For information only

Pharmacovigilance (PV) Clauses for GENERAL SERVICE PROVIDERS AGREEMENTS with Reporting PV Requirements

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

1. List of defined Terms

- **"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 unfavorable 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.

- **"Business Day" (another term for Working Day definition**) 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, such as clinical research organizations or distributors, that have contractual and/or regulatory obligations to report Adverse Events or a PV Data to that Party, the date on which such Third Parties first become aware of that Adverse Event or a PV Data. For both Parties 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.

- **"Emerging Safety Issue":** means a Product(s) safety issue considered by the MAH to require urgent attention / urgent safety restriction by the regulator related or not to [Product quality complaints/Customer complaints] because of the potential major impact on the risk-benefit balance of the medicinal product and / or on patients' or public health, and the potential need for prompt regulatory action and communication to patients and healthcare professionals.

- **"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.

- **"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 (PV Data)"** means all safety information relating to known or potential risk to humans, obtained or otherwise received from any available Source of information for the Product (including spontaneous unsolicited and/or other interventional solicited).

  PV Data shall include:

  I. Any Adverse Event / Experience (Serious or not)

  II. Any of the following special situations (with or without Adverse Events) : any report of misuse; any report from Lawsuits; 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 therapeutic efficacy (or disease progression); 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; any suspected transmission of infectious agents ; suspected drug interactions involving active ingredients or their metabolites

  III. Unintended beneficial effects and any other information relevant to the safety of the Product(s) or unexpected therapeutic benefit

  IV. Counterfeits with AE (see below Product Technical Complaint or PTC)

  I. In addition, PV Data include Adverse Event associated with a suspected or confirmed PTC of falsified Product(s) or with a quality defect of a Product(s). When a Product Technical Complaint arises in conjunction with an AE, such complaints are subject to the reporting obligations applicable to PV Data.

  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.

- **"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 Technical Complaint (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 Incident" in connection with medical device** 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.

- **Serious used in connection with adverse 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/birth defect.

- **Source of Safety Information - PV Data:** In service providers agreements for Products on the market, available sources of information mean unsolicited spontaneous reports that arise from the following sources but not limiting to e.g., healthcare

provider/professional (HCP), patient-consumer, legal, medical information, Regulatory Authorities (RAs), media, Literature articles, Digital media web's sites, e.g., social media, mobile apps, internet.

2. Reporting of PV Data

- GENERAL REQUIREMENTS: 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 and according to Applicable Law. PROVIDER must ensure that their employees and agents including contractors are informed and trained on the content of this PV Clause. Both Parties shall agree s to co-operate throughout the Term of this PV Article and within the scope of the obligations described in this PV Article as well as its spirit, to facilitate the diligent ongoing evaluation of urgent safety issues and protecting public health relating to the use of such CLIENT Product[s]

- PROVIDER shall report to CLIENT potential Adverse Events and/or any other Pharmacovigilance (PV) Data or any other Emerging Safety Issue, Incident or Product Technical / Customer Complaint or inquiry of which it becomes aware during the course of performing the services and from any Source of information within one (1) Business Day of becoming aware of such data (Day (0).

- PROVIDER shall complete the PV Data Reporting Transmittal Form when included by CLIENT at the outset of Services, and provide the following information:

  I. a description of the original source of such information (whether healthcare professional, consumer, Regulatory Authority, literature, or otherwise) including patient identifiers, reporter name and contact information,
  II. a CLIENT suspect Product (drug, dose, route, date of administration),
  III. Information regarding the Adverse Event, Safety Issue, Incident or Complaint as defined in this PV Clause and from which the safety issue arose including one or more of the following: (1) known or suspected Product quality defects, (2) known side effects, (3) medication or device errors or in vitro diagnostic error, (4) medication abuse, misuse, or overdose (deliberate or accidental); or (5) other uncertainties (6) information relating to unexpected therapeutic or clinical benefit from use of the Product(s)

- PROVIDER shall provide its initial report with the Receipt Date as well as detailed reporter contact information for follow-up purposes by CLIENT PV. Any information relating to outcomes of use of the Product(s) special situations should be included in the report.

- PROVIDER shall report such available data for a CLIENT product within one (1) Business Day 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.

- If the required information cannot be obtained within the applicable periods of time aside

from at least the name of one suspect medicinal Product cover under the Commercial Agreement, PROVIDER shall still send the report with available information to CLIENT within the required period.

- If any subsequent information is received by the PROVIDER, it shall also be transmitted as soon as practicable but no later than One (1) Business Day from the receipt date using the same transmission procedure with source documentation including records of correspondence as requested.

3. Transmission Verification

- CLIENT shall acknowledge receipt for each report received from PROVIDER or issue a periodic reconciliation report as agreed. Should such acknowledgment / reconciliation report not received, PROVIDER should make as many attempts as necessary till successful confirmation of receipt is obtained or reconciliation is complete.

- PROVIDER shall maintain and make available to CLIENT a cumulative tracker listing (displaying the correspondence reference number, Products name, Receipt date, Reference ID received from CLIENT).

- 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.

4. Training in PV

- 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 agreed. 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.

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.

6. Data Privacy

- PROVIDER shall collect, use, and disclose data governed in compliance with applicable privacy and data protection laws, rules, and regulations. PROVIDER shall implement all reasonable physical, technical, and administrative safeguards to protect PV Data information from loss, misuse, and unauthorized access, disclosure, alteration, destruction and to ensure that data privacy legislations are followed. PROVIDER shall notify CLIENT promptly of any suspected breach of this clause on CLIENT's Data.

7. Audit

- Upon request and reasonable notice, PROVIDER shall permit CLIENT to audit PV records to confirm compliance with the relevant provisions of this PV Clause and of Applicable Law.