At SANOFI, we recognize the critical role that pharmacovigilance plays in ensuring the safety and well-being of patients and the positive impact it has throughout our pharmaceutical value chain. The purpose of the PV boilerplate is twofold: (i) to ensure that this value is well understood and shared with our Partners (vendors and suppliers) and that they understand the importance of complying with SANOFI standards, (ii) to be aware of their role and responsibilities if they are notified by their customers of report of adverse events, pharmacovigilance claims or safety complaints at the start of their services.

Pharmacovigilance Boilerplate

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the Partner agrees to the followings.

1.1 Definitions and Terms

The definitions and terms used in these Pharmacovigilance requirements 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 Data (PV Data –Pharmacovigilance claims)** Shall mean any Adverse Event (Serious or not), any Incident (serious or not), or any of the following special situations (with or without Adverse Events): any report of misuse; any medication error; any off-label use (intentional use outside the labelled indication); any overdose (intentional or not); any drug abuse, dependence; any lack of efficacy; any drug exposure during pregnancy or child exposure during breastfeeding or conception ( ) any occupational exposure (unintentional exposure during work); accidental exposure; unexpected therapeutic benefit; any suspected transmission of infectious agents; and/or suspected drug interactions involving active ingredients or their metabolites. PV Data include also Adverse Event associated with a suspected or confirmed PTC of falsified Product(s) or with a quality defect of a Product(s). Where a Product Technical Complaint arises in conjunction with an AE, such complaints are subject to the reporting obligations applicable to PV Data.
- **Product "Incident"** (in the context of medical devices) shall mean any malfunction or deterioration in the characteristics or performance of a medical device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect. A serious product incident shall mean Any incident that directly or indirectly led, might have led or might lead to any of the following: (a) the death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's, user's or other person's state of health, (c) a serious public health threat.
- **Product complaint, "Product Technical Complaint" or "PTC"** refers to any written, electronic, or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety, efficacy or performance of a product, device, its packaging, or any written leaflet or other information provided with such product or device, after it is released for distribution. 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.

2.1 Purpose of the Pharmacovigilance Boilerplate

The general purpose of this PV Boilerplate is to set out the standard obligations relating to Partner's operations in relation to the Pharmacovigilance activities in respect of the services for the Product[s] and its participation in the PV Articles for the purpose of, among other things. This PV Boilerplate constitutes an integral part of the [Master Service Agreement / General Conditions of Purchase] between Sanofi and the Partner.

3.1 General Requirements in Pharmacovigilance

1. The Partner shall establish and maintain a continuous service including a high-quality & compliant work management system adapted to the timely handling of claims of pharmacovigilance, adverse event reports and safety

complaints and that aligns with industry standards and regulatory requirements.

2. The Partner shall and shall be responsible to conduct training of all its employees and agents involved in the performance of the requirements in Pharmacovigilance unless otherwise agreed.

3. The Partner shall accept the right of SANOFI to perform audit or due diligence audit of the quality system applicable to Pharmacovigilance in case of identified weaknesses or limitations.

4. The Partner shall and shall cause each of its representatives to keep a record and archive of all written and oral correspondence received in Pharmacovigilance to confirm accurate and complete transmission, follow-up exchange and reception of the information to which such records apply.

4.1 Partner requirements for reporting adverse events, pharmacovigilance claims and safety complaints.

1. The Partner shall and shall cause each of its representatives to promptly notify SANOFI of any safety information and PV Data related to the Product. This notification should occur within one (1) Business Day from the time they become aware of an Adverse Event report, Pharmacovigilance claim, or Product Safety complaint or incident. The Partner shall contact the SANOFI Information Centre or the relevant office contact point by telephone or secure email as specified by SANOFI.

2. The Partner should include in the initial email communication an identified SANOFI product, a brief description of the context of the report and contact details for SANOFI to follow up and investigate directly with the primary reporter and in accordance with applicable data privacy laws.

3. The Partner shall, and shall cause each of its representatives to, notify SANOFI within one (1) Business Day (before the end of next business day) from the time it, he or she becomes aware of any information of product complaint or incident that might necessitate the filing by SANOFI of a field alert report, as required under 21 C.F.R. § 314.81(b)(1) (a "Field Alert"), by contacting the SANOFI Information Center by telephone at such telephone number as SANOFI will designate.

4. The Partner shall, and shall cause any of its representatives to, reasonably assist SANOFI in clarifying any inconsistent information and/or obtaining further information as required by SANOFI's designated contact person or contractor and in accordance with the procedures including the use of a reporting form provided or returned by SANOFI.

5. The Partner shall and shall cause each of its representatives to notify SANOFI of the public posting of any reportable [Adverse Event / PV Data, or Complaint] on Partner's owned website or social media network in respect of the Product(s) such Partner has under its management or responsibility, such Partner shall record and report information in respect thereof in accordance with the same required timeframe.

6. The Partner accepts when applies that its obligations will continue after the expiry or termination of the underlying agreement and d will continue to provide SANOFI with all safety reports in order to cover a transitional period or until a defined number of months after the expiry date of the last batch shelf life of the product.

Apart from the requirements mentioned above, no additional communication is necessary from the Partner's personnel.

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