RESPONSIBLE PRODUCT STEWARDSHIP

Access to safe and effective medicines is crucial for universal healthcare coverage.

Our R&D is focused on patient-centred innovation and strategic investments in advanced technologies. We are committed to meeting the highest quality standards for our products and complying with all regulatory requirements.

Quality Healthcare

Committed to Quality and Equitable Healthcare

Access to safe and effective medicines is an important prerequisite for universal health coverage. We are committed to providing high-quality medications to patients and healthcare professionals worldwide.

With a team of 3,000+ skilled Research and Development (R&D) professionals coupled with strategic R&D investments (representing 6.7% of our sales in FY24), we focus on developing specialty, branded generics and generic medications across various therapeutic areas targeted at improving healthcare access for our patients. Our strong distribution network of distributors, stockists, and wholesalers, ensures global access to medical products for patients in need.

Patient Safety

We conduct rigorous reviews and quality assurance to maintain high standards of quality for our products and ensure compliance with all regulations. Promptly identifying and addressing potential health and safety risks is imperative for product quality, safeguarding patient safety, and building trust with our stakeholders[33]. We continuously assess the risk-benefit profile of our offerings by adhering to globally benchmarked quality and regulatory compliance standards while rigorously monitoring product safety[34].

Pharmacovigilance at Sun Pharma

Our Pharmacovigilance department adopts a proactive approach to mitigating risk and ensuring product safety. Our pharmacovigilance system continuously monitors product safety and swiftly addresses any adverse events[35]. The Product Safety Committee supports our Global Pharmacovigilance Policy, and the Independent Pharmacovigilance Quality Assurance team reports to the Chief Quality Officer.

Our pharmacovigilance team focuses on contingency planning, risk mitigation and resolution of adverse events to enhance quality control, workforce training, and patient safety. We utilise advanced IT solutions for efficient data processing. Comprising around 100 qualified professionals, including physicians and scientists, our pharmacovigilance team handles Adverse Drug Reaction (ADR) cases, expedited reporting, risk management, safety signal management and consolidating safety data into a centralised database for reporting to global regulatory authorities.

The Product Safety Committee oversees pharmacovigilance processes, ensuring compliance with standards addressing safety issues and setting necessary remedial measures. Our Chief Quality Officer monitors an independent pharmacovigilance quality audit, guided by a five-year strategy and annual plan. We also undergo regular inspections by regulatory bodies, including US Food and Drug Administration (US FDA), European Medicines Agency (EMA), UK Medicines and Healthcare products Regulatory Agency (UK MHRA), Health Canada (HC), the Pharmaceuticals & Medical Devices Agency (Japan PMDA) and other such regulatory agencies to ensure compliance. Further details on some of the US FDA inspections can be found in our FY24 Annual Report on page 276 via the link - https://sunpharma.com/wp-content/uploads/2024/07/SPIL-Annual-Report-2023-24.pdf

Product Quality

Our **'Quality Vision'** aims to globalise, standardise, and streamline Good Practices (GxP) processes, promoting a culture of Quality excellence and sustainability. We are dedicated to continuously improving our Quality Management System (QMS) and using latest generation electronic systems for better functionality. Our focus on employee development, empowerment, and training helps us in fostering a culture centered on product quality.

We have created a comprehensive approach to quality management under our 'Quality Vision', aligning our global QMS with industry best practices and assurance processes. Our quality standards also cover procurement, product distribution, stakeholder complaint management, investigations, and corrective and preventive measures.

Our dedicated quality management team ensures strict adherence to quality and safety standards. Our strategy focuses on sustainable quality design, data governance, process harmonisation, and global quality metrics implementation.

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

Quality Management System (QMS)

- Global QMS
- Cross-functional implementation of QMS including R&D, quality, and operations
- Adopting best practices, tools and procedures to ensure a comprehensive end-to-end product quality

Quality Practices

- Sustainable quality design
- Quality data governance
- Process harmonisation for enhanced compliance
- Global Quality metrics
- Sharing of internal and external learnings

Key QMS Elements

- **Procedural Documents:** Electronic document management systems - access controlled, printing control, and version control
- **Deviation and Investigation Analysis:** Periodic trend analysis
- **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
- **Management Review Meeting:** Sun Pharma's senior management ensures the quality system governance through periodic quality reviews

Quality Assurance Process

Compliance with GxP and country-specific regulations	Periodic inspections by regulatory agencies at manufacturing sites ensure compliance with cGMP certification requirements	Release of input and packaging material post qualification and testing
Ensuring product quality through in-process testing, finished goods testing, and stability testing	Stringent compliance is ensured with specifications relevant to each market/ geographical requirement	Prevention of recurring deviations, failures, and discrepancies by recording, of investigation in the QMS
Comprehensive QMS system including change management, deviation, and investigation management, CAPA, adverse events management, field alert reporting, complaint management, and recall process	Periodic audits conducted by the Company's Corporate Quality team at all manufacturing facilities contract manufacturing sites, a and vendor locations	Training of employees involved in GxP activities through modules curated for job-specific roles

Quality Healthcare

Product Quality Complaint Management Process

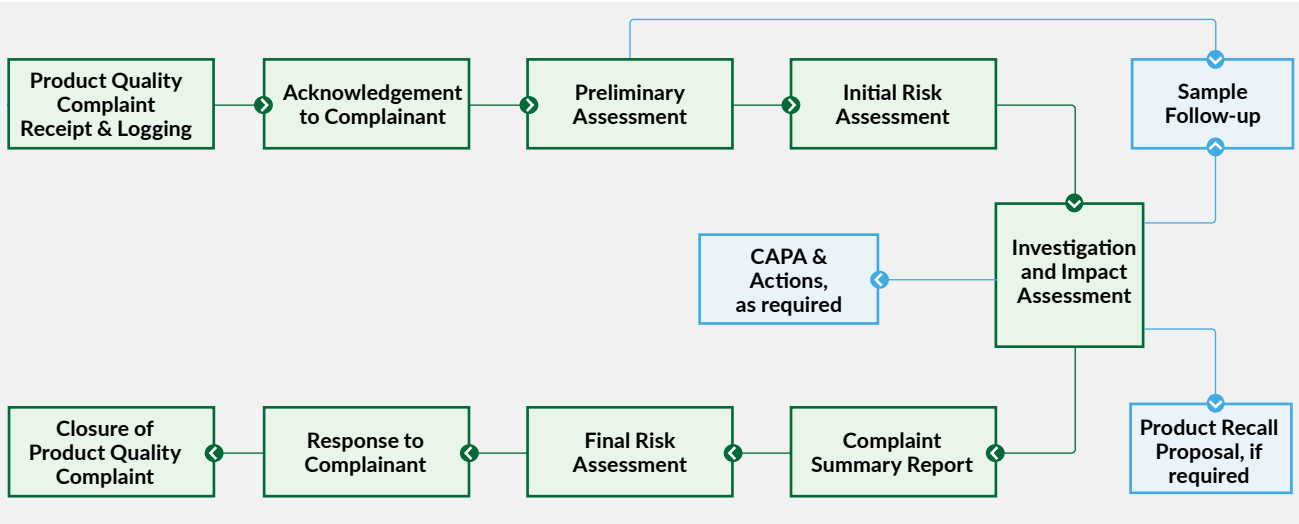
The guidance for managing product recalls and the conditions to determine product recalls are provided in our Global Standard Operating Procedure (GSoP). Product recall steps include, reviewing the suggestions of the Site Recall Committee, processing the proposal for product recall, notification of recall, closure and analysis of trends.

A thorough approach is followed to address the complaints on product quality. After receiving complaints, they are documented on the system and undergo an initial evaluation. During the investigation process, we perform a primary risk assessment along with sample follow ups.

Based on the results, Corrective and Preventive Actions (CAPA) are implemented to resolve identified issues. We record a summary of the complaint throughout this procedure and perform a review. A response is provided to the complainant, facilitating clear communication and resolution of the complaint.

For FY24, we had zero Class-I recalls and 20 Class-II Recalls. The total value of recalled products was $ 0.22 Million. In the reporting year, our manufacturing facilities underwent 48 regulatory inspections conducted by regulatory agencies like USFDA, UK MHRA, EMA, PMDA and others. The USFDA conducted 7 inspections at our manufacturing facilities resulting in 11 Form-483 observations.

Process of Redressal of Product Quality-related Complaints



Responsible Product Stewardship

At Sun Pharma, we are committed to responsible product stewardship, upholding the highest ethical standards throughout a product's lifecycle, from development to manufacturing, labelling, and disposal[36].

Product Accessibility

We aim to improve the accessibility of our product across global markets covering both urban and rural areas. Our distribution network, including retailers, distributors, wholesalers, and carrying & forwarding agencies (CNFs) ensures worldwide availability of our products to our patients.

Product Labelling and Information

We adhere to all regulations related to product labelling and information, including pharmacokinetics, safe use, composition, clinical pharmacology, drug interactions and side effects, and storage requirements, as a part of our commitment to responsible product stewardship[37].

In FY24, there were no incidents of noncompliance, resulting in any fines, penalties, warnings, or breaches of voluntary codes[38].

Responsible Product Disposal

We follow local safety and environmental regulations for the safe disposal of returned or recalled products, ensuring compliance with relevant laws and regional standards. We also maintain records of disposed 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

Anti-counterfeit Measures

Awareness and Processes

We are committed to raising awareness about the risks of counterfeit medicines in affected markets by implementing an effective anti-counterfeit governance management system. A dedicated task force has been established to manage these threats and improve safety. This task force ensures seamless monitoring of counterfeit medicines for enhanced safety and security through our trace-and-track technology and complaint management system.

Governance Mechanism

- The trademark and learning and development (L&D) teams train the entire field force for identifying and reporting counterfeit medicines.
- A designated task force of senior field personnel is trained to identify counterfeit medications, supported by a trained field team for detection and reporting on counterfeit medicines. The identification process is linked with associated KPIs.

Management System

- Feedback mechanism in place to receive complaints from the complainant and marketing representatives.
- Prompt reporting of complaints and queries relevant to counterfeit products to concerned regulatory authorities.
- Trace-and-track technology to detect and prevent sale of counterfeit products.
- Improving product packaging for easy distinction between genuine and counterfeit medicines. We continually strive towards standardised and unique packaging to mitigate counterfeit risk.
- Well-established complaint management system for seamless management of suspected cases of counterfeit products.

Research and Development

Focus on Innovation

Our Research and Development (R&D) expertise reinforces our commitment to developing innovative, safe and effective products that cater to the unmet medical needs of patients across the globe[39]. A strong team of 3,000+ R&D professionals along with our chemistry and technological skills help us in developing a strong pipeline of specialty and complex generic products. Our R&D capabilities extend across various dosage forms, including injectables, orals, liquids, ointments, gels, sprays, hormones, and oral products. Our R&D centres undergo regular audits by multiple international regulatory authorities, ensuring compliance with stringent quality and regulatory standards. In addition to our internal efforts, we also collaborate with academia and industry experts to enhance our R&D capabilities.

FY24 R&D Highlights

₹ 31.8 Bn
In R&D investment

2,301 Patents
Granted till date

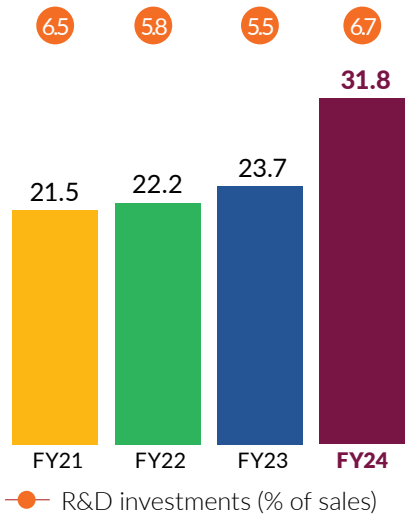
~250
Global formulation dossiers filed

3,000+ Member
Strong R&D team

Note – All facts and figures are for FY24

R&D Investments

₹ 31.8 Bn



Intellectual Property

Our intellectual property team specialises in chemistry, analytical techniques, dosage forms, and global patent practices.

As of March 31, 2024, our patent portfolio comprised 3,154 patents filed and 2,301 granted patents, reflecting our unwavering commitment to innovation and adopting cutting-edge science.

[39]GRI 3-3

Our R&D Approach and Capabilities

Enablers

- Significant investments in R&D with focus on developing specialty, complex generics, APIs, and process improvement
- Dedicated R&D team of 3,000+ professionals with state-of-the-art R&D infrastructure
- Compliant with global regulatory standards for maintaining high-quality
- Aim to create new technologies using green reagents in API synthesis, applying Process Analytical Technology (PAT) tools, and executing advanced processing techniques
- Comprehensive product life cycle management with backward integration for key products
- Enhancing operational efficiency using Quality by Design (QbD) framework and Six Sigma methodologies
- Development of innovative compact dosage forms with enhanced stability and decreased pharmacokinetic variability
- Expansion of product portfolio to cater to the evolving needs of patients

Capabilities

- Capability to develop various dosage such as orals, liquids, ointments, gels, sprays, and injectables
- Biological capabilities, chemistry skills, and new drug development capabilities
- Capability to develop non-infringing formulations and specialty/complex products
- Broad product portfolio covering multiple therapeutic segments catering to diverse patient needs
- Competencies to undertake clinical studies for specialty products and complex generics

Ambitions

- Targeted investments to expand the specialty pipeline
- Focus on developing complex generics
- Growing focus on developing the R&D pipeline for Emerging Markets and India
- Improved efforts in developing strategically important APIs
- Collaborate with academia and industry experts to enhance our R&D capabilities

Research and Development

Our Specialty R&D Pipeline (as of November 2024)

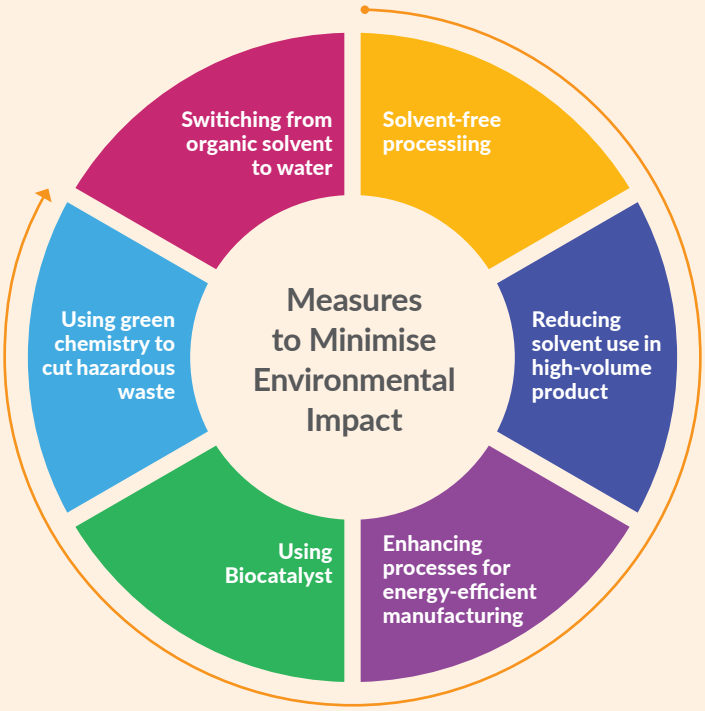
Candidate	Mechanism of Action	Indication	Preclinical	Phase 1	Phase 2	Phase 3	Registration
Leqselvi	JAK Inhibitor	Severe alopecia areata					
Nidlegy™	Immunocytokines	Melanoma & non-melanoma skin cancers					
Ilumya	IL-23 Antagonist	Psoriatic arthritis					
Fibromun	Innovative anti-cancer immunotherapy	Soft tissue sarcoma Glioblastoma					
MM-II	Liposomal intra-articular lubrication	Pain in osteoarthritis					
SCD-044	Selective SIPR1 Agonist	Atopic dermatitis Psoriasis					
GL0034	GLP-1R Agonist	Obesity					

Note - 1. Leqselvi received USFDA approval in July
2. All molecules for global markets except Nidlegy™ where Sun Pharma is commercial partner for Europe, Australia & New Zealand. Nidlegy™ is a trademark of Philogen.

Reducing Environmental Impact through 'Green Chemistry'

The pharmaceutical industry is adopting a benign-by-design approach, employing non-toxic methods/tools/techniques/solvents for sustainable product development. Our R&D teams continuously innovate to minimise our products' ecological footprint through **'Green Chemistry'** approaches.

Steps Taken to Reduce Environmental Impact



Innovation and Technology

Harnessing Technology for Global Impact

Through strategic investments in world-class technologies, we have expanded the accessibility of medicines across the globe. We prioritise strict compliance with global safety standards while constantly assuring the quality of our varied portfolio[40].

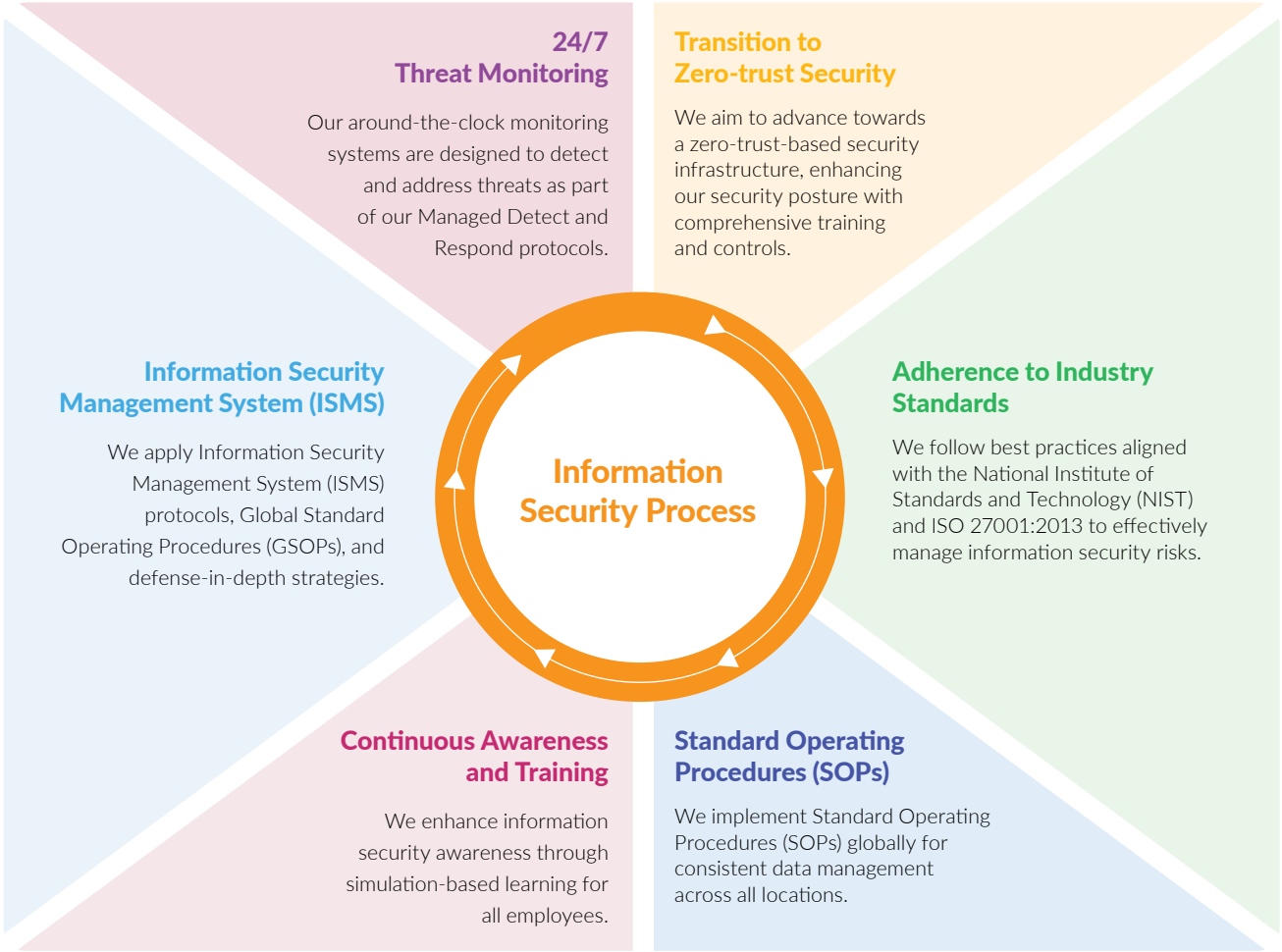
We focus on innovation to enhance safety, improve efficacy, optimise operations, advance technical capabilities, and ensure cost-effectiveness. To drive innovation and achieve sustained business growth, we have established a dedicated Centre of Excellence (CoE) which supports key organisational functions such as R&D, quality assurance, finance, manufacturing, HR, and supply chain operations. We make decisions related to technological incorporation in a collaborative manner while taking into consideration proof of concept and business case approvals.

We have established technology guidelines to ensure effective project execution, adhering to global standards like the Information Security Management System (ISMS) and the Information Technology Infrastructure Library (ITIL). The Corporate Technology team has developed a detailed IT innovation and technology plan, and each department allocates an annual budget for information security. This budget considers the current hardware landscape, ongoing initiatives, new projects, and external factors influencing information security. We also maintain a robust monitoring system to enhance reliability and data protection.

Zero Incidents

During FY24, we did not incur any information security/data privacy incidents.[41]

Our Approach to Information Security



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

Our Compliance with Global Data Integrity and Security Standards

Compliance with USFDA data integrity and cGMP standards

Complying with ISO 27001 Information Security Management System (ISMS) standards

Following PDA Report 80 for creating a data integrity management system in our laboratories

Adhering to data protection regulations to safeguard personal data at operational locations

Our Focus on Data Integrity and Security

Policy Enforcement and Training

We enforce stringent policies and processes, supported by mandatory training on information security awareness, to maintain data security and integrity throughout the organisation.

Data Integrity and Security Segmentation

We address data integrity and security issues by segmenting them into three main areas: Cyber-attacks, Insider threats, and manufacturing process integrity.

Comprehensive Defence Strategies

We use multiple strategies to mitigate cyber-attack risks, including a 24/7 Security Operations Centre (SOC), threat intelligence governance services, and collaboration with security experts.

Incident Management Alignment

We align our Incident Management Policy with ISO 27001 standards to ensure effective response protocols.

Coordinated Investigations

Deployment of data leakage prevention tools to address insider threats, with further investigation conducted in collaboration with the business and HR functions.

Standard Operating Procedures (SOPs) Implementation

We implement globally benchmarked Standard Operating Procedures (SOPs) for manufacturing operations, focusing on root cause analysis and risk assessment.

Supply Chain Management

Focusing on Supply Chain Efficiency

Product accessibility is integral to sustainable value creation for all stakeholders. To achieve this, we have implemented a robust supply chain management system that combines logistics, procurement, production planning, and inventory management, ensuring efficiency, and reliability at every step.

Our supply chain management system works diligently to ensure that we manufacture and supply products in line with market demand[42].

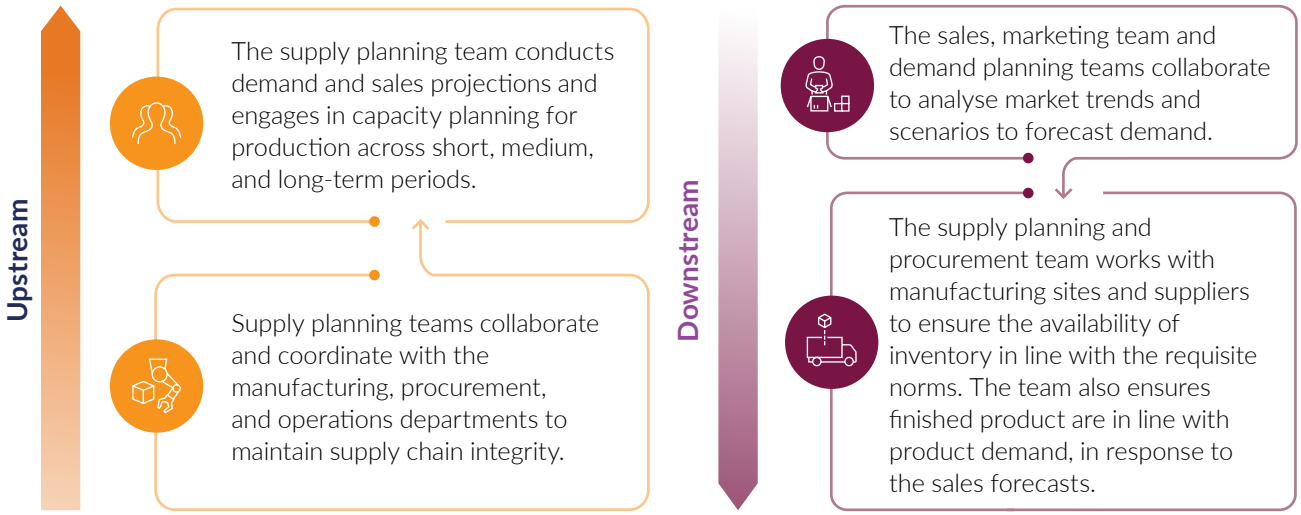
To ensure efficiency and effectiveness, we regularly review our procurement and supply chain policies, systems, and processes under the supervision of senior management. These evaluations are conducted to align our operations with the industry's best practices and strategic objectives, allowing us to identify areas for improvement, and enhance our overall processes.

Through a robust, cross-functional approach to supply chain management, we are committed to optimising resource utilisation, reducing waste, and streamlining operations. This strategy ensures timely delivery of medicines to patients. By enhancing access to healthcare while promoting the sustainability of our operations, we reaffirm our commitment to the well-being of the patients we serve.

Supply Chain Approach – Foundational Pillars

Procurement	Planning and Inventory Management	Distribution, Logistics & Finished Goods Delivery
Our procurement team ensures a continuous supply of raw materials, primary and secondary packaging materials, and finished formulations. This approach supports the development and production of APIs and formulations to ensure their availability in the targeted markets.	Our integrated management system uses Distribution Requirement Planning (DRP), Market Requirement Planning (MRP), and other planning insights to evaluate inventory needs and efficiently monitor supply chain operations.	Our distribution and logistics team ensures the timely delivery of finished goods and services by efficiently coordinating with the supply chain team.

An Overview of our Supply Chain Operations[43]



In FY24, there were no significant changes or modifications to our supply chain.

[42]GRI 3-3 | [43]GRI 2-6

Effective Supply Chain Monitoring

At Sun Pharma, we have established a comprehensive monitoring framework in our supply chain processes to identify, evaluate, and mitigate potential risks that may arise throughout our operations. Our systematic approach employs specific principles and checklists to evaluate risks and enable us to proactively develop targeted strategies to address any identified challenges.

We conduct regular evaluations of our vendors as a part of our monitoring process, making sure there is full coverage of all critical suppliers by Critical Quality Attributes (CQA) audits, every three years. During the reporting year, we carried out screening for our vendors, evaluating their adherence to a broad range of ESG indicators. These indicators encompass legal compliance, safety standards, respect for human rights, labour practices, working conditions, and environmental sustainability. We also organised knowledge-sharing sessions with external experts focused on our supplier Environmental, Social, and Governance (ESG) programmes.

In order to strengthen our dedication to ESG principles across our business operations, we have established a Supplier Code of Conduct. We expect all third-party vendors, suppliers, and business partners to adhere to the principles outlined in the Supplier Code of Conduct.

Initiatives

- Systematic suppliers and inventory reviews per guidelines
- Assessment of 100+ suppliers to ensure compliance with ESG parameters through desk-based audit
- Sourcing essential materials from diverse suppliers
- Reviewing compliance management practice and contract performance periodically
- Assessing new suppliers through regular audits aligned with the CQA policy, Supplier Code of Conduct, internal quality parameters, ESG parameters, and relevant regulations
- The Strategic Procurement Committee identifies and prioritises major risks and implements mitigation strategies
- Conducting ESG-focused training and capacity-building workshops for internal stakeholders

Local Sourcing

We aim to locally source whenever feasible to promote and enhance local businesses. For the standalone entity, Sun Pharmaceutical Industries Limited (SPIL), local suppliers accounted for 83% of our procurement[44].

Local sourcing reduces currency risk exposure by decreasing reliance on imports and fosters partnerships. Local sourcing supports the growth of local industries and economies. By engaging with local suppliers, we actively participate in 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.

[44]GRI 204-1