



Pharmacovigilance

Monitoring Product Safety to

Protect Patients

**GRI Standards:**

103: Management approach

417: Marketing and Labeling

EXECUTIVE SUMMARY

Monitoring the quality, efficacy and safety of our products throughout their life cycle, from clinical development to prescription and consumption, is a priority to protect patient safety. Some rare or late onset adverse events are often only detected at this time.

In order to maximize our knowledge on the use of our portfolio in real-world conditions, Sanofi's Global Pharmacovigilance Department (GPV) has established an effective global organization to passively and actively collect pharmacovigilance data from all sources of information around the world. Thanks to this data collection, the teams monitor safety and are able to adjust the benefit-risk profile of our products: prescription medicines, vaccines, consumer health products, generics, and medical devices. Pharmacovigilance helps determine the best conditions of use for treatments, and provides physicians, healthcare professionals and patients with comprehensive, up-to-date safety information, including potential risks associated with a product.

TABLE OF CONTENTS

- 1. *Definition*..... 3
- 2. *The purpose of pharmacovigilance*..... 3
- 3. *A best-in-class pharmacovigilance organization*..... 3

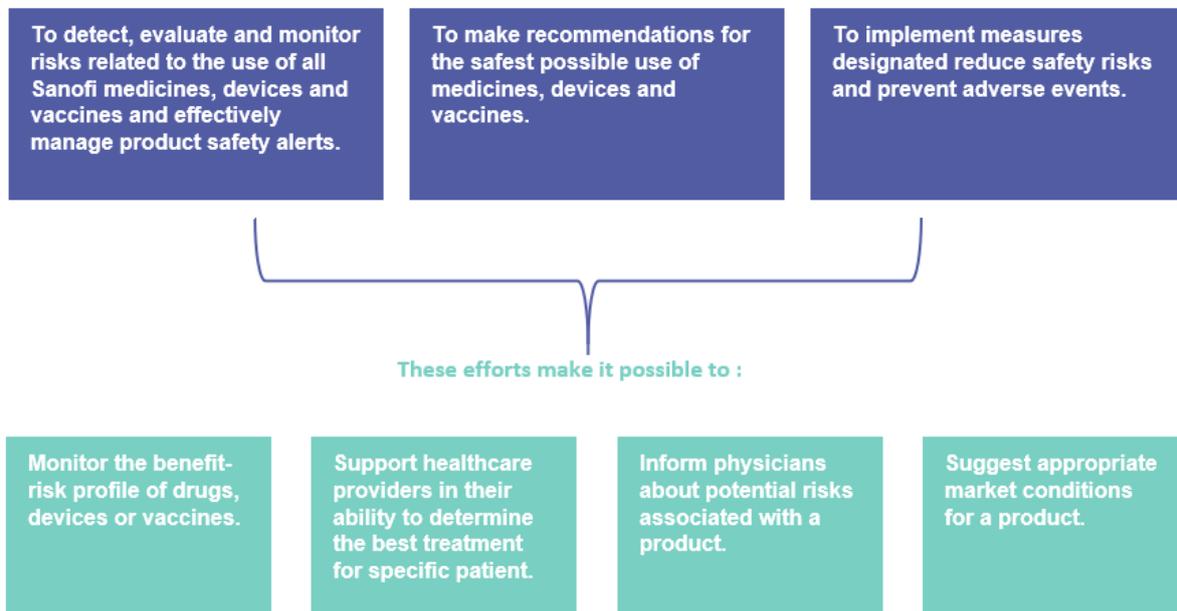
1. Definition

Pharmacovigilance is the process of monitoring safety and contributing to the continuous assessment of the benefit-risk profile of our products at every stage of their life cycle.

2. The purpose of pharmacovigilance

The diagram below summarizes the purpose of pharmacovigilance in an international pharmaceutical company in line with regulatory requirements:

Figure 1: The purpose of product safety monitoring is threefold



3. A best-in-class pharmacovigilance organization

The Global Pharmacovigilance (GPV) organization at Sanofi is responsible for managing all pharmacovigilance tasks and activities worldwide. GPV is the reference center of excellence for conducting health and safety surveillance duties of all Sanofi medicinal products as a marketing authorization holder or as a sponsor. As per Sanofi's Chief Safety Officer, the key aspiration of GPV is to be a cutting-edge safety organization, to enable Sanofi to optimize the monitoring of the benefit-risk of its therapies, so we can serve better our prescribers and safeguard our patients.

Our view is that a corporate culture that aligns safety and risk management with the corporate business strategy is key for operating best-in-class pharmacovigilance. Sanofi considers that the risk of occurrence of misaligned priorities between a company's responsibility to shareholders and corporate social responsibility (CSR) duties may prevent it from fully upholding pharmacovigilance obligations toward external stakeholders.

The framework of our Pharmacovigilance operating governance model consists of transversal and multidisciplinary safety governance teams comprised of both empowered and senior decision-making individuals with safety, ethics, legal, scientific, medical, clinical, and regulatory skillsets.

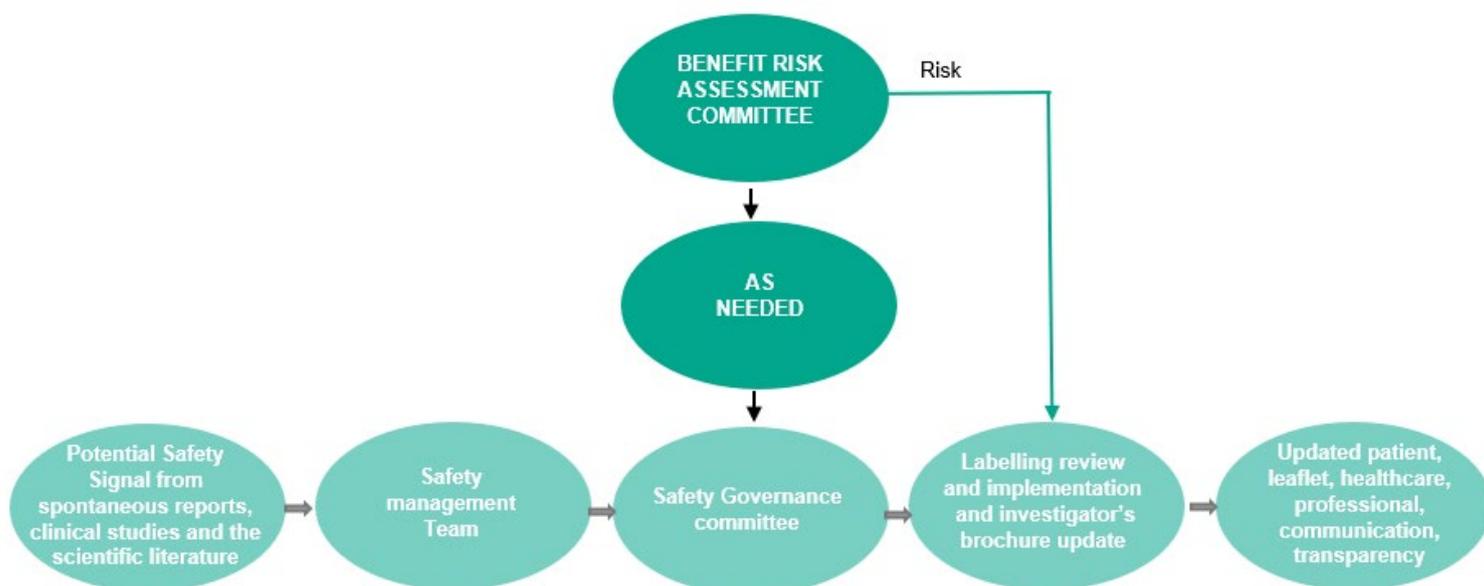
The Global Pharmacovigilance Organization (GPV) commits to ensuring that safety information about our portfolio of medicinal therapies brought to the marketplace is:

- appropriately updated to reflect advancements in knowledge;
- compliant with high ethical and transparency standards to protect patient safety;
- consistent with legal and most stringent regulatory obligations;
- reliable and reconcilable; and
- regulatory inspection-robust.

Our high-performing safety governance operating model set-up includes:

- driven senior leadership;
- patient-centric model approach;
- structured benefit-risk approach of our portfolio;
- integration of pharmacovigilance into corporate policies;
- a transversal, cross-functional design organization empowering the in-house stakeholders for protecting patient safety;
- one integrated organization comprised of both globally and locally qualified personnel in Pharmacovigilance;
- qualification of our service providers;
- one Integrated Pharmacovigilance System worldwide;
- edge technology driven with One GPV toolbox;
- onboarding highly specialized scientific and medical people with in-depth, potential safety signals identification and data-driven analysis capabilities;
- dedicated strategic training capabilities in Pharmacovigilance;
- one model of operational excellence for decision-making based on the assessment of high-quality safety data;
- use of edge techniques and excellence in safety sciences:
 - > signal detection, visualization, and adjudication,
 - > structured benefit-risk assessment,
 - > risk best approach identification and determination of risk dimensions,
 - > efficiency of risk minimization measures, and
 - > translational and Genomic Medicine Safety,
- a robust multidisciplinary core safety information assessment:
 - > from signal detection to patient's leaflet, end to end, and
 - > label alignment worldwide: from signal detection to labeling implementation, end to end.
- robust escalation processes to empower multidisciplinary groups of people qualified for the assessment of adjudicated safety concerns; and
- robust and secured channels of communication concerning the benefit-risk profiles of our products, to protect patient safety.

Figure 2: Sanofi's Global Pharmacovigilance (GPV) Department process



Our teams of safety experts are using best-in-class practices (i) to identify early potential safety risk signals raised during the use of our medicinal products, (ii) to assess their benefit-risk balances, and (iii) to monitor their safety outcomes. Our teams of safety experts are preparing robust Risk Management Plans with sound scientific and medical risk minimization measures approved by the regulators in the countries.

Sanofi's GPV considers that to maintain compliance with regulatory requirements, a patient-centric protection model needs strong, trustful, and efficient exchange of information between all the stakeholders (i.e., sponsor, manufacturer, patients and healthcare professionals, regulatory bodies). For this purpose, the performance of our Pharmacovigilance system is assessed periodically for ensuring that any adverse event brought-up during our therapeutic treatments is collected, assessed, and submitted diligently from the early stage of clinical development to the end of the post marketing period.

To make sounded data-driven safety decisions under real-life conditions from all data sources available, GPV Operations has put in place effective passive and active collection processing schemes of adverse events. Sanofi GPV has also innovated with the growing use of leading-edge robotic artificial intelligence and digital technologies to automate and to standardize the assessment intake of adverse events from all sources of information worldwide.

Sanofi's GPV and its Pharmacovigilance service providers commit to pay attention for being compliant to the Sanofi Standards in Data privacy regarding Global Data Protection Regulations (GDPR) around the world.

In the era of big data and healthcare initiatives, Sanofi's GPV has an active role as member of several public-private consortia for the purposes of developing new edge patient safety protection solutions and methodologies.

For maintaining leadership, GPV is also very attentive to benchmark the performance of its safety organization and to assess the value of its strategic insight as permanent membership of world-class Pharma networks of influence and workstreams.