Enhancing Access to Quality Healthcare

The realisation of the goal of universal health coverage relies on access to safe and efficacious medicines at affordable prices. As a prominent global generic pharmaceutical Company, we are committed to delivering high-quality and affordable medications to patients and healthcare professionals in 100+ countries worldwide.

Aligned with our overarching vision of 'Reaching People, Touching Lives Globally as a Leading Provider of Medicines' we strive to enhance the presence and reach of our products in diverse international markets, urban centres, towns, and even rural areas. Our strong distribution network, comprising carrying and forwarding agents (CNFs), stockists, distributors, and wholesalers, empowers us to deliver our pharmaceutical products to patients worldwide, ensuring widespread accessibility and availability to those needing medical products.

We aim to provide high-quality generic and branded medicines via our global workforce of 43,000+ (including executives on contract) people, across 43 manufacturing locations. Our proven R&D capabilities, comprising 2,800+ people and focused investments (representing 5.5% of our sales in FY23), bolster our commitment to developing specialty medications to address unmet medical needs and the development of generic medications. Ensuring good health for all is attainable with access to essential pharmaceutical products, and our focus is on improving access to healthcare by delivering safe effective, and responsibly priced products.

Patient Safety

We deploy stringent mechanisms of review and quality checks to ensure regulatory compliance and maintain the product quality of our medicines and manufactured APIs, at the highest levels. Timely identification and mitigation of risks associated with our products' health and safety impacts, is critical to enhance product quality, patient safety and retain stakeholder trust[33]. Failure to maintain product quality may lead to penalties and warnings from regulatory authorities, ultimately, to an erosion of brand value and perception with our stakeholders. We comply with all quality and regulatory compliance standards and monitor product safety to ensure that our products' risk-benefit profile undergoes continuous assessment[34].

Pharmacovigilance at Sun Pharma

Our pharmacovigilance department is one of the first of its kind in India. It has been operational for 17 years, with a rich legacy signifying our focus on adopting a beyond-compliance approach to risk mitigation and product safety. Our pharmacovigilance system is designed to maintain stringent oversight on the safety of all our products and quickly implement risk mitigation measures in case of any adverse event reports[35]. We have established a global pharmacovigilance policy, which is supported by a Product Safety Committee and the Independent Pharmacovigilance QA reports to the Global Quality Head. The pharmacovigilance policy showcases the Company's commitment and efforts towards patient safety.

The senior management undertakes periodic policy reviews to ensure smooth and effective implementation. Our pharmacovigilance team provides robust contingency planning, enabling timely and effective risk mitigation and resolution. This further streamlines our efforts to identify opportunities for workforce training, quality control and establishing robust safeguards to ensure patient safety. We have also incorporated industry-leading IT solutions to ensure efficient and accurate data processing, providing a solid technological backbone to our pharmacovigilance operations.

Comprising nearly 100 qualified physicians, Ph.D. holders, postgraduates, and graduates in science/pharmacology, our pharmacovigilance team performs Adverse Drug Reaction (ADR) case processing, periodic reporting, risk management and safety signal management activities. We consolidate our safety information in a central database and provide periodic reports to statutory authorities worldwide.

The Product Safety Committee provides guidance, monitors all pharmacovigilance processes and ensures strict compliance. Further, this committee is also responsible for addressing our products' safety issues and implementing appropriate remedial measures. Our Global Quality Head supervises our independent pharmacovigilance quality audit, driven by a five-year strategic plan and an annual audit plan. We also undergo regular regulatory inspections from the US Food and Drug Administration (US FDA), the European Medicines Agency (EMEA), the UK Medicines and Healthcare products Regulatory Agency (UK MHRA), and Health Canada (HC), among others, ensuring compliance with pharmacovigilance requirements. Further details on some of the US FDA inspections can be found in our FY23 Annual Report on page 269 via the link - https://sunpharma.com/wp-content/uploads/2023/07/SPIL-AR2022-23-Complete-Annual-Report.pdf.

Through these comprehensive measures, Sun Pharma demonstrates its commitment to upholding the quality standards of its products, ensuring patient safety, and fostering trust among stakeholders and regulators.

[33]GRI 3-3, [34]GRI 416-1, [35]GRI 416-2

Responsible Future (continued)

Product Quality

Our Quality Vision is to globalise, harmonise, and simplify Good Practices (GxP) processes to create a long-term quality culture. We strive to continuously improve the Quality Management System (QMS) and all its components. We inculcate a high-quality culture through continuous employee development, training, and empowerment. We believe that it is everyone's obligation to produce safe, high-quality products.

Aligned with our Quality Vision, we have embraced an all-encompassing approach to quality management, integrating our global QMS with industry-leading practices and assurance procedures. Our commitment to quality extends to a robust framework for managing complaints, enabling thorough investigations, and implementing corrective actions. Our dedicated teams, such as the quality management team, ensure that product quality follows strict quality and safety standards. Some of our API and formulations manufacturing sites have obtained ISO 9001:2015 certification, reinforcing our dedication to maintaining and implementing high-quality standards in our manufacturing processes. Our Quality Practices include elements of sustainable quality design, quality data governance, harmonisation of processes for internal compliance, and global quality metrics, underscored by past learnings.

Quality Management System (QMS)

- 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 of our QMS

- **Procedural documents:** Electronic document management systems - controlled printing, access controlled, and version controlled
- **Deviation analysis:** Periodic trend analysis of deviations
- **Training:** Instructor-led and electronic learning management systems, including a focused training course on Advanced Pharmacovigilance
- **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

Periodic inspections are undertaken at manufacturing locations in line with the requirements of GxP certifications by regulatory agencies

Release of raw materials, inclusive of API and packaging material post qualification and testing

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

Stringent compliance is ensured with specifications approved by regulatory agencies relevant to each specific market requirement

Prevention of deviations, failures, and discrepancies by recording investigations in the QMS

Comprehensive QMS system inclusive of change management, deviation management, CAPA, adverse product events, field alert reporting, complain management and recall process

Periodic audits are conducted by the Company's Corporate Quality team at all manufacturing sites, contract manufacturing sites, and vendors

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

Product Quality Complaint Management Process

Our Global Standard Operating Procedure (GSoP) establishes the guidelines for managing product recall and states the conditions determining product recall. We recall the product after evaluating the recommendation of the site recall committee, processing the product recall proposal, recall intimation, closure and trend analysis. Sun Pharma deploys a comprehensive approach to address product quality complaints. Upon receiving complaints, they are promptly logged into the system and undergo a preliminary assessment. We conduct an initial risk assessment as part of the investigation process and perform sample follow-ups.

Corrective and Preventive Actions (CAPA) are implemented based on the findings to address any identified issues. We document a complaint summary throughout this process and conduct an assessment. Finally, a response is provided to the complainant, ensuring effective communication and closure of the complaint.

Process of Redressal of Product Quality-related Complaints

Product Recalls in FY23

1 Class I

33 Class II

Responsible Future (continued)

Responsible Product Stewardship

At Sun Pharma, we emphasise establishing ethical procedures throughout the whole life cycle of a product, including accessibility, labelling, and disposal[36].

Product Accessibility

We strive to boost product accessibility and availability in various international markets, urban centres, and rural locations. Our extensive distribution network of retailers, distributors, wholesalers, and carrying and forwarding agencies (CNFs) enables us to make our products accessible to patients worldwide.

Product Labelling and Information

As a part of our commitment to responsible product stewardship, we ensure that customers have access to all pertinent product information, including pharmacokinetics, safe use, composition, clinical pharmacology, drug interactions and side effects, and storage requirements.[37] In the reporting year, there were no incidents of non-compliance with regulations resulting in a fine, penalty, warning, or non-compliance with voluntary codes.[38]

Responsible Product Disposal

We adhere to a well-established disposal process for the safe disposal of returned or recalled products as per local rules governing safety and environmental protection. We strictly abide by applicable laws and ensure that we meet the established standards for requirements unique to a given geography. Additionally, we document the identification method of product quantity and destruction date.

[36]GRI 3-3, [37]GRI 417-1, [38]GRI 417-2, GRI 417-3

Foundational Pillars of Product Stewardship

Imperative

- Enhanced product quality and safety profile
- Increased transparency and trust among stakeholders
- Augment the culture of innovation across the organisation
- Ensure prompt evaluation and redressal of product queries/complaints

Cornerstones

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

Strategic Enablers

- A well-established global pharmacovigilance policy
- A highly capable global pharmacovigilance and quality team
- Product Safety Committee
- A global QMS integrated with industry-leading practices

Aspirations

- Continue to ensure ethical use of products
- Raise awareness about proper use and disposal of our products

Anti-counterfeit Awareness and Processes

Through an effective anti-counterfeit governance management system, we are committed to increasing awareness about the dangers posed by counterfeit medicines, especially in the markets where we encounter this issue. To tackle this problem, we have established a dedicated task force responsible for mitigating the risks associated with counterfeit medicines. This task force ensures seamless monitoring of counterfeit medicines for enhanced safety and security by collaborating with our trace-and-track technology and complaint management system.

Anti-counterfeit Governance Mechanism

- The trademark and learning and development (L&D) teams train the entire field force for identifying and reporting counterfeit medicines.
- A dedicated task force, including senior field members across clusters, is trained to identify counterfeit products. We have interlinked the identification with relevant KPIs.

Anti-counterfeit Management System

- Immediate reporting of complaints and queries related to counterfeit products to relevant regulatory authorities.
- Our trace-and-track technology prevents the sale of counterfeit products.
- We receive feedback and complaints from the complainant and marketing representatives.
- We enhance our product packaging for ease of distinguishing genuine from counterfeit medicines.
- Our robust complaint management system ensures smooth management of suspected counterfeit cases.
- Our task force continually strives towards standardised and unique packaging to mitigate counterfeit risk.

Responsible Future (continued)

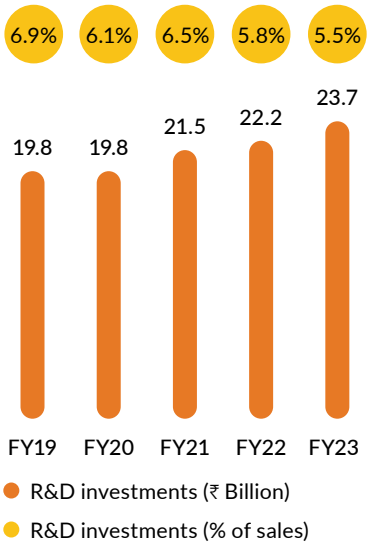
Research and Development (R&D)

Our strong expertise in R&D helps us realise our unwavering commitment to developing complex and innovative products that address the unmet medical needs of patients worldwide.[39] A strong R&D team of 2,800+ employees and scientists spread across multiple research centres globally helps us focus on developing specialty and generic products, novel and cost-effective processes and technologies. R&D plays a crucial role in driving our patient-centric approach to innovation. We aim to provide patients with innovative and affordable solutions to address their healthcare challenges. To achieve this, we consistently invest in building a robust pipeline of generics, branded generics, and specialty products for the global markets.

Leveraging our strong capabilities in evidence-based scientific and technical expertise, we strive to accelerate the development of next-generation innovative therapies. To further bolster our R&D endeavours, we actively collaborate through strategic industry-academia partnerships that enable us to deliver cutting-edge treatments.

Our R&D capabilities encompass a wide range of dosage forms, including injectables, orals, liquids, ointments, gels, sprays, and hormones, among others. Our legacy of creating robust intellectual properties supports our R&D team in pursuing innovation.

R&D Investments (in ₹ Billion)



Intellectual Property

Our skilled intellectual property team specialises in chemistry, analytical techniques, dosage forms, and global patent practice. We harness our strong research and implementation capabilities to showcase the breadth and depth of our patent portfolio. We file patents to safeguard and protect our valuable intellectual property.

As of March 31, 2023, our patent portfolio comprised 2,300+ patents filed and 1,600+ granted patents. This portfolio is a testament to our commitment to innovation. Furthermore, our R&D centres undergo regular audits by multiple international regulatory authorities, ensuring compliance with stringent quality and regulatory standards.

[39]GRI 3-3

Our R&D Approach and Capabilities

Enablers

- Significant investments in R&D to develop complex products, specialty products, generic products, APIs and for process improvement technologies.
- Dedicated R&D workforce of 2,800+ highly skilled individuals with access to state-of-the-art infrastructure.
- Stringent adherence to global regulatory requirements to maintain the highest quality standards.
- Focus on developing novel technologies, including using green reagents in API synthesis, applying Process Analytical Technology (PAT) tools, and implementing advanced processing techniques.
- Comprehensive strategies implemented for managing the product life cycle, including backward integration for key products.
- Process optimisation based on the Quality by Design (QbD) concept and Six Sigma calculations to improve efficiencies and enhance in-process capability.
- Development of innovative compact dosage forms with improved stability and reduced pharmacokinetic variability.
- Commitment to excellence and pushing boundaries in pharmaceutical innovation.
- Continuous advancement of the product portfolio to meet evolving patient needs globally.

Capabilities

- Capabilities in finished dosage development, biological support, chemistry, and new drug development.
- Ability to develop products across various dosage forms, including orals, liquids, ointments, gels, sprays, and injectables.
- Expertise in developing non-infringing formulations and specialty/complex products.
- Comprehensive portfolio of products spanning multiple therapies to meet diverse patient needs.
- Capabilities to conduct clinical studies for complex generics and for specialty products.

Ambitions

- Strategic investments to expand the specialty pipeline.
- Focus on developing complex generics.
- Increased emphasis on building the R&D pipeline for emerging markets and India.
- Enhanced efforts in developing strategically important APIs.

FY23 Highlights

Overall R&D investments of

₹23.7 Billion in FY23

Developed and filed

200+

formulation dossiers globally (including market extensions) in FY23

Global portfolio of

1,100+

molecules across multiple geographies

Responsible Future (continued)

Foundational Pillars

Imperative

- Implementation of improved technology and innovation to support sustainable manufacturing processes.
- Focus on achieving cost-effectiveness across all business activities.

Approach

- Utilisation of lean manufacturing principles and process optimisation to unlock operational potential.
- Focus on developing specific products tailored for diverse markets.

Strategic Enablers

- Continuous adoption of relevant new technologies, such as Robotics Process Automation (RPA) and AI/ML.
- Dedicated teams to drive R&D for specialty and generic products.
- Regular reporting to the Board of Directors and Managing Director on progress.
- Organisational units focused on improving the rigour of cybersecurity practices and data management.

Aspirations

- Foster groundbreaking treatments and elevate the global healthcare landscape through amplified investments in R&D and innovation.

Sun Pharma – Specialty R&D Pipeline

Asset	Indication	Route of administration	Mechanism of action	Preclinical	Phase 1	Phase 2	Phase 3	Registration
CTP-543 (deuruxolitnib)	Alopecia Areata	Oral	JAK Inhibitor					
Ilumya (tildrakizumab)	Psoriatic Arthritis	Injection	IL-23 Antagonist					
MM-II	Pain in osteoarthritis	Injection	Liposomal intra-articular lubrication					
SCD-044	Psoriasis, Atopic Dermatitis	Oral	Selective SIPR1 Agonist					
GL0034	Type 2 Diabetes	Injection	GLP-1R Agonist					

Innovation and Technology

Through our strategic investments in state-of-the-art technologies, we have successfully enhanced the accessibility and affordability of medicines worldwide. We prioritise strict adherence to global safety standards while continuously improving the overall quality of our diverse product portfolio.[40]

Our commitment to technological advancement is evident through several projects that have yielded significant benefits. These include heightened safety measures, operational efficiency, technical improvements, and cost-effectiveness. To facilitate the adoption of pioneering technologies and foster long-term business growth, we have established a specialised Centre of Excellence (CoE). This CoE supports various functions such as R&D, quality, finance, manufacturing, HR, and supply chain. Collaborating closely with business units, our IT CoEs develop strategies that promote innovation. We make decisions regarding technology adoption collaboratively, considering proof of concept and business case approvals.

To ensure effective project implementation, we have comprehensive technology guidelines in place. These guidelines align with worldwide compliance and technology standards, such as the Information Security Management System (ISMS) and the Information Technology Infrastructure Library (ITIL). Our Corporate Technology Team has devised a comprehensive IT innovation and technology plan, which directs the adoption of necessary IT policies throughout the organisation.

In support of information security, we allocate an annual budget at the departmental level. This budget considers the existing internal hardware and application landscape, ongoing initiatives, new projects, and external factors influencing information security. Additionally, we have implemented a robust monitoring system to enhance the integrity and security of our data.

On March 1, 2023, we disclosed one information security incident that impacted some of the Company's IT assets. Remedial measures were immediately implemented to contain and manage the impact of the information security incident, including employing appropriate containment protocols to mitigate the threat, enhancing security measures and utilising global cyber security experts to ensure the integrity of the Company's IT systems' infrastructure and data. As part of the containment measures, we also proactively isolated our network and initiated recovery procedures. As a result of these measures, certain business operations were also impacted. In the reporting year, one breach was reported with respect to customer privacy data[41].

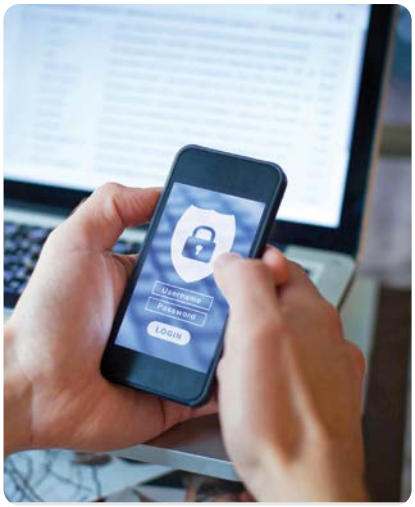
To prevent the risk of any future incidents, we have strengthened our cybersecurity infrastructure and are in the process of implementing further improvements to our cyber and data security systems. We are also implementing certain long-term measures to augment security control systems across the organisation. In coordination with legal counsel across relevant jurisdictions, all applicable regulatory and data protection authorities, where required, were informed of the breach and remedial measures implemented.

[40]GRI 3-3, [41]GRI 418-1

Responsible Future (continued)

Our Approach to Information Security

- Going forward, the intent is to transition to a zero-trust-based security architecture, coupled with increased training and controls. We adopt best practices based on industry-recognised information security standards like the National Institute of Standards and Technology (NIST) and ISO 27001:2013 to manage information security risks effectively.
- Global implementation of Standard Operating Procedures (SOPs) for data management across all locations.
- Continuous awareness building about information security using simulation-based learning within the organisation for all users.
- Deployment of Information Security Management System (ISMS), Global Standard Operating Procedures (GSOPs), and defence-in-depth strategies.
- 24x7 monitoring systems to identify threats and threat perceptions as part of Managed Detect and Respond protocols.



Compliance with Global Data Integrity and Security Standards, Including:

- US FDA requirements for data integrity and compliance with Drug cGMP.
- PDA technical report 80 for implementing a data integrity management system in our laboratories.
- Adherence to ISO 27001 Information Security Management System (ISMS) standards.
- Compliance with Data Protection regulations for protecting personal data in the geographies in which we operate.

Our Focus on Data Integrity and Security

- Implement policies, processes, and mandatory information security awareness training to ensure data integrity and security throughout the organisation.
- Categorisation of data integrity and security challenges in three main areas: cyber-attacks, insider threats, and data integrity at the manufacturing level.
  - Utilisation of defence in-depth strategies, 24x7 security operations centre, threat intelligence governance services, and partnerships with security experts to mitigate cyber-attack risks.
  - Alignment of Incident Management Policy with ISO 27001 standards.
  - Deployment of data leakage prevention tools to address insider threats, with further investigation conducted in collaboration with the business and HR functions.
  - Adoption of global Standard Operating Procedures (SOPs) for manufacturing operations' root cause analysis and risk assessments.

Sustainable Supply Chain

Product accessibility is integral to sustainable value creation for all stakeholders. Our supply chain management system, encompassing logistics, procurement, planning, and inventory management, aims to ensure that we manufacture and supply products in line with market demand[42].

To ensure the efficiency and effectiveness of our supply chain management, we conduct regular reviews led by our senior management. These periodic assessments continuously evaluate and enhance our processes, aligning them with industry best practices and strategic goals. We optimise resource utilisation, minimise waste, and streamline operations by prioritising a strong and cross-functional supply chain management system.

This approach enables us to deliver products and services to our customers timely and sustainably, supporting our commitment to long-term success and value creation.

Supply Chain Approach – Foundational Pillars

Procurement

Our procurement team guarantees an uninterrupted supply of raw materials, primary and secondary packaging materials, and finished formulations. This approach facilitates the development and manufacturing of APIs and formulations and ensures their availability in the designated markets.

Planning and Inventory Management

Our integrated management system incorporates Distribution Requirement Planning (DRP), Market Requirement Planning (MRP), and other planning insights to assess inventory needs and efficiently monitor supply chain activities.

Distribution, Logistics & Finished Goods Delivery

Through effective coordination with the supply chain team, our distribution and logistics team ensures the timely delivery of finished goods and services and meets customer requirements.

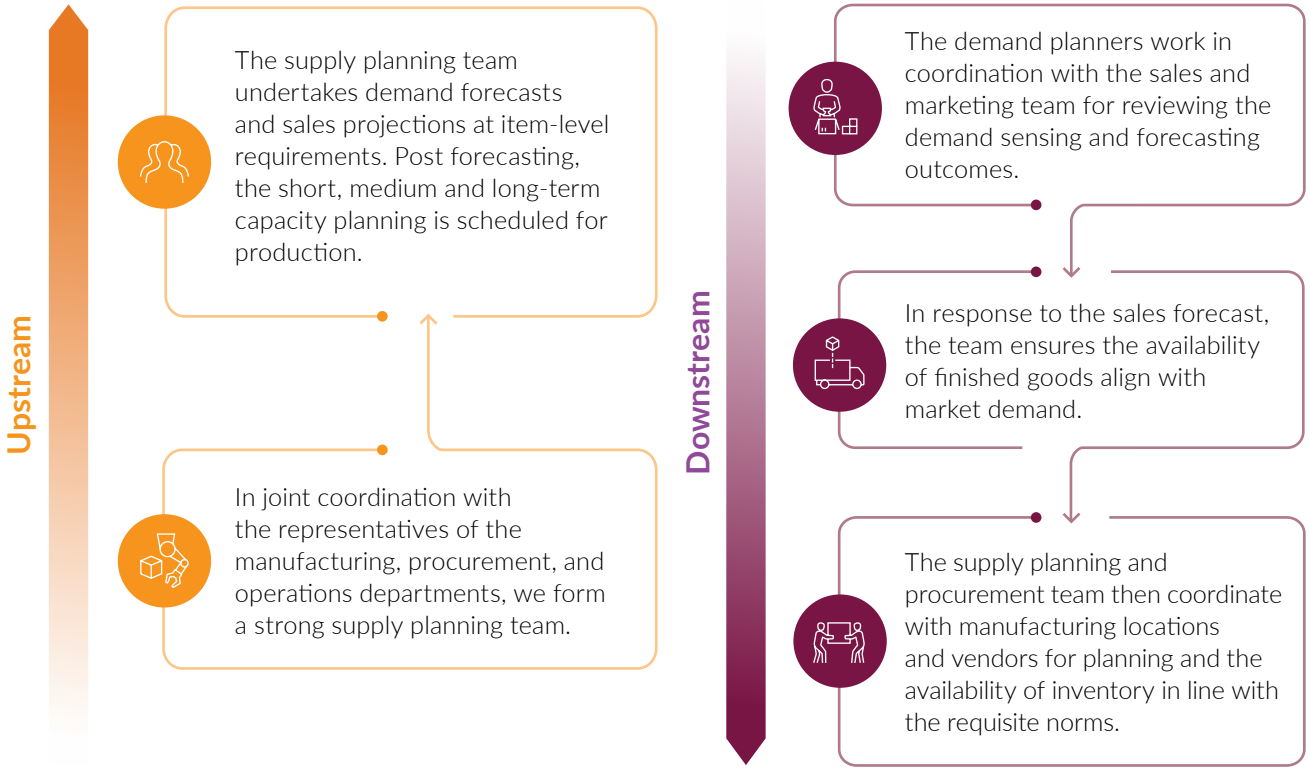
The team also selects the optimal mode of transport for swift delivery of consignments.

In case of any disruptions in the supply chain, the logistics team collaborates with the supply chain team to overcome challenges and fulfil the delivery of consignments.

[42]GRI 3-3

Responsible Future (continued)

An Overview of Our Supply Chain Operations[43]



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

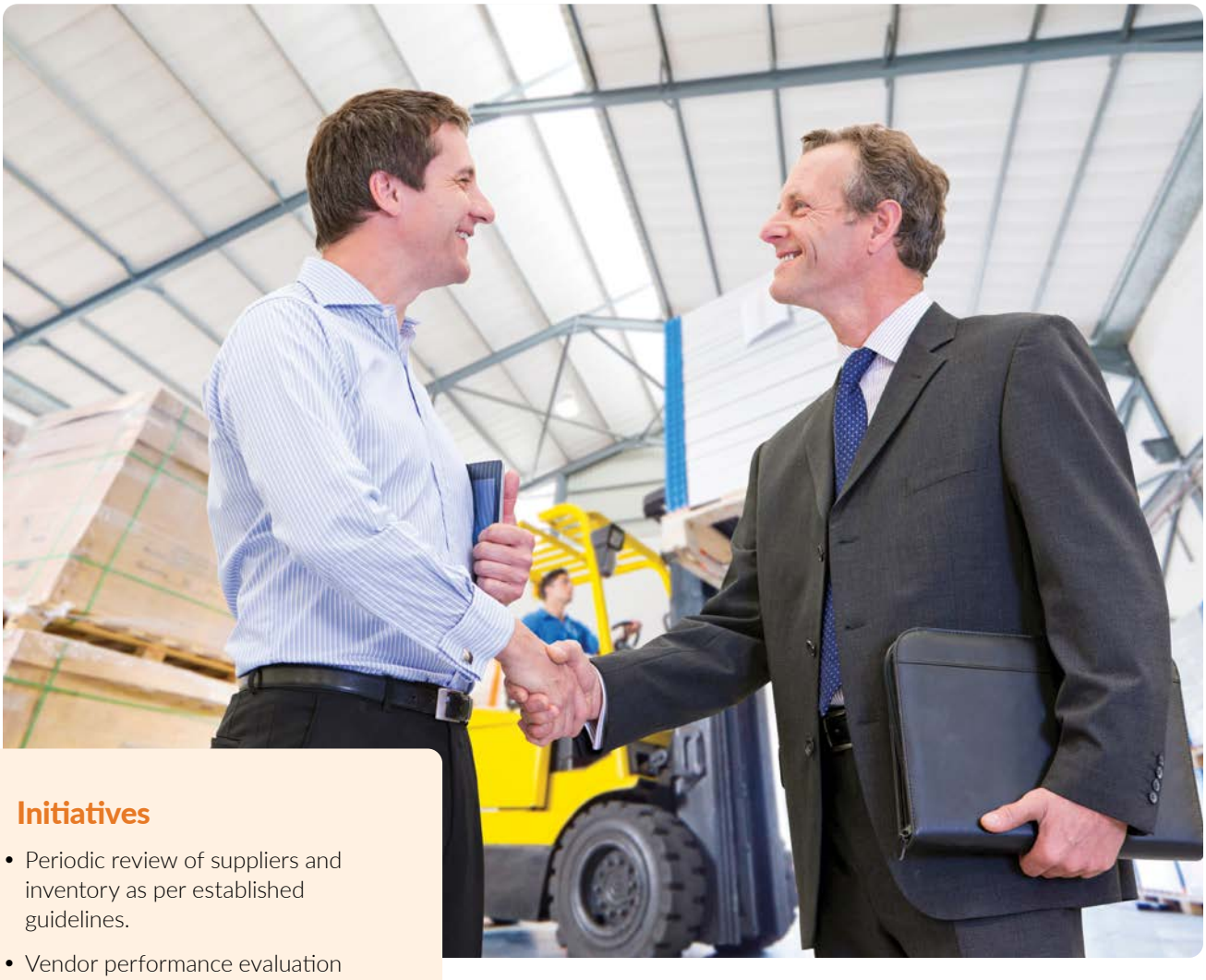
Effective Supply Chain Monitoring

We have implemented a robust monitoring mechanism within our supply chain processes to ensure the identification, assessment, and mitigation of risks. Our approach involves using principles and checklists to evaluate potential risks and develop strategies to address them systematically. As part of our monitoring process, we conduct periodic assessments of our vendors, ensuring 100% coverage of all critical suppliers through Critical Quality Attributes (CQA) audits within a three-year cycle. In FY22, we enhanced our CQA audit checklist by incorporating ESG parameters.

In FY23, we conducted scheduled assessments for some of our key vendors, ensuring compliance with the requirements of the CQA checklist. This proactive approach allows us to monitor and improve our supply chain practices continuously.

We have established a Supplier Code of Conduct that further strengthens our commitment to ESG practices within our business value chain. We expect all third-party vendors, suppliers, and business partners to adhere to the principles outlined in the Supplier Code of Conduct.

[43]GRI 2-6



Initiatives

- Periodic review of suppliers and inventory as per established guidelines.
- Vendor performance evaluation through a scorecard mechanism and evaluating adherence to the Company's Supplier Code of Conduct.
- Empanelment and sourcing of critical items from multiple suppliers.
- Monitoring effective compliance management and contract performance.
- Assessment of new vendors through periodic supplier audits aligned with the CQA policy, Supplier Code of Conduct, internal quality parameters, ESG parameters, and relevant regulatory requirements.
- Identify and prioritise key risks, followed by implementing mitigation measures by the Strategic Procurement Committee.

Local Sourcing

We strive to prioritise local sourcing wherever feasible to help develop the local business ecosystem around our areas of operation. For our India operations, in FY23, we sourced 81% of indirect procurement and 71% of direct procurement from local suppliers.[44]

The emphasis on local sourcing brings multiple benefits to our operations. Firstly, it helps to mitigate our exposure to currency risks by reducing our reliance on imports. Additionally, it strengthens our supply chain by fostering closer collaboration and flexibility with local partners. Furthermore, local sourcing contributes to developing national skill sets, supporting the growth of local industries and economies. By engaging with local suppliers, we actively participate in the enhancement of local capabilities and the creation of employment opportunities. Another significant advantage of local sourcing is the reduction of our environmental footprint. Minimising transportation distances decreases carbon emissions associated with long-distance logistics reducing our overall impact on the environment.

Through our focus on local sourcing, we aim to embed resilience in our operations, support indigenous economic development, and promote sustainability within our value chain and the local communities.

[44]GRI 204-1