# Co-creating a Responsible Future

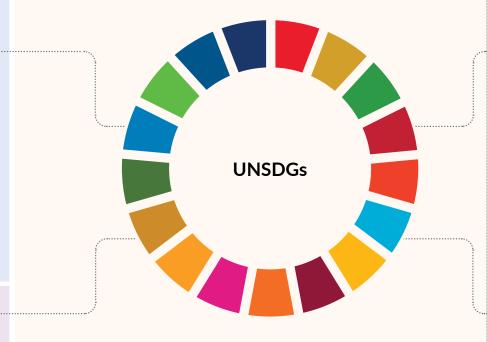
# Envisioning a Better Tomorrow

At Sun Pharma, we strive to create a conscious future by investing in R&D to develop innovative products, in addition to implementing data security practices and collaborating with responsible suppliers.



#### **Material Topics**

- Product accessibility
- Responsible product pricing
- Investment in innovative technologies
- Development of complex molecules
- Data integrity and security
- Technology and digitalisation
- Product responsibility
- Responsible supply chain





#### **Our Corporate Values**

- Quality
- Reliability
- Trust
- Consistency
- Innovation



# **Target 12.7**

~95% of indirect procurement in FY22 was from local sourcing



# Target 3.b

Invested ₹22.2 Bn in R&D for FY22



# Target 9.5

R&D investments at 5.8% of sales for FY22





#### **Governance Enablers**

- Global Code of Conduct
- Audit Committee
- Stakeholder Relationship Committee
- Corporate Governance and Ethics Committee



## **Key Highlights and Targets**

- Supplier Code of Conduct rolled out
- Developed and filed ~200 formulation dossiers globally in FY22
- 2,154 patents filed and 1,420 patents granted
- Presence in more than 100 countries



# Financial Performance<sup>14</sup>

While we continue to expand our global business, we are committed to optimising efficiency, cash flows, and cost structure in order to provide long-term value to all our stakeholders. To provide protracted benefit to all our stakeholders, we are constantly improving our core capabilities so that we can supply value-added products to communities around us and the geographies that we operate in. We prioritise the health of our patients and aspire to boost the global healthcare system by establishing a robust portfolio of innovative and affordable pharmaceutical products.

## Sun Pharma's Growth Strategy



#### **Create Sustainable Revenue Streams**

- Enhance share of specialty business globally
- Achieve differentiation by focusing on technically complex products
- Focus on key markets achieve critical mass
- Focus on speed to market
- Ensure sustained compliance with global regulatory standards
- Remain committed to governance, community upliftment, access to affordable healthcare & environment conservation



# Balance Profitability and Investments for the Future

- Increasing contribution of specialty and complex products
- Direct future investments towards specialty and differentiated products



#### **Cost Leadership**

- Optimise operational efficiency and cost effectiveness
- Focus on vertically integrated operations



#### **Business Development**

- Use acquisitions to bridge critical capability gaps
- Focus on access to products, technology, and market presence
- Ensure acquisitions yield a targeted return on investment
- Focus on payback timelines





# Patient Safety Is Imperative<sup>15</sup>

Sun Pharma places a strong emphasis on the health and safety of our patients all around the world. We adhere to stringent quality and regulatory compliance in this respect. We monitor product safety and ensure that the risk-benefit profile of our products is continuously assessed throughout their life cycle.

#### **Pharmacovigilance**

Our pharmacovigilance department has been operational for the last 17 years, making it the first of its kind in the Indian pharmaceutical industry. To monitor the safety of all our products and quickly execute risk mitigation measures, our pharmacovigilance system takes a 'beyond-compliance' approach. A Company-wide pharmacovigilance policy was adopted, which is backed up by a Product Safety Committee.

Our pharmacovigilance policy reflects our commitment to patient safety and is subject to periodic senior management review. The VP of Medico-Regulatory Affairs, Clinical Data Reporting (MACR), and Global Pharmacovigilance leads our pharmacovigilance team (GPV). The team supports us with strong contingency planning, which enables effective risk evaluation and mitigation. This also helps enhance training and quality control and assists us in establishing necessary safeguards to ensure patient safety. Periodic safety update reports, risk evaluation and mitigation strategies, health hazard evaluations, training, and quality control are some of the responsibilities undertaken to replace services provided by the team.



Product Stewardship Management Approach

#### The Imperative

- Enhanced product quality and safety profile
- Increased transparency and trust with stakeholders
- Enhanced culture of innovation across the organisation

# Cornerstones of Our Approach

- Established Quality Vision
- Quality, Compliance, and PV Management System
- Seamless and strategic
   Quality Assurance Process

#### Strategic Enablers

- A well-established global pharmacovigilance policy
- A highly capable global pharmacovigilance and quality team and Product Safety Committee

#### **Aspirations**

We are focused on:

- Continue to ensure ethical use of products
- Raising awareness about proper use and disposal of our products
- Promptly evaluating and addressing product queries/complaints

<sup>&</sup>lt;sup>15</sup>GRI 103-1, GRI 103-2, GRI 103-3, GRI 416-1





### Pharmacovigilance at Sun Pharma

- The pharmacovigilence function undergoes periodic inspections from regulatory authorities, including the US FDA, UK MHRA, Health Canada, URPL Poland, and OGYI Hungary, among others.
- The Independent Pharmacovigilance QA reports to the Global Quality Head.
- Global pharmacovigilance quality audits are driven by a 'five-year' strategic audit plan and an annual audit plan.
- Nearly 100 team members of the pharmacovigilance team are qualified physicians, PhD holders, postgraduates, and graduates in science/pharmacology.
- The pharmacovigilance function is adequately supported by a strong technology backbone using the best-in-class industry software for data processing.

## **Product Quality**

In line with our Quality Vision, we have adopted an integrated and comprehensive quality management approach, encompassing our global QMS and best-in-class quality practices and quality assurance procedures. Additionally, we follow a robust quality complaint management procedure to ensure investigation of complaints received and integration of corrective actions. A number of our API and formulations manufacturing sites are ISO 9001: 2015 certified; we aim to increase the coverage of certified sites in future.

#### Quality Vision

Our vision is to globalise, harmonise, and simplify Good Practices (GxP) processes to ensure a sustainable quality culture. At Sun Pharma, we work towards continuous improvement of our QMS and all its elements. We are building and maintaining a strong culture of quality through ongoing development, training, and empowerment of our personnel. We believe that producing safe, high-quality products is everyone's responsibility.

#### - oms -

Global QMS

Cross-functional implementation of QMS including R&D, quality, and operations

Implementation of best practices to ensure delivery of high-quality products

#### — Quality Practices —

Sustainable quality design

Quality data governance

Harmonisation of processes for enhanced compliance

Global quality metrics

Lessons learned strategy

#### Key Elements Strengthening Our QMS —

# Procedural Documents

Electronic document management systems

- Controlled printing
- Access controlled
- Version controlled

#### Deviation Analysis

Analysis of global deviation by undertaking periodic trend analysis

#### **Training**

Instructor-led and electronic learning management systems

# Good Documentation Practices

Implementation of good documentation practices in line with SOPs

#### Corrective and Preventive Actions (CAPA)

Robust product quality complaint management encompassing preliminary assessment, investigation, and corrective actions

#### Quality Assurance Process —

Compliance with GxP regulations and country-specific regulations

Ensuring quality of finished products through in-process testing, finished goods testing, and stability testing

Comprehensive QMS system inclusive of change management, deviation management, CAPA, adverse product events, field alert reporting, and compliant management and recall process Periodic inspections at manufacturing locations in line with the requirements of GxP certifications by regulatory agencies

Ensuring compliance with specifications, approved by regulatory agencies, relevant to each specific market requirement

Periodic audits conducted by the Company's Corporate Quality team at all manufacturing sites, contract manufacturing sites, and vendors Release of raw materials, inclusive of API, and packaging material post qualification and testing

Prevent any deviation, failures and discrepancies by recording investigations in the QMS

Training of employees involved in GxP activities through modules curated for job-specific roles

# Our Product Quality Complaint Management Process

At Sun Pharma, we implement an all-inclusive approach towards product quality complaints. The complaints received are logged into the system, which is followed by a preliminary assessment. An initial risk assessment is conducted as part of the investigation procedure. A sample follow-up is carried out during the course of the investigation. Based on the outcome, CAPA are undertaken. A complaint summary is noted and assessment is conducted. A response to the complainant is submitted, leading to the closure of the complaint.

#### **Number of Product Recalls**

2 Class I

L7 Class II Product quality complaint receipt and logging

Complaint acknowledgement and preliminary assessment

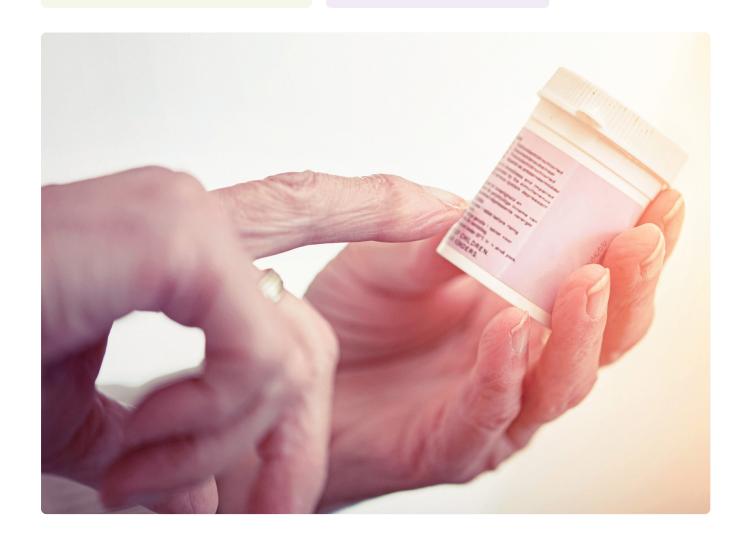
Initial risk assessment

Sample follow-up

Product recall proposal, if required

Complaint summary and final risk assessment undertaken

Response to complainant and closure



of product quality complaint

#### Responsible Product Stewardship<sup>16</sup>

At Sun Pharma, we focus on implementing responsible practices across the product life cycle, including accessibility, labelling, and disposal.



#### **Product Accessibility**

At Sun Pharma, in line with our vision of 'Reaching People, Touching Lives', we endeavour to augment product availability and accessibility across multiple global markets, cities, towns, and rural areas. Our robust distribution network of carrying and forwarding agents (CNFs), stockists, distributors, and wholesalers facilitates us to reach and deliver our products to patients across the world.



#### **Product Information and Labelling**

As part of our responsible product stewardship, we ensure the relevant product information in terms of pharmacokinetics, safe use of product, sourcing of ingredients, composition, clinical pharmacology, drug interactions and side effects, and storage conditions, among others, is made available to customers through product labelling. In FY22, there were no cases of non-compliance concerning the health and safety impact of products or product information and labelling.



#### **Responsible Product Disposal**

In line with the local regulations regarding safety and environmental protection for the disposal of pharmaceutical products, we follow a well-established disposal procedure for the safe disposal of returned or recalled products. We strictly adhere to relevant regulations and ensure compliance with established guidelines for country-specific requirements. Additionally, we document the method of identification of product, quantity, and date of destruction.



#### **Anti-counterfeit Awareness**

With the support of a robust anti-counterfeit governance management system, we strive to raise awareness about risks associated with counterfeit medicines, in markets where we face the problem of counterfeit products. We have a dedicated taskforce responsible for mitigating the risks associated with counterfeit medicines. The taskforce works in congruence with our trace-and-track technology and complaint management system, enabling seamless monitoring of counterfeit medicines.

#### Anti-counterfeit Governance at Sun Pharma

The trademark team and the learning and organisation development team train the entire field force for identifying and reporting counterfeit medicines.

A dedicated taskforce, inclusive of senior field members across clusters, is trained for identifying counterfeit products. The identification is interlined with relevant KPIs.



#### R&D<sup>17</sup>

At Sun Pharma, we continually strive towards the development of complex and innovative products, aimed at addressing the needs of patients. With the support of ~2,700 employees across multiple research centres globally, we develop specialty and generic products, as well as novel cost-effective processes and technologies.

#### **Intellectual Property**

We have a robust intellectual property team specialising in chemistry, analytical techniques, dosage forms, and global patent practice. We leverage our strong research and implementation capabilities to exemplify our patents' portfolio. We file numerous patents for protecting our intellectual property. As of FY22, we had a portfolio of 1,420 granted patents. Additionally, our R&D centres are audited by various international regulatory authorities.

Responsible R&D is pivotal to accelerate our patient-centric approach to innovation. Our R&D efforts are supported by our robust scientific and technical expertise and propelled by strategic partnerships to deliver next-generation innovative therapies.

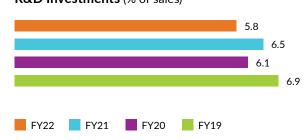
Sun Pharma strives to provide patients with innovative and affordable treatments to alleviate their healthcare problems. The Company continuously invests in developing a robust pipeline of generics, branded generics, and specialty products for the global market.

Sun Pharma has wide-ranging R&D capabilities for the development of products across dosage forms, such as injectables, orals, liquids, ointments, gels, sprays, hormones, and oral products. A strong intellectual property capability supports the R&D team.

#### **R&D Investments** (₹ in Bn)



#### **R&D Investments** (% of sales)





<sup>&</sup>lt;sup>17</sup>GRI 103-1, GRI 103-2, GRI 103-3

#### Sun Pharma-Specialty R&D Pipeline

Molecule/Asset	Indication	Route of Administration	Mechanism of Action	Pre-clinical	Phase-1	Phase-2	Phase-3	Registration	Approved
Ilumya (tildrakizumab)	Psoriatic Arthritis	Injection	IL-23 Antagonist						
SCD-004	Psoriasis, Atopic Dermatitis	Oral	Selective SIPR1 Agonist						
MM-II	Treatment of pain in osteoarthritis	Injection	Liposomal intra-articular lubrication						
GL0034	Type 2 Diabetes	Injection	GLP-1R Agonist						

#### Our R&D Approach and Capabilities

Guided by our key enablers and capabilities in research and innovation, we strive to achieve our ambition of catering to the unmet medical needs of patients globally.



# Our Enablers

- Significant investments in R&D to develop complex products, specialty products, generic products, and API technologies
- 2,700+ scientifically skilled workforce dedicated towards R&D with best-in-class infrastructure
- Adherence to global regulatory requirements to ensure high standards of quality
- Emphasis on development of novel technologies such as the use of green reagents for chemical transformations in API synthesis, use of PAT tools in process development, and advanced processing techniques
- Product life cycle management has been undertaken for key products; backward integration is a key strategic objective and many of our products enjoy the benefit of this backward integration
- Process optimisation based on Quality by Design (QbD) concept and robustness by six sigma calculation have been implemented for a wide range of products to target efficiencies and increase in-process capability
- Novel compact dosage forms having differentiation with regards to improved stability and/or reduced pharmacokinetic variability have been developed



# Our Capabilities

- Capabilities in finished dosage development, biological support, chemistry, and new drug development
- Ability to develop products across dosage forms like orals, liquids, ointments, gels, sprays, injectable means
- Capabilities to develop noninfringing formulations and development of specialty/ complex products
- Offers a comprehensive basket of products across therapies to cater to needs of patients
- Ability to conduct clinical studies for complex generics at in-house clinical pharmacology units



# Our Ambitions

- Invest to further build the specialty pipeline
- Develop complex generics for developed markets
- Enhance focus on developing R&D pipeline for Emerging Markets and India
- Augment the development of API,s which are strategically important



# Key Highlights for FY22

- Overall R&D investments for FY22 was ₹22 Billion
- Developed and filed ~200 formulation dossiers globally in FY22
- As of March 31,
   2022, the cumulative portfolio consisted of:
  - 605 ANDAs and 67 NDAs/BLA filed with USFDA
  - 512 ANDAs and 54 NDAs/BLA approved by USFDA
  - 2,154 number of patents filed and 1,420 patents granted (excluding expired/abandoned patents)
  - 490 DMF/CEP filed and 377 approved DMF/CEP

#### Innovation and Technology<sup>18</sup>

Our investments in cutting-edge technologies enable us to enhance the affordability of medicines across the world, ensuring strict adherence to global safety standards, while improving the overall quality of our product portfolio.

We have undertaken a series of projects that have yielded a variety of benefits, including increased safety, improved operational efficiency, technical advancements, and cost efficiency. We have a specialised Center of Excellence (CoE) that aids in the adoption of pioneering technology in order to promote long-term business growth. R&D, quality, finance, manufacturing, HR, and supply chain are all supported by the CoE. Further, our IT CoEs collaborate closely with business functions to develop strategies that enable innovation. Proof of concept and business case approvals are used to make a collaborative decision on technology adoption.

We have detailed technology rules to ensure that our projects are implemented effectively and are supported by worldwide compliance and technology standards such as the Information Security Management System (ISMS) and the Information Technology Infrastructure Library (ITIL). A comprehensive IT innovation and technology plan has also been formed by our Corporate Technology Team, and it directs the adoption of necessary IT policies across the entire organisation.

To support the implementation of information security, we have earmarked an annual budget at the departmental level that takes into consideration the current internal hardware and application landscape, ongoing initiatives, new projects, and external factors that influence information security. We have also put in place an effective monitoring system to improve the integrity and security of our data.





#### The Imperatives

- Sustainable manufacturing processes are facilitated by improved technology and innovation
- The formation of a distinct generic and specialty pipeline
- Cost effectiveness across business activities



In FY22, there were zero cases of substantiated complaints pertaining to breaches of customer privacy.19

#### **Aspirations**

variety of markets

**Cornerstones of Our Approach** 

process optimisation

Unlocking the potential of lean manufacturing and

Development of unique products for a

To offer transformational cures and enhance the global healthcare system, increase investments in R&D and innovation

#### **Strategic Enablers**

- Development of new technologies, including Robotics Process Automation (RPA) and Augmented Reality (AR)
- Presence of a dedicated R&D team
- Periodic reports with the Board of Directors and Managing Director for continual development
- To promote the use of new technology, a CoE has been established

## Our Approach to Information Security

- Implementation of global SOP on data across locations
- Alignment with ISO27001:2013 for information security risk management
- Presence of a risk-based approach to mitigate security risk across people, processes, and technologies
- Implementation of the Information Security Awareness Programme, ISMS, Global Standard Operating Procedures (GSOPs), and defense in depth
- Presence of 24x7 monitoring systems for threat identification and defined incident management processes

#### Adherence to global data integrity and security standards:

- US FDA data integrity and compliance with Drug cGMP
- PDA technical report 80 data integrity management system for pharmaceutical laboratories
- ISO27001 ISMS
- GDPR personal data protection in the EU

#### Our Focus on Data Integrity and Security

- Policies, processes, and obligatory information security awareness trainings for all users within the organisation are used to implement data integrity and security initiatives.

#### Data integrity and security challenges are categorised across three broad parameters:

- Breaches due to cyber attacks
- Insider threats
- Data integrity at the manufacturing level
  - Presence of defense in depth, 24x7 security operations centre, and threat intelligent governance services as well as security partners to address the risk of cyber attacks
  - Alignment of Incident Management Policy with ISO 27001:2013
  - Established a data leakage prevention tool for insider threats; data leaks are further investigated with the business and HR functions
  - Established global SOPs to carry out root cause analysis and risk assessments for manufacturing operations

# Responsible Sourcing and Supply Chain<sup>20</sup>

As a leading pharma company with the vision of reaching people with valued medicines, product accessibility forms an integral factor for our sustainable value creation model. We work towards creating a strong cross-functional supply chain management system, encompassing logistics, procurement, planning, and inventory management to ensure the feasibility of production in line with market demand. The efficacy of our supply chain management system is reviewed periodically by the senior management. Further, the system is embedded with KPIs for enabling continuous improvement as outlined below.

We have defined KPIs embedded within each function of our supply chain management system for effective monitoring of our supply chain activities and initiatives.



#### **Procurement**

Our procurement team ensures a seamless supply of raw materials, and primary and secondary packing materials for both the development and manufacturing of APIs, and formulations and also the availability of finished formulations at the designated market.



# Planning and inventory management

Our integrated management system undertakes Distribution Requirement Planning (DRP), Market Requirement Planning (MRP), and other planning insights to gauge the inventory requirements and enable efficient monitoring of the supply chain activities.



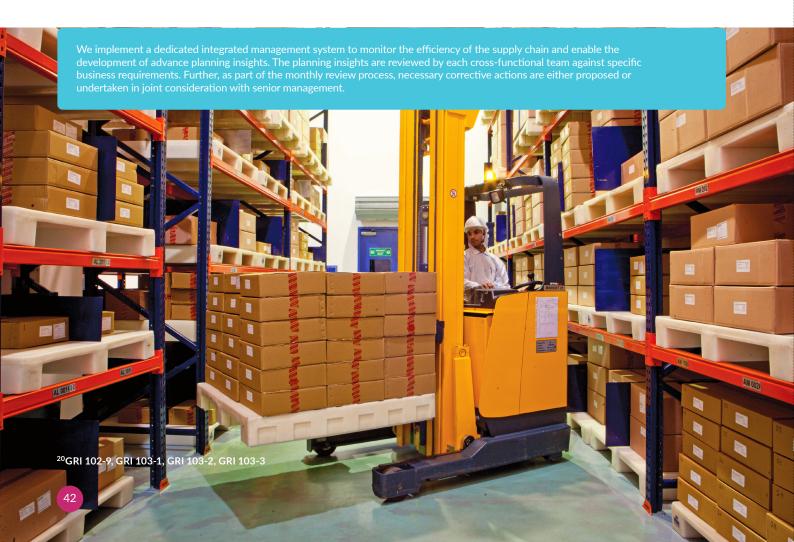
#### Distribution and logistics

Our distribution and logistics team enables timely delivery of finished goods and services in line with customer requirements. Further, the logistics team works in coordination with the supply chain team to overcome any disruption in the supply chain, ensuring uninterrupted delivery of consignments.



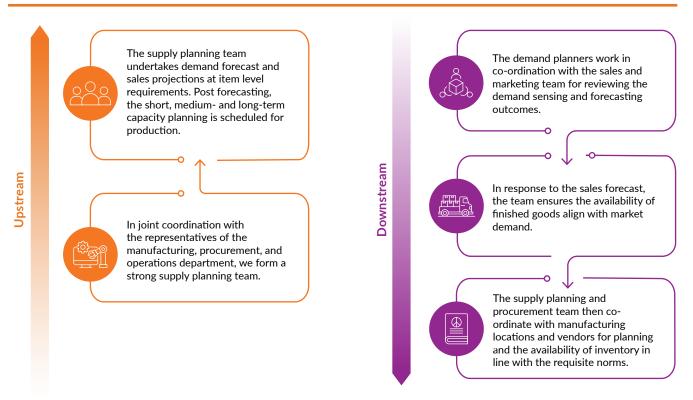
#### Finished goods delivery

The distribution team ensures delivery of finished goods as per the timelines and customer requirements; further, the team co-ordinates with the supply chain team to determine the mode of shipment for speedy transportation of consignments.





#### An Overview of Our Supply Chain Operations<sup>21</sup>

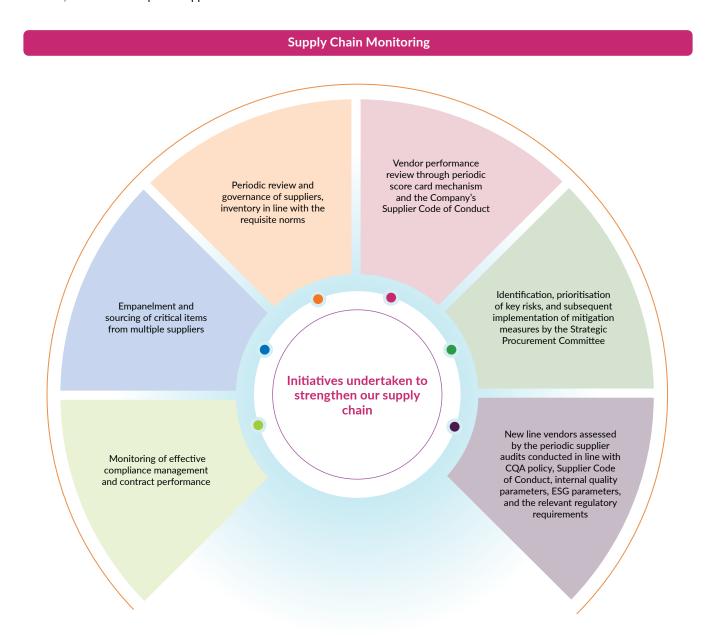


In FY22, there were no significant changes to the organisation's size, structure, ownership, or supply chain.

#### **Effective Supply Chain Monitoring**

We implement a robust supply chain monitoring mechanism encompassing principles and checklists for the identification, assessment of supply chain risks, and implementation of mitigation strategies. We undertake periodic assessment of our vendors every three years, enabling 100% coverage of vendors through the CQA audits. In FY22, we revised our CQA audit checklist by including ESG parameters in line with the recommendations of the PSCI and other relevant frameworks. Further, we have developed a Supplier Code of Conduct that

enables us to integrate ESG parameters across the supply chain. We expect all third-party vendors, suppliers, and business partners to adhere to the principles of the Supplier Code of Conduct. In FY22, we have conducted scheduled assessments for some of our vendors, in line with requirements of the revised CQA checklist.



#### Local Sourcing<sup>22</sup>

As part of our responsible supply chain practices, we endeavour to spend a major portion of our sourcing from local sources. In FY22, we sourced ~95% of indirect procurement, 61% of direct procurement, and 67% of services from local suppliers. The local sourcing facilitates in averting currency

risks in addition to strengthening our supply chain due to augmented dependency on flexible local operations. Further, it facilitates our contribution to the development of national skill sets and lowers the environmental footprint.

<sup>22</sup>GRI 204-1



~95% sourcing of indirect procurement is from local suppliers

61% sourcing of direct procurement is from local suppliers

67% sourcing of services is from local suppliers