Pharmacovigilance & Safety

Introduction: At SANOFI, we prioritize Pharmacovigilance and safety before our vendors provide services for our products. This text boilerplate, part of the [Master Service Agreement / General Terms and Conditions of Purchase], ensures our service providers, vendors, and suppliers: (i) comply with SANOFI's pharmacovigilance standards; (ii) handle and report any report of Adverse Events or safety complaints from their individual customers diligently.

1. Definitions and Terms

The definitions and terms used in this schedule shall have the following meaning as defined by the regulatory authorities and associated guidelines concerning medicinal products for human use, as amended from time to time.

1. **Adverse Event:** AE shall mean any untoward medical occurrence in a patient or clinical trial subject administered Product and which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of a Product, whether-or-not considered related to the Product.
2. **Business Day** means in respect to any note, any day other than a Saturday, a Sunday or a day which is not declared to be holiday or rest day on which the companies of one of the Parties are authorized or required by law or executive order to close or be closed.
3. **Day 0 (Awareness Date Clock Start Receipt Date)**: means the date on which a Party first becomes aware of an Adverse Event or a PV Data and, in relation to a third-party Representative of a Party. This is considered “Day Zero" for reporting the other party of such information irrespective of whether the information is received during a weekend or public holiday.
4. **Pharmacovigilance (PV) Data** includes any Adverse Event (serious or not), Incident (serious or not), or special situations (with or without Adverse Events) such as misuse, medication error, off-label use, overdose, drug abuse, dependence, lack of efficacy, drug exposure during pregnancy or breastfeeding, occupational exposure, accidental exposure, unexpected therapeutic benefit, suspected transmission of infectious agents, and suspected drug interactions. PV Data also covers Adverse Events linked to suspected or confirmed falsified products or quality defects. Product Technical Complaints with Adverse Events are subject to reporting.
5. **Product “Incident”** (when applying in the context of medical devices) refers to the definitions in the Master Agreement. Where an incident is also associated with PV Data this should be notified to SANOFI as set out in Article-2.
6. **Product complaint, “Product Technical Complaint”** or “PTC” refers to the definitions in the Master Agreement. Where a PTC is also associated with PV Data, this should be notified to SANOFI in accordance with the procedure set out in Article 2 below.
7. **Product(s)** shall mean all the Products owned and/or manufactured and/or commercialized by SANOFI or any of its Affiliates, including medicinal products, devices, cosmetics, and food supplements.

2. Purpose and Scope

1. This schedule outlines the standard obligations of the Service Provider of SANOFI Goods or Services and participation in the Pharmacovigilance Article, which is part of the [Master Service Agreement / General Terms and Conditions of Purchase] between SANOFI and the Service Provider.
2. Service Provider(s)/Vendor(s) in scope refers to all types of business-to-customer services for SANOFI products, with the exception of services related to patient support programmes, market research and other digital projects that follow specific SANOFI requirements.

3. General Requirements

1. The Service Provider must maintain a continuous, high-quality, and compliant work management system for timely identification, handling of PV data, adverse event reports, product incidents, and safety information, in line with industry standards and local regulations.
2. The Service Provider shall ensure that all its agents, including any contractors or subcontractors involved in fulfilling these Pharmacovigilance requirements, are informed of their obligations and shall maintain documentation of this communication.
3. The Service Provider shall acknowledge SANOFI’s right to initiate a compliance, verification, or due diligence audit of pharmacovigilance activities in the event that critical weaknesses or limitations are identified, in accordance with the terms and conditions set forth in the Master Agreement.
4. The service provider and its agents will record and archive all pharmacovigilance correspondence, requesting individual receipt acknowledgements. These records will be compared at SANOFI's request to ensure correct and comprehensive transmission and receipt.

4. Reporting Procedure

1. The Service Provider and its agents must notify SANOFI of any AE, PV Data, and other safety information related to the Product within One (1) Business Day of becoming aware (Day 0). Transmission shall be made to the SANOFI Centre / Web Portal address or relevant office by phone or email designated by Sanofi in the Main Contract.
2. During the initial contact (Day 0), the Service Provider and its agents must collect and include the following in the report: the customer’s email address; personal & business identifiers; Information relating to the SANOFI product involved; and details of adverse events or PV data, including the context and date of collection. If the customer refuses to provide personal data or to be contacted by SANOFI, this refusal must be documented and communicated to SANOFI.
3. The Service Provider and its agents must assist SANOFI in clarifying discrepancies and obtaining follow-up information from the reporting customer. They must also request and obtain an acknowledgment of receipt for any written correspondence with SANOFI.
4. The Service Provider and its agents must notify SANOFI of any reportable adverse event, PV data, or complaint published on their company owned website or social media regarding the Sanofi products when applicable. They must record and report this information within the required timeframe.
5. The Service Provider agrees that obligations will continue after the Main Agreement ends, providing SANOFI with any received safety information until 6 (six) Months after the last product batch expires when applicable to the terms and conditions of the contract.

Apart from the reporting obligations mentioned above, no additional communication or action or obligation is required from the third party to Sanofi.