

## 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) "BI" means Boehringer Ingelheim Danmark A/S and Boehringer Ingelheim Animal Health Denmark A/S and any ordering Affiliate of BI.
- (c) "Conditions" means the terms and conditions of purchase set out in this document and any special terms and conditions BI 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 BI 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, trade mark, 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 BI to order the Goods or the Services.
- (k) "Supplier" means the supplier to whom BI'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 BI 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) BI 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 BI and Supplier, to the exclusion of all other agreements, terms or conditions unless otherwise accepted by BI in writing. However, in case BI 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 BI's Purchase Order using the form of acknowledgement provided by BI. However, if Supplier delivers or commences work related to the Deliverables, or sends an invoice or similar statement to BI, then such action will constitute acceptance by Supplier of BI's Purchase Order and these Conditions.
- (d) No variation of the Purchase Order or counter-offer by Supplier shall bind BI without BI's written acceptance thereof.
- (e) Supplier shall not provide any gifts or benefits to any of BI'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 BI.
- (g) The Deliverables shall be provided in accordance with laws and regulations applicable from time to time.
- (h) BI's rights under these Conditions are in addition to BI'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 BI 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 BI'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 BI'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 BI. 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 BI and the costs for which are passed through to BI (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 BI, it shall not make any additional profit. All expenses incurred for PTI must be preapproved by BI. Supplier shall ensure full transparency on the costs and expenses for PTI to be reimbursed by BI and shall provide a detailed and itemized list of PTI. Upon request of BI, 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, BI shall have the right to examine and audit Supplier's financial and commercial records relating to any PTI to be reimbursed by BI. If the examination or audit determines that Supplier overcharged BI, then the expenses of such examination or audit shall be borne by Supplier, and Supplier shall remit to BI the total amount of the overcharges as well as the expenses of examination or audit within five (5) calendar days from demand by BI. This clause shall survive any termination or expiry of the Purchase Order.

## 4. BI'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 BI or used by Supplier specifically in the manufacture or the supply of Deliverables shall at all times be and remain the exclusive property of BI. 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 BI. Supplier may only use such property to fulfil the Contract. Disposal of such property shall be in accordance with BI's written instructions.

## 5. Delivery

5.1 Delivery shall be made DDP BI'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 BI at the delivery address stated in the Purchase Order or, otherwise stated by BI.

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, BI's premises shall be carried out during BI's standard working hours. Timely delivery and performance is essential to BI.

5.4 In case of late delivery, BI 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 BI in obtaining substitute Deliverables from a third party; and
- (d) claim damages for costs, losses and expenses incurred by BI 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 BI has not exercised its rights of termination under 5.3 (b) above, BI 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 BI, Supplier shall at no cost to BI repair or replace, at BI'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. BI reserves the right to hold damaged Goods at Supplier's risk or return them at the risk and expense of Supplier.

5.6 If BI 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 BI of any of its rights under the Contract. If Supplier fails to deliver under any such single contract, BI has the right to terminate the Contract in its entirety.

5.7 If the Deliverables are delivered or provided to BI 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 BI**

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 BI 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 BI. 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 BI. If any Deliverables do not conform to the Specification(s), BI is entitled to reject the Deliverables at Supplier's expense. BI 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 BI to inspect and, if appropriate, reject the Deliverables prior to delivery or performance.

7.3 Inspection by BI 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 BI 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 BI's premises. If BI has already paid for such Goods, ownership in the Goods shall pass to Supplier when BI has been fully reimbursed; or
- (b) require Supplier within a reasonable time to repair or replace the Goods, at BI's option and at Supplier's expense, with Goods in compliance with Clause 11 below. Supplier shall reimburse BI for any costs incurred by BI 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 BI for all costs and expenses of having the Deliverables performed by a third party.

7.5 If BI agrees to destroy any Goods at Supplier's request, Supplier shall reimburse BI 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 BI.

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 BI 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 BI's Purchase Order number. Invoices shall be marked for the attention of BI's Accounts Payable department.

9.2 In order to enable BI 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 BI and shall be supplied as a whole. No partial shipments or invoices are allowed unless explicitly approved by BI.

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 BI is without prejudice to any rights BI may have under law or contract.

10.3 Supplier shall submit appropriate VAT invoices in relation to all Deliverables

supplied to BI, including BI's PO- 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 BI 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 BI under or in relation to the Contract or otherwise.

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

11.1 The Goods shall be marked in accordance with BI'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 BI 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 BI and in accordance with regulatory requirements, when BI 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 BI, 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 BI, and shall be performed with care, skill and diligence.

12.1.4 If the Deliverables are to be provided at BI'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 BI.

12.1.6 The Deliverables shall not contain any Open Source Software.

12.2 The warranties apply also to Deliverables which 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 BI 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 BI's sole option, whether or not BI 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 BI may have under this Contract or under law.

#### **13. Indemnity**

13.1 Supplier shall keep BI 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 BI 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 BI; 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 BI; or

(e) any claim against BI 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 BI 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 BI 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 BI, the IP Rights therein shall as between the parties be vested in BI. Supplier shall execute all documents and do all such things as may be reasonably required by BI to confirm or perfect the ownership.

#### **17. Termination**

17.1 BI 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 BI shall pay to Supplier fair and reasonable compensation for work-in-progress at the time of termination, as decided by BI, but such compensation shall not include loss of anticipated profits or any consequential loss or damage.

17.2 BI 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 BI 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 BI accrued prior to termination. Clauses 1, 3.3, 4, 12, 13, 14, 16, 18, 21 and 22 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 BI ("Trademarks") in relation to the supply or the provision of any Deliverables, Supplier shall obtain the prior written consent of BI on each occasion of proposed use and shall comply with such stipulations and requirements as BI 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 both as to 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 and Anti-Corruption Policy**

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 BI 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.

#### **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 which 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 BI 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 BI 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, BI 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 BI becomes aware that Supplier appears in a Sanctioned Party List, BI 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 BI 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 BI access to such information. Supplier shall inform BI, 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 BI 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 BI 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 BI's request, enter into any additional contractual arrangement which is, in BI'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) BI'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 BI to comply with its worldwide regulatory reporting responsibility, Supplier shall forward to BI, 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 BI, 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 BI is available, and all other information (e.g. about counterfeits) regarding a product of BI 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 BI, indicating the date of receipt of such information: [PV\\_local\\_Denmark@boehringer-ingelheim.com](mailto:PV_local_Denmark@boehringer-ingelheim.com).

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

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

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

#### **27. Waiver**

No waiver or forbearance by BI (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 BI. BI 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.