## Pharmacovigilance & Safety

**Introduction:** At SANOFI, we prioritize Pharmacovigilance and safety before our vendors provide services for our products. This Schedule, 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 adverse events or safety complaints 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.

- **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.

- **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.

- **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.

- **Pharmacovigilance (PV) Data or PV claims)** 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.

- **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 .

- **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.

- **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

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.

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 pharmacovigilance claims, adverse event reports, product incidents, and safety information, in line with industry standards and regulations.

2. The Service Provider shall ensure that all its agents involved in fulfilling these Pharmacovigilance requirements are informed of the execution of these obligations and shall maintain documentation of this communication.

3. The Service Provider shall accept the right of SANOFI to request and perform audit or due diligence audit in Pharmacovigilance in case of identified critical weaknesses or limitations and in accordance with the terms and conditions defined in the Master Agreement.

4. The service provider and its agents will record and archive all pharmacovigilance correspondence, requesting acknowledgements of receipt. At SANOFI's request, these records will be compared to ensure correct transmission and receipt, as per the Master Agreement.

### 4. Reporting Procedure

1. The Service Provider and its agents must notify SANOFI of any AE, PV Data/Claim, and other safety information related to the Product within one business day of becoming aware (Day 0). Notifications should be made to the SANOFI Centre or relevant office by phone or email.

2. The Service Provider and its agents must collect the Customer's email, personal identifiers, reporter's details, SANOFI product info, and adverse event / PV Claims details at first contact. This initial report should be emailed to SANOFI. Document to Sanofi if the customer refuses to provide personal data.

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 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's agrees that obligations will continue after the agreement ends, providing SANOFI with safety information until 6 (six) Months after the last product batch expires when applicable.

*Apart from the obligations mentioned above, no additional communication or action and obligation is required from the vendor.*