

PHARMACOVIGILANCE: MONITORING PRODUCT SAFETY TO PROTECT PATIENTS

G4 indicators: G4-DMA, G4-PR3

GRI Standard:

103: Management approach

417: Marketing and Labeling

I. INTRODUCTION

Our pharmacovigilance 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.

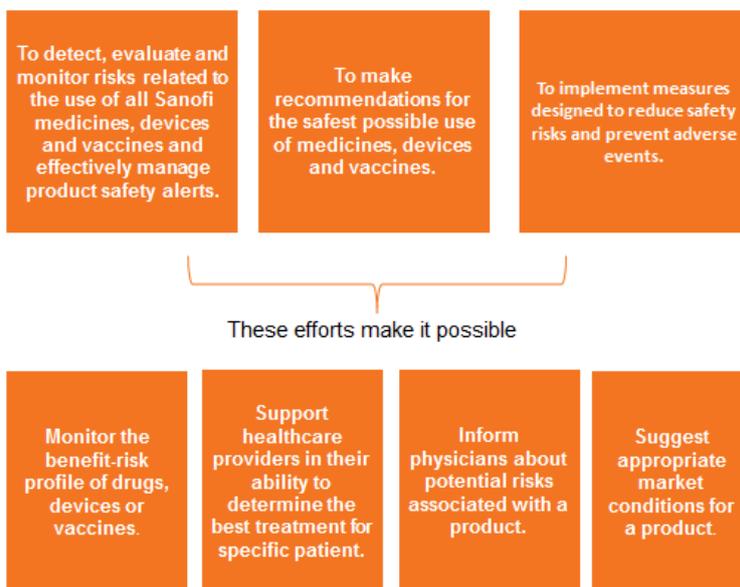
II. DEFINITION

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

III. 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



IV. A BEST-IN-CLASS PHARMACOVIGILANCE ORGANIZATION

Sanofi's Global Pharmacovigilance (GPV) organization is responsible for pharmacovigilance tasks and activities worldwide. At Sanofi, GPV is the center for safety. Ensuring effective pharmacovigilance requires a corporate culture that aligns safety and risk management with the corporate business strategy. Misaligned priorities between a company's responsibility to shareholders and corporate social responsibility (CSR) may prevent it from fully upholding pharmacovigilance obligations toward external stakeholders. Sanofi's safety governance model is implemented by transversal and multidisciplinary safety governance teams comprised of individuals with pharmacovigilance, ethics, legal, scientific, medical, clinical and regulatory knowledge and skills.

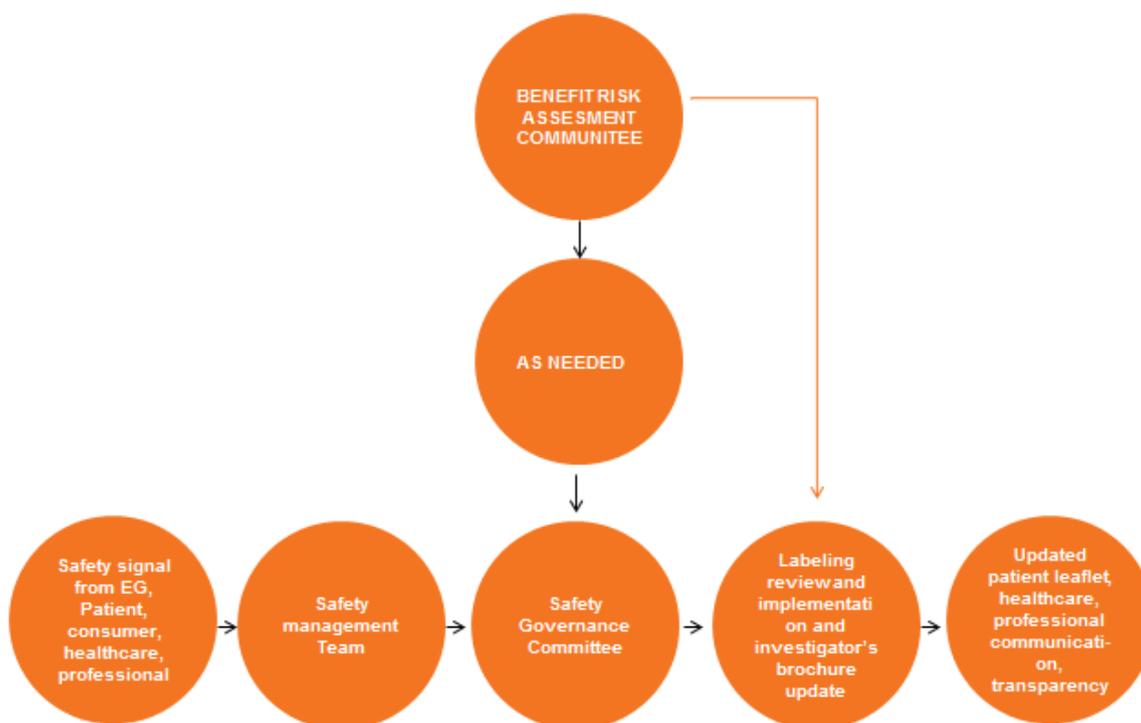
GPV as a whole is committed to ensuring that safety information about Sanofi products provided to both healthcare professionals and patients is:

- Appropriately updated to reflect advancements in knowledge ;
- Compliant with high ethical and transparency standards to protect patient safety;
- Consistent with legal obligations ;
- Reliable;
- Reconcilable;
- Inspection-robust.

The pillars of our safety governance model framework include the following:

- Driven senior leadership ;
- Integration of pharmacovigilance into corporate policies;
- A transversal, cross-functional design for our organization to involve all stakeholders and to protect patient safety;
- One organization made up of pharmacovigilance people, the pharmacovigilance system, and the GPV toolbox;
- Expertise with strong specialized knowledge of Sanofi products' mechanisms of action across each pharmacovigilance global business unit and in-depth, data-driven analysis;
- Operational excellence with quality safety data;
- Excellence in safety sciences:
 - Signal detection and adjudication;
 - Risk identification;
 - Determination of risk dimensions;
 - Efficiency of risk minimization measures;
- A robust multidisciplinary core safety information assessment:
 - From signal detection to labeling variation, end to end;
 - Label alignment worldwide: from signal detection to labeling implementation, end to end;
- Robust escalation mechanisms;
- Robust communication mechanisms concerning the benefit-risk profiles of our products, to protect patient safety.

Figure 2: Sanofi's global pharmacovigilance (GPV) department process



Our teams' safety experts follow best pharmacovigilance practices on a continuous basis to proactively detect potential risks associated with the use of our portfolio, assess benefit-risk balances, and monitor outcomes. At the same time, the safety experts tailor risk management plans to deploy adequate risk minimization measures approved by the regulators to ensure follow-up and data protection.

To maximize our knowledge about the use of our portfolio under real-life conditions, Sanofi's Global Pharmacovigilance (GPV) Department has put in place an effective global organization to collect pharmacovigilance data from all sources of information worldwide in a passive and an active manner. The effectiveness of our patient data collection model depends on strong interactions with all stakeholders (i.e., patients and healthcare professionals) during both clinical development and product life cycle management. In addition to processing patient data, Sanofi's GPV is highly committed to complying with data privacy protection rules, which apply from the step of data collection to the use of data for strictly medical and scientific purposes to protect public health.

In the field of big data and healthcare, Sanofi's GPV is also an active member of several public-private consortia focused on patient safety. The company continues to explore the value of digital media screening as a potential source of safety signals using epidemiological methodologies. Sanofi's GPV also made a significant contribution to the development of the Innovative Medicines Initiative (IMI) WEB-RADR project, which evaluated the use of mobile devices and social media to improve the reporting of suspected adverse drug reactions by patients. Finally, Sanofi's GPV is deeply involved in foreseeing how these tools may be used to proactively detect potential safety issues related to medicines and to improve interactions with healthcare professionals and patients.