

## 1. Definitions

1.1 In these Conditions, the following definitions will apply:

- (a) "Affiliate": shall mean with respect to each party, any company which (i) 50% or more of its outstanding securities or assets are owned or controlled, directly or indirectly, by said party or (ii) owns or controls, directly or indirectly, 50% or more of the outstanding securities or assets of said party, or (iii) is owned or controlled, directly or indirectly, to the extent of 50% or more of the outstanding securities or assets, by any of the companies described in (i) or (ii) above, or (iv) any company that is under the common control of any of said companies according to (i), (ii) or (iii).
- (b) "Boehringer Ingelheim" means Boehringer Ingelheim AB and any ordering Affiliate of Boehringer Ingelheim.
- (c) "Conditions" means the terms and conditions of purchase set out in this document and any special terms and conditions Boehringer Ingelheim has agreed in writing.
- (d) "Confidential Information" means all information obtained by one party, directly or indirectly, from the other leading up to or pursuant to this Contract, unless expressly marked as or stated not to be confidential.
- (e) "Contract" means the contractual relationship between Boehringer Ingelheim and Supplier for the sale and purchase of the Goods or the supply and acquisition of the Services, including the Purchase Order, the Conditions, any Specification and any other contractual documents agreed by the parties in writing.
- (f) "Deliverables" mean Goods and Services.
- (g) "Goods" means all goods covered by the Purchase Order.
- (h) "IP Rights" means patent, trademark, trade name, registered design, copyright, design right or any other intellectual property rights anywhere in the world.
- (i) "Open Source Software" includes software licensed under licenses listed or described at [www.opensource.org/docs/definition.php](http://www.opensource.org/docs/definition.php) or at [www.opensource.org/licenses](http://www.opensource.org/licenses) or any successor websites.
- (j) "Purchase Order" means the form issued by Boehringer Ingelheim to order the Goods or the Services.
- (k) "Supplier" means the supplier to whom Boehringer Ingelheim's Purchase Order is or has been issued.
- (l) "Specification" means plans, drawings, data and other information relating to the Goods or Services.
- (m) "Services" means services of any description provided by Supplier to Boehringer Ingelheim pursuant to the Purchase Order.

1.2 The headings in these Conditions are for convenience only and shall not affect the interpretation hereof.

## 2. General

- (a) Boehringer Ingelheim will take responsibility only for the supply of the Goods and / or the provision of the Services as referred to in the Purchase Order.
- (b) These Conditions shall apply to all interactions between Boehringer Ingelheim and Supplier, to the exclusion of all other agreements, terms or conditions unless otherwise accepted by Boehringer Ingelheim in writing. However, in case Boehringer Ingelheim and Supplier have executed a (Master Service) Agreement the provisions of such (Master Service) Agreement shall prevail in connection to the goods and services covered therein (c) Supplier shall accept Boehringer Ingelheim's Purchase Order using the form of acknowledgement provided by Boehringer Ingelheim. However, if Supplier delivers or commences work related to the Deliverables, or sends an invoice or similar statement to Boehringer Ingelheim, then such action will constitute acceptance by Supplier of Boehringer Ingelheim's Purchase Order and these Conditions.
- (d) No variation of the Purchase Order or counter-offer by Supplier shall bind Boehringer Ingelheim without Boehringer Ingelheim's written acceptance thereof.
- (e) Supplier shall not provide any gifts or benefits to any of Boehringer Ingelheim's employees or their families or associates.
- (f) The quantity, quality and description of the Deliverables shall, subject to these Conditions, be as specified in the Purchase Order or in any Specification supplied or agreed in writing by Boehringer Ingelheim.
- (g) The Deliverables shall be provided in accordance with laws and regulations applicable from time to time.
- (h) Boehringer Ingelheim's rights under these Conditions are in addition to Boehringer Ingelheim's rights and benefits under the applicable laws of the countries where the Deliverables are provided.

## 3. Price and Costs

3.1 Unless otherwise agreed by Boehringer Ingelheim in writing, the price as stated in the

Purchase Order is based upon the term "Delivered Duties Paid" (DDP), includes carriage, packaging and insurance, and all prices shall be firm and fixed, not subject to any escalation without Boehringer Ingelheim's written consent, for the duration of the Contract and excluding VAT.

3.2 Any change in conditions (e.g. in price, delivery, insurance) will be subject to Boehringer Ingelheim's approval in writing. An amendment of the Purchase Order is only effective if made in writing and confirmed by an amended Purchase Order submitted to Supplier by Boehringer Ingelheim. Such amendment request and confirmation may be validly executed via exchange of a signed pdf via e-mail.

3.3 Supplier may engage third parties for the provision of goods or services to be delivered by Boehringer Ingelheim and the costs for which are passed through to Boehringer Ingelheim (Pass-Through-Items: PTI). PTI are goods and services such as travel, transportation, accommodation, meals, catering, deliveries, production and any other travel or hospitality services. Supplier undertakes that for any PTI delivered to Boehringer Ingelheim, it shall not make any additional profit. All expenses incurred for PTI must be preapproved by Boehringer Ingelheim. Supplier shall ensure full transparency on the costs and expenses for PTI to be reimbursed by Boehringer Ingelheim and shall provide a detailed and itemized list of PTI. Upon request of Boehringer Ingelheim, Supplier shall provide copies of all third party invoices, receipts and/or debit notes regarding PTI. From the Purchase Order and for five (5) years thereafter, Boehringer Ingelheim shall have the right to examine and audit Supplier's financial and commercial records relating to any PTI to be reimbursed by Boehringer Ingelheim. If the examination or audit determines that Supplier overcharged Boehringer Ingelheim, then the expenses of such examination or audit shall be borne by Supplier, and Supplier shall remit to Boehringer Ingelheim the total amount of the overcharges as well as the expenses of examination or audit within five (5) calendar days from demand by Boehringer Ingelheim. This clause shall survive any termination or expiry of the Purchase Order.

## 4. Boehringer Ingelheim's Property

Materials, equipment, tools, dies, moulds, copyright, design rights or any other forms of intellectual property rights in drawings, specifications and data supplied by Boehringer Ingelheim or used by Supplier specifically in the manufacture or the supply of Deliverables shall at all times be and remain the exclusive property of Boehringer Ingelheim. Such property shall be held by Supplier in safe custody at Supplier's risk and shall be maintained, insured and kept in good condition by Supplier until returned to Boehringer Ingelheim. Supplier may only use such property to fulfil the Contract. Disposal of such property shall be in accordance with Boehringer Ingelheim's written instructions.

## 5. Delivery

5.1 Delivery shall be made DDP Boehringer Ingelheim's local premises according to the Purchase Order, as the agreed place of delivery, unless explicitly specified otherwise in the request and/or Purchase Order, promptly at the agreed date and/or time, or within the agreed period.

5.2 Delivery will be made when the Goods and Services have been received by an authorised representative of Boehringer Ingelheim at the delivery address stated in the Purchase Order or, otherwise stated by Boehringer Ingelheim.

5.3 The date of delivery or performance of the Deliverables shall be as specified in the Purchase Order. Deliveries to, and Services to be performed at, Boehringer Ingelheim's premises shall be carried out during Boehringer Ingelheim's standard working hours. Timely delivery and performance is essential to Boehringer Ingelheim.

5.4 In case of late delivery, Boehringer Ingelheim shall be entitled to:

- (a) agree with Supplier a reduced price for the Deliverables actually delivered or performed; or
  - (b) terminate the Contract. If so, Supplier shall promptly, at Supplier's cost, collect any Goods delivered; or
  - (c) recover from Supplier any expenditure reasonably incurred by Boehringer Ingelheim in obtaining substitute Deliverables from a third party; and
  - (d) claim damages for costs, losses and expenses incurred by Boehringer Ingelheim and attributable to Supplier's failure to deliver or perform the Deliverables on the due date.
- If Supplier delivers a lower quantity of Deliverables than specified and Boehringer Ingelheim has not exercised its rights of termination under 5.3 (b) above, Boehringer Ingelheim may:
- (i) accept the Deliverables which correspond to the Contract; and
  - (ii) recover from Supplier any losses resulting from the failure to deliver in full; and
  - (iii) require Supplier promptly to deliver or provide sufficient Deliverables which correspond to the Contract to comply with the quantity required; or
  - (e) require Supplier to re-perform all or part of the Deliverables free of charge.

5.5 Upon receipt of notice thereof from Boehringer Ingelheim, Supplier shall at no cost to Boehringer Ingelheim repair or replace, at Boehringer Ingelheim's option, Goods damaged or

lost in transit. Delivery of the Goods will have been made when the replacement or repaired Goods have been delivered in accordance with Clause 5.1 above. Boehringer Ingelheim reserves the right to hold damaged Goods at Supplier's risk or return them at the risk and expense of Supplier.

5.6 If Boehringer Ingelheim has agreed to accept partial deliveries under a Contract, each such delivery shall be construed as a single contract and shall in no way be interpreted or construed as a waiver of Boehringer Ingelheim of any of its rights under the Contract. If Supplier fails to deliver under any such single contract, Boehringer Ingelheim has the right to terminate the Contract in its entirety.

5.7 If the Deliverables are delivered or provided to Boehringer Ingelheim in excess of the quantities ordered, any such excess shall be free of charge and, as regards Goods, shall remain at Supplier's risk and shall be returnable at Supplier's expense.

#### **6. Passing of Ownership and Risk to Boehringer Ingelheim**

6.1 Ownership of the Goods shall pass on delivery or upon payment whichever is the earlier without prejudice to any right of rejection pursuant to Clauses 5 and 7.

6.2 Risk in the Goods shall pass to Boehringer Ingelheim upon the later of delivery in accordance with Clause 6.1 or inspection and testing. Supplier shall insure the Goods with a reputable insurer on a comprehensive and full replacement value basis until risk has passed to Boehringer Ingelheim. In the event Clause 7.4 (a) applies, Supplier shall insure the Goods until ownership has passed back to Supplier.

#### **7. Acceptance**

7.1 All Deliverables shall be subject to inspection and testing by Boehringer Ingelheim. If any Deliverables do not conform to the Specification(s), Boehringer Ingelheim is entitled to reject the Deliverables at Supplier's expense. Boehringer Ingelheim shall notify Supplier of such non-conformity as soon as possible upon discovery.

7.2 Supplier shall allow free access to Supplier's premises for representatives of Boehringer Ingelheim to inspect and, if appropriate, reject the Deliverables prior to delivery or performance.

7.3 Inspection by Boehringer Ingelheim shall not relieve Supplier of responsibility or liability for the Deliverables and shall not imply acceptance thereof.

7.4 Rejection of the Deliverables shall entitle Boehringer Ingelheim to:

(a) return the Goods to Supplier at Supplier's expense. Risk in and ownership of the Goods shall pass to Supplier when the Goods leave Boehringer Ingelheim's premises. If Boehringer Ingelheim has already paid for such Goods, ownership in the Goods shall pass to Supplier when Boehringer Ingelheim has been fully reimbursed; or

(b) require Supplier within a reasonable time to repair or replace the Goods, at Boehringer Ingelheim's option and at Supplier's expense, with Goods in compliance with Clause 11 below. Supplier shall reimburse Boehringer Ingelheim for any costs incurred by Boehringer Ingelheim in connection thereto; or

(c) terminate the Contract in respect of any further deliveries or performance of the Deliverables, without liability to Supplier; or

(d) require Supplier to re-perform all or part of the Deliverables, or to reimburse Boehringer Ingelheim for all costs and expenses of having the Deliverables performed by a third party.

7.5 If Boehringer Ingelheim agrees to destroy any Goods at Supplier's request, Supplier shall reimburse Boehringer Ingelheim for any costs incurred.

#### **8. Packaging**

8.1 Supplier shall provide suitable containers and/or packaging materials for the safe delivery and storage of the Goods. Carriers shall be informed of any risks associated with any particular Goods. Supplier shall mark the Goods ordered in accordance with reasonable instructions of Boehringer Ingelheim.

8.2 All packages and documents must carry appropriate warnings in English and/or local language and shall be labelled in accordance with all applicable laws, rules and regulations of the countries of delivery.

8.3 Supplier shall be liable for and shall indemnify Boehringer Ingelheim in respect of claims in relation to loss of, or damage to, or caused by the Goods due to inadequate packaging or packaging which does not comply with any relevant laws, rules or regulations.

#### **9. Documentation**

9.1 All invoices and other documents issued by Supplier relating to a Purchase Order shall include Boehringer Ingelheim's Purchase Order number. Invoices shall be marked for the attention of Boehringer Ingelheim's Accounts Payable department.

9.2 In order to enable Boehringer Ingelheim to check the consignment in detail, an advice note with full particulars of the Goods must precede or accompany delivery of all Goods. The description of the Goods in the advice note shall correspond to the Purchase Order.

#### **10. Terms of Payment**

10.1 Deliverables must be invoiced in the month of receipt of the Deliverables by Boehringer Ingelheim and shall be supplied as a whole. No partial shipments or invoices are allowed unless explicitly approved by Boehringer Ingelheim.

10.2 Unless otherwise agreed in writing or the invoice has been disputed, payment shall be made in accordance with the Purchase Order or, if not stated in the Purchase Order, 60 days from receipt and approval of the invoice, after delivery. Payment by Boehringer Ingelheim is without prejudice to any rights Boehringer Ingelheim may have under law or contract.

10.3 Supplier shall submit appropriate VAT invoices in relation to all Deliverables supplied to Boehringer Ingelheim, including Boehringer Ingelheim's Purchase Order- and line-number.

10.4 Supplier is not entitled to suspend any delivery or performance of the Deliverables due to any outstanding payments. In the case of an undisputed invoice, Supplier shall not be entitled to any interest over the amount due.

10.5 Boehringer Ingelheim shall be entitled to withhold payment of all or any sums payable by it under the Contract if Supplier shall be in breach of any of its obligations, and may set off against any such sums any amount Supplier owes to Boehringer Ingelheim under or in relation to the Contract or otherwise.

#### **11. The Goods**

11.1 The Goods shall be marked in accordance with Boehringer Ingelheim's instructions, comply with all legal requirements, and shall be packaged in accordance with Clause 8.

11.2 Supplier shall comply with all applicable local and EU standards and legal requirements concerning the design, manufacturing, processing, testing and storage of the Goods.

11.3 Supplier shall specify in writing operational and health risk(s) related to handling, storage, use or disposal after use.

11.4 Supplier shall provide Boehringer Ingelheim with end of life treatment information relating to the Goods and any other information required under applicable laws and regulations regarding electrical and electronic equipment, and Supplier shall take responsibility for the collection, recycling and disposal of Goods, at no cost for Boehringer Ingelheim and in accordance with regulatory requirements, when Boehringer Ingelheim notifies Supplier that the Goods in question have reached their end of life.

#### **12. Warranties**

12.1 Supplier warrants that:

12.1.1 The design, construction quality and performance of any Deliverables manufactured or supplied complies in all respects with any Specification supplied by Boehringer Ingelheim, and the Deliverables shall be fit for their purpose, of satisfactory quality and made of sound materials.

12.1.2 The possession, sale or use of any Deliverables or produced by any Deliverables shall not infringe any IP Rights anywhere in the world.

12.1.3 The Deliverables shall be provided by properly qualified and trained personnel of Supplier in accordance with best standards prevailing in Supplier's industry, in accordance with any Specifications supplied by Boehringer Ingelheim, and shall be performed with care, skill and diligence.

12.1.4 If the Deliverables are to be provided at Boehringer Ingelheim's site, the Deliverables and their providers will comply with the site rules and regulations.

12.1.5 No software forming part of or resulting from the Deliverables including any bespoke software contains or will contain any viruses, worms, trojans or other malwares including but not limited to any codes or instructions that may be or will be used to access, modify, delete or damage any data files or other computer programs used by Boehringer Ingelheim.

12.1.6 The Deliverables shall not contain any Open Source Software.

12.2 The warranties apply also to Deliverables that are replaced or repaired, and to Deliverables re-performed in accordance with the terms of the Contract.

12.3 Without limiting any other remedy, if any Deliverables are not supplied or performed in accordance with the Contract, then Boehringer Ingelheim shall be entitled:

12.3.1 To require Supplier to repair the Goods or to supply replacement Deliverables in accordance with the Contract within seven days; or

12.3.2 At Boehringer Ingelheim's sole option, whether or not Boehringer Ingelheim has required Supplier to repair the Goods or to supply replacement Deliverables, to terminate the Contract with immediate effect without prejudice to any other rights Boehringer Ingelheim may have under this Contract or under law.

#### **13. Indemnity**

13.1 Supplier shall keep Boehringer Ingelheim fully indemnified against all loss, damages, injury, liabilities, costs and expenses (whether direct, indirect, consequential or otherwise) including legal and other professional fees and expenses, suffered or incurred or paid by or

awarded against Boehringer Ingelheim or arising from or as a result of :

- (a) any negligence, breach of contract or warranty, wilful act or omission of Supplier or its employees or agents; or
- (b) any claim that the Deliverables or any product or output from them, or their importation, use or resale, infringes the IP Rights of any other person, except to the extent that the claim arises from compliance with any Specification supplied by Boehringer Ingelheim; or
- (c) any liability under the ABAC (as defined in Clause 22), the Export Control Laws and the export control warranties and undertakings (as outlined in Clause 23), the applicable data protection laws and under the applicable consumer protection legislation; or
- (d) arising from any defect in the Goods or from the performance of Services any defective workmanship, quality or materials, or arising from any breach by Supplier of the Conditions including the warranties under Clause 12, save to the extent that such a claim arises directly as a result of negligence of Boehringer Ingelheim; or
- (e) any claim against Boehringer Ingelheim in respect of any liability, loss, damage, injury, cost or expense to the extent caused by or arisen from the Deliverables as a consequence of Supplier's breach or negligent performance or failure or delay in performance of the terms of the Contract.

#### **14. Insurance**

Supplier undertakes to effect and maintain insurance cover adequate for the risks and liabilities specified in Clause 13 and as stipulated elsewhere in these Conditions and will upon request produce the relevant policy and evidence of payment of the current premium.

#### **15. Force Majeure**

15.1 If delivery or performance of the Deliverables by Supplier or the acceptance by Boehringer Ingelheim of delivery or performance is delayed or prevented because the manufacture, delivery or performance, as applicable, of any Deliverables in accordance with Clause 5 or the consumption or use of the Deliverables (or their product or output) by Boehringer Ingelheim in the ordinary course of his business has been or is being prevented or hindered by circumstances beyond the reasonable control of either party, including any form of Government intervention, war, strikes, lockouts, industrial action, fire, flood, drought or tempest, such delivery or performance shall be suspended and if it cannot be made or done within 14 days after the due date, or the manufacture, performance, consumption or use cannot occur within 30 days of the anticipated date, the delivery or performance may be cancelled by either party by notice in writing to the other.

15.2 Where more than one delivery or performance is to be made against the Purchase Order, deliveries and performances not cancelled will be resumed as soon as the circumstances causing the delay cease, but, except as otherwise agreed by both parties, the period during which deliveries are to be made or performance carried out will not be extended.

15.3 BI reserves the right to seek alternative sources of supply to mitigate any losses it might sustain and to recover any difference in price from Supplier.

#### **16. Intellectual Property**

16.1 Where any specification(s) and design(s) of the Deliverables or any of the Deliverables have been provided or commissioned by Boehringer Ingelheim, the IP Rights therein shall as between the parties be vested in Boehringer Ingelheim. Supplier shall execute all documents and do all such things as may be reasonably required by Boehringer Ingelheim to confirm or perfect the ownership.

#### **17. Termination**

17.1 Boehringer Ingelheim shall have the right at any time and for any reason to terminate the Contract in whole or in part by giving Supplier written notice whereupon all work on the Contract shall be discontinued and Boehringer Ingelheim shall pay to Supplier fair and reasonable compensation for work-in-progress at the time of termination, as decided by Boehringer Ingelheim, but such compensation shall not include loss of anticipated profits or any consequential loss or damage.

17.2 Boehringer Ingelheim shall have the right to terminate the Contract at any time and with immediate effect by giving notice in writing to Supplier if:

- (a) Supplier commits a material breach of this Contract, which shall include but is not limited to non-compliance with the Specifications, late delivery of the Goods or Services, as well as non-compliance with the Conditions; or
- (b) any distress, execution or other process is levied upon any of the assets of Supplier; or
- (c) Supplier is declared bankrupt or makes an arrangement or composition with his creditors or enters into liquidation (whether voluntary or compulsory) or any proceedings are commenced relating to the insolvency or possible insolvency of Supplier; or
- (d) Supplier ceases or threatens to cease to carry on its business; or
- (e) the financial position of Supplier deteriorates to such an extent that in the opinion of

Boehringer Ingelheim the capability of Supplier to fully meet its obligations under the Contract has been placed in jeopardy; or

(f) anything analogous to anything stated in sub-clauses (b) and (c) occurs in relation to Supplier in any jurisdiction.

17.3 The termination of the Contract, however arising, shall be without prejudice to the rights and duties of Boehringer Ingelheim accrued prior to termination. Clauses 1, 3.3, 4, 12, 13, 14, 16, 18, 21, 22, 23 and 24 shall survive the termination of the Contract and shall continue to apply.

#### **18. Confidentiality and Trademarks**

18.1 Each party shall treat as confidential all Confidential Information and shall not divulge such Confidential Information to any person except to such party's own employees and then only on a need-to-know basis without the other party's prior written consent, except information which was rightfully in the possession of such party prior to the commencement of the negotiations leading to this Contract, or which is already public knowledge or becomes so at a future date otherwise than as a result of a breach of this Clause or which is required to be disclosed by law or which is trivial or obvious. Each party shall ensure that its employees are aware of and comply with the provisions of this Clause. The foregoing obligations as to confidentiality shall survive any termination of this Contract. In case of contradiction between this Clause 18.1 and any separate secrecy agreement executed between the parties, the provisions of such separate secrecy agreement shall prevail.

18.2 To the extent it is necessary for Supplier to use any of the registered or unregistered trademarks, service marks, trade names, logos or brand names of Boehringer Ingelheim ("Trademarks") in relation to the supply or the provision of any Deliverables, Supplier shall obtain the prior written consent of Boehringer Ingelheim on each occasion of proposed use and shall comply with such stipulations and requirements as Boehringer Ingelheim may impose from time to time in relation to the use of Trademarks.

#### **19. No Partnership or Agency**

Nothing in the Contract or these Conditions shall be deemed to constitute a partnership or joint venture between the parties. No party shall have authority to act as agent for or bind the other party in any way.

#### **20. Notices**

20.1 Any notice or other communication required to be given under the Contract shall be in writing and shall be sent for the attention of the person specified in the Contract or as otherwise specified by the relevant party by notice in writing to the other party.

20.2 A notice required to be given under the Contract shall be validly served if sent by email with receipt/read confirmation.

#### **21. Law and Disputes**

21.1 This Contract shall be governed by and construed as to both validity and performance in accordance with the laws of the ordering Affiliate without regard to its conflict of laws rules or otherwise of the countries where the Deliverables are provided. The International Sale of Goods Act (CISG) shall not apply.

21.2 Any dispute arising out of or in connection with this Contract, including any disputes regarding the existence, validity or termination thereof, shall be finally and exclusively settled by the competent courts of the ordering Affiliate.

#### **22. Anti-Bribery & Anti-Corruption Policy and Supplier Code of Conduct**

22.1 Supplier agrees to comply with the contents of the Boehringer Ingelheim Anti-Corruption Policy (ABAC), which can be found on the respective local Boehringer Ingelheim website, and acknowledges that the ABAC is an integral part of Supplier's obligations.

22.2 Supplier is aware that any violation of the ABAC can result in amongst other things the immediate termination of the Contract and adverse legal consequences or legal action being taken against Supplier as is permitted or required by contract or law.

22.3 To reinforce the standards to which we are committed, Boehringer Ingelheim developed a [Supplier Code of Conduct](#) (SuCoC), founded upon the Pharmaceutical Supply Chain Initiative's (PSCI) ([www.pharmaceuticalsupplychain.org](http://www.pharmaceuticalsupplychain.org)), the 10 Principles of the United Nations Global Compact ([www.unglobalcompact.org](http://www.unglobalcompact.org)) and Boehringer Ingelheim's values and principles. Boehringer Ingelheim's SuCoC expresses the expectations for how business is conducted between Boehringer Ingelheim employees and its Suppliers, also covering Suppliers acting on behalf of Boehringer Ingelheim and it can be found on Boehringer Ingelheim's website.

### **23. Export Control.**

23.1 For the purpose of this Clause 23 the following definitions shall apply: “*Item*” means any good, product, material, service, technical data, software or technology. “*Technology*” means specific technical information necessary for the development, production, or use of a product. “*Trade Restrictions*” means any restriction on *Transactions* including, but not limited to, license requirements, notification requirements, embargoes, sanctioned party lists, prohibitions or any other sanction. “*Transaction*” means any form of export, re-export, transfer, disclosure, supply, provision or other comparable *Transaction*, regardless of the way of transfer. “*Controlled Item*” means any *Item* that is subject to *Trade Restrictions* under the applicable *Laws*. “*Export Control Law*” means all laws, statutes, ordinances, directives, bylaws, rules and regulations and whether international, supranational, federal, state, local government or by any other legally constituted public authority of the European Union or any other applicable *Law* imposing *Trade Restrictions*. This includes, without limitation, all treaties, regulations, directives and decisions of the European Union and its institutions.

23.2 Supplier agrees and covenants that if an *Item* provided to Boehringer Ingelheim under the Contract is subject to *Trade Restrictions*, Supplier shall comply with all such *Laws*.

23.3 Supplier represents that Supplier is not and it is not controlled by a restricted party sanctioned by any *Law*. Supplier shall immediately notify Boehringer Ingelheim without delay in case it becomes listed on any Sanctioned Party List or in case it becomes controlled to 50% or more by a restricted party.

23.4 Supplier acknowledges that in order to comply with the applicable Export Control Laws, Boehringer Ingelheim will, directly or through any of its Affiliates, check all parties with which it has business relations periodically against all sanctioned party lists, including without limitation, the sanctioned party lists issued by the European Union, or any national sanctioned party list, including those of the United States of America (collectively the “Sanctioned Party Lists” and individually a “Sanctioned Party List”). In case that Boehringer Ingelheim becomes aware that Supplier appears in a Sanctioned Party List, Boehringer Ingelheim shall have the right to immediately terminate this agreement for cause and to withhold any payments due thereunder.

23.5 To the extent applicable, Supplier shall determine whether an *Item* is a Controlled *Item* and shall identify the specific trade control status of each Controlled *Item*.

23.6 Supplier shall notify Boehringer Ingelheim of any *Trade Restrictions* applying to a specific *Item* by the *Laws* prior to performing any *Transaction* with regard to the Controlled *Item* or provide Boehringer Ingelheim access to such information. Supplier shall inform Boehringer Ingelheim, where the Controlled *Item* is listed (e.g. on the U.S. Commerce Control List) and what *Trade Restrictions* apply to the *Transaction* with the Controlled *Item*.

23.7 Supplier shall obtain and maintain, at its own expense, any governmental consents, authorizations, approvals, filings, permits or licenses required for Supplier to perform any *Transaction* with regard to any Controlled *Item* under the Contract.

23.8 Supplier shall cooperate with Boehringer Ingelheim by providing, upon request, information and other assistance necessary for the classification (e.g. on the US Export Control List), export documentation, license determination, export licensing etc. of any Controlled *Item*.

### **24. Data Protection.**

Supplier shall comply with applicable data protection *Laws* in the execution of the Contract. To the extent that Supplier, collects, processes or uses personal data on behalf of Boehringer Ingelheim when rendering the *Services* (“*Processing*”) in accordance to the applicable data protection laws and as of May 25, 2018, according to Article 28 of the EU General Data Protection Regulation 2016/679, Supplier shall, upon Boehringer Ingelheim’s request, enter into any additional contractual arrangement which is, in Boehringer Ingelheim’s reasonable opinion, required by applicable law, especially in case of transfers of personal data to recipients outside the European Union. Such contractual arrangements may include (i) Boehringer Ingelheim’s standard contract for *Processing*, and/or (ii) the European Union’s Standard Contractual Clauses for the transfer of personal data to processors and/or (iii) any other agreement that competent data protection authorities have declared to be compulsory or acceptable to comply with obligations under data protection laws.

### **25. Pharmacovigilance.**

25.1 For the purpose of this Clause 25, “*Adverse Event*” or “*AE*” shall mean any untoward medical occurrence in a patient or clinical trial subject to whom a medicinal product was administered and which does not necessarily have a causal relationship with this treatment.

25.2 In order to enable Boehringer Ingelheim to comply with its worldwide regulatory reporting responsibility, Supplier shall forward to Boehringer Ingelheim, within one (1) business day after receipt, all information of which Supplier becomes aware by any means, related to:

- a) all *AEs*;
- b) all reports where the embryo or fetus may have been exposed to the medicinal product via mother or semen with and without event and any *AEs* in conjunction with breastfeeding;
- c) any report of lack of effect, medication error with / without *AE*, overdose with/without *AE*, abuse with/without *AE*, misuse with / without *AE*, drug-drug or drug-food interaction, occupational exposure, unexpected benefit, transmission of an infectious agent via a product of Boehringer Ingelheim, off label use with/without *AE*;
- d) any report of product complaints or falsified product associated with an *AE*;
- e) any information where at least adverse event information after intake of an active substance or product developed, manufactured or commercialized by Boehringer Ingelheim is available, and all other information (e.g. about counterfeits) regarding a product of Boehringer Ingelheim that might lead to a risk for a patient.

25.3 Supplier shall forward all information listed under a) to e) above as it has been received, without screening, selection or further processing, either by fax or secure e-mail to following contact person of Boehringer Ingelheim, indicating the date of receipt of such information: [PV\\_local\\_Sweden@boehringer-ingelheim.com](mailto:PV_local_Sweden@boehringer-ingelheim.com).

25.4 Upon request of Boehringer Ingelheim, Supplier shall provide Boehringer Ingelheim with further information. Supplier is responsible to ensure that its staff working for Boehringer Ingelheim is adequately informed and trained to comply with the reporting obligations described in this Clause.

### **26. Set-off**

Boehringer Ingelheim may set off any financial obligation owed by Boehringer Ingelheim to Supplier (whether arisen under this Contract or not) against any financial obligation owed by Supplier to Boehringer Ingelheim.

### **27. Waiver**

No waiver or forbearance by Boehringer Ingelheim (whether express or implied) in enforcing any of its rights under these Conditions shall prejudice its right to do so in the future.

### **28. Sub-contracting and/or Assignment.**

Supplier shall not assign, sub-contract, license or otherwise dispose of any part of its rights or obligations under this Contract without the prior written consent of Boehringer Ingelheim. Boehringer Ingelheim shall be able at all times to transfer its rights and obligations under these Conditions to an Affiliate.

### **29. Severance**

In case any provision of these Conditions is in all or part declared void or unenforceable, such circumstance shall not affect the validity or execution of the other provisions of these Conditions, which shall continue in full force and effect as if the affected provision was never declared void or unenforceable.