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Reviving API sector and investing in new solutions

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Vaccine companies are currently in the limelight while scaling up COVID-19 vaccine plans for local and global needs.



The pharma industry is being pushed to access the benefits of digital technology including artificial intelligence & big data analytics to support the virtual world, rejuvenating the telemedicine platforms, reviving the Active Pharmaceutical Ingredient (API) sector and investing in new solutions to drive differentiation in an increasingly competitive market. BioSpectrum brings to you plans of the leading pharma/biopharma players for 2021.

“Launching new generic formulations in the US”

Looking ahead, we expect the generic formulations business to continue to drive growth, based on new launches in the US for products, which are currently under regulatory review. We also plan to commercialise Remdesivir in India as part of our commitment towards providing treatment for COVID-19. We have submitted drug master files for three APIs in the US and seven APIs in other markets. We also received licenses from MHRA, UK, to import and distribute products there. This is in line with our plans to commercialise our formulations directly in the UK. The construction of a greenfield facility in Visakhapatnam for immunosuppressant APIs has been slightly impacted due to delays by our vendors on account of COVID-19. We expect this facility to be commissioned by CY 2022.

Siddharth Mittal, Chief Executive Officer & Managing Director, Biocon, Bengaluru

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“Saving countless lives with COVISHIELD vaccine”

As promised, before the end of 2020, we have applied for emergency use authorisation for the first made-in-India vaccine, COVISHIELD. This will save countless lives. COVISHIELD is by far the most advanced vaccine in human testing in India. We have already manufactured 40 million doses of the vaccine, under the at-risk manufacturing and stockpiling license from Drugs Controller General of India (DCGI).

Adar Poonawalla, Chief Executive Officer, Serum Institute of India, Pune

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“Rolling out 2 dose schedule for COVAXIN”

The Phase III human clinical trials of COVAXIN began in November, involving 26,000 volunteers across India. This is India’s first and only Phase III efficacy study for a COVID-19 vaccine, and the largest Phase III efficacy trial ever conducted for any vaccine in India. COVAXIN trials are based on a 2-dose schedule, given 28 days apart. The vaccine efficacy will be determined two weeks after the second dose. We should look at the COVID-19 vaccine distribution as a global public policy. There should be a logistical strategy wherein there is also less impact on our environment.

Dr Krishna Ella, Chairman & Managing Director, Bharat Biotech, Hyderabad

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“Continuing digital trend”

In 2021 we expect continuation of the digital trend that started in 2020 to further develop and become a constant in the healthcare space. Face to Face and digital interactions will coexist and our commitment is to ensure that integrity remains one of our foundational behaviours.

Luca Visini, Managing Director, Eli Lilly and Company India, Gurugram

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“Working with USFDA to for clinical trials of PegiHep”

We are encouraged by the results of Phase II study of Pegylated Interferon alpha 2-b (PegiHep), which has shown the potential to reduce virus titres when given earlier in the COVID-19 disease. We have now commenced the Phase III trials that will be conducted on 250 patients across 20-25 centres in India. We are working with the United States Food and Drug Administration (USFDA) to open an Investigational New Drug (IND) application for PegiHep in order to initiate appropriate clinical trials in US. In addition, we will be conducting Phase I trial on ZYIL 1, a small molecule new chemical entity (NCE) positioned for management of critically ill COVID-19 patients. Also, the Phase II clinical trials of Desidustat in the management of COVID-19 is underway at Mexico.

Dr Sharvil Patel, Managing Director, Cadila Healthcare, Ahmedabad

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“Expecting to sustain momentum”

We are very pleased with the strong recovery of our business in 2020, demonstrated by sequential growth across all our geographies, in particular US and India. This marks the start of monetization of our complex generic pipeline with the launch of Etanercept biosimilar in Europe and generic Albuterol in the US. We expect to sustain the momentum on margin improvement led by optimization efforts underway and robust growth in our key businesses.

Nilesh Gupta, Managing Director, Lupin, Mumbai

“Increasing capacity for vaccine supply”

With an investment of Rs 75 crore in the upcoming facility in Genome Valley, we expect to increase our capacity to supply additional quantities of high-quality and safe vaccines. The new facility will be specially designed as a multi-product facility and to cater to the need for viral vaccines in the pipeline that includes dengue, zika and varicella. We have also recently inaugurated a new sterile filling facility that was commissioned last year at an additional investment of Rs 75 crore. This facility will increase our capacity to supply lifesaving vaccines such as the anti-rabies vaccine (ARV) – Abhayrab. As a part of the expansion plan, we will add over 150 new positions, bringing the total staff strength close to 1,500. The new facility will boost the production capacity by over 35 per cent and increase the supply capacity to key markets where rabies vaccine is critically needed. The new plant is expected to be ready for operation by October 2021.

Dr K Anand Kumar, Managing Director, Indian Immunologicals, Hyderabad

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“Aiming to access SGLT2 inhibitors market of diabetes”

Diabetes is a key area of focus for Micro Labs and with the recent launch of the anti-diabetic drug combo Dapagliflozin plus Metformin tablets under the brand name ZUCAPRIDE- M, we aim to access the Rs 1000 crore SGLT2 inhibitors market, by providing an effective, high quality and world-class treatment option to patients in India. Besides, strong R&D efforts have helped us develop our own API, which is at par with the innovator brand.

Ashok Jain, Executive Director, Micro Labs, Mumbai

“Offering potential option for prophylaxis of COVID-19”

We have initiated a Phase I/II clinical trial of the COVID-19 subunit vaccine candidate in India following approval from the Drugs Controller General of India (DGCI). The results of this clinical trial are expected to be available by February 2021. We are very happy indeed to transition our potential vaccine candidate to clinical trials and offer one more potential option for the prophylaxis of COVID-19.

Mahima Datla, Managing Director, Biological E, Hyderabad

“Making Sputnik V available with import and indigenous production model”

Our research teams are working on several potential remedies for COVID-19 in addition to the already launched products. We have seen a year-on-year growth of 21 per cent and sequential growth of 46 per cent, which is primarily on account of revenues from the acquired business of Wockhardt and contribution from new products including the Avigan (Favipiravir) and Remdesivir launched for treatment of COVID-19. We have further strengthened our development pipeline for COVID-19 treatment drugs including the vaccine candidate Sputnik V. We are working towards making the vaccine available with a combination of import and indigenous production model.

GV Prasad, Co-chairman & Managing Director, Dr. Reddy’s Laboratories, Hyderabad

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“Seeding multiple products across various regions”

Glenmark Life sciences has successfully developed the API for Favipiravir (FabiFlu) for the treatment of COVID-19 in India. We continue to look at opportunities with various partners and has been seeding multiple products across various regions. During 2020, we have submitted one drug master file (DMF) in Japan, four in the rest of the world (ROW) markets and two in gulf cooperation council (GCC) markets. The company is looking to file at least 12 -15 DMFs in 2021.

Glenn Saldanha, Director, Glenmark Life Sciences, Mumbai

“Launching vaccine against Lumpy Skin Disease in cattle”

We expect to grow in the market by expanding our reach, improving our product performances and adding new products and offering new solutions in our portfolio. In line with global health practices to move away from antibiotics, we will focus on herbal products. Most new products would be natural or herbal in nature for our poultry as well as animal division. Lumpy Skin Disease (LSD) in cattle is an emerging disease in India, which is of economic importance for cattle farmers. We are currently working towards developing a vaccine against LSD. We have already received the test license for evaluation of safety & efficacy of the vaccine. We have plans to commercially launch the vaccine in 2021. Also, our developmental activities are ongoing for the human COVID-19 vaccine with Indian Institute of Technology, Guwahati. Discussions are on with various human vaccines manufacturing companies to take the vaccine development and trial activities further.

Rajiv Gandhi, Chief Executive Officer & Managing Director, Hester Biosciences, Ahmedabad

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“Collaborating with government to contain AMR”

Globally, we have been working with partners and suppliers across the value chain, to improve antimicrobial resistance (AMR) awareness and raise standards through policies. In this context, we have set an internal target of meeting the science-based targets for antibiotic discharges in effluents, also defined as predicted no effect concentrations (PNEC), for all our own wastewater streams, as well as those at our supplier sites, by 2021. We are well on track having already met the PNEC targets for Centrient’s largest Active Pharmaceutical Ingredient (API) product range of semi-synthetic Penicillins. In line with that, in India, we will keep collaborating with central and state governments as well as other stakeholders in the ecosystem to support their initiatives in the containment of AMR and ensuring that during the current pandemic, antibiotics continue to save lives.

Rex Clements, Chief Executive Officer, Centrient Pharmaceuticals, The Netherlands

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“Working on various digital transformation initiatives”

With its rapidly evolving healthcare system, India remains a core market for Takeda. We are keen to offer innovative therapies, especially within rare diseases, oncology and vaccines, to serve critical unmet medical needs. We are also looking at expanding our current immunology and hematology businesses and continue to build on our launch pipeline. As digital has been the new normal, Takeda is working on various digital transformation initiatives both internally and externally to bring added value to our employees and partners.

Koki Sato, Country Head & General Manager, Takeda India, Gurugram

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“Rolling out digital solutions”

AstraZeneca will continue to prioritise investments in its focus areas in-line with its global growth platforms. To detail out further: innovating with partners and piloting new ideas at scale and rolling out digital solutions to benefit large numbers of patients. We will also focus on improving the Healthcare Professionals (HCPs) experience, orchestrating across both digital and F2F; continue to work on the ecosystem around the HCP with virtual care clinics, e-pharmacy support and importantly the patient education initiatives (Tele-Educators); develop end-to end supplies of our oncology products and strengthening the patient support services with supplies to paramedics on home-day care for essential oncology products; continue to leverage technology and accelerate innovative science by educating and empowering HCPs and connecting with national and international experts through virtual continued medical education meetings/conferences/workshops. Similarly, for patient’s as well as educated and empowered patient’s will play an important role in shaping healthcare policies and treatment protocols to improve health outcomes for community. Product or new indication launches from conventional ways have gone into virtual platforms and have been quite successful in reaching out effectively.

Gagandeep Singh, Managing Director, AstraZeneca Pharma India, Bengaluru

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“Investing more in research work”

As we step into the new normal, organizations like ours have shed age-old monitoring mechanisms and brought in work ethics, accountability, and responsiveness and introduced more innovative employee engagement practices. Our early success with the equine antibodies' project has given us confidence that we must invest more in research work. BSV has also been conducting Phase III trials on Ulinastatin. More recently, global research teams have shared their belief in Ulinastatin potentially preventing the cytokine storm that causes death in COVID-19 patients. These developments reinforce my faith in the calibre of our scientists. I’m certain that most other players in healthcare have had similar experiences. India is blessed to have a brilliant team of scientists and technocrats and if our government continues to provide more grants to nurture R&D culture, our country could be a burgeoning research hub over the next year or two.

Sanjiv Navangul, Managing Director & Chief Executive Officer, Bharat Serums and Vaccines, Mumbai

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“Building on digital innovation”

The digital medium has played a very important role, which was an underutilized asset prior to COVID-19. We moved to digital interaction out of necessity and we have realized our stakeholders are more welcoming and available to interact via digital. Leveraging this opportunity, we have launched several digital platforms to interact with our customers and employees and sharing content, which is meaningful and engaging. The key focus for 2021 is to ensure a strong business recovery post COVID and continue to build on the digital innovation to drive our marketing initiatives and customer interaction. We have learnt a lot during COVID and we can continue to imbibe the good practices, which have evolved in the area of employee engagement and empathy to drive organisational culture.

Suresh Pattathil, Managing Director, Allergan India, Bengaluru

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"Adhering to main strengths"

We are watching and researching the pattern of the disease ever since it broke out in China. Our research team has also begun to focus on potential avenues for treating Covid-19. The time available is, of course, short since no one has the time to perform the phase through studies. It is too early for everyone to suggest they have discovered a cure. Existing drugs like

remdesivir have played an important role in the early treatment and reduction of viral therapy before vaccinations have reached the market. Asymptomatic and moderate patients were also helped with an early remedy by a product such as favipiravir. I feel by 2021 it is time for Indian companies to understand that they need to master what they are good at instead of being a jack of all. I will still say that adhering to the main strengths would significantly help the pharmaceutical industry and might see a new horizon.

Dharmesh Shah, Chairman & Managing Director, BDR Pharma, Mumbai

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“Launching transformative therapy options”

At Roche, we were going through an organization transformation when the pandemic hit. It was a massive disruption to our 2020 plans. However, the team responded with agility and purpose to emerge better and stronger. In 2021, we will focus on implementing our transformation agenda, sharpening the execution engine with a strong focus on our strategic initiatives. There are multiple new launches lined up which will make transformative therapy options available for people in India. We will also forge strong partnerships aimed at ecosystem shaping access initiatives.

V Simpson Emmanuel, Managing Director, Roche Products India, Mumbai

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“Housing data scientists to support drug discovery”

As a company, we have accelerated our use of digital solutions and platforms during the pandemic. We now use digital media more extensively than before for customer engagement and multiple other processes. We plan to build on the progress made in 2020 on several fronts. We already have a good presence in India through our three global R&D support groups in Bengaluru, and have just announced the opening of a global capability centre in Bengaluru. This centre will house data scientists and analysts, who will support our drug discovery efforts.

Sridhar Venkatesh, Managing Director, GSK Pharmaceuticals, Mumbai

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