

## STANDARD TERMS AND CONDITIONS OF SALE OF ASTRAZENECA BV

As filed on 23 January 2012 at the registry of the district court of The Hague under number 3/2012

### 1. DEFINITIONS AND INTERPRETATION

- 1.1 In these Standard Terms, unless the context requires otherwise, the following words and expressions shall have the following meanings:

**"Applicable Laws and Regulations"** means all national, supra-national, federal, state, local, foreign or provincial laws, rules, regulations, including case law, as well as any guidances, guidelines and requirements of any Regulatory Authorities and any industry codes of practice in effect from time to time applicable to the possession, use, distribution or sale of the Products or the performance of these Standard Terms, including Good Distribution Practices ("**GDPs**") and Good Storage Practices ("**GSPs**").

**"AstraZeneca"** means AstraZeneca BV, with offices at Louis Pasteurlaan 5, 2719 EE Zoetermeer.

**"Code of Conduct"** means the AstraZeneca Code of Conduct available at [www.astrazeneca.com](http://www.astrazeneca.com), as in force from time to time.

**"Country"** means the Netherlands.

**"Customer"** means the person (which term shall include firm, company, institution, government body or other legal entity) purchasing Products from AstraZeneca under these Standard Terms.

**"Insolvency Event"** means any of the following events: where a Party ceases to do business, becomes unable to pay its debts when they fall due, becomes or is deemed to be insolvent, has a receiver, manager, administrator, administrative receiver or similar officer appointed in respect of it or the whole or any part of its assets or business, any composition or arrangement is made with any one or more classes of its creditors, takes or suffers any similar action in consequence of debt, an order or resolution is made or passed for its dissolution or liquidation (other than for the purpose of solvent amalgamation or reconstruction) or enters into liquidation whether compulsorily or voluntarily or any analogues or comparable event takes place in any other jurisdiction.

**"Order"** means an order by the Customer for Products.

**"Parties"** means AstraZeneca and the Customer and **"Party"** means either of them.

**"Price"** means the price of the Products quoted by AstraZeneca, agreed by the Parties in writing or, where neither of the foregoing applies, set out in the currently applicable AstraZeneca price list.

**"Products"** means the AstraZeneca pharmaceutical products, the sale and purchase of which is governed by these Standard Terms.

**"Regulatory Authority"** means any court or government body, whether national, supra-national, federal, state, local, foreign or provincial, including any political subdivision thereof, including any department, commission, board, bureau, agency, or other regulatory or administrative governmental authority or instrumentality, and further including any quasi-governmental person or entity exercising the functions of any of these.

**"Standard Terms"** means these Standard Terms and Conditions of Sale.

- 1.2 In these Standard Terms (unless the context requires otherwise) headings are for convenience only and shall not affect interpretation, references to the singular include the plural and vice versa, references to one gender include all genders, any phrase introduced by the expressions "**including**", "**include**", "**in particular**" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms and a reference to any law includes all bye-laws, licences, statutory instruments, rules and regulations, etc made under that law and includes any law which replaces, re-enacts, amends or consolidates such law.

### 2. APPLICATION OF THESE STANDARD TERMS

- 2.1 No terms other than these Standard Terms (including any terms provided by the Customer in any order form, acknowledgement or other document,) shall apply to the sale of the Products.
- 2.2 Any addition to or modification, variation or exclusion of any provision of these Standard Terms must be in writing agreed in advance by AstraZeneca to have effect. AstraZeneca reserves the right to amend, vary or alter these Standard Terms at any time. Any such amendment, variation or alternation will apply to all Products ordered from the date the Customer is made aware of such amendment, variation or alteration.

### 3. ORDERS

- 3.1 All Orders are subject to any minimum quantities applied by AstraZeneca at any time.

3.2 Unless AstraZeneca logs a back order, the partial fulfilment of an Order by AstraZeneca constitutes a new offer, which is deemed to be accepted by the Customer through acceptance of the Product supplied. If AstraZeneca logs a back order, AstraZeneca will inform the Customer of the earliest possible date of delivery.

#### 4. **CUSTOMER'S OBLIGATIONS**

4.1 The Customer shall distribute and sell the Products in compliance with all Applicable Laws and Regulations.

4.2 The Customer shall not offer for sale or sell the Products directly or indirectly to any person in any country that is outside the European Economic Area.

4.3 The Customer shall distribute and sell Products under the brand, logo, trademark and specifications under which the Products were delivered to the Customer. The Customer may not change the quality of the Products purchased from AstraZeneca, including their labelling, imprints and instructions, unless permitted under Applicable Laws and Regulations.

4.4 The Customer shall ensure that neither it nor any of its officers, employees, directors, consultants, agents, representatives or sub-contractors (i) take any action which could render any AstraZeneca group company liable under the US Foreign Corrupt Practices Act of 1977, the UK Bribery Act 2010 or any other Applicable Laws and Regulations for the prevention of fraud, corruption, racketeering, money laundering and/or terrorism or (ii) cause any employee of an AstraZeneca group company to be in violation of the Code of Conduct.

#### 5. **PRICE**

5.1 Unless otherwise stated in writing, the Price is exclusive of Value Added Tax and other similar sales taxes which shall be paid by the Customer.

#### 6. **DELIVERY**

6.1 AstraZeneca shall deliver all Products to the Customer **Ex Works** (as defined in Incoterms 2010). The delivery address will be notified by AstraZeneca to the Customer in advance.

6.2 Delivery dates are estimates only and time shall not be of the essence for delivery.

6.3 Subject to clause 10.3, AstraZeneca shall not be liable for any loss caused by the late delivery of any Products.

6.4 The Customer shall sign AstraZeneca's delivery note as acknowledgement of the delivery of Products.

#### 7. **PAYMENT**

7.1 AstraZeneca will invoice the Customer for each shipment of Products delivered to the Customer. Each such invoice shall be due and paid by the Customer within thirty (30) days of delivery of the Products. If payment is not made by the date due, the Customer will be in default by operation of law and will be required to pay statutory interest (with the meaning of Article 6:119 (a) of the Dutch Civil Code) with effect from the invoice date.

7.2 The Customer shall pay all reasonable costs (including legal fees on a solicitor client basis) that AstraZeneca incurs as a result of the Customer failing to fulfill any of its payment obligations on time.

7.3 At AstraZeneca's request, the Customer will provide security acceptable to AstraZeneca for payment of the price of Products before making delivery.

7.4 The Customer may not set off any amount owed to AstraZeneca against any claim it has against AstraZeneca.

#### 8. **TITLE AND RISK**

8.1 Notwithstanding delivery, title to the Products shall remain with AstraZeneca until payment is received by AstraZeneca in full in cleared funds. The Customer shall keep any Products in which title has not passed to it in satisfactory condition in accordance with any requirements of AstraZeneca from time to time as AstraZeneca's bailee on a fiduciary basis. The Customer shall during such time: (i) keep (at no cost to AstraZeneca) such Products separate and readily identified as AstraZeneca's at a location belonging to the Customer (or at a location agreed in writing with AstraZeneca), (ii) not destroy, deface or obscure in any way any identifying mark or packaging on such Products and (iii) keep such Products insured on AstraZeneca's behalf for their full Price against all risks to the reasonable satisfaction of AstraZeneca.

8.2 The Customer may sell any Products in which title has not passed to it solely on the condition that any sale is in the ordinary course of the Customer's business at full market value and such sale shall be a sale of AstraZeneca's property on the Customer's own behalf and the Customer shall deal as principal when making such a sale. The Customer shall hold the amount of the proceeds that represent the amount owed by the Customer on AstraZeneca's behalf.

- 8.3 On the occurrence of any Insolvency Event in relation to the Customer, the Customer's right to possession of any Products in which title has not passed shall terminate immediately and AstraZeneca shall be entitled to enter any premises owned or controlled by the Customer or any of its Affiliates to recover such Products.
- 8.4 AstraZeneca shall be entitled to recover payment for the Products notwithstanding that ownership of any of the Products has not passed to the Customer.
- 8.5 Risk in the Products shall pass to the Customer on delivery. AstraZeneca shall have no responsibility in respect of the safe custody of any Products after delivery. The Customer should insure the Products against all risks (if any) that the Customer thinks appropriate.

## 9. DAMAGED PRODUCTS

- 9.1 The Products shall be deemed to have been delivered to and accepted by the Customer as being in a satisfactory condition and in accordance with these Standard Terms unless a written complaint is sent to AstraZeneca within thirty (30) days after delivery or, if in respect of any defect that would not have been apparent on careful inspection of the Products on delivery, within fifteen (15) days of discovering such defect but not later than one (1) year from delivery. The Customer must retain any damaged Products and/or packaging for inspection by AstraZeneca and produce them as required.
- 9.2 Subject to clause 10.3, AstraZeneca's liability in respect of any defects in the Products shall be limited to giving credit for any such defective Products or replacing them free of charge, as determined by AstraZeneca.

## 10. PRODUCT WARRANTY AND LIABILITY

- 10.1 AstraZeneca warrants that the Products will at the time of delivery meet the standards required by Applicable Laws and Regulations as these apply to the distribution and sale of the Products in the Country. AstraZeneca will not be liable for any fault or defect caused by deliberate damage, negligence or misuse (other than by AstraZeneca) or failure to follow AstraZeneca's instructions from time to time (including storage requirements).
- 10.2 Subject to clause 10.3, all representations, conditions, warranties and other terms not expressly set out in these Standard Terms including any term as quality of Products, satisfactory quality or fitness for a particular purpose are expressly excluded to the extent permitted by law.
- 10.3 Nothing in these Standard Terms shall limit or exclude any liability for (a) death or personal injury caused by negligence, (b) fraud or fraudulent misrepresentation or (c) where such limitation or exclusion would be contrary to law.
- 10.4 Subject to clause 10.3, AstraZeneca shall not be liable in respect of these Standard Terms or the Products, whether in contract (including for deliberate repudiatory act), tort (including negligence), for breach of statutory duty, or otherwise:
- (A) for any special, indirect or consequential loss; or
  - (B) for any loss of goodwill, business, revenue, profit or saving (in each case whether direct or indirect); and
  - (C) in aggregate in respect of an Order, for any loss in aggregate exceeding the Price of Products under that Order.

## 11. QUALITY ASSURANCE / PRODUCT SECURITY / ADVERSE EVENTS

- 11.1 The Customer shall conduct all Product-related activities in compliance with Applicable Laws and Regulations. Where no such laws and/or regulations exist in the Country relating to GDPs and GSPs, these standards shall be established with reference to good distribution practices for pharmaceutical products as published in Annex 5, WHO Technical Report Series 957, 2010, Good Storage Practices as published in Annex 9, WHO Technical Report Series 908, 2003 and the EU guidelines on Good Distribution Practice of Medicinal Products for Human Use (as published in the Official Journal of the European Union C 63 p. 3 on 1 March 1994).
- 11.2 The Customer shall appoint a designated person at each distribution point with responsibility for ensuring that a quality management system for pharmaceutical products that it handles is implemented and maintained.
- 11.3 The Customer shall have a documented quality policy describing the overall policies regarding the quality of pharmaceutical products that it handles and must have procurement and release procedures sufficient to ensure that such pharmaceutical products are only sourced from legally approved suppliers and distributed by legally approved entities in all cases in accordance with Applicable Laws and Regulations.
- 11.4 All transactions of the Products in the Customer's supply chain must be traceable. The Customer shall have written procedures and records to ensure traceability of distributed, sold and discarded Products. These records shall be kept for a period of at least six (6) years and shall be made available to AstraZeneca on demand for quality assurance and/or product security purposes. The Customer shall operate a system that ensures that Products due to

expire first are sold and/or distributed first. Storage conditions for the Products shall be in compliance with the instructions on the label, any other requirement of Applicable Laws and Regulations and any requirements of AstraZeneca.

- 11.5 The Customer shall confirm and document the identity and the quantity of all Products received.
- 11.6 The Customer shall handle and store all Products in such a manner as to prevent contamination, mix-ups and cross-contamination.
- 11.7 The Customer may only sell and/or distribute the Products to persons or entities that are entitled pursuant to Applicable Laws and Regulations to acquire such Products. Written proof of such authority must be obtained prior to the dispatch of Products to such persons or entities.
- 11.8 The Customer shall have a written procedure and system in place to recall promptly and effectively Products known or suspected to be defective, with a designated person(s) responsible for recalls. The Customer shall cooperate with AstraZeneca in conducting any recall. In the event of a recall, the Customer shall ensure that all recalled Products at Customer's site, or supplied from Customer's site, are reconciled and shall provide AstraZeneca with all requested information regarding the distribution and sales of recalled Products. The Customer shall ensure that recalled Products under the Customer's control are secured and are subsequently destroyed if required and are at all times handled in accordance with AstraZeneca's instructions.
- 11.9 The Customer shall immediately inform AstraZeneca of any counterfeit or suspected counterfeit or illegally traded AstraZeneca products as the Customer becomes aware of them. The Customer shall record and segregate immediately any counterfeit or suspected counterfeit or illegally traded AstraZeneca products found in its premises or stock. The Customer shall clearly label such products to prevent further distribution or sale. The Customer shall fully co-operate with AstraZeneca during any investigation related to any of the above-mentioned incidents.
- 11.10 Customer shall inform AstraZeneca of any complaint or adverse event report received by Customer relating to any of the Products within twenty-four (24) hours of Customer's receipt of such complaint and in writing within seven (7) days of Customer's receipt of such complaint.
- 11.11 For quality assurance and/or product security purposes, the Customer shall permit AstraZeneca to inspect and audit the Customer's premises, systems, processes, practices and stocks of the Products as well as records ensuring traceability of distributed, sold or discarded Products at any time upon reasonable notice during normal working hours.
- 11.12 Obsolete or out of date Products shall, if not returned to AstraZeneca, be discarded in such way that eliminates the possibility of re-use and be kept in a secure manner until they have been discarded.

## 12. RETURNS

- 12.1 No Products that require refrigerated storage or which AstraZeneca has discontinued to offer for sale will be accepted for return and credit by AstraZeneca. AstraZeneca will only accept Products for return and credit the Customer for such Products where: (i) they have been stored correctly at all times, and (ii) Products are returned no later than within the time limits set by AstraZeneca from time to time.
- 12.2 AstraZeneca may refuse to accept the return of Products if they are not in current whole packs with unbroken seals or, if in AstraZeneca's sole opinion, are not in a good condition or unfit for sale.

## 13. SUSPENSION

- 13.1 In the event that the Customer becomes subject to an Insolvency Event, AstraZeneca has reason to believe (acting reasonably) that an Insolvency Event is likely or about to occur in relation to the Customer or the Customer commits a breach of these Standard Terms then, without prejudice to any other right or remedy available to AstraZeneca:

(A) AstraZeneca shall be entitled on notice to:

- (1) suspend any further deliveries of Products with immediate effect; and/or
- (2) enter without prior notice any premises where the Products may be, and to repossess and dispose of the Products so as to discharge any sums owed to AstraZeneca by the Customer hereunder; and

(B) all sums owing to AstraZeneca by the Customer shall become immediately due and payable without the need to give any prior notice.

## 14. INSPECTION

The Customer shall permit or procure the right for AstraZeneca to inspect any facilities, warehouses and any other locations used by the Customer and its suppliers in connection with the distribution of the Products and the

performance of Customer's obligations under these Standard Terms and all records pertaining thereto at any time on AstraZeneca giving at least twenty-four (24) hours notice. The Customer shall take corrective measures to address any breaches of these Standard Terms or Applicable Laws and Regulations identified by AstraZeneca arising from such inspections to the reasonable satisfaction of AstraZeneca.

15. **NOTICE**

15.1 Any notice to be given to AstraZeneca shall be made in writing for the attention of the Financial Controller and sent to Postbus 599, 2700 AN Zoetermeer and shall be deemed to have been duly given, if sent by post, forty-eight (48) hours after posting or if by fax transmission, at the time of sending.

15.2 Any notice to be given to the Customer shall be made in writing and sent to the delivery address specified by the Customer and approved by AstraZeneca or, if none, the address set out in the Order, and shall be deemed to have been duly given, if sent by post, 48 hours after posting or if by fax transmission, at the time of sending.

16. **GENERAL**

16.1 These Standard Terms shall be governed by laws of the Country to the exclusion of the Vienna Sales Convention, and AstraZeneca and the Customer submit to the exclusive jurisdiction of the courts of the County.

16.2 The Customer may not assign, delegate, sub-contract, transfer, charge or otherwise dispose of all or any of its rights and/or obligations under these Standard Terms without the prior written consent of AstraZeneca. Such consent will not relieve the Customer from any liability or obligation under these Standard Terms.

16.3 The invalidity or unenforceability of any provision of these Standard Terms shall not affect the validity or enforceability of any other provision which shall remain in full force and effect.

16.4 The failure by AstraZeneca to enforce any right or provision contained in these Standard Terms shall not constitute a waiver of that right or provision.

16.5 The Customer shall in all its contracts with its own customers include clauses equivalent to clauses 4.1, 11.1, 11.9, 11.10 and 16.5 of these Standard Terms.