# Co-creating a Responsible Future (continued)

## Patient Safety Is Imperative[15]

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

[15]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.