Pharmacovigilance (PV) clauses for GENERAL AGREEMENTS with PV requirements

which do not fall in the category of Patient Program (PP), Market Research (MR) and/or Digital project and do not qualify for a local SDEA

1. DEFINITIONS

"Adverse Event" or "**AE**" shall mean any untoward medical occurrence in a patient who takes or uses a Product, and which does not necessarily have a causal relationship with that Product. An Adverse Event can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease, temporally associated with the use of such a Product, whether or not considered related to that Product.

"Pharmacovigilance" or **"PV"** is taken to include the concepts of Cosmetovigilance, Nutrivigilance, and Device Vigilance as applicable to the Product(s) covered by the General Terms and Conditions and Order.

"Pharmacovigilance Data" or **"PV Data"** shall mean any Adverse Event (Serious or not), any incident, 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, addiction, (withdrawal syndrome); any lack of efficacy; any drug exposure during pregnancy or child exposure during breastfeeding or conception (whether from the male or female); 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. Where a PTC arises in conjunction with an AE, such complaints are subject to the reporting obligations applicable to PV Data in Article-2 below.

"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.

"Serious 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(s)" shall mean all the products owned and/or manufactured and/or commercialized by CLIENT or any of its Affiliates, including medicinal products, devices, cosmetics and food supplements.

“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 CLIENT in accordance with the procedure set out in Article-2 below.

"Serious" used in connection with events, reactions and experiences shall mean any untoward medical occurrence that at any dose results in, or may have resulted in, death, is immediately life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability and/or incapacity or is a congenital anomaly or birth defect.

2. PV DATA REPORTING

- Notwithstanding any other provisions in these General Terms and Conditions and the Order, or other attachments or amendments thereto, where applicable, PROVIDER is responsible for appropriate identification and reporting of PV Data consistent with the provisions below and any other obligations described below.

- PROVIDER shall report to CLIENT potential Adverse Events and/or any other Pharmacovigilance (PV) data of which it becomes aware during the course of performing the Services within one (1) business day of becoming aware of such data. PROVIDER shall complete the PV Data Reporting Form provided by CLIENT at the outset of Services, and provide the following information: patient identifiers, reporter name and contact information, a CLIENT suspect Product (drug, dose, route, date of administration), and information regarding the Adverse Event, by email to the appropriate generic email addresses on the list provided by CLIENT at the outset of Services, according to the country of origin of the relevant PV Data.

3. PV TRAINING

- PROVIDER is responsible for training all its employees and agents involved in the performance of Services on PV Data reporting and the requirements set forth above prior to such employee or agent performing Services under the General Terms and Conditions and Order. Training materials are provided by CLIENT PV at the outset of Services. PROVIDER commits to provide annual refresher training going forward as needed. Upon request from CLIENT, PROVIDER shall provide within the best delay any justification and documentation relating to the training that has been performed.

4. RECONCILIATION

- On a monthly basis PROVIDER generates, and forwards to CLIENT a listing of all PV Data received by PROVIDER since the last reconciliation.

- CLIENT PV notifies PROVIDER if any reports on the listing are not received by CLIENT PV and full details of those reports (including copies of the relevant PV Reporting Forms) are forwarded by PROVIDER to CLIENT PV within one (1) business day of notification by CLIENT PV under this paragraph. The Parties keep records of these reconciliations according to the Record Retention provisions below.

5. RECORDS RETENTION

- For a minimum period of three (3) years following the completion of the Services, PROVIDER shall retain all PV Data reporting forms, PV training records, audit and inspections reports and responses as well as proof that such data and documents were sent to CLIENT in accordance with this Article. During such period, all source data and information shall be made available to CLIENT upon request as soon as possible but, in no event, later than one (1) business day following the request. After the end of the retention period, PROVIDER shall inform CLIENT in writing of any intention to destroy the documents. If, within ninety (90) calendar days of receiving such notice, CLIENT does not confirm in writing any request to obtain copies or original versions of such documents, PROVIDER may proceed with the planned destruction.