong workforce capable of driving innovation in diagnostics.

Additionally, infrastructure development is essential. Well-equipped labs and research facilities with cutting-edge technology are necessary for R&D in diagnostics. Partnering with international experts and organizations can bring fresh ideas and perspectives to the Indian diagnostic industry. Furthermore, regulatory frameworks need to be streamlined. Clear and efficient regulations can help in faster approvals and market access for new diagnostic technologies. Lastly, data sharing and patient privacy protection should be balanced. Sharing research data while safeguarding patient information is essential for advancements in diagnostics.

How has Empe been helping in supporting the mission?

EMPE Diagnostics is committed to bringing a revolutionary change in the methods of identifying and assessing tuberculosis disease to minimize ineffective treatment with their cutting-edge multiplex test, yet simple to read. Our aim is to provide user-friendly diagnostic tests that can provide confirmatory results among TB patients in order to reduce life-threatening complexities and effects in TB-burdened countries. Our multiplex molecular test indicates the presence of Mycobacterium Tuberculosis (MB) and its genotypic resistance profile by developing a visual signal. The novel TB diagnostic kit — mfloDx MDR-TB — by EMPE is inexpensive, easy to interpret, customizable and suitable for resource-limited clinical laboratories which provide sample results in the shortest possible time of 3 hours without any advanced instrument. ■

GST implications on Pharma Sector

Smita Singh
Partner- Indirect Tax
Custom & Trade, S&A Law Offices

Indian Pharma sector is estimated to be worth USD 42 billion in 2021 and is expected to reach USD 65 billion by 2024. The Pharma sector in India plays a major role in manufacturing and supplying medicines globally, being 3rd largest by volume and 14th largest by value. Hence, it becomes imperative that issues faced by the pharma sector are addressed and resolved to enable it to play a leading role. Smita Singh discusses few issues faced by the Pharma sector in relation to GST and their possible solutions.

Expired Goods

As a regular practice in the Pharma sector, unsold expired or near expiry goods are returned by the distributor/ retailer to the manufacturer who is in turn required to destroy such expired goods. Since, the manufacturer is required to dispose off the expired goods, input tax credit (ITC) availed by the manufacturer with respect to such expired goods is consequently required to be reversed as per GST laws.

Typically, the shelf life of Pharma products is longer and hence return of such goods would be made after the time limit prescribed for issuance of credit note under GST laws. Accordingly, manufacturer would in any case lose on the benefit of adjustment of GST on receipt of returned goods.

Thus, due consideration must be given on this aspect by the Government so that manufacturers of Pharma products do not have to suffer double loss i.e. firstly reversal of ITC on destruction of expired goods and secondly, when goods are returned after the prescribed time limit for issuing a credit note and output tax adjustments. Keeping in view that the longer shelf life of the Pharma products and losses borne by the sector, GST authorities should make an exception for such goods.

Placement of medical equipment on free of cost basis

There are situations where manufacturers of medical devices place their medical equipment at a hospital/ doctor's clinic on free of cost basis without transfer of ownership. The condition attached to the placement of such equipment is that the hospital/ doctor is required to make minimum purchase of the reagents required to operate the equipment from them or their distributors only.

Medical equipment manufacturing companies do not discharge GST on such placement of medical equipment, since this transaction does not involve any flow of consideration by hospital/ doctor for such placement of medical equipment. This position is adopted by many medical equipment providers. However, the Kerala Authority for Advance Ruling (AAR) in the case of Abott Healthcare has ruled that placement of medical equipment is a 'supply of service' and is subject to GST since agreement to purchase agreed value of reagents exclusively from distributors constitutes a valid consideration. Thus, the ruling by Kerala AAR is contradictory to the position adopted by many companies and has left room for varied interpretations and future litigation.

Time limit for sale on approval basis

Further as a matter of practice, various Pharma companies provide certain medical implants to hospitals/ doctor's clinic on sale on approval basis. Invoice is raised by the companies at the time when the medical implants are used by the hospital/ doctor's clinic. In case the goods are not used within 6 months i.e. the maximum time prescribed for goods to be sent on approval basis, hospital/ doctor's clinic return the goods which are replaced with fresh stock of the same goods.

This is a continuous process and dealing with voluminous transactions of such kind and compliance with respect to documentation under GST laws is also complex.. The Gernment should consider extension of the time limit of goods sent on sale on approval basis from 6 months to atleast 2 years for Pharma goods to ease the compliance requirements.

Exemption on rare-disease or cancer related drugs

GST on sale of rare-disease or cancer related drugs is exempted. Accordingly, Pharma companies are not eligible to avail ITC in respect of such goods. Hence, any GST paid on procurement of raw material or services on manufacturing such goods becomes a cost. Thus, this becomes a sunk cost in the Pharma Company's hand and the Government should consider this aspect and bring such drugs under zero-rated supplies which will eventually reduce the costs burden.

Discount and promotional schemes

Various marketing and business promotional activities are undertaken by Pharma companies wherein discounts, free samples, brand reminder goods such as wall clocks, notepad, and gifts are given to hospitals/ doctors etc. Since, this is a common marketing practice to promote sales, it constitutes a genuine business expenses. There have been many instances where GST authorities have denied ITC on expenses incurred on such marketing and business promotional activities on the ground that such free samples and brand reminder goods are 'gifts' and ITC on gifts is disallowed. This issue has led to increase in litigation and writ petition has been filed in the Bombay High Court seeking directions whether free samples can be considered as a business expense or not under GST. In order to avoid a prolonged litigation on denial of ITC on marketing and business promotion expenses, the Government should proactively provide clarification on the issue.

GST has completed 6 years and the issues discussed above have been lingering throughout this journey. The Pharma industry being a major player in India's economy and India's share in the world pharma arena is looking towards the Government to address the issues in order to avoid unnecessary litigations adding to cost burden of this major sector, which will ultimately provide impetus to promote domestic manufacturing and increase self-reliance. Hopefully, Government in near future will come up with required resolution to the relief of the pharma sector on all the above aspects. ■

INTERVIEW

"Pharmacogenomics allows for personalized and optimized medication therapies, leading to better treatment outcomes"

Amol Naikawadi
Joint Managing Director & Preventive Healthcare Specialist
Indus Health Plus

Indus Health Plus recognizes genetics as the cornerstone of future preventive healthcare, and through its genetic testing portfolio, it aims to contribute significantly to enhancing the healthcare ecosystem in India. **Amol Naikawadi** emphasizes about the Pharmacogenomics and future outlook in the field of preventive healthcare and genetic testing.

What is Pharmacogenomics? How it helps in effective treatment?

Pharmacogenomics is the study of how an individual's genetic makeup influences their response to various medications. It involves analysing an individual's unique genetic profile to identify specific genetic variations that can impact drug metabolism, efficacy, and safety. Pharmacogenomics can help you know in advance whether a drug is likely to be beneficial to you and safe for you to consume, which can improve your health.

By integrating genetic information into prescription process, healthcare professionals can tailor treatments to suit each patient's needs, ultimately leading to more targeted and effective therapies. Pharmacogenomics offers a more precise and efficient treatment experience. It can also streamline the trial-and-error process associated with finding the right medication, ultimately reducing the overall healthcare costs.

How does pharmacogenomics work in practice?

Pharmacogenomics analyses an individual's genetic makeup to identify genetic variations impacting drug responses. Genetic data is compared to a database to inform drug selection and dosage. This approach optimizes healthcare by tailoring treatments to each patient's unique genetic profile. By considering the genetic factors that affect how a person processes and responds to drugs, pharmacogenomics allows for personalized and optimized medication therapies, leading to better treatment outcomes and a reduced risk of adverse drug reactions.

What all categories and parameters can be included in the testing?

MEDNAwise is a comprehensive pharmacogenomics (PGx) report, encompassing 72 drugs spanning 11 medical specialties.

Anaesthesiology, Neurology, Cardiology, Oncology, Psychiatry, Gastroenterology, Pain management, Gynecology, Infectious disease, Pulmonology, Organ transplantation are a few categories included in the testing.

What is the future outlook in the field of preventive healthcare and genetics? How can genetic testing aid in disease prevention?

In the upcoming months, we plan to advance our genetic testing offerings. Our aim is to increase the accessibility, affordability and availability of these tests across the nation. Genetic testing empowers individuals to proactively assess their risk of developing certain health conditions well in advance, enabling them to take necessary precautions for prevention. By identifying potential health conditions risks based on genetic insights, individuals can adopt precautionary measures from an early stage. Through lifestyle modifications and adherence to fitness regimens, they can effectively mitigate the risk and work towards safeguarding their health for the future.

How it helps Indus Health Plus to enhance the preventive healthcare ecosystem in India?

By leveraging genetic testing, Indus Health Plus strives to make proactive strides in preventive care, ensuring a healthier and more resilient population in the country. Genetic testing from preventive standpoint helps in identifying disease predisposition and allows people to take action in advance. However, pharmacogenomics offers personalized drug recommendations, eliminates the need for the hit and trial method in medication selection. This innovative solution enhances treatment efficiency, reduces adverse reactions, and revolutionizes the way healthcare providers approach drug prescriptions.

What is the future of genetic testing in India? What is your revenue target for next year?

The field of genetics continues to evolve, holding immense growth potential for preventative healthcare. Ongoing research and technological advancements are driving progress in this area. Genetic testing, as one of the most advanced approaches, is poised to compliment traditional laboratory tests in the coming years. Its application is particularly promising in managing diseases like cardiovascular diseases, diabetes, obesity and assessing the susceptibility to various chronic illnesses, revolutionizing the way we approach healthcare.

We are looking at 25% to 30 % growth year on year and taking the services to every Pincode from where the sample can be collected & beyond the borders especially in southeast Asia & Gulf. ■

Standardizing Molecular Diagnostics: A Critical Step toward affordable and effective healthcare in India

In an era, where evidence-based medicine prevails and bioinformatics continually advances, molecular diagnostics is becoming the cornerstone of healthcare. **Ram Ray, Chief Growth Officer, Mylab** highlighted the importance of molecular diagnostics and step toward effective healthcare in India.

The emergence of precision medicine, particularly in complex areas like cancer care, has solidified the role of molecular diagnostics as the future's dominant diagnostic technology. It has been nearly two decades that molecular diagnostics has been projected to be the most dominant of all diagnostic techniques and many healthcare entrepreneurs invested forward, including high-end machines, and hiring highly trained scientific talent, however, the economic output to justify such investments has not been the most stellar in many cases.

Two things are noticeably clear, One, Molecular Diagnostics is the need of the hour and necessity of the future. Had the molecular diagnostic technology not been well established all over the world, the story may not have been different from the Spanish flu of an earlier era. Second, a collective effort is required from the healthcare sector, including governments, regulators, caregivers, inventors, and manufacturers, to create sustainable commercial models. This will enable molecular diagnostics to fulfill its pivotal role in infectious disease management and precision medicine.

We will focus more on this second aspect and understand what can be done to ensure this scientific quest meets the sustenance objectives too. One of the aspect is that molecular diagnostics need is standardization of reporting values and minimum technological standards. Given that India in many ways is the epicenter of infectious diseases, with some outbreak or the other hitting us almost every year, like Malaria, Dengue, Chikungunya, H1N1, H2N3 and, it's critical that a reporting standard is developed where the quality and efficacy of the reports do not fluctuate from one lab to the other. In an infectious disease setting if a physician chooses to employ molecular diagnostic techniques this implies that the clinician is not just

looking for precision in quality of diagnosis, but also looking for additional information about the infection, which may help the physician manage the condition better.

A similar rationale applies to detecting Sepsis or major Respiratory Infections. Standardization should encompass technology used and the reporting format, including mandatory reporting elements. These standards will provide clarity for reporting physicians, define the minimum technological prerequisites for labs entering this field, and offer test kit manufacturers and diagnostic device makers a clear framework for operation. Standardization usually leads to massive adoption and solid supply side economies-of-scale which ultimately brings the price down.

A standard for report format, the key values that one must report in cases of those diagnostics where molecular methodologies have been used and minimum amount of technology including a certain level of automation must be present across all molecular labs. The manual extraction methodologies employed in molecular labs are sometimes the root cause of many errors. Automation in extraction would be a great step.

The other aspect to work towards is to prevent over-reporting phenomenon in molecular diagnostics. The absence of minimum standards cuts both ways, while sometimes, reports are not reliable enough for the physicians, which may not contain enough information, and there are times when unnecessary information is reported, simply to create a niche and expensive market.

Let us take the case of HPV detection using molecular technologies. While the medical fraternity recognizes that detecting strain 16 and 18 should be sufficient in most cases to identify the infection, there are players in the market who sometimes offer multiple additional strains which does not add a lot of weight to the clinical decision making for the doctors, however, makes the test kit more expensive. Such cases of over reporting become unofficial standards in the industry and ultimately lead to expensive testing, which in turn ensures that most people do not test, where it is needed the most. With one of the highest cervical cancer burdens in the world, Indian women are at incased risk of HPV infection.

A good step in this direction would be to standardize the minimum reporting standards and aim towards lowering the price of the test, so that physicians can test when needed without worrying about the cost. Standardization of what must be reported in TB or HPV are simple examples where molecular diagnostic can proliferate, solve the problems that need solving and eventually become a viable commercial endeavor to the risk-capital providers as well.

While the significance of molecular diagnostics is undeniable, it's crucial to emphasize the paramount importance this field holds. India, with one of the world's highest tribal populations at heightened risk for infectious diseases like Hepatitis B in regions such as Ladakh, Arunachal Pradesh, and among tribes like Nicobarese, Shompen, and Jarwa in the Andaman and Nicobar Islands, must take substantial steps to not only promote molecular diagnostics but also ensure its viability and sustainability.

The COVID-19 pandemic revealed an unexpected gap in our healthcare infrastructure. Many large public health institutions, tasked with caring for extensive populations, lacked essential molecular diagnostic capabilities. Addressing this issue should be an immediate priority. While we addressed COVID-19 testing challenges by developing smaller devices and implementing rapid antigen tests, the larger battle against infectious diseases necessitates comprehensive adoption of molecular diagnostics across the country's public health infrastructure.

There is need to focus on three critical elements: standardization of technology, establishment of minimum reporting standards, and the full integration of molecular diagnostics into public healthcare systems. This approach can significantly enhance our readiness and resilience in managing healthcare challenges and contribute to a healthier and more secure future. ■

Author

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Chief Growth Officer
Mylab

Complete Pharma Solution with testo Saveris Pharma

Complete Pharma Solution – testo Saveris Pharma

A sector like pharmaceuticals which is, governed by strict norms and regulations must operate with utmost efficiency. Testo provides the best-in-class solution for comprehensive data monitoring & management for equipment as well as environmental parameters in pharma industry called as the **testo Saveris Pharma.** It is an automated system that is integrated in the facility & constitutes of wireless or Ethernet probes installed at different locations that are connected to one base station to document and monitor all measurement data of its own. The monitoring process is uninterrupted, and the system provides number of alarm options in case the measurement values violate the defined limit values.

Some advantages of testo Saveris Pharma for environment and equipment monitoring system include:

- Holistic system comprising sensors, software, and services
- In accordance with 21 CFR Part 11 and GAMP compliance
- Provides seamless recording, automated tamper proof documentation
- Secure triple layer storage of the measurement data of all audit-relevant parameters
- The data is stored in the probes, so even if software connectivity is lost the data is safe and can be downloaded once the software is logged in
- Real time alarm facility to highlight unexpected results

Testo Saveris Pharma system consists of testo Saveris base V 3.0 which is the core component of the system. It manages & evaluates data from all over the facility from 3000 channels. The four testo 150 data logger modules can be flexibly combined with the three communication modules (WLAN, LAN, testo UltraRange) making it very convenient and user-friendly system along with the web-based, intuitive cockpit to detect alarms, initiate corrective measures and to acknowledge them whenever necessary.

Application areas

Manufacturing/ Production area | Research & QC labs | Cleanrooms and data centers | Warehouses and packaging | Deep freezers, refrigerators, cold rooms | Incubators, Stability test and walk-in chambers | Blood and tissue banks | Autoclaves and nitrogen tanks | Sterilizers and many more

Our specially trained service team supports you throughout the process in a very systematic way – from planning, documentation, system qualification and software validation through to service and support. Testo also has a NABL accredited service & calibration LAB that takes care of the after sales support locally from Pune. ■

For more details, login to our website www.testo.com or write back to us on info@testo.in

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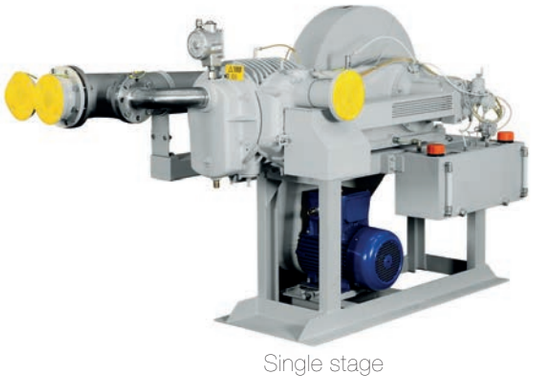
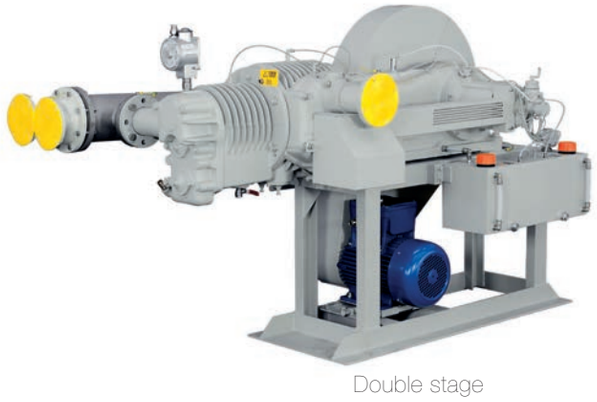


Single stage



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