

# Sustainability Report 2019 - 21 GRI 2018 - In Accordance - Core



Paving a Sustainable Pathway through **COLLABORATION** 



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Paving a sustainable pathway through collaboration



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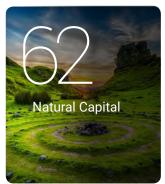
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#### 2.1 Foreword from MANAGING DIRECTOR





In paving a sustainable future through collaboration, we at Biological E are committed to discovering, developing and delivering innovative medicines for people around the world.

#### Dear friends and colleagues

I'm glad to present our fourth sustainability report, titled 'Paving a Sustainable Pathway through Collaboration'. The report details our performance and commitment towards the 'Triple Bottom Line of Sustainability'.

Globally, the pandemic has forced companies to consider the impact of environmental risks on business continuance along with similar other probable issues, more than ever. It is now imperative for businesses to commit to new targets, define and develop sustainable action plans and holistically contribute to sustainable development – through all endeavors possible. This would mean reducing the stress on resources, adopting mitigation strategies around climate change and a comprehensive shift in the way we treat our environment and the planet.

In paving a sustainable future through collaboration, we at Biological E are committed to discovering, developing and delivering innovative medicines for people around the world. Our commitment and determination, backed by decades of scientific research, have been instrumental in our transformation from a generic vaccine manufacturer to a novel vaccine developer. Our strategic acquisition and collaborations with international organizations help us in the development of affordable and accessible medicines. You should be proud to know that we have begun Phase III trials for Subunit Vaccine candidate in India. Our acquisition of Akorn India Limited has enhanced our manufacturing capabilities. The collaboration with Coalition for Epidemic Preparedness Innovation (CEPI) has aided in the development and manufacture of our COVID-19 subunit vaccine. Through the pre-qualification of Typhoid Conjugate Vaccine (TCV) by WHO, we currently have eight WHO pre-qualified vaccines. This prequalification from WHO enabled us to make a significant contribution to unmet public health needs in developing countries. We are one of the only two pre-qualified suppliers of TCV to the UN agencies.

With state-of-the-art infrastructure and a highly dedicated team of professionals, we have made significant additions to our product portfolio. Our R&D programs and collaborations help us stay abreast of the competition and ensure affordable medicine access to all, despite the dynamic economy and technology-driven environment. In all our pursuits, we seek guidance from our 2025 framework, built on four pillars - affordable medicines; water and energy; employee health and safety; and responsible procurement. We have identified eight focus areas to minimize our environmental and social footprints. The framework has been a guiding force in adopting a precautionary approach and hence minimize any adverse impact of our business operations.

With our focus on employee health and safety, we continue to achieve Recordable Injury Free operations at all our sites. Sustainability is the primary driver for us in meeting our targets ethically. Our continuous engagement with communities enables us to better understand their challenges. We envision to bring about a positive impact on the underprivileged sections of society through our initiatives.

In our pursuit of being a responsible business, we consider challenges as opportunities to improve. I would also like to take this opportunity to express my gratitude to all our stakeholders for partnering with us in our journey towards a sustainable future. Your views and suggestions in this journey are important and I welcome your feedback.

Sincerely yours

Mahima Datla Managing Director

bahine Dalle

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#### 2.2 Message from **SENIOR VICE PRESIDENT**



Dear Readers,

I am proud that Biological E could stand up during the rough weather followed by the global COVID-19 pandemic and is well equipped to manufacture the COVID-19 vaccine, clearing phase one clinical trials. Our approach of providing accessible and affordable therapeutics to all stakeholders gained more strength post the onset of the pandemic and was the center of our global focus, in general.

A periodic publication of our sustainability performance report enables a transparent dialogue with all our stakeholders. The report enumerates our long-term sustainability vision, as per the 2025 framework, along with the highlights of our performance across all six capitals. This transparent articulation strengthens our stakeholder's trust and belief in Biological E as a sustainable organization. We at BE work towards implementation of sustainable practices across our operations. We are cognizant of the interdependency of our growth with the constraint in natural resource consumption and the increasing need of the society. We are determined in paving a sustainable pathway through collaboration, for the benefit of all stakeholders.

Our vision is to "Become the largest Indian vaccines company and be among the top few Indian companies in complex generics & specialty pharmaceuticals by 2025." To achieve this, it is essential for us to improve our product quality and stay competitive. Our business continuance, despite the restrictions imposed by the pandemic is indicative of our innate business resilience and agility. With the inauguration of our massive state-of-the-art plant last year, to manufacture Typhoid Conjugate Vaccine (TCV), we would contribute to curb the global mortality

of typhoid fever. Through our strategic collaborations, we have enhanced our product offerings, which is in line with our business strategy to provide innovative healthcare solutions for our customers. Through the adoption of innovative technology and world-class management practices at all our facilities, our manufacturing units produce eight WHO pre-qualified vaccines and all other products in our portfolio. We also cater to both Indian and foreign market demands.

We concentrated on achieving our targets under the eight focus areas, as defined in our 2025 sustainability framework built upon four pillars, namely, accessible medicines, employee health and safety, responsible procurement practices and lastly water and energy. Through sustainable business practices and continued support to state and central government initiatives towards attainment of the 17 goals, we abide by our commitment to contribute and achieve the United Nations' Sustainable Development Goals (UNSDGs), focused on improving the wellbeing of the environment and people. Our strategy section elaborates our progress in our quest for survival towards achieving our 2025 goals.

We are moving forward with enhanced vigor to achieve our business objectives. The continued trust and support of our stakeholders, on our endeavor to create a sustainable society is highly appreciated. With this, I present to you Biological E's Sustainability Report and welcome you to be an active part of our sustainable business journey.

Best Regards,

Narender Mantena

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# 2.3 From the desk of CHIEF OPERATING OFFICER – VACCINE BUSINESS



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BE has historically developed and manufactured generic vaccines for emerging markets. As we continue to evolve, BE has transitioned from being a generic vaccine manufacturer to a novel vaccine developer.

#### Dear Stakeholders.

Living up to the aspirations of our stakeholders, we at Biological E constantly strive to produce and market a range of pediatric and adult vaccines, a broad range of pharmaceutical formulations and ensure a sustainable quality supply, in the Indian and global markets. In alignment with our mission, we collaborate and invest in research and development for discovering, developing and delivering breakthrough medicines for patients with unmet medical needs. Our employees play a vital role to support us wholeheartedly to manage our environmental footprint for a healthy planet. This report gives the insights into the various facets that helps Biological E achieve sustainable business operations.

We are committed to make a meaningful difference in the world of vaccines by making it accessible and affordable. BE has historically developed and manufactured generic vaccines for emerging markets. As we continue to evolve, BE has transitioned from being a generic vaccine manufacturer to a novel vaccine developer. We entered into an exclusive license agreement with the National Cancer Institute (NCI), part of the National Institutes of Health, in the United States for BK and JC Polyomavirus Vaccines, which augmented our development pipeline of novel vaccines.

Recognized as a global vaccine company, we have signed exclusive license agreements with technology transfer from renowned organizations globally, for further evaluation and development with clinical trials. The COVID-19 pandemic in 2020 demanded on a war footing, a vaccine solution to stop the rising fatalities and address the unprecedented health emergency. BE has initiated a Phase I/II clinical trial of its COVID-19 subunit vaccine candidate in India following approval from the Drugs Controller General of India (DGCI). We have eight WHO pre-qualified vaccines and are constantly undergoing WHO approval processes for new products in our R&D pipeline.

Our emphasis on investment in technologies adoption and infrastructure upgrades for Research and Development has reaped immense benefits. We embrace our responsibility to address health care needs around the world. We work tirelessly to deliver truly innovative and life-changing therapies. Our dedicated and highly qualified R&D team, in collaboration with global leaders, has helped us to develop new products for clinical trials and build a strong pipeline of globally accepted products.

We take special efforts to ensure the reach of vaccines meet the increasing demands from communities, especially in the low- and middle-income groups in developing countries. We as a responsible organization are committed to developing products that meets global demand and provide them at prices that enhance access to healthcare. We collaborate with healthcare professionals, governments and other corporates to improve technologies. We have global market presence in diversified geographies.

We confirm making steady progress in achieving our goals set for our 2025 Sustainability Framework. Our commitment to environmental and social responsibility is highlighted in this report. Our principle to hire the best talent and equip them to continuously grow with relevant trainings, helps deliver their full potential; contributing to innovation and development. We believe in maintaining a culture of strong values, ethics and integrity in every facet of our work. This has helped us to achieve our business and strategic objectives and reach out to the needy. My sincere thanks to all our stakeholders for your continued support.

Best Regards,

Lakshminarayana Neti

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# 2.4 Message from CHIEF OPERATING OFFICER PHARMACEUTICAL BUSINESS



#### Dear Colleagues

The year 2020, put the world to test and the pharma sector emerged as a critical sector during the pandemic. I thank each one of you, to help us brave the situation and keep our promise of ensuring accessible and affordable medicines for all.

We, at Biological E recognize the necessity to integrate sustainable practices with core business activities to identify opportunities that meet the critical needs relating to economic, environmental and social aspects. Through this sustainability report, we showcase and transparently report on our performance against all material topics, to all our stakeholders. We have tried to integrate all data pertaining to pharmaceutical business to the maximum extent possible. This is one among the many initiatives to produce a standard report across all our businesses and geographies.

To achieve our vision, by 2025, necessitates us to stay abreast of market trends, thus encouraging us to stay competitive and ahead in our quest for excellence. Changing and challenging spectrum of regulations impact production, registration of medicines and pricing. This hasn't deterred us from expanding our product portfolio and venturing into new markets, especially in the low- and middle-income countries. We are, as always, focused towards developing new products which are accessible to everyone. With the COVID-19 pandemic, our R&D capabilities and commitment to achieve, was put to test. Our strategic R&D collaborative effort with both national and international institutions / medical centers / companies makes life better and has a lasting impact on human health.

The untiring and zealous efforts of our plant employees and corporate team helped Biological E in achieving the timely delivery of our first commercial consignment of Daptomycin injection exported to the United States on September 4, 2019. During the reporting period we also received an Abbreviated New Drug Application (ANDA) approval from the U.S. Food and Drug Administration (USFDA) for Fosaprepitant, Daptomycin and Neostigmine Methylsulfate Injections. This is a major boost for market penetration of our pharma products globally. This also aligns with BE's commitment to contribute towards UNSDGs on good health and well-being. We, as a responsible organization have committed short and long-term targets across eight focus areas within the four fundamental pillars of our 2025 sustainability framework. Our commitment towards incorporating sustainability is visible through this report, based on our performance. Moreover, this report, covering all our Indian operational facilities, is indicative of our determination towards ensuring business sustainability, which as a practice is ingrained in all our activities and is intricately entwined into all our business functions

We aim to work towards strengthening the organization as responsible, transparent and responsive to its stakeholder's requirements. Our strong commitment to sustainability will ensure our international competitiveness and promote a comprehensive sustainable growth. We will continue to deliver reliable and approved products, by expanding our product portfolio through acquisitions, partnerships and innovation. I would like to this take this opportunity to thank all our stakeholders for their belief in the brand - Biological E.

Best Regards,

B.M. elsela

Madhu E

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More than
6 years
of reportable injury free
operations across the
organization

Energy savings of 2,45,996 kWh in FY 19-20 and 3,22,637 kWh in FY 20-21

Reduction in specific energy consumption cumulating to a savings of INR 3.8 Million

100% Water Recycled at Gaganpahad, Dehradun and Azamabad facility More than
600 Saplings
planted across
all facilities

Cumulative environmental expenditure on INR 37.87 million

Saving of
INR 35 Million
achieved by implementing
Kaizen projects

Cost reduction of INR 20 Million by implementing 'Focused Improvement Projects'

Majority of our procurement requirements are sourced locally.

90% of our suppliers are indigenous







# ABOUT BIOLOGICAL E

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  - 4.1.2 Our vision & mission
  - 4.1.3 Our growth story
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#### 4.1 Biological E

#### **4.1.1 WHO WE ARE**

Since inception in 1953 as Biological Products Private Limited, the company in the first decade manufactured, generic biological products, such as heparin injections, an anticoagulant that prevents blood clots, for the Indian market. In 1963, the company entered an equity partnership with Evans Medical, a UK based pharmaceutical and vaccine manufacturer and the company changed its name to Biological Evans Limited, later transitioning into Biological E. Limited², a public limited company, which is headquartered in Hyderabad, Telangana³.

Being a pioneer in the Indian vaccine industry, we continuously strive to expand our offerings. Our vigor to surmount higher peaks has enabled us to innovate and expand. We are also the 'first private sector biological products company' in India. Our core values and quality customer centric policies are the foundation for our

investments in systems and infrastructure. Our vaccine division, being among the largest vaccine manufacturers in emerging markets, contributes to about 60 percent of our revenue. Our products are sold through B2B marketing in India, while a combination of B2B and B2C approach is adopted for the international market. We have been instrumental in providing pharmaceuticals and vaccines to the Indian Defense Forces, National and International Government agencies along with direct exports. With our upcoming COVID subunit vaccine, we look forward to further enhance upon our market presence.

Through our presence in the preventive medicines sector, we contribute to access of high-quality innovative products through our international divisions. Thus, catering to the health and wellbeing of people worldwide.





#### 4.1.2 OUR VISION & MISSION



Late Dr. Vijay Kumar Datla, the force behind the organization's thrust, strongly believed in individual learning and development at Biological E. Limited. We are committed to improve the quality of human life by ensuring equitable accessibility of our products to all.<sup>4</sup>

## **VISION**



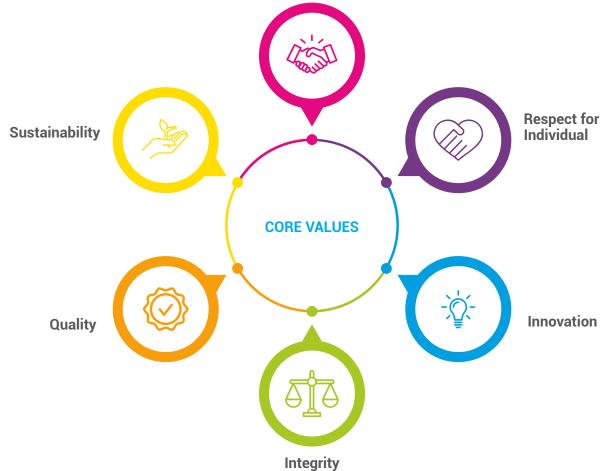
By 2025, become the largest Indian vaccines company and be among the top few Indian companies in complex generics & specialty pharmaceuticals.

## **MISSION**



Improve health & survival of people by providing equitable access to quality vaccines & pharmaceutical products.

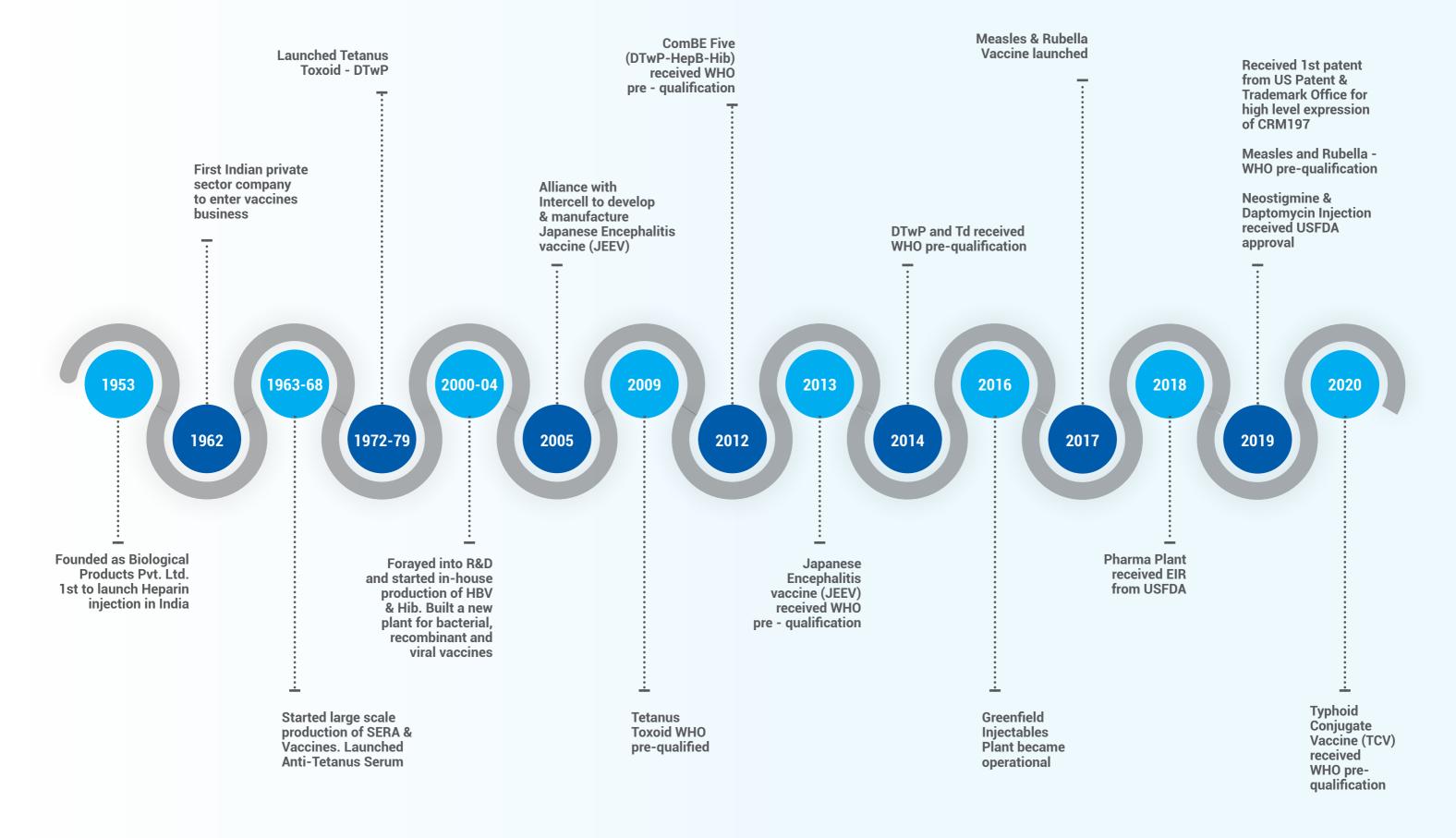
# Collaboration



<sup>4102-16</sup> Values, principles, standards and norms of behavior



#### 4.1.3 OUR GROWTH STORY



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# 4.2 Our global footprint<sup>5</sup> San Francisco Hyderabad Along with our operations in India, Singapore and San Francisco, we export APIs, Finished Formulations and Biologics to over 130 countries.



Offices



Countries where our products are exported

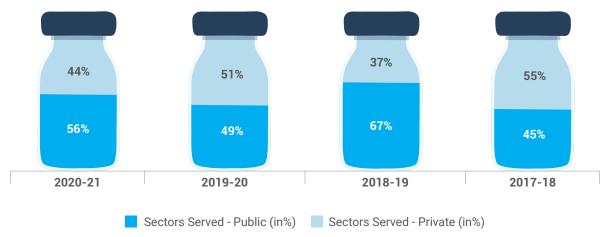
Countries we operate	India, Singapore and San Francisco
Head Office	Hyderabad - Azamabad
Corporate Office	Hyderabad - Jubilee Hills
Vaccine Division	Hyderabad - Shameerpet, Azamabad and Gaganpahad
Pharma Division	Hyderabad - Patancheru, Shameerpet and Azamabad; and Uttarakhand- Dehradun
R&D Units	Hyderabad - Shameerpet Pilot & RD - Vaccine MN Park Pharma R&D – IKP
Marketing and Sales Office	Hyderabad, Delhi and Singapore

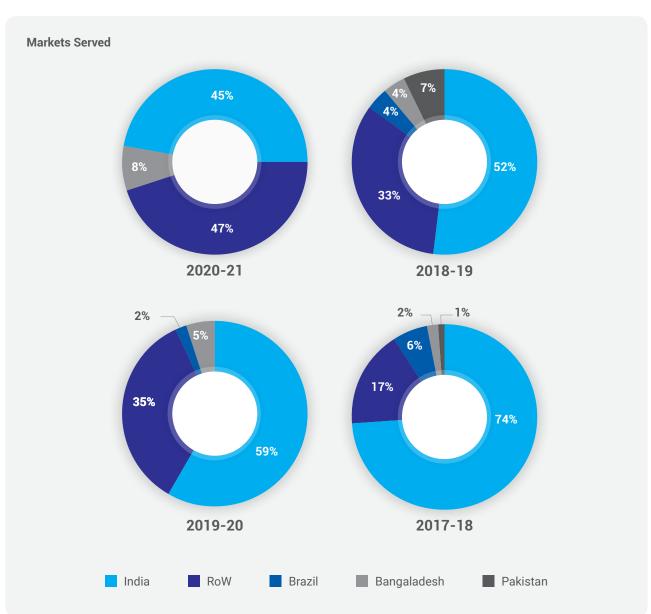
#### Scale of our organization<sup>6</sup>

Parameters	2020-21	2019-20	2018-19	2017-18
Net Sales (in Lakhs INR)	1,22,761.1	92,117.81	93,434.05	81,014.93
Equity (in Lakhs INR)	1,72,807.59	1,56,588.47	1,46,678.25	1,38,832.66
Debt (in Lakhs INR)	86,756.72	81,463.89	26,609.74	59,888.59
Contribution of sales in India (%)	45%	59%	52%	72%
Total Quantity of Products Sold - Vaccine (in MDS)	316.52	284.00	305.00	325.00
Total Quantity of Products Sold - Pharma (in Crores)	17.96	15.18	17.27	12.87
Total Production - Vaccine (in MDS)	452.67	372.46	483.00	452.00
Total Production - Pharma (in Crores)	15.25	12.92	14.47	12.54

### 4.3 Our market presence<sup>7</sup>

#### **Indian Market Presence**





#### 4.4 Accolades

#### The following is a snapshot of our accolades:



4-Star rating for Gaganpahad Facility - CII EHS Excellence Awards 2020



First Prize in CII EHS Excellence Awards 2019



**Appreciation award** in CII Kaizen competitions 2020



Won British Safety Council Award 2020



Ranked 7th among Top 20 Biopharma Companies in India, by the BioSpectrum's Industry Survey in 20208



Ranked 9th among
Top 20 Biotech Companies
in India, by the
BioSpectrum's Industry
Survey in 2019



Web Communication:
Online Campaign
International
Women's Day - ABCI
(Association of Business
Communicators of India)
Awards

Corporate Intranet:
Biological E. Employee
Portal (BEEP) – ABCI
(Association of Business
Communicators of India)
Awards



International Recognition

- "Certified Women'e
Business Enterprise"
by "WeConnect
International"

# 4.5 Memberships and Associations

We have a representation across business and industrial associations. Through our memberships<sup>9</sup>, we are moving along with the industry trends and best practices, thus, contributing to influence public policy. This also helps us gain an all-inclusive understanding of our stakeholders' expectations and provides us with an opportunity to share our experiences, capabilities and resources with industry

bodies, academia and other relevant organizations. Participation in different forums help us collaborate with other organizations on issues that affect our industry<sup>10</sup>. Cumulative and collaborative efforts gain all the more prominence in the current context. We strive to leverage our collaborations to augment our in-house capacity, which then enabled us in developing COVID vaccines to combat the pandemic. Our sustainability targets are in alignment with UNSDGs.





#### 4.6 Precautionary approach

As a precautionary measure, the business risks and opportunities are continually assessed by our Board level committees and functional heads through specified risk management procedures<sup>11</sup>. We address our product, environment and safety risks with the established international standards such as ISO 14001, ISO 45001 and ISO 50001, at some of our production facilities. Ensuring the integrity of our business architecture is essential, due to the nature of our business. We have established an IT security management system to address cyber security related risks12. Trainings provided on cyber security aspects is one among the ways that we sensitize our workforce in this regard. With the pandemic induced lockdowns, cyber security is one of the paramount importance for us to ensure near to normal operations. It was due to our precautionary approach and agile planning, that we could devise an effective business continuity plan, during COVID-19 imposed lockdowns and maintain all our manufacturing units completely functional. Furthermore, our strategic planning for development of our vaccine through key business collaborations along with enhancement of manufacturing capacity in India, is indicative of our resilience.

#### 4.7 Our Governance model

#### 4.7.1 CORPORATE GOVERNANCE<sup>13</sup>

Our robust governance architecture lays emphasis on professional business conduct with accountability, transparency and fairness in all transactions. It implements the quidelines and defines the roles and responsibilities of

each member in the Board or committees formed with a view to safeguard the best interests of our stakeholders. Our governance committee develops strategy to meet corporate goals. It is our persistent effort to adopt the best corporate governance practices, keeping in view the international codes of corporate governance and practices of global companies.

Our Board of Directors, comprising of highly qualified professionals, provide the required guidance and direction to govern our business operations. With the wealth of knowledge, they bring to the board, in addition to their wide-ranging expertise and skills, we have developed a strong foundation of corporate governance. Insights and approval on our material topics are provided by our MD led BoD. All our sustainability initiatives are formulated taking cognizance from the guidance of our BoD. The collaboration of all prime resources with our operational excellence team is key to the success of all initiatives. The overall performance is periodically reviewed by our BoD. The senior management ensures the execution of strategy, leadership development, innovation, encouragement, reward allocation, talent retention, etc. The senior management has been provided with functional freedom to operate and while being accountable for their individual function's operational targets<sup>14</sup>.

The senior management submits the performance reports on a regular basis to the Board through the Managing Director. This report along with company's governance policies, risk and compliance framework and business plans, is reviewed by the Board and all the functional heads to identify underlying risks and opportunities. During the reporting period, our Board consisted of three members 15.

Names	Designation	Tenure	Gender	Age
Mahima Datla	Managing Director	5 years	Female	44
Ippagunta Yasodhara Rama Krishna Rao	Director	5 years	Male	66
Rudaraju Anand Kumar	Whole time Director	5 years	Male	67
Mahipal Reddy Saddi	Company Secretary	5 years	Male	57

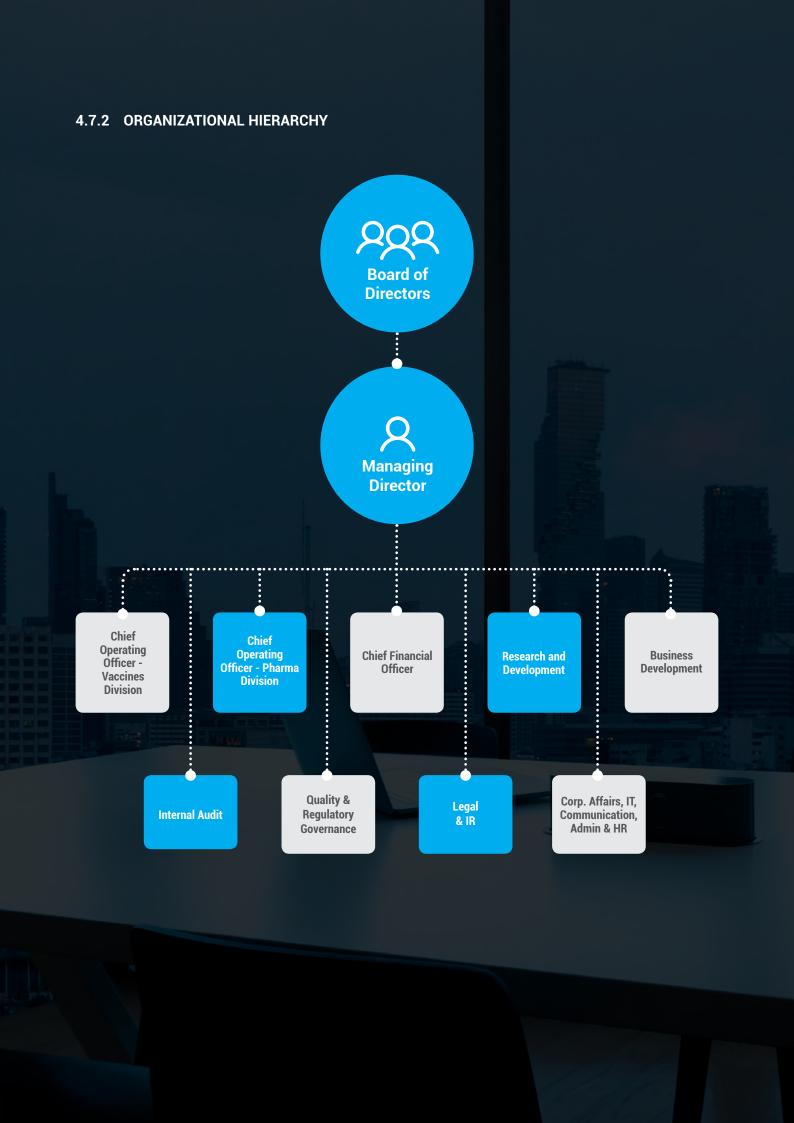
<sup>&</sup>lt;sup>11</sup> 102-11 Precautionary Principle or approach

<sup>&</sup>lt;sup>12</sup> 103-2 The management approach and its component, 103-3 Evaluation of the management approach

<sup>&</sup>lt;sup>13</sup> 102-18 Governance structure

<sup>&</sup>lt;sup>14</sup> 102-19 Delegating authority

<sup>&</sup>lt;sup>15</sup> 102-22 Composition of the highest governance body and its committees, 405-1 Diversity of governance bodies and employees



Below are the various board committees and their functions.



#### **SCIENTIFIC ADVISORY BOARD (SAB)**

Distinguished academic and industry researchers constitute our Scientific Advisory Board (SAB). They internally appraise all our Research and Development activities.



#### **INSTITUTIONAL BIOSAFETY COMMITTEE (IBSC)**

This statutory committee operates from the premises of the institution. The committee includes the Head of the Institution, Scientists engaged in DNA work, a medical expert and a nominee of the Department of Biotechnology.



#### **INTEGRATED BUSINESS REVIEW COMMITTEE (IBR)**

The IBR Committee is responsible for organizing quarterly performance review of various functions of the management. This review team discusses the quarterly progress of the different annual goals.



#### **INSTITUTIONAL ANIMAL ETHICS COMMITTEE (IAEC)**

The IAEC has been constituted under the provisions of Prevention of Cruelty to Animals Act, 1960 and Breeding of and Experiments on Animals (Control & Supervision) Rules of 1998, 2001 and 2006. The committee comprises of a group of distinguished persons, for the purpose of control and supervision of experiments on animals, performed in the organization.



#### **AUDIT COMMITTEE**

The Chairman of the Committee is an Independent Director. The committee is responsible for risk identification, strengthening the internal process to review and monitor business risk, establishment of stringent internal controls, accounting, financial reporting, internal and external audit mechanisms and compliance of the company.



#### **MANAGEMENT REVIEW BOARD**

The Management Review board is chaired by the Managing Director and mainly focuses on discussing the quality related reports with heads of all department.

#### 4.7.3 RISK MANAGEMENT

Our Risk Management Framework enables us to identify the potential risks across our operations, thus ensuring business stability. The expertise of our risk team aid in analyzing our risk profile and maintains the risk management framework. The team identifies, monitors and controls the risks as per the levels defined by the risk management process. The risk team appraises the Board

and senior management with report on the principal risks that can impact our ability to achieve our strategic objectives. Our audit team, through its committees for the system of risk management and internal controls, provides an independent assurance to the Board. In line with this, in the current context, the organization adopted a collaborative approach to mitigate the risks posed by the pandemic, thus ensuring business sustainability.

Following are the sectoral risks<sup>16</sup> that we are trying to address through our business strategies with help of various internal functions.

Key Risks	Description
	Strategic Risk
Business continuity	The COVID-19 pandemic globally impacted all businesses and brought about a new risk to be addressed towards business continuity. During the pandemic, our business continuity has been imperative to ensure access to medicine for all patients and sustain the R&D efforts to combat the fight against COVID-19.
Keeping pace with technological advancements	The fast pace of advancements in technology necessitates continuous investments on R&D infrastructure. We have given due importance to maintaining the competitive edge. By addressing this risk, we foresee an enhanced product line and associated revenue growth.
	Reputational Risk
Counterfeit Drugs	Increased availability of counterfeit drugs is a deterrent to both company's reputation and human health. Counterfeit drugs pose greater risk of litigation because of side effects to consumers. This risk to be addressed to prove the genuinity of products with suitable measures and relevant approvals from authorities.
Product quality	Non-compliance with good manufacturing practices at any stage of product development and manufacturing could compromise its quality. This could be potentially fatal to human health, on consumption, which would in-turn have reputation, regulatory, legal and financial consequences.  We comply with all requirements of USFDA to ensure manufacture of safe, effective and high-quality drugs. We also maintain documented information on key aspects such as clinical trials, pharmacokinetics, etc. which are required for approval.  Our Clinical and Regulatory Affairs department engages in conducting Phase II to Phase IV clinical research programs for international markets, in compliance with ICH-Good Clinical Practice (GCP) guidelines. With latest cGMP compliance and WHO prequalified vaccine facility, we have been able to expand our international presence in almost all countries globally



Key Risks	Description
	Compliance Risk
Evolving regulatory environment	To meet the growing stakeholder expectations and evolving regulatory environment, compliance to operational processes is mandatory. To avoid failure which has time and cost implications, strict control on development, manufacturing, testing, approval, distribution and marketing of products is necessary.
Compliance requirements of new markets	With expansion of operations into global markets, the regulatory compliances of each country are mandatory. As these vary with country, non-compliance will have a huge impact due to associated high costs of sales and marketing litigations.
IP rights	With heavy investments in R&D and continuously evolving product line, it is imperative to ensure Intellectual Property Rights.  We ensure compliance with all IP regulations thus preventing any financial repercussions. This would also secure our brand reputation and sustain business success. We have taken-up patents and requisite WHO approvals for our products.
	Operational Risk
Supply Chain Dissonance	Although we predominantly source from local suppliers, the pandemic has hampered our production.
Cyber security	Increased reliance on digital platforms due to the pandemic has increased concerns around information security. A failure of information technology infrastructure through malicious attacks / hacking could lead to business disruption and severe financial loss.
Data privacy	For maintaining business confidentiality, data privacy is of prime importance. With the onset of the pandemic, increased reliance on digital platform for data access / remote working has increased the risk of data privacy laws. This could potentially affect the business operations and thus lead to serious financial loss.
Employee safety, health and environment risk	Non-compliance to the integrated health and safety management system could adversely affect the company's financial results and reputation. The restorative cost for the environment and communities that we operate, could be significant. The pandemic has necessitated adoption of stringent employee health procedures to successfully operate in the highly infectious COVID-19 environment.
	Financial Risk
Product pricing	A dynamic pricing strategy to be followed to achieve improved margins. Market intelligence on pricing in various geographies is crucial to achieve revenue maximization.



#### 4.7.4 SUSTAINABILITY GOVERNANCE

Implementation of a robust sustainability governance system is key to demonstrate our economic, environment and social performance to our stakeholders. Sustainable practices with early identification of risks and opportunities forms the basis to enhance our performance across the triple bottom line. The 'Safety, Health and Environment (SHE) and Sustainability committee' is entrusted with the specific task to aid our sustainability governance.

#### SHE and Sustainability Committee<sup>17</sup>

At Biological E, sustainability is an integral part of our management structure under the Safety, Health and Environment (SHE) committee. The SHE committee is headed by the COO and the department heads as its core members. The committee reviews the overall sustainability performance of the organization and the related management system practices. The committee also ensures compliance to regulatory requirements alongside the sustainability goals and SHE objectives.

The function of the SHE committee apart from its usual functional role, also includes:

- Developing an all-inclusive approach and providing direction to handle safety, health, environmental and sustainability matters
- Reviewing the policies, processes and systems periodically and recommend measures for improvement from time to time.
- Overseeing the implementation of SHE related guidelines/policies

#### 4.7.5 BUSINESS ETHICS

Ethical business practices in compliance to the applicable national laws and regulations are core to any good governance system.

We acknowledge that our employee conduct has a direct bearing on the relationship with our business partners. Our "Code of Conduct and Ethics" provides the guidelines for employee conduct. Regular awareness sessions are provided to our directors and employees on key aspects such as organizational culture, vendor relationships, gender-neutral workplace, legal compliance, health & safety, avoidance of conflict of interest, transparency in all

<sup>17 102-20</sup> Executive-level responsibility for economic, environmental and social topics



their actions, protection of confidential information, etc. thus ensuring ethical decision making.

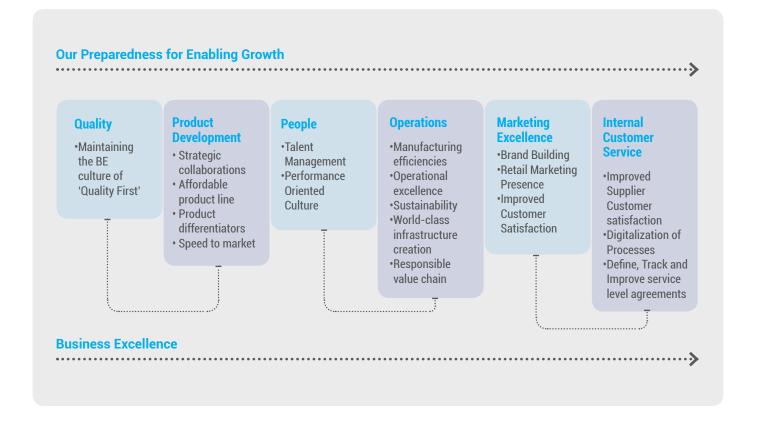
The Mission, Vision and the Values of the company get imbibed from senior management to every employee of BE. This has a strong bearing, even in their goal setting exercise. In addition to regular awareness training sessions, the workforce is also kept constantly abreast on these aspects, through mailers, posters and other modes of communications from the senior management. This is to ensure that all employees are constantly reminded of responsible working practices. All employees are encouraged to notify corrupt practices observed, if any. The company has a defined process to take appropriate actions on these, after appropriate investigation and collection of validated evidence.

#### 4.8 Our strategy

Biological E's journey to become the largest Indian vaccine manufacturing company and be among the top few Indian companies in complex generics & specialty pharmaceuticals - envisions to sustain global leadership position in chosen areas of business and to constantly create new opportunities

for growth. Our strategy is to position the company as an integrated global life sciences organization, with a commitment to building a sustainable society. Our specialty injectable business vertical, along with our pharma and vaccine division, is of strategic importance through which we would be delivering products of high efficacy. We intend to enhance our in-house capabilities and our product portfolio, through strategic collaborations. Key acquisitions and investments in state-of-the-art technologies have been essential ingredients in enhancement of our production capabilities. We lookforward to successfully delivering our indigenous COVID-19 vaccine, thus bolstering our value proposition. We are focused on creating a business model that offers products which are affordable and accessible to all.

At Biological E, sustainability is an integral part of strategic management and corporate planning. The economic, environmental and social aspects are given due regard while defining innovative strategies for the company's growth, further resulting in improved revenues. The Company's growth strategies are implemented at three levels - through mergers and acquisitions at the organizational level, various operational excellence initiatives at the site level and safety, health and human resource development at the individual level.



We embrace global best practices in all our processes by adopting leading technological interventions, operational efficiency measures, safe operational initiatives and business ethics. We have strategized to drive our current business through our existing know-how while investing in future collaborations and endeavors. Our conscious

efforts towards responsible investments in upcoming business prospects ensure inclusive growth and development of our business. We are working towards achieving our 2025 Sustainability Framework built across four strategic pillars, which are integrated into our overall business approach.

#### Responsible Procurement Implement 3Ps (People, Planet and Profit) practice across the value chain



# Accessible Medicines Innovations around Low-cost Medicines which are accessible to everyone

# Employee Health and Safety Cultivate a strong culture of Health and Safety to all employees, being Employer of Choice and Develop and Implement Policies

#### Water and Energy Efficient use to minimize Water Footprint; Focus on use of Non-fossil Fuels





#### **Progress on Sustainability Goals**

Linking Sustainability Strategy	Focus Areas	Short Term Goals (FY 2019-2020)	Long Term Goals (FY 2020-2022)	2019-21 Progress Report
Accessible Medicines	Investment Invest for developing new facilities and new products	Invest 300 Cr in vaccine business	Invest 1000 Cr in vaccine business for developing new facilities	Invested around INR 1,000 Crores in vaccine business for developing new facilities.
\\$;	Operational Excellence Implementation of Operational Excellence in all manufacturing facilities	Implement operational excellence in vaccine business	Implement operational excellence in all business divisions	Operational Excellence implemented in Shameerpet Vaccines, SEZ, Gaganpahad and Azamabad facilities. Details are mentioned in section 8.1.1
Water	Water Management Conduct water audits and water balance assessment	Complete water audits and water balance assessment in vaccine business	Complete water audits and water balance assessment in all business divisions	Water audits completed for Gaganpahad and Shameerpet Vaccines.
Employee Health and Safety	Management Systems Implementation of ISO14001 and OHSAS 18001/ISO 45001	Implement both ISO14001 and ISO 45001 in vaccine business	Implement both ISO14001 and ISO 45001 in all business divisions	ISO 14001 and ISO 45001 are implemented in Shameerpet Vaccines, SEZ and Gaganpahad facilities
	Zero Accidents Continue to focus on Zero Accidents through establishing a comprehensive incident reporting system	Implement in vaccine business	Implement in all business divisions	Implemented and been ensured
	Policy Implementation Develop and implement relevant policies on EHS, biodiversity, human rights and non-discrimination	To develop and implement or with respect to EHS, human in non-discrimination by 2022	Policy has been developed and implemented which specified about EHS, biodiversity.	
	Employer of Choice Become the employer of choice in the pharmaceutical sector	Implement the BE connect concept (Inspire, Ignite and Involve) at Shameerpet facility	Implement the concept of BE connect. To be among the top 5 in the healthcare sector by 2020	BE Connect concept implemented
Responsible Procurement	Develop Code of Conduct and Implement 3Ps Practice Develop a supplier Code of Conduct and assess all critical and major suppliers based on environment, health & safety and social practices	Develop and implement Code of Conduct for suppliers	By 2022 commence on-site audits at critical and major supplier facilities based on environment, health & safety and social (EHSS) practices	On-site audits initiated. These audits cover the compliance of EHS practices by the vendor
Energy ©	Energy Management Implement ISO 50001	Implement ISO 50001 in vaccine business	Implement ISO 50001 in all business divisions	Implemented ISO 50001 at Shameerpet vaccine division and Gaganpahad division Energy Audit done for Shameerpet Vaccines, SEZ, Gaganpahad, Azamabad sites in Oct 2020 - Action items are under implementation



#### 4.9 Our business model

#### Inputs

#### **Human Capital**

Emphasis on continuous L&D to drive a performance-oriented culture across our talent pool.

No. of employees - 4954

Male to Female ratio of employees-10:1 GMP training imparted in man hours - 23001

#### **Natural Capital**

Optimize resource consumption. minimize water footprint and incorporate non fossil fuel sources.

Investment on energy and water saving initiatives - INR 3.8 million Total water consumption - 859ML

Total energy consumption - 37,56,37,200.95 GJ

#### **Financial Capital**

Enhance stakeholder value through market proliferation and optimized utilization of financial resource (FY 20-21) in INR lakhs Economic Value Generated -1,41,807.60 Operating costs -17.993.00 Employee wage and Benefits -29,383.40 Economic Value Retained -16,973.20

#### **Intellectual Capital**

R&D Workforce - 387 R&D Investment - INR 45.598 Lakhs

#### **Manufacturing Capital**

World class infrastructure Manufacturing facilities – (Only in India) Gaganpahad, Shameerpet Pharma, Shameerpet Vaccine, Shameerpet SEZ, Patancheru, Azamabad, Dehrarun

#### Social & Relationship Capital

**During the reporting year** 

No. of local suppliers - 3365 Spend on local suppliers - INR 14092 million Spend on CSR activities - INR 12 million

#### **Process**



Largest Indian Vaccines Company

#### **Product Portfolio**

#### **Product Pipeline**

#### **Biologics – Our vaccine pipeline includes:**

- COVID 19
- Hep A
- Hexavalent (DTwP-HepB-Hib- IPV)
- Human Papilloma Virus (HPV)
- Inactivated Polio Vaccine (IPV)
- · Measles and Rubella (MR) Meningococcal Conjugate
- Vaccine (MCV)
- Mumps
- Novel Oral Polio Vaccine type 2 (nOPV)
- Pneumococcal conjugate Vaccine (PCV)
- Polyoma
- Respiratory Syncytial virus (RSV)
- TdaP
- Typhoid Conjugate Vaccine (TCV)
- Varicella
- Yellow Fever

#### **Outputs**

#### **Human Capital**

Provided performance development reviews for all employees LTI (Reporting year) - 0

#### Outcomes

#### **Human Capital**

Vibrant and skilled talent pool Safe working environment Become the employer of choice

#### **Natural Capital**

Amount of water recycled -77% and 49% of discharge during FY 19-20 and FY 20-21 Energy saved (INR) - 16,97,373 and 22,26,196 in FY 2019-20 and FY 2020-21 More than 30% green belt has been maintained

#### **Natural Capital**

Promote use of renewable energy; Optimize water consumption

#### **Financial Capital**

EBDITA - (FY19-20) 1,600 lakhs; (FY 20-21) 12,146 lakhs PAT - (FY 19-20) 10,085 lakhs; (FY 20-21) 16,973 lakhs Enhanced ROCE - (FY19-20) 7.76%: (FY20-21) 11.58%

#### **Financial Capital**

Sustained cash flows

**Intellectual Capital** 

#### **WHO Pregualified Vaccines**

- DTwP-HepB-Hib (Liquid) Pentavalent Vaccine (ComBEFive)
- · DTwP-HepB-Hib (Lyophilized) Pentavalent Vaccine
- Typhoid Conjugate Vaccine (TYPHIBEV)
- Measles & Rubella (MRBEV)
- Japanese Encephalitis (JEEV)
- Tetanus Toxoid (BETT)
- Tetanus low dose diphtheria (BETd)
- DTwP (TRIPVAC)

Note: Explore more under 8.1.2 Product Portfolio

#### **Intellectual Capital**

No of patents filled - 38 No of patents granted - 23 No. of US ANDA filed - 6 No of EU MAAs filed - 3 No of EU MAAs filed - 2 WHO prequalified vaccines - 8 Successfully completed phase 1 trial of COVID Vaccine

Driving a culture of innovation with WHO Prequalification for vaccines Significant player to advance development and manufacture of COVID-19 Vaccine

#### **Manufacturing Capital**

**Biologics** Pharmaceutical **APIs** 

#### Manufacturing Capital

**Customer Health and Safety** Speed to Market for products

#### Social & Relationship Capital

New suppliers - 1362 Outreach - over 300 million doses of vaccines for routine immunization to Indian Ministry of Health & Family Welfare 2 billion doses of multiple vaccines to children across the globe

#### Social & Relationship Capital

Improved customer satisfaction Accessible to affordable vaccines and medicines

Sustainability Report 2019-21 Biological E. Limited Global immunization is by far the most effective method to combat the pandemic. This calls for development of high efficacy vaccines that are scalable. On this front, we have collaborated on with three COVID vaccines candidates.

One among the three, the Protein subunit vaccine an in-house developed product in collaboration with Baylor College of Medicine and Dynavax Technologies Corporation. It consists of an antigen developed by the Texas Children's Hospital Center for Vaccine Development and Dynavax Technologies' advanced adjuvant, CpG 1018. The protein antigen, SARS-CoV-2 Spike RBD, adsorbed to the adjuvant Alhydrogel (Alum), is in combination with the approved adjuvant, CpG 1018. The RBD of S1 subunit binds to the Angiotensin Converting Enzyme-2 (ACE2) receptor on host cell membrane. The Baylor College of Medicine was selected to construct "RBD N1C1" as the final vaccine antigen candidate based on its manufacturability, due to the yields of protein antigen achieved, ease of process steps and favorable formulation aspects. Few key advantages of our vaccine include scalability and thermostability, that is suitable for deployment at scale in low-resource settings, thus ensuring access to all. The initial investment from Coalition for Epidemic Preparedness Innovations (CEPI) comes on the heels of investments from the Bill and Melinda Gates Foundation and The Government of India's Biotechnology Industry Research Assistance Council (BIRAC) provided the impetus for accelerated efforts towards a successful and scalable outcome for Global Access by supporting the Phase I/II clinical trials to evaluate safety and immunogenicity and the upcoming Phase III trial.

Second vaccine candidate, collaborated with **Johnson & Johnson** "Ad26.COV2.S" is a single dose vaccine that has demonstrated robust protection against infection with

99

Global immunization is by far the most effective method to combat the pandemic. This calls for development of high efficacy vaccines that are scalable. On this front, we have collaborated on with three COVID vaccines candidates.

SARS-CoV-2 in pre-clinical studies. The technology transfer agreement of Johnson & Johnson, although currently in process validation stage, would enable us to cater to a larger audience, by leveraging our manufacturing capabilities. It's highly coincidental that the foundation stone of the facility chosen for manufacturing the vaccine was laid by Mr. Paul Stoffels, vice chairman of the executive committee and chief scientific officer at Johnson & Johnson.

Third vaccine candidate is in association with **Ohio State Innovation Foundation (OSIF).** The novel live attenuated recombinant measles viruses (rMeVs) vectored vaccine candidate developed against SARS-CoV-2, by Ohio State University College of Veterinary Medicine has been licensed to BE.





COVID-19
VACCINE

Market and rain earners

See Market and rain earners

Se

1

In-House developed in collaboration with

Baylor College of Medicine and Dynavax Technologies Corporation 2

collaborated with

Johnson & Johnson single dose vaccine

3

in association with

Ohio State Innovation Foundation (OSIF)



The French Ambassador to India, His Excellency Mr. Emmanuel Lenain, heading the French delegation, during their visit to our vaccine plant in March 2021, were highly impressed with our manufacturing capabilities and appreciative of the breadth of our operations.





We at BE acknowledge that our vibrant workforce is vital for our business growth. We strive to augment our employee productivity and satisfaction through creation of conducive atmosphere. A collaborative work environment with mutual respect and equal opportunities creates the right framework for optimum work results and a mindset for development. Our core principle "respect for the individual" ensures diversity and inclusion of our workforce, with no discrimination based on gender, race, religion and geographies.

We are an equal employment opportunity provider and expect the same from our business partners. We abide by all the applicable regulations and standards to guard our social performance. We give equal opportunities to our employees to invest themselves in trainings and development as well as represent itself in various committees. Regular training programs and workshops / seminars are conducted towards skill enhancement as well as occupational health and safety to encourage a healthy lifestyle for the workforce.

We are committed to providing a fair and safe work environment to ensure that our employees are not subjected to any form of harassment. Our 'Code of business conduct and ethics'



We are an equal employment opportunity provider and expect the same from our business partners. We abide by all the applicable regulations and standards to guard our social performance.

advocates no personnel shall indulge in sexual harassment whether directly or by implication. No incidence of substantiated discrimination or sexual harassment was reported in the reporting period. Through our grievance redressal mechanism, our employees can apprise their concerns, which are promptly addressed and resolved.

#### **HR** policies



# Employee Referral Policy

Employee Relocation & Related Expense Reimbursement Policy

Medical Examination Immunization of Personnel

Past Employee Re-hire Policy

Recruitment & Selection Policy



# Compensation & Benefits

**Advance Policy** 

Amendment to Leave & Time off Policy

......

**COVID Relief Policy** 

Leave & Time Off

LTA Policy

Employee Rewards & Recognition Policy



Employment Continuance, Retention, Resignation & Relief, Superannuation

**Retirement Policy** 

Notice Period & Relief



Code of Conduct & Workplace Behavior

Prevention of Sexual Harassment



#### 6.1 Our talent pool

The emergence of advanced healthcare systems and pharmaceuticals have enhanced the growth of pharmaceutical industry tremendously over the years. Recruitment of the right workforce, within India and their retention is crucial for achieving the operational growth. Special focus is given to onboard technically competent resources with desired expertise in the field of healthcare. Conducive work environment is provided for ensuring efficient output; while

relevant trainings help enhance skill sets resulting in optimal performance of workforce. We ensure that all employees are treated with dignity and receive fair remuneration with no discrimination of any sort. The compensation to both our permanent and contract employees is above the minimum wage rules stipulated by the state government<sup>19</sup>. Our contract workforce is predominantly deployed in production, packing, engeering, housekeeping and security services. Reduction in contract female employees during the reporting period is attributable to the COVID-19 induced restrictions.

Description	UoM	Permanent Male Employees			
		2020-21	2019-20	2018-19	2017-18
Corporate Office	No	101	91	142	152
Pharma Division	No	809	1,158	745	668
Vaccine Division	No	1,657	1,266	1,236	1,038
Total	No	2,567	2,515	2,123	1,858

Description	UoM	Permanent Female Employees			
	OOW	2020-21	2019-20	2018-19	2017-18
Corporate Office	No	22	21	30	35
Pharma Division	No	91	72	83	78
Vaccine Division	No	116	81	81	174
Total	No	229	174	194	287

Description	UoM	Contract Male Employees			
		2020-21	2019-20	2018-19	2017-18
Corporate Office	No	22	20	0	28
Pharma Division	No	653	477	478	513
Vaccine Division	No	1245	1185	846	593
Total	No	1920	1,682	1,324	1,134

Description	UoM	Contract Female Employees			
		2020-21	2019-20	2018-19	2017-18
Corporate Office	No	3	2	0	6
Pharma Division	No	81	164	126	114
Vaccine Division	No	154	110	309	253
Total	No	238	276	435	373

Description	UoM	Total Employees			
	OOW	2020-21	2019-20	2018-19	2017-18
Corporate Office	No	148	134	172	221
Pharma Division	No	1,634	1,871	1,432	1,373
Vaccine Division	No	3,172	2,642	2,472	2,058
Total	No	4,954	4,647	4,076	3,652

#### **Our Workforce**







#### 6.2 Training and development

Just as hiring the right talent is crucial, nurturing them through extensive induction training followed by on the job, professional trainings are necessary for smooth onboarding of the new recruits. We expect our employees to be up to date with the latest advancements and help them hone their knowledge and skills, which are critical for success of our products. We have an operational excellence team, that is supported by all our functions, in implementation of training and monitoring activities to achieve continual improvement results with respect to productivity, quality, cost, delivery, safety, morale (PQCDSM). This team extensively trains the

workforce to continuously achieve better results and shape their career growth.

Our HR department carries out competence mapping and develops a list of all the necessary trainings for the workforce depending upon their nature of work. Regular trainings are scheduled thereafter, which includes both functional and behavioral trainings. The outcomes of these trainings are discussed with our employees for further improvements. The major focus areas for trainings include, occupational health and safety, skill enhancement and good manufacturing practices (GMP)<sup>20</sup>. The below table on GMP training is inclusive of all facilities, except Patancheru, following the calendar year.

GMP Training	UoM	2020	2019	2018	2017
Permanent Employees	Man hours	15,973.00	9,464.00	8927.50	5,586.20
Contract Employees	Man hours	7,028.00	5,264.00	2,736.00	6,000.00

GMP Training	UoM	2020-21	2019-20	2018-19	2017-18				
Permanent Employees									
Number of trainings attended	No	13,222	1,714	65,528	2,049				
Training Hours	Hrs	13,190 2,758		21,569	7,723				
Contract Employees									
Number of trainings No attended		150	179	1,122	259				
Training Hours	Hrs	301	292	374	202.5				

OHS training data from Gaganpahad, Shameerpet Vaccine, Shameerpet SEZ and Azamabad facilities are populated for the reporting period. We are developing a formal mechanism to track the safety related trainings across all our facilities, to enhance the safe consciousness of our workforce and the ensure zero accidents and incidents. During the reporting period, the average OHS training hours per employee was 1.08 hrs<sup>21</sup>.



#### 6.3 Attracting and retaining talent

To sustain our position as one of the most preferred pharmaceutical company, we ensure to retain our talented workforce and attract the best talents in the industry. Our HR department proactively manages our workforce and brings in new pool of talent every year - a balanced mix of young and experienced individuals. We make significant efforts on equipping our employees with the

necessary skill upgrades required to facilitate their career progression and development to meet the company's business requirement. The annual performance review provided for our employee augments our workforce morale and skill honing. We provide regular trainings and skill-development workshops to keep the workforce abreast with the latest advances in the pharmaceutical industry<sup>22</sup>. Below is the snapshot of our workforce turnover and new joiners. A system is being developed to record the same.

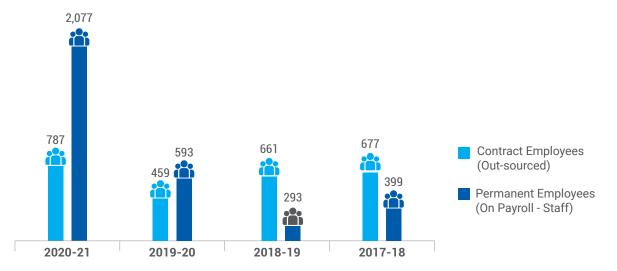
#### **New Joiners**

Employee category	UoM	<30 years	30-50 years	>50 years	Male	Female	2020-21	2019-20	2018-19	2017-18
Permanent Employees (On Payroll - Staff)	No	873	1,138	66	1,936	141	2,077	593	293	399
Contract Employees (Outsourced)	No	500	269	17	576	211	787	459	661	677
Total New Joinees	No	1,373	1407	83	2,512	352	2,864	1,052	954	1,076

#### Workforce Turnover (include cases of retirement, transfer and death)

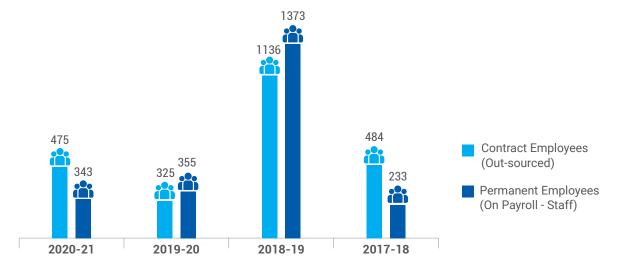
Employee category	UoM	<30 years	30-50 years	>50 years	Male	Female	2020-21	2019-20	2018-19	2017-18
Permanent Employees (On Payroll - Staff)	No	148	181	14	318	25	343	355	1,373	233
Contract Employees (Outsourced)	No	258	192	25	382	93	475	325	1136	484
Total Workforce	No	406	373	39	700	118	818	680	2,509	717

#### **Total New Joinees**





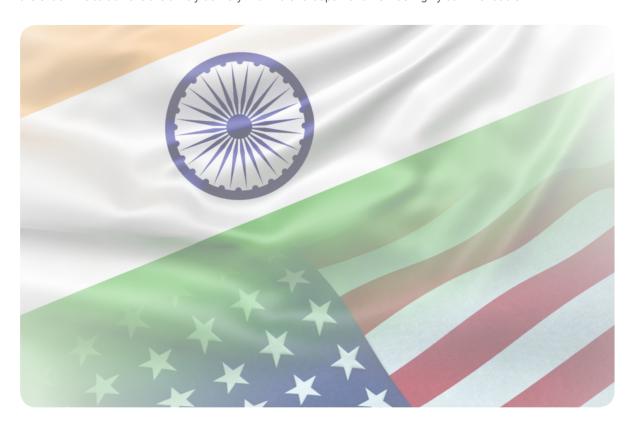
#### **Workforce Turnover**



#### **CASESTUDY**

## **First Commercial Export to US from BE**

Our first commercial consignment of Daptomycin injection was exported to the United States on September 4, 2019. Our COO – Pharma Division, Mr. B Madhu, flagged off the first consignment from the Shameerpet (SMPT) pharmaceutical plant. He put on record, the management's appreciation for the plant employees and the corporate team for the timely completion of the dream project. The relentless commitment and zeal of our workforce for going the extra mile to achieve the timely delivery within a short span of time was highly commendable.



#### **6.3.1 EMPLOYEE BENEFITS**

We ensure that our employees are always satisfied with the work they do and enjoy the benefits of their hard work. Apart from the mandatory benefits, paid leaves and ESI, we offer commutation facilities, regular health check-ups and a full-time occupational health clinic at our premises. These facilities are made available for both the permanent and contractual staff. Whereas, the permanent employees are also eligible for employee provident fund, pension schemes, gratuity, medical reimbursement and leave encashment<sup>23</sup>. The following benefits are provided to our employees: -



<sup>&</sup>lt;sup>23</sup> 401-2 Benefits provided to full-time employees that are not provided to temporary or part-time employees, 403-6 Promotion of worker health



		FY 2020-21						
Sl. No.	SI. No. Benefits Provided	Sum Insured (INR)	Premium Paid (INR)	Employee Coverage	Family Members			
1	Group Term Policy	6,030,619,326.00	15,936,934.00	3349	N.A.			
2	Group Personnel Accident	5,415,500,000.00	767,000.00	3258	N.A.			
3	EDLI	2,144,926,000.00	2,910,665.00	4021	N.A.			
4	COVID-19	260,000,000.00	3,100,000.00	5492	N.A.			
5	GMC 1+3 (2864 Employees and 7245Lives)	717,900,000.00	28,886,400.00	2349	6573			
6	GMC Parental Policy (1009 Lives)	190,000,000.00	13,444,518.00	N.A.	999			
7	Provision for Gratuity	157,044	1,516.00					
8	Provision for PL Encashment	115,275,144.00			<b>L</b> L			

		FY 2019-20						
Sl. No.	Sl. No. Benefits Provided	Sum Insured (INR)	Premium Paid (INR)	Employee Coverage	Family Members			
1	Group Term Policy	10,600,852,505.00	15,783,132.00	3168	N.A.			
2	Group Personnel Accident	598,800,000.00	882,876.00	2902	N.A.			
3	EDLI	1,780,162,000.00	2,078,265.00	2962	N.A.			
4	COVID-19	N.A.	N.A.	N.A.	N.A.			
5	GMC 1+3 (2864 Employees and 7245Lives)	645,600,000.00	34,570,810.00	2427	4114			
6	GMC Parental Policy (1009 Lives)	274,700,000.00	16,073,514.00	N.A.	1162			
7	Provision for Gratuity	49,337	804.00	0.1	70			
8	Provision for PL Encashment	76,950	3170					



The below table is a snapshot of the employees who received performance and career development reviews during the reporting period<sup>24</sup>:

	FY 2019-20										
Employee		N	lo. of Employee	es .	Percentage of Employees						
Sl. No.	Category	Male	Female	Total	Male	Female	Total				
1	Staff & Workmen	669	17	686	98%	2%	100%				
2	Executive	1054	134	1188	89%	11%	100%				
3	Manager	233	19	252	92%	8%	100%				
4	GM & Above	40	1	41	98%	2%	100%				

	FY 2020-21										
Cl. No.	Employee	N	lo. of Employee	es .	Percentage of Employees						
Sl. No.	. Category Ma		Female	Total	Male	Female	Total				
1	Staff & Workmen	734	9	743	99%	1%	100%				
2	Executive	1248	164	1412	88%	12%	100%				
3	Manager	542	70	612	89%	11%	100%				
4	GM & Above	50	1	51	98%	2%	100%				

The below table is a snapshot of the trend in parental leave availed by our employees during the reporting year.<sup>25</sup>

Davamatava	2020-21		2019-20		2018-19		2017-18	
Parameters	Female	Male	Female	Male	Female	Male	Female	Male
Number of employees that were entitled to parental leave	93	1372	82	1221	88	1285	57	717
Number of employees who took parental leave	9	177	9	125	6	108	6	111
Number of employees who returned after their parental leave ended	9	177	9	125	6	108	6	111
Number of employees who took parental leave in previous year	9	125	6	108	6	111	2	80
Total number of employees retained 12 months after returning to work following a period of parental leave	4	64	2	36	4	99	2	63
Return to work rate (%)	5	1%	3	6%	8	8%	79	9%

<sup>&</sup>lt;sup>24</sup> 404-3 Percentage of employees receiving regular performance and career development reviews

<sup>&</sup>lt;sup>25</sup> 401-3 Parental leave



#### 6.4 EMPLOYEE ENGAGEMENT

We give equal opportunities for our talent to invest themselves in training and development as along with representation in various committees. The company is committed to providing a fair and safe work environment to ensure that its employees are not subjected to any form of harassment. We provide a conducive environment for the over-all development of our employee capabilities, by providing developmental feedback, thus ensuring that they stay ahead in their growth curve. This in turn, augments our business performance.

#### **Our aspirations**



#### **CASESTUDY**



# Town Hall Meeting with the Managing Director and Leadership Team

Town Hall Meetings are occasions for the employees to listen to and interact with the top management of BE. These are events where the leadership team, led by the Managing Director, takes the opportunity to provide updates about the Company's Strategy and Long-term Business Plans. The Managing Director also emphasizes upon the goals & objectives along with the ethics & values to be ensured in our business conduct. This is also a great platform for the leadership to seek feedback and respond to queries from employees.

#### **CASESTUDY**

# **Sports Fest at Biological E. Limited**



The sports fest of BE was held on March 2019. It was held in Shameerpet Vaccine Plant across different business units. A mix of indoor and outdoor games such as Cricket, Chess, Table tennis, Caroms, Volleyball, Badminton, throw ball etc. were organized in the presence of umpires/referees.



The opening of the event witnessed spirited Tug of War, followed by Volleyball, Table Tennis and other games in following days. In total BE registered participation of its 1096 employees divided in 261 teams for varied games. The Shameerpet pharma team emerged victorious in the cricket match, while the vaccine team of Shameerpet emerged victorious in Badminton, Carroms, Chess, Table tennis and Volleyball. These enabled the Shameerpet team in securing the trophy. The winners were felicitated in a presentation ceremony on July 12, 2019.



#### 6.4.1 HUMAN RIGHTS

We are a 60+ year old pharmaceutical company, with a great reputation of business ethics. We comply with all the applicable labor laws, minimum wage rules etc. We do not encourage discrimination, child labor, compulsory or forced labor in any of our operations across our supply chain. We have clauses pertaining to labor and industrial laws in our contract agreements with all our partners. During the reporting period there have been no violations with respect to labor laws and human rights in our operations and supply chain. The aspects related to human rights are communicated during the induction trainings and it is also made available in the intranet portal.

within team and interpretation of policies and rules. The company HR ensures the privacy of the complaints and the effective implementation of redressal mechanism. At an organization level, we have a designated three-member grievance redressal committee consisting one from HRD and other two at a level of senior manager/ functional head. Based on evidence obtained, the committee investigates addresses the issue within seven days of submission of the written employee grievance.

The HR is entrusted with maintaining proper documentation, both in soft and hard copy, not limited to, preparation of grievance checklist guidance, grievance redressal committee member details, filing of grievance registers and preparation of grievance redressal report.

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We do not encourage discrimination, child labor, compulsory or forced labor in any of our operations across our supply chain.

# 6.4.3 FREEDOM OF ASSOCIATION AND COLLECTIVE BARGAINING<sup>26</sup>

We have recognized employee union at our Gaganpahad facility and engage with them periodically to understand their work life, welfare, career development and other issues which may require our attention including grievances. We give all the rights to our workmen to follow freedom of association based on the service conditions in the MoU made through collective bargaining and codetermination. 11% of workers are covered by collective bargaining agreements. In case of any significant changes in the policies, procedures and practices, we inform our employee union with priority and they are given a minimum notice period of 2 weeks to update any major changes in the operations or facility set up.

#### 6.4.2 GRIEVANCE REDRESSAL MECHANISM

As an employee friendly organization, we encourage an open approach for communication and foster a dynamic and challenging work environment. We give utmost importance to employee grievance redressal and have an effective process for reporting and addressing employee disputes and complaints. In compliance with the Industrial Dispute Act, 1947, we have a well-developed employee grievance redressal mechanism. This procedure is conveyed to all new employees during their induction and accessible to all employees through the Biological E. Employee Portal "BEEP".

Employees can report their grievances in writing, pertaining to matters such as discrimination based on gender, race, color, region, age, marital status and disability, unfair treatment, working conditions, leave denial, issues

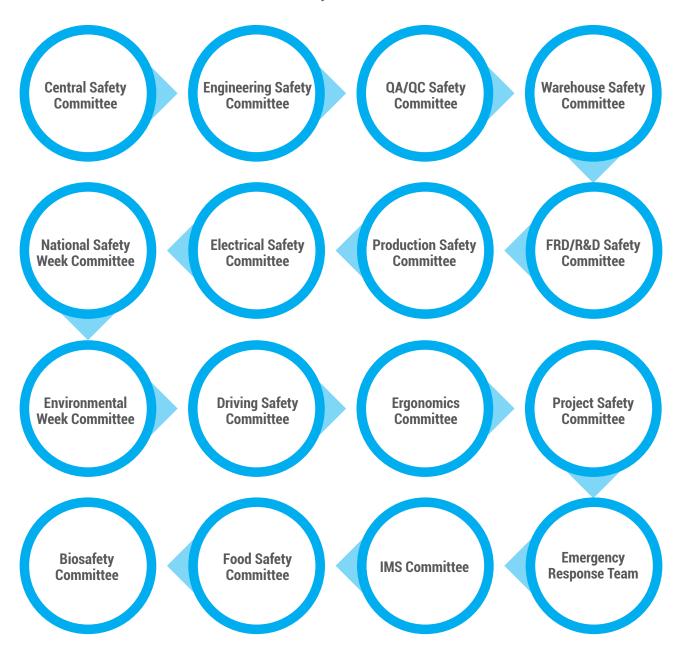


#### 6.5 Employee Health and Safety

Providing a safe workplace for its employees is the key responsibility of any organization. We have developed a robust integrated health and safety management system<sup>27</sup> aligned to the International Standards of ISO 45001. The system is currently being implemented at Gaganpahad, Shameerpet Vaccine and Shameerpet SEZ<sup>28</sup>, primarily covering all employees in these facilities. Our Occupational Health and Safety Policy clearly defines hazard identification, risk assessment and mitigation at the company's premises and ensure a safe, healthy environment for the employees to work safely. Our OH&S policies and practices are strictly reviewed and updated by our Central Safety, Health & Environment (SHE) committee.

The OH&S policy is applicable to all workforce at BE, including the permanent and contract staff<sup>29</sup>. The new recruits are given specific training on our occupational health and safety policy as part of their induction training. All our employees including contract staff and workmen are trained and are required to identify, alleviate and control risks specific to their operation. All the activities carried out as part of our operations are covered in the health and safety management system. Regular safety inspection is carried by authorized team at all our operational sites to monitor, measure and analyze the risk compliance and mitigation strategies employed. Our safety performance and compliances are monitored, measured and analyzed using internally developed dashboards <sup>30</sup>.

#### **Our safety consciousness**



<sup>&</sup>lt;sup>27</sup>403-1 Occupational health and safety management system

<sup>&</sup>lt;sup>28</sup> 403-8 Workers covered by an occupational health and safety management system

<sup>&</sup>lt;sup>29</sup> 403-4 Worker participation, consultation and communication on occupational health and safety

<sup>&</sup>lt;sup>30</sup>403-2 Hazard identification, risk assessment and incident investigation





Our workforces' zeal in nurturing safety culture was evident as we could successfully conduct the celebration, despite the pandemic.

At each operational location of BE, a safety committee is set up, with equal representation from senior management and workers, to periodically review and improve the health and safety performance. These safety committees are entrusted with the responsibility of initial review and mitigation followed by report submitted to the Central Safety, Health and Environment Committee (SHE) for further review and feedback. The report must cover details not limited to the number of incidents occurred with fatalities if any, risks identified, mitigation efforts taken up as per the defined process laid out. The SHE Committee plays a vital role to improve the safety statistics of the company by identifying the OH&S risks and ensures that relevant mitigation processes and procedures are regularly updated31. To nurture the safety culture amongst our employee and staff in commemoration of 'National Safety Day', we organize a weeklong celebration from 4th March to 11th March annually. Among other competitions such as poster making, slogan conceptualization, quiz, elocution, skits, etc. we perform an emergency drill, the details of which are duly recorded. Our workforces' zeal in nurturing safety culture was evident as we could successfully conduct the celebration, despite the pandemic.

We have also provided additional health services for the wellbeing of our employees that includes - conducting health check-up & blood donation camps, pre-employment medical check-up and tie-ups with local hospitals. In the reporting period<sup>32</sup>, we recorded 46 first-aid cases and 11 medical treatment cases along with 2 near miss cases being reported from the facilities that have implemented ISO 45001. We have not received any reportable occupational disease cases in the reporting period . We are in the

process of formal monitoring and reporting mechanism for all other facilities beyond the coverage of ISO 45001. We encourage employees to report near miss and incident cases. We have an Emergency Management Framework<sup>33</sup> that will ensure consistency across safety concepts and strategies adopted at sites and functions through its approach to preparation, response and escalation. The framework will also provide guidance on preventing or mitigating significant negative occupational health and safety impacts that are directly linked to our operations.







<sup>31403-3</sup> Occupational health services

<sup>32403-9</sup> Work-related injuries

<sup>33403-7</sup> Prevention and mitigation of occupational health and safety impacts directly linked by business relationships

# 6.6 Organizational resilience to COVID-19

The sudden outbreak of the COVID-19 pandemic hardly left us any time to respond. Maintaining business continuance was essential for us, to complete development, clinical trials and deploy our COVID subunit vaccine. This necessitated the functioning of all our manufacturing and business operations in tandem with each other. Our systematic planning and factoring of externalities, ensured near to normal operations even during the pandemic-imposed lockdowns and later. An emergency response team was

instituted to define processes, implement strategy, drive action plans and take decisions to address COVID-19 related queries. To ensure safety of our workforce and product quality, we developed and implemented precautionary measures and emergency preparedness for situations pertaining to COVID-19. We continue to comply with all safety measures as per the World Health Organization (WHO) guidelines and those specifically put-forth by the Government of India. We additionally provided insurance coverage for COVID-19 treatment along with incentives for all employees who worked during the lockdown.

#### **COVID-19 action plan**

Percolate adequate communication to the employees to avoid panic and anxiety

Test all primary contacts identified through tracing

Investigate, if the confirmed case is due to negligence

Isolate the primary contacts and provide them adequate support as per safety guidelines



Provide safety advisory to all employees

Communicating key aspects to employee of all shifts, twice a week

Monthly self audit carried out by site specific IMS team along with night vigilance to ensure safety

Forthrightly validation of the ERP 2.0 compliance and release site specific COVID Index

Primary contact tracing upon detecting a positive case Testing and monitoring of employees and contractors.

Screening of all employees and ensure compliance with safety rules



Among the new normal checks such as temperature screening of employees / visitors/ vendor's / contract employees at the gate entrance, providing sanitizers at all common areas, encouraging social distancing while commuting and use of face masks, we replaced our biometric system with facial recognition system for providing access to employees. This ensured reduced transmission of virus through touch. We mandatorily obtained a 'self-health declaration' from all employees, visitors and other business partners at the entry gates of all facilities. We also take ownership in spreading the safety culture by ensuring that all visitors at our facilities comply with our safety protocols.

# Thermal Scanning Please cooperate with security staff for thermal scanning of your body and only proceed if security staff allows

# Keep Social Distancing Please stand in the circles marked only, to ensure safe distance of 1 meter

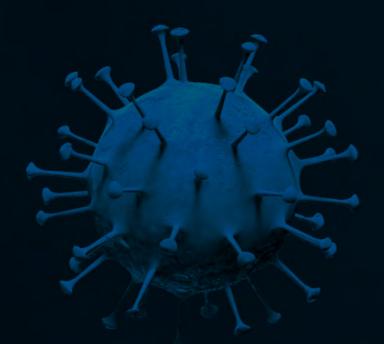


#### **Proper Sanitization**

Please sanitize your hands properly before and after using Kiosk or touching any other object such as washroom gates, equipments, machines etc.

# Ensure Safety First Use Face Mask and gloves to ensure yours and others safety

# Be Responsible Avoid coming to office if your facing cold flu symptoms such as cough, fever etc. and immediately inform to HR department







We are cognizant of the increasing concern of environmental impacts and are committed to reducing our environmental footprint. Water consumption, energy consumption, emissions, effluents and waste cumulatively contribute to our environmental footprint. A responsible management of our environmental footprint is mandatory for the overall interest of the communities we serve. Carrying out periodic review of our processes to identify areas of potential adverse environmental impacts and proactively mitigating them is of paramount importance.

The monitoring process present in all our vaccine and pharma facilities, enables us to review our systems and processes; if required make course correction. Our Shameerpet vaccine division, Shameerpet pharma division, Gaganpahad is certified to ISO 14001, 45001 and 50001, while Shameerpet SEZ facility is certified to ISO 14001 and 45001 only. We would eventually apply for ISO certifications for all our facilities. Our steadfast approach in operational transformation through incorporation of energy efficiency along with reduced dependence on natural resources and biodiversity conservation, enables us in contributing to a safe and healthier tomorrow for the present and the future generations.

It is our earnest endeavor to consume less energy, less water and produce fewer emissions. This pro-active approach coupled with streamlined supply chain equips us in



Carrying out periodic review of our processes to identify areas of potential adverse environmental impacts and proactively mitigating them is of paramount importance.

mitigating multiple environmental impacts across our value chain. We have always strived to contribute for a healthier planet through defining sustainable strategies, structured implementation with measurable outcomes. Through our annual celebration of world environment day on 5th June, we foster a culture of environmental consciousness amongst our employees. We also encourage ideas/practices that could be incorporated in our processes, to transition into a sustainable business. Through the implementation of these business initiatives, we could contribute to United Nations SDG 6, SDG 13 and SDG 15<sup>34</sup>.

<sup>34 103-2</sup> The management approach and its components, 103-3 Evaluation of the management approach



## 7.1 Water stewardship

#### 7.1.1 WATER CONSUMPTION

UN estimates indicate that the global water availability would reduce 40% by 2030<sup>35</sup>. Factoring population growth, economic development and changing consumption patterns will result in an annual increase of 1% in global water demand. These have a negative impact on the global water stress. India is ranked among the top thirteen countries globally for water scarcity by WRI<sup>36</sup>.

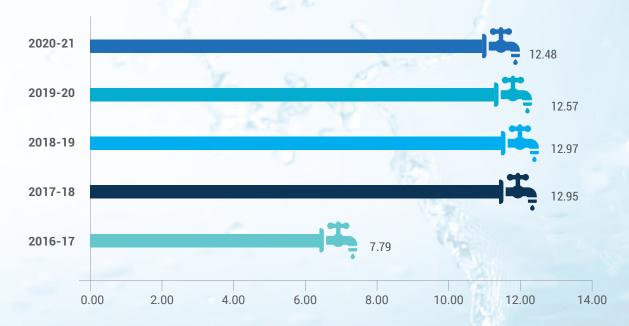
Water is among our prime dependencies for our operations. Moreover, with our facilities operating in water stress regions<sup>37</sup>, our contribution to water conservation is imperative. This necessitates us to optimize our water consumption and promote water conservation initiatives. We recognize the importance of access to fresh water and the need to effectively manage water discharges at all our operations. Our water balancing exercise performed across all facilities, enables us to effectively monitor and regulate our usage<sup>38</sup>. Below are the facility wise data on water withdrawal<sup>39</sup>

## Gaganpahad

Water parameters	Unit	2020-21	2019-20	2018-19	2017-18	2016-17
Tanker Water - Third Party	KL	9,500.00	8,520.00	9,660.00	8,940.00	0.00
Ground Water (bore well) *	KL	2,981.00	4,053.00	3,306.00	4,011.00	2,323.00
Surface Water	KL	0.00	0.00	0.00	0.00	5,470.00
Total Water Withdrawal	ML	12.48	12.57	12.97	12.95	7.79

<sup>\*</sup>The borewell mentioned are outside the reporting boundary and not under our ownership

#### **Total Withdrawn (ML)**



<sup>35</sup> https://www.unwater.org/world-water-development-report-2020-water-and-climate-change/

<sup>&</sup>lt;sup>36</sup> https://www.wri.org/blog/2019/08/17-countries-home-one-quarter-world-population-face-extremely-high-water-stress

<sup>&</sup>lt;sup>37</sup> https://www.wri.org/applications/aqueduct/water-risk-atlas

<sup>38 303-1</sup> Interactions with water as a shared resource, 303-2 Management of water discharge-related impacts

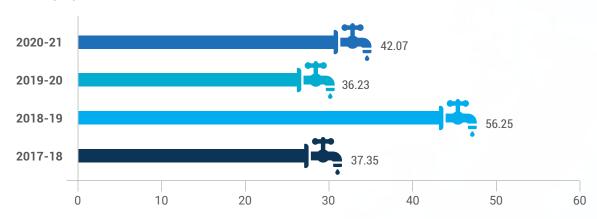
<sup>&</sup>lt;sup>39</sup> 303-3 Water withdrawal

# **Shameerpet Pharma**

Water parameters	Unit	2020-21	2019-20	2018-19	2017-18
Municipality Water - Third Party	KL	42,067.00	36,230.00	18,992.00	0.00
Tanker Water - Third Party	KL	0.00	0.00	37,256.00	37,347.00
Total Water Withdrawal	ML	42.07	36.23	56.25	37.35

<sup>\*</sup>The borewell mentioned are outside the reporting boundary and not under our ownership

#### Total Withdrawn (ML)



# **Shameerpet Vaccine**

Water parameters	Unit	2020-21	2019-20	2018-19	2017-18	2016-17
Municipality Water	KL	1,62,371.00	1,60,294.00	1,42,769.00	1,10,475.00	1,07,295.00
Tanker Water - Third Party	KL	34,080.00	32,480.00	0.00	0.00	0.00
Ground Water (bore well) *	KL	38,901.82	49,255.42	0.00	0.00	0.00
Total Water Withdrawal	ML	235.35	242.03	142.77	110.48	107.30

<sup>\*</sup>The borewell mentioned are outside the reporting boundary and not under our ownership

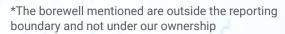
#### **Total Withdrawn (ML)**

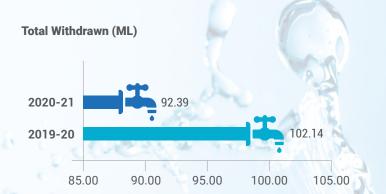




# **Shameerpet SEZ**

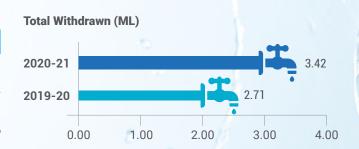
Water parameters	Unit	2020-21	2019-20
Municipality Water	KL	60,870.00	70,329.00
Tanker Water - Third Party	KL	18,938.00	6,106.00
Ground Water (bore well) *	KL	12,580.00	25,708.00
Total Water Withdrawal	ML	92.39	102.14





#### **Patancheru**

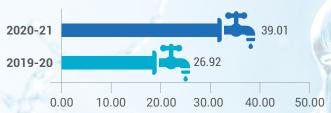
Water parameters	Unit	2020-21	2019-20
Tanker Water - Third Party	KL	3,420.00	2,707.00
Total Water Withdrawal	ML	3.42	2.71



#### **Azamabad**

Water parameters	Unit	2020-21	2019-20
Municipality Water	KL	3,778.00	2,761.00
Tanker Water - Third Party	KL	35,235.00	24,160.00
Total Water Withdrawal	ML	39.01	26.92

#### Total Withdrawn (ML)

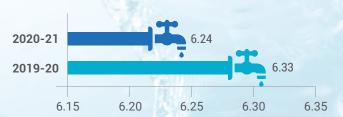


## **Dehradun**

Water parameters	Unit	2020-21	2019-20
Ground Water (bore well) *	KL	6,241.60	6,333.20
Total Water Withdrawal	ML	6.24	6.33

<sup>\*</sup>The borewell mentioned are outside the reporting boundary and not under our ownership

#### Total Withdrawn (ML)

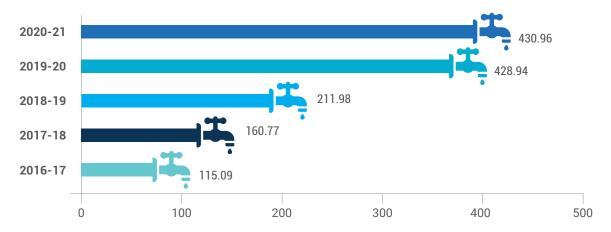


#### **Combined water withdrawal**

Water parameters	Unit	2020-21	2019-20	2018-19	2017-18	2016-17
Municipality Water	KL	2,69,086.00	2,69,614.00	1,61,761.00	1,10,475.00	1,07,295.00
Tanker Water - Third Party	KL	1,01,173.00	73,973.00	46,916.00	46,287.00	-
Ground Water (bore well) *	KL	60,704.42	85,349.62	3,306.00	4,011.00	2,323.00
Surface Water (External pond / river)	KL	-	-	-	-	5,470.00
Total Water Withdrawal	ML	430.96	428.94	211.98	160.77	115.09

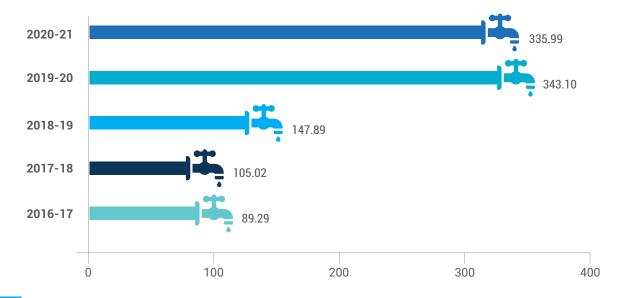
<sup>\*</sup>The borewell mentioned are outside the reporting boundary and not under our ownership

#### **Total Withdrawn (ML)**



#### Below table is indicative of our overall water consumption<sup>40</sup>

Water parameters	Unit	2020-21	2019-20	2018-19	2017-18	2016-17
Total Annual Water Consumption	ML	335.99	343.14	147.89	105.02	89.29



<sup>40 303-5</sup> Water consumption



# 7.1.2 RESPONSIBLE DISPOSAL OF WASTEWATER

We acknowledge the importance of limiting the impacts on water pollution from our business operations. We comply with relevant regulations to ensure the release of pollutants to surface waters are kept within acceptable limits. Just as responsible disposal, significant reduction of waste generation is also of prime importance. We follow the 'reduce, reuse and recycle' (3R) principle in

spirit to ensure wastage reduction. Our wastewater treatment plants installed at all our operational facilities handle both industrial and domestic wastewater. Through our process optimization and continuous improvement to our wastewater treatment facilities, we enhance the recycling and reusing of treated wastewater. Below are the facility data on wastewater discharged & reuse<sup>41</sup>.

Description	UoM	Gaganpahad	Shameerpet	Shameerpet Vaccine	Shameerpet SEZ	Patancheru	Azamabad	Dehradun
ETP Capacity	KLD	50	300	125	280	30	20	12
STP Capacity	KLD	50	100	125	75	30	20	12

Diocharga					2020-21			
Discharge Details		Gaganpahad*	Shameerpet Pharma	Shameerpet Vaccine	Shameerpet SEZ	Azamabad	Dehradun	Patancheru
Total Discharge	ML	12.48	12.54	49.43	14.51	3.69	1.59	0.73
Total water recycled and reused (Gardening)	ML	12.48	3.40	24.39	0.86	3.69	1.59	0.00
Percentage of water recycled and reused (wrt to discharge)	%	100%	27%	49%	6%	100%	100%	0%

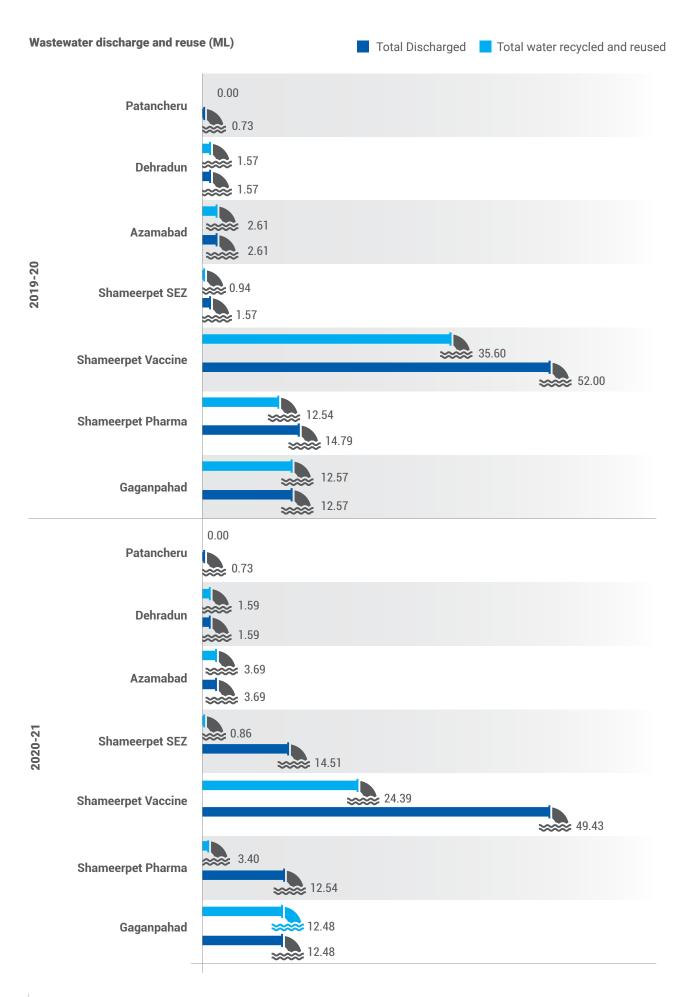
<sup>\*</sup>At Gaganpahad, recycled water is used in cooling towers and for gardening.

Discharge					2019-20			
Discharge Details	UoM	Gaganpahad*	Shameerpet Pharma	Shameerpet Vaccine	Shameerpet SEZ	Azamabad	Dehradun	Patancheru
Total Discharge	ML	12.53	14.79	52.00	1.57	2.61	1.57	0.73
Total water recycled and reused (Gardening)	ML	12.53	5.21	35.60	0.94	2.61	1.57	0.00
Percentage of water recycled and reused (wrt to discharge)	%	100%	35%	68%	60%	100%	100%	0%

<sup>\*</sup>At Gaganpahad, recycled water is used in cooling towers and for gardening.

<sup>&</sup>lt;sup>41</sup> 303-4 Water discharge,

<sup>306-1</sup> Water discharge by quality and destination

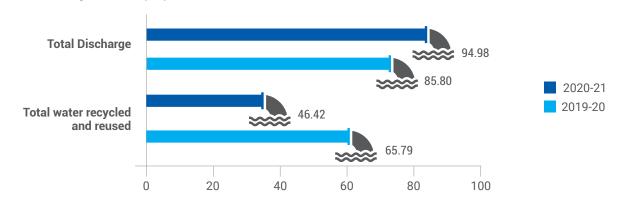




#### Combined wastewater discharge details

Wastewater parameters	Unit	2020-21	2019-20
Total Discharge	ML	94.98	85.80
Total water recycled and reused	ML	46.42	65.79
Percentage of water recycled and reused (wrt to discharge)	%	49%	57%

#### Water Discharge & Reuse (ML)





#### 7.2 Our waste our responsibility 50% of output **Collection Tank Live Effluents** Kill Tank **ETP** is reused for To align with environment conservation, we strive to internal processes reduce the waste generation through in-house process and remaining is optimization or by moving it to a higher level in the waste disposed in PCB hierarchy. We are particularly focused on reducing or authorized CETP diverting the amount of waste that we send to the landfill. Non-Live Our waste management flow-chart (below) is in the essence **Collection Tank Effluents** of waste management process followed at all facilities. Through our waste management process action plans, we try to reuse and repurpose the waste by composting or recycling, recover energy through incineration and ensure its effective disposal Recycled in STP and **Septic Tank** Sewage ........ used for gardening Through our waste management process action Disposed to PCB **Waste Oil '. . . . .** . authorized recycler plans, we try to reuse and repurpose the waste by composting or recycling, **Liquid Waste** recover energy through Disposed to PCB E-Waste incineration and thus ensure authorized recycler its effective disposal. Waste Management **Disposed to PCB Used Batteries** authorized recycler Flow Chart Our waste management efforts extend beyond our own operations. We have strict requirements to qualify only appropriate and the State Pollution Control Board **Disposed to PCB** approved vendors to manage our waste. We screen the **Plastic Waste** authorized recycler vendors to ensure responsible disposal of waste. The strict **Solid Waste** documentation review helps us evaluate our vendors waste handling and repurposing. This in turn supports reducing the amount of waste that we send to landfill. We would Disposed to explore options of incorporating circularity in our existing **Bio-Waste storage** . . . . . . . . . . . . . . **Bio-Waste** authorized vendor processes. We have been disposing the waste generated shed at scrap yard (GJ Multiclave Pvt. Ltd.) at all facilities to authorized third party vendors as per the state pollution control board. Sludge from ETP Disposed to Hyderabad **Hazardous Waste Waste Management** Project (HWMP)

Expired Chemicals ...

We are referring to 2018 disclosures on waste - 'Effluent and Waste' in the present report. We intend to develop a management system to capture end disposal of waste generated in the upcoming years. Below is the consolidated data on the quantity of waste generated  $^{42}$ 

Hazardous Waste	Disposal Method	Unit	2020-21	2019-20	2018-19	2017-18	2016-17
Used / Spent oil	Disposal to TSPCB Authorised Vendor	KL	0.39	5.38	1.44	0.67	2.80
Wastes / Residues containing Oil - Oil Soaked Cotton Waste	Disposal to TSPCB Authorised Vendor	MT	0.00	0.20	0.30	0.00	0.00
Discarded containers / barrels / Liners contaminated with hazardous wastes / chemicals	Disposal to TSPCB Authorised Vendor	Nos.	7111.00	10333.00	7403.00	0.00	8132.00
Chemical sludge from wastewater treatment (ETP Sludge)	Disposal to TSPCB Authorised Vendor	MT	17.72	9.80	14.71	13.65	4.16
Used Batteries	Returned to the supplier	Nos.	34.00	161.00	139.00	0.00	377.00
E-Waste	Disposed to the PCB Authorized Recycler	MT	8.06	116.18	5.23	6.66	6.04
Biomedical Waste	Disposal to TSPCB Authorised Vendor	МТ	383.68	334.52	334.79	246.26	296.84
Glass Bottles	Disposal to TSPCB Authorised Vendor	Nos.	7023.00	3807.00	4441.00	0.00	0.00
Forced evaporation salt from wastewater treatment (FE Salt)	Disposal to TSPCB Authorised Vendor	MT	2.32	0.00	-	-	-

Non-Hazardous Waste	Disposal Method	Unit	2020-21	2019-20	2018-19	2017-18	2016-17
Packaging waste (Wood)	Reused in House	MT	47.13	33.30	57.91	44.72	26.78
Corrugated Box	- Disposed	MT	90.31	90.45	173.94	116.09	126.33
Cardboards	through local	Nos.	480.12	314.22	270.00	183.00	594.00
Paper & Stationery / Shredding Paper (Craft)	scrap dealers Disposed through local	MT	111.79	142.06	38.77	5.62	2.33
Metal Scrap (MS,GI,SS & Aluminium)	scrap dealers	MT	136.07	163.38	87.02	193.00	104.77
Plastic Waste	Disposal to TSPCB Authorised Vendor	MT	46.84	65.25	31.40	24.49	327.68
HDPE Containers	Reused in House	Nos.	14,885.00	13,139.00	2,807.00	8,908.00	8,741.00
Empty Corncob Bags	Disposed	Nos.	9,701.00	12,288.00	3,791.00	-	-
Waste Rubber Stoppers	through local scrap dealers / Recycle	Nos.	0.24	0.49	33.29	-	-



#### 7.3 Energy and emissions

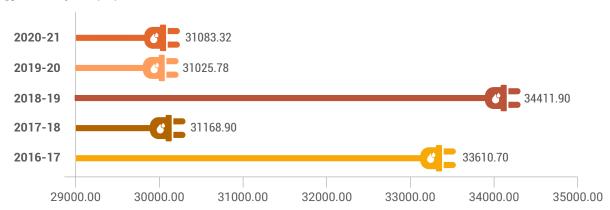
#### 7.3.1 ENERGY MANAGEMENT

HVAC and manufacturing processes are the major energy guzzlers of our primary energy sources, viz. grid electricity, furnace oil, diesel and coal. We have presented all the energy consumed during the reporting period in GJ using generic conversion factors. Our ubiquitous approach in tapping opportunities for energy saving is aided by the energy management system, ISO 50001 implemented at all our Shameerpet vaccine and Gaganpahad. It better equips us to set objectives for energy use reduction, thus, ensuring continual improvement.

Our proactive energy conservation initiatives include system redesign, retrofitting, operational upgrades and inclusion of advanced sensors and controls. During the reporting period, we had implemented 31 energy efficiency projects, that enabled us to reduce our energy consumption by 2,45,996 kWh in FY 2019-20 and 3,22,637 kWh in FY 2020-21<sup>43</sup>, helping us save INR 16,97,373 and INR 22,26,196 in FY 2019-20 and FY 2020-21 respectively, along with the associated greenhouse gas emission. During the reporting year, electricity consumption was predominantly for lighting and HVAC. Below is the data on facility wise energy consumption.<sup>44</sup>

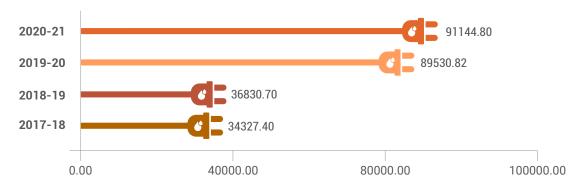
#### **Gaganpahad**

#### **Total Energy Consumption (GJ)**



#### **Shameerpet Pharma**

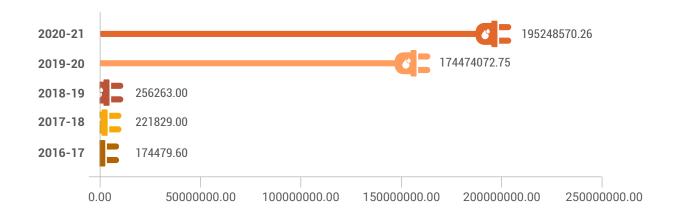
#### **Total Energy Consumption (GJ)**



<sup>&</sup>lt;sup>43</sup> 302-4 Reduction of energy consumption

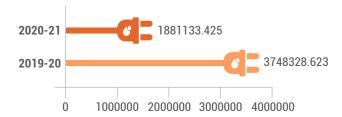
#### **Shameerpet Vaccine**

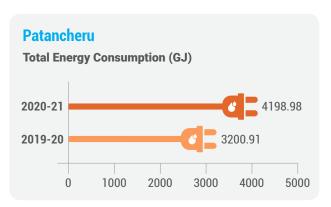
#### **Total Energy Consumption (GJ)**

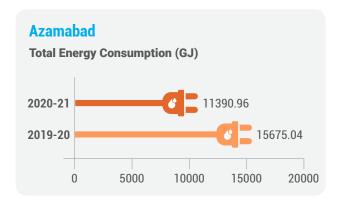


#### **Shameerpet SEZ**

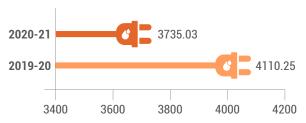
**Total Energy Consumption (GJ)** 







# **Dehradun Total Energy Consumption (GJ)**



#### Snapshot of all sources of energy consumption

Material	UoM	2020-21	2019-20	2018-19	2017-18	2016-17
Coal	GJ	22,229.28	20,819.57	20,873.90	18,048.80	20,209.40
HSD	GJ	44,70,983.03	61,20,266.77	6,185.50	7,159.50	9,366.90
Furnace Oil	GJ	19,25,73,488.18	17,20,20,574.34	1,56,022.20	1,33,306.80	94,141.70
LPG*	GJ	656.07	683.99	-	-	-
Electricity	GJ	2,03,900.22	2,03,599.52	1,44,424.00	1,28,810.20	84,372.30
Total	GJ	197,271,256.77	178,365,944.18	327,505.60	287,325.30	208,090.30

<sup>\*</sup> Currently LPG fueled boilers are operational in the Dehradun facility only

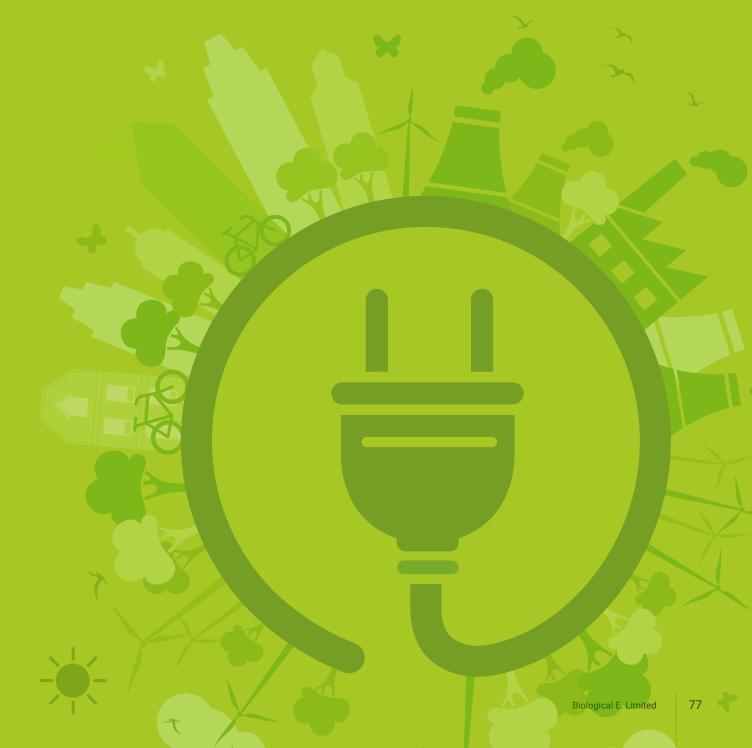


#### **Notable energy saving initiatives**

Enhancement of 300TR Cooling tower to meet the heat load (FY 2019-20)

MEDS cooling tower fan interlocked with the return temperate (FY 2019-20) Fabricating auto glass wash to conserve energy (WFI) (FY 2019-20)

Installation of VFD's for OAU and VAU for executive change rooms (FY 2020-21) Installation of Economizer for boiler flue gas (FY 2020-21)



#### 7.3.2 EMISSION MONITORING

Being cognizant of the impacts of climate change along with the national and global efforts to curb the average temperature rise below 1.5°C, we have identified emissions as one of our key material topics. Operating in a sector which focuses on improving human health in the global perspective, it is imperative that we take decisive steps to reduce our greenhouse gas emissions and contribute to global and national targets. We intend to extend this commitment beyond our operating boundaries and include our complete value chain.

One among the aims of the Intended Nationally Determined Contribution (INDC) for India is to reduce the emissions intensity of its GDP by 33 to 35 percent by 2030 from its 2005 Level. At Biological E, direct emissions are generated onsite, from burning of fuel or from processes in our operations. We also have indirect emissions from the offsite generation of purchased electricity. In the coming years, we intent to incorporate clean energy and energy

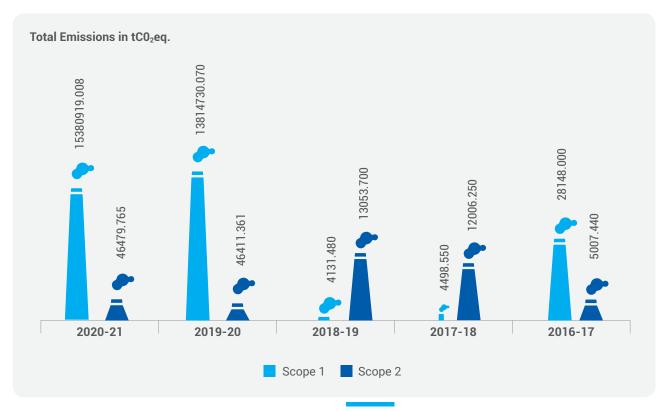
efficient technologies within our operations adds to the national narrative of INDC.

We have used IPCC 2006 guidelines and user guide (version 1.0), Assessment Report 5 (AR5) of IPCC along with CDM database user guide 15 of Central Electricity Authority (Ministry of Power) for calculation of greenhouse gas emissions and global warming potential, taking a conservative approach. As per CEA CDM database user guide 16, the grid emission factor for FY 20-21 is 0.79. For consistency the grid emission factor for 0.82 as per CEA CDM database user guide 15 has been adopted for calculating emissions for the reporting period, taking a conservative approach. Financial control approach, as GHG Protocol was adopted while quantifying the emissions for the reporting boundary. The base year for comparing the emission trend for Shameerpet-Vaccine and Gaganpahad is 2016-17 whereas for Shameerpet-Pharma shall be 2017-18. The base year will be 2019-20 for all other facilities viz. Azamabad-Vaccine and Pharma plant, Patancheru and Dehradun plants. Below is the data on GHG emissions. 45

#### Snapshot of emissions from all facilities

Description	Unit	2020-21	2019-20	2018-19	2017-18	2016-17
Scope 1	tCO <sub>2</sub> eq.	1,53,80,919.008	1,38,14,730.070	4,131.480	4,498.550	28,148.000
Fuel Consumption	tCO <sub>2</sub> eq.	1,53,80,085.796	1,38,12,267.225	0.000	0.000	0.000
ODS*	tCO <sub>2</sub> eq.	833.212	2,462.845	0.000	0.000	0.000
Scope 2	tCO <sub>2</sub> eq.	46479.765	46411.361	13053.700	12006.250	5007.440

\*GWP of R508 B isn't considered



<sup>&</sup>lt;sup>45</sup> 305-1 Direct (Scope 1) GHG emissions, 305-2 Energy indirect (Scope 2) GHG emissions 305-6 Emissions of ozone-depleting substances (ODS)



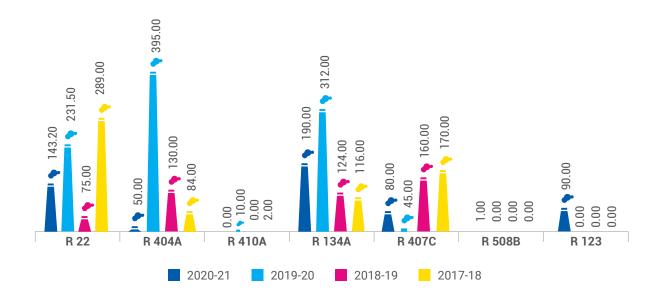
The stack emission parameters namely SOx, NOx and SPM; are monitored by a government accredited external agency. As the continuous monitoring was hampered due to the COVID-19 induced disruptions, we aren't disclosing data pertaining to 305-7 disclosure on Nitrogen oxides (NOX), sulfur oxides (SOX) and other significant air emissions. The monitored values, though inconsistently recorded, were found to be well within the prescribed limits of the national and state level pollution control boards. For the newly added facilities within the scope, a data management system is being developed and the corresponding KPIs would be disclosed in the next report.

We have used ODS (Ozone depleting substances) as a part of routine maintenance activity of air-conditioning systems. Facility wise data on ODS (Ozone depleting substances) is as below. Although the consumption of R 508B\* is recorded, its GWP (Global Warning Potential) isn't considered in calculating scope 1 emissions, being a non-ozone depleting azeotrope of R-23 and FC-116. ODS data pertaining to Azamabad, isn't currently recorded. We are in the process of developing management systems to monitor the same and will report on this KPI in our next report. In our Shameerpet Pharma facility, no ODS has been used during the reporting year.

#### The combined ODS emission for all facilities is as below:

ODS	Unit	2020-21	2019-20	2018-19	2017-18
R 22	kg	143.20	231.50	75.00	289.00
R 404A	kg	50.00	395.00	130.00	84.00
R 410 A	kg	0.00	10.00	0.00	2.00
R 134 A	kg	190.00	312.00	124.00	116.00
R 407 C	kg	80.00	45.00	160.00	170.00
R 508 B	kg	1.00	0.00	0.00	0.00
R 123	kg	90.00	0.00	0.00	0.00
Total	kg	554.20	993.50	489.00	661.00

#### Ozone Depleting Substance (kg)



<sup>46 305-7</sup> Nitrogen oxides (NOX), sulfur oxides (SOX) and other significant air emissions



## 7.4 Environmental compliance

Our legal team ensures compliance with all applicable national and local environmental regulations. To ensure our operational harmony with nature and local communities, we are prompt in resolving all stakeholder complaints on environmental issues, if any<sup>47</sup>. No environmental compliance failure was recorded in the reporting period and hence no fines were incurred. We have also not identified any non-compliance with environmental laws and/or regulations.



To ensure our operational harmony with nature and local communities, we are prompt in resolving all stakeholder complaints on environmental issues, if any.

# 7.5 Biodiversity

Our environmental management systems encompass integrated conservation of biodiversity. This is indicative of our commitment to preserve the biodiversity in the area we operate. The cumulative green belt coverage in all our manufacturing facilities is more than 30% of our site.

We have multiple initiatives in place to preserve the ecological value our operational area. In Shameerpet facility, we have developed herbal garden, this functions as ideal nesting spot for a variety of birds and home to butterflies.

We often conduct plantation programs which increases our green belt eventually sequestering our carbon emissions. **'Haritha Haram'**, a flagship program of the Telangana Government, envisages to increase the present 24% tree cover in the State to 33% of the total geographical area of the State. BE in coordination with the Factories department, since 2016, has taken the initiative and planted more than 600 saplings across all the seven facilities. Silver Oak, Bauhinia Blakeana, Anthocephalus cadamba and Millingtonia are among the few plant species chosen for plantation.

In FY 2019-20 and 2020-21 our overall environmental expenditure was INR 17.18 million and INR 20.69 million respectively which included expenditure of treatment, disposal, equipment, maintenance and implementation of energy saving initiatives.

Year	Unit	Total
2020-21	INR Million	20.69
2019-20	INR Million	17.18
2018-19	INR Million	21.60
2017-18	INR Million	20.50



'Haritha Haram', a flagship program of the Telangana Government, envisages to increase the present 24% tree cover in the State to 33% of the total geographical area of the State.

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<sup>&</sup>lt;sup>47</sup> 307-1 Non-compliance with environmental laws and regulations





Our global operational footprint in 130 countries is one among the key drivers of growth. We have several products being exported to 130 countries, which contributes to 55% of our revenue. Implementation of state-of-the-art technology and efficient processes enhances the operational capabilities of our Manufacturing Capital. This aid our Intellectual Capital, which is the foundation to our ability in providing high quality healthcare products.

We aim to enhance and leverage our R&D capabilities to achieve our vision to become the largest Indian vaccines company and be among the top few Indian companies in biologics, pharmaceuticals & active pharmaceutical ingredients (API). We are a company that innovates for better discovery, diagnostics and delivery. Innovation and new product development are key to advancing in these areas. Through our rigorous product and process quality systems, we ensure our adaptability to the evolving regulatory requirements. This would cumulatively strengthen our market position and achieve our vision.

## 8.1 Manufacturing Capital

#### 8.1.1 OUR BUSINESS EXCELLENCE

Operational excellence at BE is a cultural enabler to impart improvement among our employees. The operational excellence team, which is supported by all functions, trains and monitors the functions to achieve continual improvement in aspects related to PQCDSM (Productivity, Quality, Cost, Delivery, Safety, Morale).

'IDEA-Identify, Develop, Empower and Achieve' generation campaign is one among our operational excellence initiatives, driven along-side other trainings, through which we obtain inputs and suggestions pertaining to operational enhancement. We have received 375 valuable inputs till date, of which 325 have been successfully implemented. We also reward the beneficiary upon implementation of their idea. These suggestions, also known as Kaizens, have resulted in a cost savings of around INR 35 Million and a saving of 6121-man hours. They have also contributed to ease of operation along with improvement in safety and quality. It has also served



in tracking and augmenting the gender-wise participation of both permanent and contract employees in our training programs.

Additionally, our operational excellence team constantly engages with various business functions to identify potential opportunities for improvements, termed as 'Focused Improvement Projects'. These mainly revolve around our key focus areas namely - accessible medicines, water, employee health and safety, responsible procurement and energy. A cross functional team is deployed for

implementation of qualified Focused Improvement Projects. Throughout the implementation, we adopt the DMAIC (Define, Measure, Analyze, Improve, Control) approach and leverage our understanding of several lean tools of quality management in various phases of project implementation. Upon completion, we analyze and validate the actual savings obtained. Such projects have yielded a saving of around INR 20 Million. We also conduct periodic audits of such projects and all Kaizens, to ensure its sustenance. The top management will be keenly involved in these initiatives.





#### 8.1.2 PRODUCT PORTFOLIO

The core strategic dimensions which enable us to better serve the domestic markets as well as international markets in Asia, the CIS countries, the USA and Latin America is our product portfolio<sup>48</sup>. It can be broadly categorized into three core elements namely

#### **Biologics**

From our maiden products in classical biologics such as Heparin, we continue to innovate and develop new age genetically engineered biologics. Our enormous breadth of products includes pediatric and adult vaccines which have a significant market share in India. Our current research comprises of developing low molecular weight heparin (LMWH), conjugate vaccines and a portfolio of flavivirus vaccine for unmet need. Massive investments are underway in development and commercial of new products. We are also focusing on developed markets in the medium and long term.

#### **Our Product Portfolio includes:**

#### **Biologics – Our vaccine pipeline includes:**

- COVID 19
- Hep A
- Hexavalent (DTwP-HepB-Hib- IPV)
- · Human Papilloma Virus (HPV)
- Inactivated Polio Vaccine (IPV)
- Measles and Rubella (MR)
- Meningococcal Conjugate Vaccine (MCV)
- Novel Oral Polio Vaccine type 2 (nOPV)
- Pneumococcal conjugate Vaccine (PCV)
- Polyoma
- Respiratory Syncytial virus (RSV)
- Typhoid Conjugate Vaccine (TCV)
- Varicella
- Yellow Fever

#### Some of our other vaccines include:

- DT
- HepB (BEVAC)
- · Haemophilus Influenzae type B (Hib)

#### Our anti snake venom vaccines (SERA) include:

- Diphtheria Anti Toxin
- Monovalent Snake Antivenom (Africa Specific)
- Polyvalent Snake Antivenom (Asia & Africa Specific)
- Tetanus Anti Toxin

#### **Pharmaceutical**

We have a broad range of pharmaceutical formulations which include oral dosages and injectables. This range of branded formulations encompass Non- Narcotic Cough Preparations, Digestive Enzymes and Vitamins, Anti coagulants and Liver extracts, Anti-injective, Antibiotics and Heamatenics. We are in the process of establishing partnership with potential customers in US and EU. We are also looking to file at least one injectable ANDA this year. Some of our key brands include: -

- BE TT
- Befer
- Benom
- Beparin
- Bestozyme
- Bethadoxin
- Bethox
- Binex
- Bipaz
- Calium
- Cetrorelix
- Coscopin
- Coscorest
- Coscoril

- Fnoxatil
- G2K
- Gaspaz
- Leuprorelin
- Livsure
- Lofh
- Megacef Obvit
- Onecal
- PH4 Raft
- Sekur
- X Pain
- Zizant

#### **Active Pharmaceutical Ingredients (APIs)**

The API division of BE supports the captive consumption needs of the company. Specializing in alkaloids such as Noscapine and its derivatives and biologics such as Heparin, LMWH and PSGAG (Chondroitin Sulphate), BE has committed to ensure a sustainable quality supply to global markets.



# 8.1.3 WHO PREQUALIFIED **VACCINES**

BE has WHO pre-qualified vaccines and we are one of the most reliable suppliers for the same. We are also constantly undergoing WHO approval processes for new products in our R&D pipeline. The vaccines that are WHO Pregualified are:

- Pentavalent vaccine (DtwP-rHeb-Hib) in liquid form (LPV)
- · Pentavalent vaccine (DtwP-rHeb-Hib) in lyophilized (freeze-dried powder) form
- Tetanus Toxoid (TT)
- Diphtheria, Tetanus, whole-cell Pertussis (DTwP)
- Tetanus and Diphtheria (Td)
- Japanese Encephalitis (JE)
- Measles and Rubella (MR)
- Typhoid Conjugate Vaccine (TCV)



Biological E ranks as one of the most reliable suppliers for Liquid Pentavalent Vaccine (LPV) and Japanese Encephalitis (JÉ) vaccine. We are also an exclusive supplier of LPV and JE in India. For our newest vaccine, Measles and Rubella (MR), we began the distribution in India in 2019.

<sup>48</sup> 102-2 Activities, brands, products, and services

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All our products are duly approved by the relevant regulatory bodies.













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#### 8.2 Intellectual Capital

#### 8.2.1 RESEARCH AND DEVELOPMENT<sup>49</sup>

Our intellectual capital mainly comprises the Research and Development team who are constantly in the process of upgrading, innovating and introducing new products. They help us leverage our scientific and technology resources to anticipate health challenges, meet local needs and deliver solutions. R&D in medical science is the process of turning knowledge about a disease at the genetic level into products that treat these diseases or illness. It creates the building blocks for next generation therapies, improved health care and financial development. As R&D is core to our business proliferation, we give special thrust with substantial investment, encourage innovation and ensure accessibility. These are part of our strategic plans to sustain the health care ecosystem and aid in discovering the next revolutionary medicine. At Biological E, we continuously strive to be a leader in therapeutic innovation and pursuing transformational science that may decipher into life enhancing medicines. In our pursuit to paving a sustainable future through collaboration, we thoroughly assess our products for their health and safety implications, thus enabling access of safe medicines to all.

Along with safety, we have an effective process that continuously monitors the protection of intellectual property (IP) rights throughout the product development lifecycle. Following table provides a snapshot of the patents.

Name of patent	# filled during reporting period		
US - ANDA	6		
EU - MAA	1		
UK - MAA	2		
China - DMF	1		
South Africa	2		
Hong Kong	1		
Malaysia	1		



<sup>49 103-2</sup> The management approach and its components, 103-3 Evaluation of the management approach



Description	2020-21	2019-20	2018-19	2017-18
R&D Workforce (No. s)	387	360	303	
R&D investments (in Lakhs INR)	21,531	24,067.27	14027.96	

We respect the IP of all third parties and are committed to ensure that no violation occur in this regard. Through specific internal trainings, our R&D team are appraised of the implications on IP rights violation. Thus, frequently ensuring that we are in-line-with our commitment. At BE, we have a governance process fine-tuned to compliance with all requisite legislations across geographies. The internal team of experts ensure periodic review of product specifications and take corrective actions.

We are committed to delivering the highest possible quality standards at every stage of the research and development process with enough funds allocated for investment and expansion of our R&D facility. Since 2008, BE has invested over USD100 million in R&D to successfully develop and deliver key six vaccines. Our majority of the R&D activities are conducted in India and some experimenting activities in France. However, in the year 2018-19, we closed our French unit for strategic reasons.

As collaboration is key to accelerating success in R&D programs, we associate with institutions, medical centers and companies alike. This helps us to innovate and

contribute towards the development of affordable and accessible medicines.

We conduct our own extensive pre-clinical research to support our R&D and regulatory programs. This research focuses on efficacy and toxicity models. Our pre-clinical testing facilities are designed to meet GMP regulations and provide for the containment of individual experiments. Our Clinical and Regulatory Affairs department engages in conducting Phase II to Phase IV clinical research programs for international markets, in compliance with ICH-Good Clinical Practice (GCP) guidelines.

In terms of products in the R&D pipeline, we are currently developing Hexavalent, a next generation vaccine, which adds protection against polio to the Pentavalent vaccine, Pneumococcal Conjugate Vaccine (PCV), Typhoid Conjugate Vaccine and Inactivated Polio Vaccine (IPV). As a pharmaceutical company, we are responsible in making our products with utmost quality and innovation to cater the global healthcare needs. We see this as an opportunity to serve people and add value to the society.

# RELATIONSHIP CAPITAL®

- 9.1 Responsible sourcing
  - 9.1.1 Supplier selection
  - 9.1.2 Supplier diversity and localization
  - 9.1.3 Building ethical supply chain
- 9.2 Building resilient communities
  - 9.2.1 Our community development focus areas
  - 9.2.2 BE volunteering initiatives
- 9.3 Customer health and safety
  - 9.3.1 Product responsibility
  - 9.3.2 Transparency in communication
  - 9.3.3 Access to medicines

We understand that no business can prosper in isolation of its host community. Equal or more importance should be given to customer relationship and value chain partners to have sustained business growth. Hence, local communities, customers and business partners of our supply chain could be considered as our Social and Relationship Capital. With growing competition, this is very true for all companies to survive the market pressure. The needs and expectations of the local communities and customers must meet satisfactorily. A widespread research across industries over the last few decades have shown that customers promote and value companies that deliver better experiences. We also acknowledge and value every link of our value chain and proactively collaborate to improve their resilience, which would improve business processes and hence our customer experience. We recognize the impact of social and relationship capital to the business and strives to effectively measure and manage customer experience for better market position. This bears a direct relation to outperform our competitors and increase profitability as well as customer credibility.

Approvals and licenses for BE's products, viz lifesaving vaccines and pharmaceuticals is of utmost importance to get market entry and to grow the customer base. We supply several essential and lifesaving Vaccines and Pharmaceuticals to UN Agencies like UNICEF, Pan American Health Organizations and other global markets, in addition to the local Indian pharma sector. We have partnered with various national and international organizations to carry out best research and development processes to cater the growing healthcare needs of the world. We value our contribution to global immunization, by leveraging these collaborations, especially during the pandemic; in our pursuit for vaccine development. Our management enforces extremely stringent compliance

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We recognize the impact of social and relationship capital to the business and strives to effectively measure and manage customer experience for better market position.

with regulations to ensure that our products are best in quality and the health solutions to our end consumers are safe and affordable.

In addition to expanding our customer base, customer retention also has due importance to create repetitive business opportunities. To understand our customer's needs better, our marketing and sales team, frequently interacts with customers through one-on-one meetings, emails, telephonic calls, web chat and other social media platforms. Extreme care is ensured to address any concerns immediately and appropriately. Special surveys and customer feedback drives are conducted on a periodic basis to assess product performance, customer relationship experiences and enhance business resilience identifying potential concern areas for improvements on process or service delivery. We intend to develop more holistic, consistent and actionable framework of customer satisfaction measurement, to understand the multidimensional nature of our customer relationships





### 9.1 Responsible sourcing

Mutual trust and understanding are the foundations of resilient relationships. We ensure value creation across our value chain, we regularly interact with our suppliers, whom we consider are an integral part of our business. In continuation to our efforts in building a Sustainable Procurement Framework, we proactively collaborate with suppliers who have the same set of business ethics. We consider essential to actively engage with the best suppliers, to provide best quality vaccines and pharmaceutical products that contribute to good health and wellbeing of people, globally. Our active engagement with our business partners, even during the lockdowns, helped us to propel forward to source the necessary inputs for our business processes. We highly acknowledge the collaborative efforts of all our business partners, in helping to develop our vaccines. Our evaluation criteria,

designed to fulfil our non-financial commitments, which enables suppliers to comply with the laws pertaining to Environment and Social requirements such as energy conservation, occupational safety, human rights and labor laws etc.

We acknowledge that our robust supply chain is the key in both raw material procurement and enables last mile delivery of all our products to every customer. Our connected network includes our employees, suppliers, vendors, contractors, distributors and logistics involved in the manufacturing and sale of our products. As there is a value addition to our products by each entity of our supply chain, we critically supervise each touch points for an overall visibility of every transaction. Along with our collaboration, we believe that the success of our supply chain is mainly attributable to our principles namely: -



The application of GET is fundamental to our supply chain management framework to evaluate our suppliers and ensure their compliance with all the applicable legal and statutory requirements. We procure materials such as chemicals, laboratory equipment, packaging material, consumables and office utilities.



### Suppliers Engaged at BE51

Description	2020-21	2019-20	2018-19	2017-18
New Suppliers	857.00	504.00	1,646.00	1,677.00
Total Procurement budget (in Crore INR)	2,399.28	944.62	407.00	679.00
Procurement budget spent on local suppliers (in Crore INR)	899.50	509.71	294.78	572.01
Percentage spending of procurement budget on local suppliers (%)	36%	52%	68%	64%
Total number of local suppliers engaged	1754.00	1611.00	185.68	401.64

### Percentage of key suppliers engaged<sup>52</sup>

Description	2020-21	2019-20	2018-19	2017-18
India	90%	90%	97%	96%
US	3%	2%	1%	1%
Europe	4%	4%	2%	3%

### 9.1.1 SUPPLIER SELECTION

Supplier selection is integral to our business success. Hence, our Standard Operating Procedure (SOP) which is in line with our sustainability procurement framework provides a yardstick in screening responsible suppliers that deliver quality products. The SOP developed encompasses activities ranging from vendor selection to vendor finalization. This is different for manufacturers and suppliers. The checklist for manufactures includes aspects of Good Manufacturing Practices (GMP) and quality systems, followed by vendor self-evaluation. Further to the evaluation and approval of the filled-in selfevaluation form by our quality department, specification of the required raw material is provided. The vendor selection and approval procedures are also documented by Quality Assurance function. Based on this, the vendors are finalized and approved. Only the approved vendors are shortlisted for us to build a business partnership. As per our Quality Assurance department, the vendor is required to provide a set of three samples from their lots for



As per our Quality Assurance department, the vendor is required to provide a set of three samples from their lots for evaluation. The suppliers are further classified as critical, major and minor, depending on the type of materials procured.

evaluation. The suppliers are further classified as critical, major and minor, depending on the type of materials procured.

Type of Vendors	2020-21	2019-20	2018-19	2017-18
Critical Vendors	11	19	21	13
Major Vendors	16	8	14	10
Minor Vendors	5	7	00	09
Total	32	34	35	32

<sup>51 102-9</sup> Supply chain

<sup>52 204-1</sup> Proportion of spending on local suppliers



### 9.1.2 SUPPLIER DIVERSITY AND LOCALIZATION

We at BE recognize that geographical diversification of suppliers is essential to avoid operational disruption. Hence, we invest in diverse geographies and produce products that create healthier impact in India and abroad. We had engaged with 504 and 857 new suppliers in FY 2019-20 and FY 2020-21 respectively. Even though we have major suppliers from USA, Germany, Japan, Switzerland and Denmark about 90% of our materials are procured locally from India. We consider local sourcing as alternative for cost reduction and empowering the growth of our small business partners. This would in turn create employment opportunities and thus a positive impact on the local communities we operate.

### 9.1.3 BUILDING ETHICAL SUPPLY CHAIN

We engage with our business partners including suppliers, vendors, contractors and logistic partners to keep a check on our supply chain with our business partners including suppliers, vendors, contractors and logistic partners. Our active engagement along with yearly risk assessment augments the improvement of our Supply Chain Management. The annual risk assessment of our value chain provides key insights of the associated risks and is instrumental in re-aligning our operations with strategic initiatives. This in turn augments our operational capabilities. Ethical sourcing of materials is of prime importance due to resource scarcity.

Compliance with the Good Manufacturing Practices (GMP) and our Principles for Responsible Supply Chain Management ensures ethical sourcing by our vendors. We also ensure that our vendors are certified and comply with all the applicable national and international standards and regulations. Since the beginning of business relations with the selected vendors, we set our expectations with our suppliers on environmental and social ethical practices. This includes fair labor practices including human rights, health, safety and environment protection.

Regular assessments are performed by our Quality Assurance and Procurement department on the new and existing vendors based on the supplier categories. We perform site audits to assess all our critical and major vendors, after completion of one year of engagement. These suppliers are assessed based on quality of their deliverables, timely delivery, processes and procedures at their facility, compliance status pertaining to all the applicable statutory requirements and ethical standards.

We have a zero-tolerance approach to any non-compliances or quality issues in our supply chain. This is indicative of the importance that we provide to product quality. We strictly adhere to all the applicable regulations and standards and expect the same from our vendors. In case of any vendor does not confirm to the applicable laws of land and holds no surety for its conformance soon, then the relationship with the vendor stands jeopardized. Following are the reasons, why a vendor could be rejected from future collaboration: Firstly, rejection of five consecutive shipments in a year, non-suitability for requalification and 'poor' rating during annual performance reviews. In case of vendor rejection, the material or the service provided by the respective vendor is thoroughly investigated. Further, the Quality Assurance function head decides whether the existing material could be utilized for the manufacturing operations based on a valid justification. In the reporting year, there were no vendor rejections.

In this scenario of regular assessments, we check our suppliers for any challenges in their processes or risks and provide technical support to resolve the issues. We also provide them continuous mentoring on setting up robust internal processes and mitigation of identified business risks.



### 9.2 Building resilient communities

As part of enhancing and enriching the social and relationship capital, BE is committed to wholesome development of the communities, which are integral part to our operational surroundings.

## 9.2.1 OUR COMMUNITY DEVELOPMENT FOCUS AREAS

As part of building resilient communities, our major CSR focus areas<sup>53</sup> are supporting government's effort on promoting sanitation through Swachh Bharat Mission, access to affordable and quality healthcare and infrastructure support to local schools. We believe that quality education grooms children on mental, emotional and physical skills preparing them for any challenge coming their way. We work with

Year **Description Contribution (INR)** Centenary 5.00.000 celebrations -BC Vedavyasa 5,00,000 Vignana Varadhi Abhaya 9,46,000 foundation FY 2019-20 Pleasant valley Lake Revival Project-1,00,000 Commandant, 1st BN TSSP, Battalion Welfare fund Chief Minister's 1,00,00,000 Relief Fund FY 2020-21 Prime Minister's 1,00,00,000 Relief Fund

government schools and local bodies to guarantee effective implementation of inclusive education. During the reporting period, we worked with various schools in setting up infrastructural facilities, conducted skill development activities and healthcare awareness sessions.

With reference to the heavy dependency on water for our operations, BE has actively supported initiative for lake revival to compensate for the water stress. During the pandemic, we supported the state and central government initiatives through contributions for the respective relief funds.

### 9.2.2 BE VOLUNTEERING INITIATIVES

We encourage our employees to actively participate in volunteering initiatives, which are the key strategic commitments for BE. In addition to offering personal development for our people, this is the way to create community legacies. We continue to support our Government in promoting access to healthcare, education and better sanitation.

<sup>53 203-2</sup> Significant indirect economic impacts



# Biological E. Limited Donates ₹ 1 Crore to CMRF



Biological E. Limited (BE) donated ₹ 1 crore to the Chief Minister's Relief Fund (CMRF) supporting the efforts of the State government in the fight against COVID-19.

Ms. Mahima Datla, Managing Director, and Ms. Indira Raju, Director, handed over the cheque to Mr. K Chandrashekhar Rao, Honourable Chief Minister, Telangana, at Pragathi Bhavan in Hyderabad on April 21, 2020.

The Chief Minister thanked and appreciated Ms. Mahima Datla and Ms. Indira Raju for their gesture.

- Corporate Communications



### 9.3 Customer health and safety

In addition to the employee OH&S, we are committed to ensuring our customer's health and safety, as our products are healthcare and pharma based.

### 9.3.1 PRODUCT RESPONSIBILITY<sup>54</sup>

We are in this industry for more than 60 years and currently export our products across the globe, which includes APIs, Finished Formulations and Biologics. We are determined to increase our product portfolio in various countries year after year by brand promotion. With latest cGMP compliance and WHO prequalified vaccine facility, we have been able to expand our international presence in almost all countries globally. We are also a leading supplier of Vaccines for National Immunization Program of India and have supplied more than 300 million doses of vaccines for routine immunization, to the Ministry of Health & Family Welfare. We also supply vaccines to several Hospitals and Medical Institutions.

All our vaccines are delivered under validated cold chain to ensure vaccine quality till the last point. It is our responsibility to implement utmost safety and stringent quality standards in our research and development operations. We understand that hygiene is the most important element in the health care sector and we strictly adhere to all the safety rules and stringent hygiene standards that we have set for ourselves. We conduct clinical trials in the premarketing stage to double check the safety aspects of our products. The trials are conducted in well controlled atmosphere and give us an understanding on their working on the consumers. These trails are crucial for the assessment of our product safety and impacts. We also conduct post-marketing pharma vigilance to understand the impacts and risks associated with the product. We comply with all the applicable regulations on product safety, quality and labelling. So far we have not received any complaints related to non-compliance or any adverse incidents related to product labelling, quality and their health and safety impacts, leading to fine or penalty or warning<sup>55</sup>.

We have Research and Development (R&D) facilities which are operated by industry experts. Our products are tested for their life cycle, keeping the health and safety of end customers as priority. We also ensure that our products do not harm the environment. Hence, we study the cradle to grave approach of all our products through in depth research. We develop and market only those products which do not create any negative impacts. We hire the best talent and hone their skills through continuous trainings.

To assess our products of any risk, we have set up an R&D committee and Quality Control/Quality Assurance Committee. These committees work in collaboration and assess all our products and processes to identify any potential risks and provide risk mitigation measures. They continuously monitor the operations, risk procedures and implementation of the mitigation measures to ensure that our products are high in quality and are safe to our society and environment.

### 9.3.2 TRANSPARENCY IN COMMUNICATION<sup>56</sup>

In today's dynamic market, companies are facing more demand by regulators, investors and customers to be transparent about their performance and strategies towards environment, social and corporate governance. The market leaders can no longer be content and be satisfied with financial performances alone. We are a company of ethical practices. We hold responsibility of our actions towards our stakeholders. When we embarked on the journey of sustainability reporting and carried out stakeholder engagement, we realized how our stakeholders expect us to be transparent in whatever we do and communicate the same. The management of Biological E believes transparency in disclosure, through reports or information on our products is essential for the Company's business ecosystem. It can help us gain legitimacy and reputational benefits and apprise the customer about our product specifications. In addition to this, we understand transparency can also be a pre-requisite for achieving both environmental and social sustainability. Hence, we consider transparency in communications crucial to build trust amongst our stakeholders. We promote our products by following the applicable advertising codes. We include critical information of our products on its packaging. We also provide an additional leaflet, containing relevant information for the user, with few products to ensure transparent communication. We also put up the necessary information about our business offerings and products on our website.

 $<sup>^{54}</sup>$  103-2 The management approach and its component,

<sup>103-3</sup> Evaluation of the management approach

<sup>55 416-2</sup> Incidents of non-compliance concerning the health and safety impacts of products and services,

<sup>417-2</sup> Incidents of non-compliance concerning product and service information and labeling

<sup>56 103-2</sup> The management approach and its component, 103-3 Evaluation of the management approach



### 9.3.3 ACCESS TO MEDICINES<sup>57</sup>

According to WHO, nearly 2 billion people have no access to basic medicines, causing a cascade of preventable misery and suffering. A third of the world's population lacks access to essential medicines. Annually about 100 million people are plunged to extreme poverty due to out-of-pocket health expenses. In many low- and medium-income countries, drug therapies are unaffordable to those who need them. Working towards achieving our vision, providing equitable access to quality vaccines & pharmaceutical products, the recent years have heralded a period of transformation for BE, both in terms of the pipeline of product offerings as well as our geographical footprint. Transitioning from being a generic vaccines manufacturer to a novel vaccine developer is indeed a momentous milestone for the company as it continues to evolve.

Historically, we developed and manufactured generic vaccines for the emerging markets. BE strive to contribute significantly to increase the accessibility of medicines to the

people who need them the most. We are putting additional efforts to further accelerate health care accessibility and affordable medicines in line with Goal 3 of UN's Sustainable Development Goals. BE has supplied more than 2 billion doses of multiple vaccines to children across the globe and the company has emerged as a leading global supplier.

While lower prices are important to increase widespread immunization, one of the greatest risks BE faces, is price erosion. Since 2018, a few suppliers left the market because they did not have the volumes to absorb the low prices. BE's large capacity allows it to deliver high volumes and this has helped the company to adapt, even as prices have continuously dropped. We are focused on technology as well as the right capacity solution at the lowest cost possible without compromising quality. We offer a vast portfolio which consists of Biologics, Pharmaceuticals and Bulk Antigens, which caters to both domestic and international markets. The portfolio caters to both pediatrics and adults for the healthcare initiatives undertaken by the Government of India to help reinforce healthcare system in the low-income groups.

# GIVING MILLIONS OF CHILDREN A HEALTHY START IN LIFE

Pentavalent is one of the most used vaccines in the world because it is effective and offers greater convenience. Fewer doses of these help the government to reduce the overall cost of vaccination, which includes the purchase price of the vaccines, cold chain logistics, as well as transportation and wages for health workers who administer the vaccines. BE's Pentavalent vaccine earned the "WHO prequalification," which enabled it to supply to UNICEF, the world's largest purchaser of vaccines.

BE supplied more than 2 billion doses of different vaccines. BE's low-cost vaccines are reaching children in many across the world. Today, BE is a leading global supplier of the Liquid Pentavalent Vaccine (LPV) and produces more than one million vaccine doses a day making it the second largest vaccine manufacturer in India.



<sup>&</sup>lt;sup>57</sup> 103-2 The management approach and its component, 103-3 Evaluation of the management approach

<sup>58</sup> https://www.who.int/publications/10-year-review/chapter-medicines.pdf

<sup>&</sup>lt;sup>59</sup> https://www.weforum.org/agenda/2019/09/half-of-the-world-s-population-lack-access-to-essential-health-services-are-we-doing-enough/



### **BE Receives Second ANDA Approval from USFDA**

USFDA Approves BE's Daptomycin Injection

Biological E. Limited (BE) is pleased to announce that it received an Abbreviated New Drug Application (ANDA) approval from the U.S. Food and Drug Administration (USFDA) for Daptomycin Injection 500 mg/Vial on June 26, 2019.

Daptomycin injection is a Lipopeptide antibacterial indicated for the treatment of complicated skin and skin structure infections (cSSSI) and Staphylococcus aureus bloodstream infections in adults.



**Hearty congratulations!** 

- Pharma Division

- Corporate Communications



- Corporate Communications

### **USFDA Approves BE's Fosaprepitant for Injection**

Biological E. Limited (BE) is pleased to announce that its Pharma Division received an Abbreviated New Drug Application (ANDA) approval from the U.S. Food and Drug Administration (USFDA) on September 05, 2019 for Fosaprepitant for Injection, 150-mg Single-Dose Vial, a day after the expiry of the patent.

Fosaprepitant for Injection was filed with the USFDA on July 31, 2018 and the FDA has assigned the product goal date as September 11, 2019. The quality of BE's dossier, technical content and facility status met the expectations of the FDA, which has issued the approval a week ahead of the assigned goal date.

Fosaprepitant for Injection, a substance P/neurokinin-1 (NK) receptor antagonist, is indicated for adults in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy / moderately emetogenic cancer chemotherapy.

**Hearty congratulations!** 



- Pharma Division



# FINANCIAL CAPITAL CAPITAL

Commencing operations in 1953, Biological E has steadily progressed and continues to evolve. It currently has four strategic business units with global footprint for commercial operations. We are striving continuously improve our partnerships with our rapidly expanding product portfolio. We supply our lifesaving vaccines at affordable prices to over 130 countries, spread across remote parts of the globe. Our therapeutic products are sold in India and USA. BE currently has 8 WHO-pregualified vaccines in its portfolio. In recent years, BE has embarked on new initiatives for organizational expansion. This investment in our business and stakeholder improvement aids in our achievement of generating increased revenues and business expansion in various regional markets. We keep pace with the market expectations and changing industrial trends and contribute to the wellbeing of the people sustaining our business growth.

The collaboration announced in Dec 2020 with CEPI, the Coalition for Epidemic Preparedness Innovations, validates the technology platform that BE works for developing an effective COVID-19 vaccine candidate. The initial investment from CEPI comes on the heels of investments from the Bill & Melinda Gates Foundation and Government of India's Biotechnology Industry Research Assistance Council (BIRAC) under the National Biopharma Mission of the Department of Biotechnology, Government of India. It provides the impetus for accelerated efforts towards a successful and scalable outcome available for global access. This is a testimony of our strong professional relationship with the Government of India and our acceptance as a quality pharmaceutical products and vaccines provider. As a world pharma leader, we aim to

continue creating healthier environments and support the well-being of people around the world.

Our skilled manpower, insightful collaboration combined with infrastructure upgrades and effective governance helped us to sustain business growth, despite the testing times during the last quarter of 2019-20, owing to the pandemic. We have always been an epitome of quality in the preventive medicine sector and are now in pursuance to emerge as a successful player in the gene therapy segment.

The COVID-19 pandemic along with the 'Make in India' mission fueled the growth of the Indian pharmaceutical sector. Living up to the evolving and growing needs of our customers, through our diverse breadth of product portfolio along with our newly developed COVID-19 vaccine, we aim to cater to the current needs of the market as well. The vaccine business has generated revenue of INR 54,484.19 Lakhs in 2019 -20 and INR 74,955.06 Lakhs in 2020-21 with a contribution of 60% and 64% respectively of BE's total revenue and the pharmaceutical product industry has generated about 40% and 36% revenues in 2019-20 and 2020-21 respectively. We are committed to develop affordable and accessible medicines and meaningfully contribute to the welfare and economic growth of the nation. Through our collaborations with national and international government and non-government organizations, we intend to innovate and develop novel drugs for the betterment of the society at large. We seek to diversify our product offerings, to better suit the current and future needs of people, thus, staying relevant in the market.

D :: 1	Economic Performance (in Lakh INR)				
Particulars	2020-21	2019-20	2018-19	2017-18	2016-17
Economic Value Generated <sup>61</sup>	1,41,807.60	1,12,364.65	95,263.51	82,452.25	1,13,753.52
Economic Value Distributed	1,17,301.70	99,869.22	89,090.15	87,845.13	81,872.31
Operating costs	17,993.00	13,291.91	13,905.64	13,922.55	12,237.00
Community investments	1,717.00	20.46	557.04	521.65	552.50
Payments to Government	7,523,80	5,040.33	1,750.00	725.71	11,403.40
Employee wage and Benefits	29,383.40	24,336.50	24,216.72	23,187.83	17,868.00
Depreciation, Amortization exceptional items, Finance Cost & Other expenses	68,208.30	59,590.36	48,660.75	49,487.39	39,811.41
Economic Value Retained	16,973.20	10,085.10	6,173.36	5,392.88	26,232.30

<sup>61 201-1</sup> Direct economic value generated and distributed



Through the bi-annual<sup>62</sup> sustainability report, we illustrate our commitment in disclosing our key financial and non-financial aspects to our stakeholders. This Report details our performance during the period<sup>63</sup> 01 April 2019 through 31 March 2021 (hereafter referred as FY 2021 in the Report) has been published as per GRI Standards (2018 version) 'in accordance - core 'criteria<sup>64</sup>.

### 11.1 Reporting guideline

At Biological E Limited, we believe that an inclusive stakeholder engagement would yield valuable insights in identification of important material topics. Through our materiality assessment, we could prioritize strategies and action plans with due focus on the triple bottom line of sustainability. In this report, we have disclosed on all the material topics, identified as high and very high in the materiality matrix, in line with the GRI standard. Aspects such as stakeholder inclusiveness, materiality, sustainability context and completeness have been considered while developing the content of this report. An attempt is also made in aligning this report to the United Nations Sustainable Development Goals (UNSDGs) and incorporating a flavor of Integrated Reporting <IR> framework from the International Integrated Reporting (IIRC)65. Please refer to GRI Content Index<sup>66</sup> for a complete listing of GRI disclosures included in this report. GRI reporting principles for defining content and quality have been adhered while preparing this report.

During the reporting year, we had acquired a manufacturing facility of Akorn India, and inaugurated the Shameerpet SEZ facility, thus enhancing our production capacity. During the reporting year, we had added three new material topics namely cyber security, intellectual property rights and promoting innovation while retaining the existing seventeen material topics. While there aren't any significant changes during the reporting period regarding the organization's size, structure, ownership, or its supply chain. There have been no restatements of data for any of the previous year's reports<sup>67</sup>.



In this report, our internal boundary coverage of vaccines and pharmaceutical (hereafter referred as pharma) business is restricted to operations in India.

### 11.2 Reporting boundary

In this report, our internal boundary coverage of vaccines and pharmaceutical (hereafter referred as pharma) business is restricted to operations in India. The general standard disclosures cover information pertaining to our vaccines and pharma business operating across all locations Whereas, the specific standard disclosures cover the performance data for the manufacturing units of vaccine division at Shameerpet, Gaganpahad and Azamabad, along with pharma business at Shameerpet, Patancheru, Azamabad and Dehradun. We have for the first time and will continue to report on all our facilities under vaccine and pharma business in our sustainability report<sup>68</sup>. Our most recent sustainability report<sup>69</sup> for the financial year 2017-19, was published in 2019.

### 11.3 Key exclusions

In this report key exclusions are as mentioned below-

- Economic performance of both vaccines and pharma business for FY 2020- 21 (1st April 2020 to 31st March 2021)
- Total production and net sales of both vaccines and pharma business for the FY 2020-21 (1st April 2020 to 31st March 2021)

<sup>62 102-52</sup> Reporting cycle

<sup>63 102-50</sup> Reporting period

<sup>64 102- 54</sup> Claims of reporting in accordance with the GRI Standards

<sup>&</sup>lt;sup>67</sup> 102-10 Significant changes to the organization and its supply chain, 102-48 Restatements of information

<sup>68 102-49</sup> Changes in reporting

<sup>69 102-51</sup> Date of most recent report



### 11.4 Stakeholder engagement

Effective stakeholder engagement is crucial to the success of any business as it enhances value to stakeholders and helps us achieve our business goals. Trust, transparency and ethical business culture forms the corner stone in nurturing our relationship with all stakeholders. We identify those stakeholders that are majorly impacted and who could possibly impact our business operation. Every stakeholder dialogue provides us an opportunity to

understand their views, key expectations and address their concerns. Thus, the feedback thus obtained are further assessed to identify critical concerns and discussed with relevant committees. The relevant departments are entrusted with the responsibility to identify and address these concerns<sup>70</sup>. The trust that we built, over the years, through our business processes and stakeholder interactions, helped us seamlessly maneuver through the pandemic. We acknowledge the collaborative efforts of all key stakeholders, that helped us materialize the vaccine development.

Below is the 4-step process for stakeholder engagement at BE71.



### **Identify**

Through
our industry
associations, we
identify our key
stakeholders,
both internal
and external, to
establish effective
dialogue.



### **Engage**

Our structured dialogue enables us in understanding key externalities. This also enables us in building lasting relationships with our stakeholders.



### **Prioritize**

We prudently examine the issues apprised by our stakeholders, basis its current and potential impact on our business. The list so developed is prioritized for internalization based on strategic business objectives.



### Manage

Our SHE and Sustainability committee formulates strategies to internalize the consolidated material topics.

Our employees, customers, suppliers, regulatory authorities, employee union, local community, media, academia, knowledge partners and industrial associations are identified as the key stakeholder groups through assessment of our value chain<sup>72</sup>. In the reporting year, we had performed a virtual limited internal stakeholder interaction (for our management) owning to the pandemic constraints and travel restrictions. Through sector and peer analysis, we had shortlisted few additional topics, which were further incorporated in addition to the existing material topics. The views of our stakeholders were sought on these new topics as well.

<sup>70 102-42</sup> Identifying and selecting stakeholders

<sup>71 102-43</sup> Approach to stakeholder engagement

<sup>72 102-40</sup> List of stakeholder groups

Key Stakeholder Groups	Mode of Engagement	Frequency of Engagement	Key expectations <sup>73</sup>
Employee	Employee satisfaction surveys	Half yearly	<ul><li>Skill development</li><li>Healthy and safe operations</li><li>Career progression</li><li>Employee engagement</li></ul>
Employee Union	One to one meeting	Need based	<ul><li>Periodic communication</li><li>Equal remuneration</li><li>Employee friendly policies</li><li>Safe work environment</li></ul>
Customers	Customer satisfaction surveys	On-going	<ul><li>Product pricing</li><li>Product availability</li><li>Quality</li><li>New product development</li><li>Timely delivery</li></ul>
Business Partners	Vendor & supplier meets, surveys	On-going	<ul><li>Knowledge and infrastructure support</li><li>Periodic communication</li><li>Collaboration opportunities</li><li>Long term partnership</li></ul>
Regulatory Authority	One to one meeting	Need based	Compliance     Community engagement
Local Community	One to one meeting	Need based	<ul><li>Frequent visits</li><li>Awareness creation</li><li>Employment opportunities</li><li>Health related programs</li></ul>
Media	Press releases	On-going	<ul><li>Periodic interaction</li><li>Future investments</li><li>Business strategy</li></ul>





### 11.5 Materiality assessment

Responding to stakeholders' concerns and adapting to the new challenges in the field of healthcare necessitates continuous improvement. We at Biological E, acknowledge materiality assessment, as a part of our continuous improvement process, which shapes our sustainability strategy. Our structured approach to materiality assessment is as below:

- I. Identify global topics based on GRI sector specific disclosures
- II. Compare identified topics against those of our peers
- III.Shortlist the topics based on organizational strategy and vision
- IV. Review and assess the impact of these topics on our value chain

The feedback gained through limited stakeholder interaction further helps with insights on relevant material topics and their impact on our business. Based on the topics identified from our materiality assessment, we define programs and initiatives to address these topics.

During the reporting period, a materiality assessment was performed. As a part of this process, we assessed internal stakeholder perspectives as well as emerging sustainability issues. The issues that emerged from the process are those that significantly impact the long-term viability of our business. The only significant change from the previous report for the existing material topics are the reporting boundary. Additionally, we have incorporated three new material topics namely cyber security, intellectual property rights and promoting innovation while retaining the existing seventeen material topics.



Material Topics <sup>74</sup>	Aspect Boundary <sup>75</sup>	Report Coverage
Water	Internal	7.1 Water Stewardship
Compliance	Internal	7.4 Environmental Compliance
Access to medicine	External	9.3.3 Access to Medicines
Product responsibility	Internal and External	9.3.1 Product Responsibility
Customer satisfaction	External	9 Social and Relationship Capital
Transparent reporting & communications	External	9.3.2 Transparency in Communication
Energy	Internal	7.3.1 Energy Management
Emissions	Internal	7.3.2 Emission Monitoring
Effluents & waste	Internal	7.2 Our waste Our Responsibility
Supply chain management	Internal and External	9.1 Responsible Sourcing
Health & safety	Internal	6.5 Employee health and safety
Workforce management	Internal	6 Human Capital
Intellectual property rights	External	8.2.1 Research and Development
Promoting innovation	Internal and External	8.2.1 Research and Development

Our present sustainability report addresses the material topics that have high and very high impact on both our business as well as stakeholders.

### 11.6 Report assurance

The content and data disclosed in this report has been independently verified and externally assured. The conformance of our Sustainability Report FY 2021 with "in accordance - core" requirements of the GRI Standard has been verified by British Standard Institution (BSI), an independent third-party assurance provider. The Report has been assured with the requirements of AA1000 Assurance Standard, AA1000AS (2008) Type I and the statement provided by BSI is included in the report.

Forward Looking Statement- The report includes forward-looking statements based on certain assumptions and management plans. In the report, these statements have been identified by words such as 'intend', 'anticipate', 'believe', 'expect', 'project', 'plan', etc., as far as possible. Should they materialize, the achievement of the projections is subject to risks and uncertainties.

<sup>74 102-47</sup> List of material topics

<sup>&</sup>lt;sup>75</sup> 102-46 Defining report content and topic Boundaries, 103-1 Explanation of the material topic and its Boundary

<sup>76 102-56</sup> External assurance



ASSURANCE STATEMENT





# OPINION STATEMENT

Statement No: SRA-IND-680600-4

Biological E. Limited (BE) Sustainability Report 2019 – 21

The British Standards Institution is independent to Biological E. Limited (BE) and has no financial interest in the operation of BE other than for the assessment and assurance of this report.

This independent assurance opinion statement has been prepared for BE only for the purposes of assuring its statements relating to its sustainability report, more particularly described in the Scope, below. It was not prepared for any other purpose. The British Standards Institution will not, in providing this independent assurance opinion statement, accept or assume responsibility (legal or otherwise) or accept liability for or in connection with any other purpose for which it may be used, or to any person by whom the independent assurance opinion statement may be read. This statement is intended to be used by stakeholders & management of BE. Owing to the prevailing extraordinary situation due to the outbreak of the COVID-19 pandemic, the stage 1 assurance was completed using hybrid model of part onsite visit and part through immersive techniques, where a remote assurance was conducted over Microsoft Teams video-conferencing tool, where the assessor and the assessee client connected through the computer systems and internet.

This independent assurance opinion statement is prepared on the basis of review by the British Standards Institution of information presented to it by BE. The review does not extend beyond such information and is solely based on it. In performing such review, the British Standards Institution has assumed that all such information is complete and accurate.

Any queries that may arise by virtue of this independent assurance opinion statement or matters relating to it should be addressed to BE only.

### Scope

The scope of engagement agreed upon with BE includes the following:

**1.** The assurance covers the sustainability Report of Biological E Limited for the years 2019-21, prepared "In accordance" with GRI Standards – Core option, and focuses on systems and activities of Biological E Limited covering the manufacturing units (vaccine division at Shameerpet, Gaganpahad and Azamabad; and pharma business at Shameerpet, Patancheru, Azamabad and Dehradun) in India during the period from 1st April 2019 to 31st March 2021.



2. The AA1000 Assurance Standard, AA1000AS v3, Type 1 moderate level engagement evaluates the nature and extent of BE's adherence to all four AA1000 AccountAbility Principles: Inclusivity, Materiality, Responsiveness and Impact. The specified sustainability performance information/data disclosed in the report has been evaluated.

### **Opinion Statement**

Our work was carried out by a team of sustainability report assurors in accordance with the AA1000 Assurance standard, AA1000AS v3 and GRI Standards 2020. We planned and performed this part of our work to obtain the necessary information and explanations we considered to provide sufficient evidence that BE's description of their self-declaration of compliance with the GRI Standards were fairly stated.

We conclude that the BE's Sustainability Report 2019-21 Review provides a fair view of the BE's CSR programmes and performances during FY 2019-21. We believe that the 2019-21 economic, social and environment performance disclosures are fairly represented. The sustainability performance disclosures disclosed in the report demonstrate BE's efforts recognized by its stakeholders.

### Methodology

Our work was designed to gather evidence on which to base our conclusion. We undertook the following activities:

- A top level review of issues raised by external parties that could be relevant to BE's policies to provide a check on the appropriateness of statements made in the report
- Discussion with senior executives on BE's approach to stakeholder engagement. We had no direct contact with external stakeholders
- Interview with staff involved in sustainability management, report preparation and provision of report information were carried out
- Review of key organizational developments,
- Onsite visit of one sample manufacturing unit and Corporate office to observe and verify the claims in person,
- Review of supporting evidence for claims made in the reports,
- An assessment of the company's reporting and management processes concerning this reporting against the principles of Inclusivity, Materiality and Responsiveness as described in the AA1000 AccountAbility Principles Standard v3.
- A sample-based assessment of the reliability and quality of information as company's performance provided in the Sustainability report

### **Conclusions**

A detailed review against the AA1000 AccountAbility Principles of Inclusivity, Materiality, Responsiveness and Impact and the GRI Standards is set out below:

### **Inclusivity**

Being the fourth year of reporting and on account of the COVID situation during the period, BE has not carried out an exclusive survey this time but intends to do so in the year 2021-2022. Moreover, owing to the pandemic situation in the reporting period, BE had performed a virtual limited internal stakeholder interaction considering the pandemic constraints and



travel restrictions. Through sector and peer analysis, BE had shortlisted few additional topics, which were incorporated in addition to the existing material topics. The views of the internal stakeholders were sought on these new topics as well.

Biological E Limited is a private sector biological products company in India that specializes in the area of low-cost vaccine production. BE supplies several essential and lifesaving Vaccines and Pharmaceuticals to UN Agencies viz. UNICEF, Pan American Health Organisations, other global markets and within India to Central and State Government Hospitals, Public Sector Undertakings, the Indian Armed Forces and the domestic retail market. In this Sustainability Report, material data disclosed is primarily restricted to the covering the activities of BE's manufacturing units (vaccine division at Shameerpet, Gaganpahad and Azamabad; and pharma business at Shameerpet, Patancheru, Azamabad and Dehradun) in India.

This report covers the stakeholder issue together with fair reporting and disclosures for economic, social and environmental information. In our professional opinion, the report covers the BE's inclusivity issues that demonstrates participation of stakeholders in developing and achieving an accountable and strategic response to sustainability. However, the future reports should be further enhanced by detailing relevant information on the relevant topics for Corporate office location and missing information of Patancheru.

### Materiality

BE publishes sustainability information that enables its stakeholders to make informed judgments about the company's management and performance. The present sustainability report addresses the material topics that have high and very high impact on both BE's business as well as stakeholders.

Compared to the previous report, BE has reworked on the material topics and added three new material topics - Cyber security, Intellectual property and promoting innovation. However, the present sustainability report addresses the material topics that have high and very high impact on both business as well as stakeholders of Biological E.

In our professional opinion the report covers the BE's material issues by using BE's materiality matrix and boundary mapping.

### Responsiveness

BE has implemented the practice to respond to the expectations and perceptions of its stakeholders. In view of the current pandemic situation, BE had performed a virtual limited internal stakeholder interaction and feedback from the internal stakeholder representatives were collected for materiality assessment. Based on the on the topics identified from materiality assessment, programs and initiatives to address these topics were defined.

In our professional opinion nothing has come to our attention to suggest that the responses related to identified material topics are not adequately represented in the Report.



### **Impact**

BE has also demonstrated that adequate systems are in place to monitor, measure and be accountable for their actions that affect the economy, the environment, society, stakeholders and the organisation itself.

### **GRI-reporting**

BE provided us with their self-declaration of compliance GRI Standards and the classification to align with "In accordance" - Core. Based on our verification review, we are able to confirm that social responsibility and sustainable development disclosures in all 3 categories (Environmental, Social and Economic) are reported with reference to "In accordance" with the GRI Standards – Core option.

The majority of data and information verified at the Head Office and at sample locations visited by us were found to be fairly accurate and reliable. Some of the data inaccuracies identified during the verification process were found to be attributable to transcription, interpretation and aggregation errors and these errors have been corrected. It is suggested that BE may implement appropriate tools for sustainability data management and initiate a process of internal reviews and validation to further strengthen the reliability of its performance disclosures. In our professional opinion the self-declaration covers BE's social responsibility and sustainability issues. On the basis of the verification undertaken, nothing has come to our attention to suggest that the Report does not properly describe the following sustainability disclosures as stipulated in the GRI Standards.

- GRI 302: Energy 2016 302-1, 302-4;
- GRI 303: Water 2018 303-1, 303-2, 303-3; 303-4; 303-5;
- GRI 305: Emissions 2016 305-1, 305-2, 305-6, 305-7;
- GRI 306: Effluents and Waste 2016 306-1, 306-2;
- GRI 307: Environmental Compliance 2016 307-1;
- GRI 401: Employment 2016 401-1, 401-2, 401-3;
- GRI 403: Occupational Health and Safety 2018 403-1; 403-2; 403-3; 403-4; 403-5, 403-6, 403-7, 403-8, 403-9;
- GRI 404: Training & Education 2016 404-1; 404-3
- GRI 405: Diversity & Equal opportunity 2016 405-1
- GRI 416: Customer Health and Safety 2016 416-2;
- GRI 417: Marketing and Labelling 2016 417-2

### **Competency and Independence**

The assurance team was composed of Lead auditors experienced in industrial sector, and trained in a range of sustainability, environmental and social standards including GRI-G4 and GRI Standard, AA1000, ISO10002, ISO 14001, OHSAS 18001, and ISO 9001, etc. BSI is a leading global standards and assessment body founded in 1901. The assurance is carried out in line with the BSI Fair Trading Code of Practice.

### **Assurance Level**

The type 1 moderate level of assurance provided is in accordance with AA1000 Assurance standard, AA1000AS, v3 in our review as defined by the scope and methodology described in this statement.



### Responsibility

It is the responsibility of BE's senior management to ensure the information presented in the Sustainability Report is accurate. Our responsibility is to provide an independent assurance opinion statement to stakeholders giving our professional opinion based on the scope and methodology described.

### Reliability

The assurance statement on the performance was issued based on the evidence collected from ground level provided by the employees of BE. The sample selection was on random basis and selection is done by BSI auditor. The assurance team was convinced that the performance information presented in the report are reliable and representative.

### Quality

The quality of information was checked through cross verification of data. Field level measurement and records were verified with the procurement and supply chain invoices/bills. Interview with the responsible persons detailed the activities, maintenance, and process performance. The fitness of the measuring devices, frequency of measurement and recording, competency of the person concerned, and review & approval of information were checked and found in conformance.

### **Performance Information**

BE Sustainability report has addressed their Environment, Social and Governance performance through GRI indicators. The assurance team has evaluated the requirements of the GRI indicators for general disclosures and those relevant to the material topics only. For the specific data presented in the report, minimal technical/compilation errors were identified during the sampling process which were corrected for the final report.

Based on the processes and procedures conducted with a moderate assurance, there is no evidence that the Environmental and Social data and information are not materially correct and are not a fair representation of their Environmental and Social performance.

For and on behalf of BSI:

Kumaraswamy Chandrashekara Head - Certification. BSI Group India

New Delhi, India 21 March 2022 AA1000 Licensed Report 000-184/V3-VIZH3



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	302-4 Reduction of energy consumption	7.3.1 Energy management	-	75
	303-1 Interactions with water as a shared resource	7.1.1 Water consumption	-	65
GRI 303: Water 2018	303-2 Management of water discharge-related impacts	7.1.1 Water consumption	-	65
	303-3 Water withdrawal	7.1.1 Water consumption	All our operational facilities, except Dehradun, are in water stress regions. The TDS data collection quality, at all our facilities, requires strengthening and would report henceforth.	65
	303-4 Water discharge	7.1.2 Responsible disposal of wastewater	All our operational facilities, except Dehradun, are in water stress regions. The TDS data collection quality, at all our facilities, requires strengthening and would report henceforth.  Data monitoring of treated effluent recycled in the chiller / cooling tower makeup water is not being adequately monitored at all facilities, except Gaganpahad.	69
	303-5 Water consumption	7.1.1 Water consumption	-	68
	305-1 Direct (Scope 1) GHG emissions	7.3.2 Emission monitoring	Emission sequestration from plantation is not calculated for the reporting period. Moreover, the contribution would be minimum, as the current plantation in restricted to shrubs and lawn.	78
GRI 305: Emissions 2016	305-2 Energy indirect (Scope 2) GHG emissions	7.3.2 Emission monitoring	-	78
	305-6 Emissions of ozone-depleting substances (ODS)	7.3.2 Emission monitoring	-	79
	305-7 Nitrogen oxides (NOX), sulfur oxides (SOX) and other significant air emissions	7.3.2 Emission monitoring	COVID-19 induced restrictions led to inconsistent recording of data, hence not disclosed for all facilities	79



ODLOGG	306-1 Water discharge by quality and destination	7.1.2 Responsible disposal of wastewater	-	69
GRI 306: Effluents and Waste 2018	306-2 Waste by type and disposal method	7.2 Our waste Our responsibility	We intend to develop a management system to capture end disposal of waste generated in the upcoming years	74
GRI 307: Environmental Compliance 2016	307-1 Non-compliance with environmental laws and regulations	7.4 Environmental compliance	-	80
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	401-1 New employee hires and employee turnover	6.3 Attracting and retaining talent	-	50
GRI 401: Employment 2016	401-2 Benefits provided to full-time employees that are not provided to temporary or part-time employees	6.3.1 Employee benefits	-	52
	401-3 Parental leave	6.3.1 Employee benefits	-	54
	403-1 Occupational health and safety management system	6.5 Employee health and safety	-	58
	403-2 Hazard identification, risk assessment and incident investigation	6.5 Employee health and safety	-	58
	403-3 Occupational health services	6.5 Employee health and safety	-	59
GRI 403:	403-4 Worker participation, consultation and communication on occupational health and safety	6.5 Employee health and safety	-	58
Occupational Health and Safety 2018 - Management approach	403-5 Worker training on occupational health and safety	6.2 Training and development	Data for Gaganpahad, Shameerpet Vaccine, Shameerpet SEZ and Azamabad is only disclosed	49
disclosure	403-6 Promotion of worker health	6.3.1 Employee benefits	-	52
	403-7 Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	6.5 Employee health and safety	-	59
	403-8 Workers covered by an occupational health and safety management system	6.5 Employee health and safety	Applicability of OHSMS is only for Gaganpahad, Shameerpet Vaccine and Shameerpet SEZ	58

GRI 403: Occupational Health and Safety 2018 - Topic specific disclosure	403-9 Work-related injuries	6.5 Employee health and safety	-	59
GRI 404: Training and Education	404-1 Average hours of training per year per employee	6.2 Training and development	Gender-wise training data would be captured and reported henceforth  Calculated based on data for Gaganpahad, Shameerpet Vaccine, Shameerpet SEZ and	49
2016	404-3 Percentage of employees receiving regular performance and career development reviews	6.3.1 Employee benefits	Azamabad only	54
GRI 405: Diversity and Equal Opportunity 2016	405-1 Diversity of governance bodies and employees	4.7.1 Corporate governance	-	29
GRI 416: Customer Health and Safety 2016	416-2 Incidents of non-compliance concerning the health and safety impacts of products and services	9.3.1 Product Responsibility	-	100
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<sup>\*</sup>Non GRI topics



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	103-3 Evaluation of the management approach	4.6 Precautionary approach	-	29
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	103-3 Evaluation of the management approach	8.2.1 Research and development	-	90
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	103-3 Evaluation of the management approach	8.2.1 Research and development	-	91

# **ABBREVIATIONS**

ANDA Abbreviated New Drug Application

API Active Pharmaceutical Ingredients

BEEP Biological E. Employee Portal

BIRAC Biotechnology Industry Research Assistance Council

CEPI Coalition for Epidemic Preparedness Innovation

CSR Corporate Social Responsibility
DGCI Drugs Controller General of India

DI Drug Intermediates

ESI Employee State Insurance
GCP Good Clinical Practice

GMP Good Manufacturing Practices
GWP Global Warming Potential

IAEC Institutional Animal Ethics Committee

ICH International Council for Harmonization of Technical

Requirements for Pharmaceuticals for Human Use

IBR Integrated Business Review Committee

IBSC Institutional Biosafety Committee

IPV Inactivated Polio Vaccine

ISO International Organization for Standardization

KL Kilo Litre

KSM Key Starting Materials

ML Million Litre

NCI National Cancer Institute

OH&S Occupational Health and Safety

PCV Pneumococcal Conjugate Vaccine

PQCDSM Productivity, Quality, Cost, Delivery, Safety, Morale

SAB Scientific Advisory Board

SHEC Safety, Health and Environment Committee

TCV Typhoid Conjugate Vaccine

UNSDG United Nations' Sustainable Development Goal

USFDA U.S. Food and Drug Administration

WHO Word Health Organization

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