

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) "Buyer" means Boehringer Ingelheim BV. 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 the Buyer 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 the Buyer and the Seller 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 or at www.opensource.org/licenses or any successor websites.
- (j) "Purchase Order" means the form issued by the Buyer to order the Goods or the Services.
- (k) "Seller" means the supplier named overleaf and to whom the Buyer'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 the Seller to the Buyer 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) The Buyer will take responsibility only for orders made in the Purchase Order.
- (b) These Conditions shall apply to all interactions between Buyer and Seller, to the exclusion of all other agreements, terms or conditions unless otherwise accepted by the Buyer in writing. However, in case Buyer and Seller 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) The Seller shall accept the Buyer's Purchase Order using the form of acknowledgement provided by the Buyer. However, if the Seller delivers or commences work related to the Deliverables, or sends an invoice or similar statement to the Buyer, then such action will constitute acceptance by the Seller of the Buyer's Purchase Order and these Conditions.

(d) No variation of the Purchase Order or counter-offer by the Seller shall bind the Buyer without the Buyer's written acceptance thereof.

(e) The Seller shall not provide any gifts or benefits to any of the Buyer'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 the Buyer.

(g) The Deliverables shall be provided in accordance with laws and regulations applicable from time to time.

(h) The Buyer's rights under these Conditions are in addition to the Buyer'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 the Buyer in writing, the price as stated in the Purchase Order includes carriage, packaging and insurance, and all prices shall be fixed 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 Buyer's approval in writing. An amendment of the Purchase Order is only effective if made in writing and confirmed by an amended and signed Order submitted to the Seller by Boehringer Ingelheim. Such amendment request and confirmation may be validly executed via exchange of a signed pdf via e-mail.

3.3 Goods and Services, such as, but not limited to, travel, transportation, accommodation, meals, catering, deliveries, production and any other travel or hospitality services provided by third parties are treated as Pass-Through-Costs. The Seller undertakes not to make any additional profit from any Pass-Through-Costs. All expenses must be preapproved by the Buyer and the Seller shall ensure full transparency on the costs and expenses to be reimbursed by the Buyer. Copies of all third party invoices, receipts and/or debit notes regarding Pass-Through-Costs (detailed and itemized) shall be made available to the Buyer, if requested so by BI. During the term of this Agreement and for five (5) years thereafter, BI shall have the right to examine and audit [vendor/provider]'s financial and commercial records relating to services / work / activities performed hereunder and any Pass-Through-Items to be reimbursed by BI. If the examination or audit determines that the Seller overcharged the Buyer, then the expenses of such examination or audit shall be borne by the Seller and the Seller shall remit to the Buyer the total amount of the overcharges as well as the expenses of examination or audit within five (5) calendar days from demand by the Buyer. This clause shall survive the termination of this Agreement.

4. Buyer'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 the Buyer or used by the Seller specifically in the manufacture or the supply of Deliverables shall at all times be and remain the exclusive property of the Buyer. Such property shall be held by the Seller in safe custody at Seller's risk and shall be maintained, insured and kept in good condition by the Seller until returned to the Buyer. The Seller may only use such property to fulfil the Contract. Disposal of such property shall be in accordance with the Buyer's written instructions.

5. Delivery

5.1 Delivery will be made when the Goods and Services have been received by an authorised representative of the Buyer at the delivery address stated in the Purchase Order or, if none is specified, to the Buyer's address as shown overleaf or otherwise stated by the Buyer.

5.2 The date of delivery or performance of the Deliverables shall be as specified in the Purchase Order or, if not specified, within 28 days of the date of the Buyer's Purchase Order. Deliveries to, and Services to be performed at, the Buyer's premises shall be carried out during the Buyer's standard working hours. Timely delivery and performance is essential to the Buyer.

5.3 In case of late delivery, the Buyer shall be entitled to:

- (a) agree with the Seller a reduced price for the Deliverables actually delivered or performed; or
- (b) terminate the Contract. If so, the Seller shall promptly, at Seller's cost, collect any Goods delivered; or
- (c) recover from the Seller any expenditure reasonably incurred by the Buyer in obtaining substitute Deliverables from a third party; and
- (d) claim damages for costs, losses and expenses incurred by the Buyer and attributable to the Seller's failure to deliver or perform the Deliverables on the due date.

If the Seller delivers a lower quantity of Deliverables than specified and the Buyer has not exercised its rights of termination under 5.3 (b) above, the Buyer may:

- (i) accept the Deliverables which correspond to the Contract; and
- (ii) recover from the Seller any losses resulting from the failure to deliver in full; and
- (iii) require the Seller promptly to deliver or provide sufficient Deliverables which correspond to the Contract to comply with the quantity required; or
- (e) require the Seller to re-perform all or part of the Deliverables free of charge.

5.4 Upon receipt of notice thereof from the Buyer, the Seller shall at no cost to Buyer repair or replace, at Buyer'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 Condition 5.1 above. The Buyer reserves the right to hold damaged Goods at the Seller's risk or return them at the risk and expense of the Seller.

5.5 If the Buyer 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 Buyer of any of its rights under the Contract] If the Seller fails to deliver under any such single contract, the Buyer has the right to terminate the Contract in its entirety.

5.6 If the Deliverables are delivered or provided to the Buyer in excess of the quantities ordered, any

such excess shall be free of charge and, as regards goods, shall remain at the Seller's risk and shall be returnable at the Seller's expense.

6. Passing of Ownership and Risk to Buyer

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 Conditions 5 and 7.

6.2 Risk in the Goods shall pass to the Buyer upon the later of delivery in accordance with Condition 5.1 or inspection and testing. The Seller shall insure the Goods with a reputable insurer on a comprehensive and full replacement value basis until risk has passed to the Buyer. In the event Condition 7.4 (a) applies, the Seller shall insure the Goods until ownership has passed back to the Seller.

7. Acceptance

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

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

7.3 Inspection by the Buyer shall not relieve the Seller of responsibility or liability for the Deliverables and shall not imply acceptance thereof.

7.4 Rejection of the Deliverables shall entitle the Buyer to:

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

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

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

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

7.5 If the Buyer agrees to destroy any Goods at the Seller's request, the Seller shall reimburse the Buyer for any costs incurred.

8. Packaging

8.1 The Seller 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. The Seller shall mark the Goods ordered in accordance with reasonable instructions of the Buyer.

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 The Seller shall be liable for and shall indemnify the Buyer 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 the Seller relating to a Purchase order shall include the Buyer's Purchase Order number. Invoices shall be marked for the attention of the Buyer's Accounts Payable department.

9.2 In order to enable the Buyer 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 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 of invoice after delivery. Payment by the Buyer is without prejudice to any rights the Buyer may have under law or contract.

10.2 The Seller shall submit appropriate VAT invoices in relation to all Deliverables supplied to the Buyer.

10.3 The Seller is not entitled to suspend any delivery or performance of the Deliverables due to any outstanding payments. In the case of an undisputed invoice, the Seller shall be entitled to the applicable legal interest over the amount due, from the due date until payment has been received in full

11. The Goods

11.1 The Goods shall be marked in accordance with the Buyer's instructions, comply with all legal requirements, and shall be packaged in accordance with Condition 8.

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

11.4 The Seller shall provide the Buyer 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 the Seller shall take responsibility for the collection, recycling and disposal of Goods, at no cost for the Buyer and in accordance with regulatory requirements, when the Buyer notifies the Seller that the Goods in question have reached their end of life.

12. Warranties

12.1 The Seller 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 the Buyer, 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 the Seller in accordance with best standards prevailing in the Seller's industry, in accordance with any Specifications supplied by the Buyer, and shall be performed with care, skill and diligence.

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

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 the Buyer shall be entitled:

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

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

13. Indemnity

13.1 The Seller shall keep the Buyer 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 the Buyer or arising from or as a result of :

(a) any negligence, breach of contract or warranty, wilful act or omission of the Seller 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 the Buyer; or

(c) any liability under the ABAC (as defined in Condition 22), the Export Control Laws and the export control warranties and undertakings (as outlined in Condition 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 the Seller of the Conditions including the warranties under Condition 12, save to the extent that such a claim arises directly as a result of negligence of the Buyer; or

(e) any claim against the Buyer 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 the Seller's breach or negligent performance or failure or delay in performance of the terms of the Contract.

14. Insurance

The Seller undertakes to effect and maintain insurance cover adequate for the risks and liabilities specified in Condition 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 the Seller or the acceptance by the Buyer of delivery or performance is delayed or prevented because the manufacture, delivery or performance, as applicable, of any Deliverables in accordance with Condition 5 or the consumption or use of the Deliverables (or their product or output) by the Buyer 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 The Buyer reserves the right to seek alternative sources of supply to mitigate any losses it might sustain and to recover any difference in price from the Seller.

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 the Buyer, the IP Rights therein shall as between the parties be vested in the Buyer. The Seller shall execute all documents and do all such things as may be reasonably required by the Buyer to confirm or perfect the ownership.

17. Termination

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

17.2 The Buyer shall have the right to terminate the Contract at any time and with immediate effect by

giving notice in writing to the Seller if:

- (a) the Seller 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 the Seller; or
- (c) the Seller 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 the Seller; or
- (d) the Seller ceases or threatens to cease to carry on its business; or
- (e) the financial position of the Seller deteriorates to such an extent that in the opinion of the Buyer the capability of the Seller 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 the Seller in any jurisdiction.

17.3 The termination of the Contract, however arising, shall be without prejudice to the rights and duties of the Buyer accrued prior to termination. Conditions 1, 3.3, 4, 12, 13, 14, 16, 18 and 21 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 Condition 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 Condition. The foregoing obligations as to confidentiality shall survive any termination of this Contract. In case of contradiction between this Condition 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 the Seller to use any of the registered or unregistered trademarks, service marks, trade names, logos or brand names of the Buyer ("Trademarks") in relation to the supply or the provision of any Deliverables, the Supplier shall obtain the prior written consent of the Buyer on each occasion of proposed use and shall comply with such stipulations and requirements as the Buyer 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 The Seller confirms it has received a copy of the Boehringer Ingelheim Anti-Corruption Policy (ABAC).

22.2 The Seller agrees to comply with the contents of the ABAC and acknowledges that the ABAC is an integral part of the Seller's obligations.

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

23. Export Control.

23.1 For the purpose of this Condition 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 Seller agrees and covenants that if an *Item* provided to the Buyer under the Contract is subject to Trade Restrictions, the Seller shall comply with all such *Laws*.

23.3 The Seller represents that Seller is not and it is not controlled by a restricted party sanctioned by any *Law*. The Seller shall immediately notify the Buyer 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 The Seller acknowledges that in order to comply with the applicable Export Control Laws, the Buyer 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 the Buyer becomes aware that the Seller 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, the Seller shall determine whether an Item is a Controlled Item and shall identify the specific trade control status of each Controlled Item.

23.6 The Seller shall notify the Buyer 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 the Buyer access to such information. The Seller shall inform the Buyer, 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 The Seller shall obtain and maintain, at its own expense, any governmental consents, authorizations, approvals, filings, permits or licenses required for the Seller to perform any Transaction with regard to any Controlled Item under the Contract.

23.8 The Seller shall cooperate with the Buyer 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.

The Seller shall comply with applicable data protection Laws in the execution of the Contract. To the extent that the Seller, collects, processes or uses personal data on behalf of the Buyer 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, the Seller shall, upon the Buyer’s request, enter into any additional contractual arrangement which is, in Buyer’s reasonable opinion, required by applicable law, especially in case of transfers of personal data to recipients outside the European Economic Area. Such contractual arrangements may include (i) Buyer’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 In order to enable the Buyer to comply with its worldwide regulatory reporting responsibility, the Seller shall forward to Buyer, within one (1) business day after receipt, all information of which Buyer 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 Buyer, 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 a an active substance or product developed, manufactured or commercialized by Buyer is available, and all other information (e.g. about counterfeits) regarding a product of Buyer that might lead to a risk for a patient.

25.2 The Seller 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 the Buyer, indicating the date of receipt of such information: PV_local_Netherlands@boehringer-ingenelheim.com.

25.3 Upon request of the Buyer, the Seller shall provide the Buyer with further information. The Seller is responsible to ensure that its staff working for the Buyer is adequately informed and trained to comply with the reporting obligations described in this section.

25.4 For the purpose of this Condition 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.

26. Set-off

The Buyer may set off any financial obligation owed by the Buyer to the Seller (whether arisen under this Contract or not) against any financial obligation owed by the Seller to the Buyer.

27. Waiver

No waiver or forbearance by the Buyer (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.

The Seller 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 the Buyer. The Buyer 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.