

**Astellas Pharma S.p.A.**

Standard terms and conditions for the purchase of goods and services

**1. Interpretation**

1.1 The definitions and rules of interpretation in this condition apply in these conditions.

**Affiliates:** any business entity which controls, is controlled by or is under the common control with either party to this Agreement. For the purposes of this definition, a business entity shall be deemed to control another business entity if it owns, directly or indirectly, in excess of 50% of the voting interest in such business entity or the power to direct the management of such business entity.

**Agreement:** this Agreement (including any attached schedule or annexure).

**Company:** Astellas Pharma S.p.A., a corporation incorporated in Italy – Fiscal Code 04754860155 with registered office at Assago (Milano), Via del Bosco Rinnovato, 6 – Building U7.

**Contract:** the Order and the Seller's acceptance of the Order.

**Goods:** any goods and/or services agreed in the Contract to be bought by the Company from the Seller (including any part or parts of them).

**Order:** the Company's written instruction to supply the Goods, incorporating these terms and conditions.

**Seller:** any person, firm or company who accepts the Company's Order.

1.2 A reference to Italian law is a reference to it as it is in force for the time being taking account of any amendment, extension, application or re-enactment and includes any subordinate legislation for the time being in force made under it.

1.3 A reference to one gender includes a reference to the other gender.

1.4 Condition headings do not affect the interpretation of these conditions.

**2. APPLICATION OF TERMS**

2.1 Subject to any variation under article 2.4, these conditions are the only conditions upon which the Company is prepared to deal with the Seller and they shall govern the Contract to the entire exclusion of all other terms or conditions.

2.2 Each Order for Goods by the Company to the Seller shall be deemed to be an offer by the Company to buy Goods subject to these terms and conditions.

2.3 No terms or conditions endorsed upon, delivered with or contained in the Seller's quotation, acknowledgement or acceptance of order, specification or similar document shall form part of the Contract and the Seller waives any right which it otherwise might have to rely on such terms and conditions.

2.4 These conditions apply to all the Company's purchases and any variation to these conditions shall have no effect unless expressly agreed in writing and signed by an authorised representative of the Company.

**3. QUALITY AND DEFECTS**

3.1 All Goods shall be supplied or carried out in accordance with the Order and the specifications and in compliance with all statutory requirements and regulations applicable to such Goods (including, but not limited to, the implied terms as to quality and fitness for purpose), and subject to the Company's approval and where applicable, approval of proofs, samples and specimens and descriptions previously issued to the Supplier and accepted by the Supplier.

3.2 At any time prior to the delivery of the Goods to the Company, the Company shall have the right to inspect and test the Goods at all times.

- 3.3 If the results of such inspection or testing cause the Company to be of the opinion that the Goods do not conform or are unlikely to conform with the Order or to any specifications and/or patterns supplied or advised by the Company to the Seller, the Company shall inform the Seller and the Seller shall immediately take such action as is necessary to ensure conformity and in addition the Company shall have the right to require and witness further testing and inspection.
- 3.4 Notwithstanding any such inspection or testing, the Seller shall remain fully responsible for the Goods and any such inspection or testing shall not diminish or otherwise affect the Seller's obligations under the Contract.
- 3.5 If any of the Goods fail to comply with the provisions set out in article 3 the Company shall be entitled to avail itself of any one or more remedies listed in article 16.

#### **INDEMNITY**

- 4.1 The Seller shall keep the Company indemnified in full against all direct, indirect or consequential liabilities (all three of which terms include, without limitation, loss of profit, loss of business, depletion of goodwill and like loss), loss, damages, injury, costs and expenses (including legal and other professional fees and expenses) awarded against or incurred or paid by the Company as a result of or in connection with:
- (a) defective workmanship, quality or materials;
  - (b) an infringement or alleged infringement of any intellectual property rights caused by the use, manufacture or supply of the Goods; and
  - (c) any claim made against the Company in respect of any liability, loss, damage, injury, cost or expense sustained by the Company's employees or agents or by any customer or third party to the extent that such liability, loss, damage, injury, cost or expense was caused by, relates to or arises from the Goods as a consequence of a direct or indirect breach or negligent performance or failure or delay in performance of the terms of the Contract by the Seller.

#### **5. DELIVERY AND DEFECTS**

- 5.1 The Goods shall be delivered, carriage paid, to the Company's place of business or to such other place of delivery as instructed by the Company prior to delivery of the Goods. The Seller shall off-load the Goods at its own risk as directed by the Company.
- 5.2 The date for delivery shall be specified in the Order, or if no such date is specified then delivery shall take place within fourteen (14) days of the Order or on a mutually agreed date between the parties.
- 5.3 The Seller shall deliver the Goods by the date specified in the Order (time being of the essence) provided that if owing to Force Majeure the Seller is unable to deliver the Goods by the specified date then provided that the Seller shall have given the Company notice in writing without delay of its intention to claim an extension of time the Company shall grant the Seller such extension of time as may be reasonable (but in any event no longer than two (2) calendar months).
- 5.4 The Seller shall invoice the Company upon, but separately from despatch of the Goods to the Company.
- 5.5 The Seller shall ensure that each delivery is accompanied by a delivery note which shows, among other things, the Order number, date of Order, number of packages and contents and, in the case of part delivery, the outstanding balance remaining to be delivered. If the Goods are to be delivered in parts, the Contract will be treated as a single contract and not severable.

- 5.6 If the Seller fails to deliver the Goods for any reason other than Force Majeure, the Company (without prejudice to any other right or remedy which it may have) reserves the right pursuant to art. 1453 of the Italian Civil Code to:
- (i) cancel that part of the Order which has not been delivered; and
  - (ii) charge to the Seller any additional costs, losses or expenses which the Company may incur due to the Seller's failure to deliver the Goods by the specified date.
- 5.7 Unless otherwise stipulated by the Company in the Order, deliveries shall only be accepted by the Company in normal business hours.
- 5.8 If the Goods are not delivered on the due date then, without prejudice to any other rights which it may have, the Company reserves the right pursuant to art. 1453 of the Italian Civil Code to:
- (a) cancel the Contract in whole or in part;
  - (b) reject the Goods (in whole or in part) and return them to the Seller at the risk and cost of the Seller on the basis that a full refund for the Goods so returned shall be paid forthwith by the Seller;
  - (c) refuse to accept any subsequent delivery of the Goods which the Seller attempts to make if the Company has no more interest in such Goods in consideration of failure to deliver the Goods on the due date;
  - (d) recover from the Seller any expenditure reasonably incurred by the Company in obtaining the Goods in substitution from another supplier; and
  - (e) claim damages for any additional costs, loss or expenses incurred by the Company which are in any way attributable to the Seller's.
- 5.9 If the Seller requires the Company to return any packaging material to the Seller that fact must be clearly stated on any delivery note delivered to the Company and any such packaging material shall only be returned to the Seller at the cost of the Seller.
- 5.10 Where the Company agrees in writing to accept delivery by instalments the Contract shall be construed as a single contract in respect of each instalment. Nevertheless failure by the Seller to deliver any one instalment shall entitle the Company at its option to treat the whole Contract as repudiated if the various deliveries and inter-connected and linked.
- 5.11 If the Goods are delivered to the Company in excess of the quantities ordered the Company shall not be bound to pay for the excess and any excess shall be and shall remain at the Seller's risk and shall be returnable at the Seller's expense.
- 5.12 The Company shall not be deemed to have accepted the Goods until it has had eight (8) days to inspect them following delivery. The Company shall also have the right to reject the Goods, provided that the Company has notified in writing the Seller the defects within fifteen (15) days for goods and within sixty (60) days for services from the date of discovery.
- 6. RISK/PROPERTY**
- 6.1 The Goods shall remain at the risk of the Seller until delivery to the Company is complete (including off-loading and stacking) when ownership of the Goods shall pass to the Company.
- 7. REJECTION**
- 7.1 If the Seller fails to comply with its obligations under article 5, pursuant to art. 1454 of the Italian Civil Code, the Company may by notice in writing to the Seller, give the Seller fifteen (15) days or such other period as may be agreed to replace those rejected Goods with goods which are in all respects in accordance with the Contract. Upon expiry in vain of such period, the Contract will be deemed as terminated.

7.2 The rejected Goods are returned to the Seller at the Seller's risk and expense.

**8. PATENT AND OTHER INTELLECTUAL PROPERTY RIGHTS**

8.1 The Seller shall protect, indemnify and hold harmless the Company and its Affiliate's, their servants and agents against any and all liability, loss or expense by reason of any claim, action or litigation in respect of any alleged or actual infringement of any patent, copyright, design right, trademark or other intellectual property rights of any other person or resulting from the use or resale of the Goods the subject of the Order or any part of them. Goods manufactured solely in accordance with the Company's design or specification shall be accepted.

8.2 Any specification supplied by the Company, or specifically produced or otherwise provided by Seller to the Company in connection with Goods or Services under this Agreement together with any patent, registered design, design right, copyright or other intellectual property right or any right to apply for any and all such rights shall be the exclusive property of the Company.

8.3 Any information, deliverables or results, including discoveries, inventions, copyright, design rights, patents, innovations, suggestions, know-how, idea, specifications and reports made by Supplier, and all present and future intellectual property rights which result from, or are related to, information disclosed by the Company to Seller or which are developed as a result of, or in connection with Supplier's services under this Agreement ("Work Product") shall be the exclusive property of the Company. The Seller assigns or will assign to the Company all of Seller's right, title and interest in all Work Product including any present and future intellectual property rights, without retaining any rights whatsoever. No other intellectual property right is granted to either party under this Agreement and the disclosure of any Confidential Information shall not result in any obligation to grant either party any rights in or to the subject matter of the other party.

**9. PRICE**

9.1 The price of the Goods shall be stated in the Order and unless otherwise agreed in writing by the Company shall be exclusive of value added tax but inclusive of all other charges.

9.2 No variation in the price or extra charges shall be accepted by the Company.

**10. PAYMENT**

10.1 The Company shall pay to Seller the price of the Goods no later than sixty (60) days from the date of a valid, undisputed invoice.

10.2 The Seller will invoice the Company for the supply of Goods as agreed with the Company in writing. Invoices will set forth the Order number, price and if relevant actual number of hours worked, itemising all other reimbursable costs if agreed in advance and in writing with an authorised Company representative and list VAT as a separate line item.

10.3 Without prejudice to any other right or remedy, the Company reserves the right to set off any amount owing at any time from the Seller to the Company against any amount payable by the Company to the Seller under the Contract.

10.4 If any valid, undisputed sum under the Contract is not paid when due then, without prejudice to the parties' other rights under the Contract, that sum shall bear interest from the due date until payment is made in full with an interest rate of 5% per year, according to and to the intents of the Legislative Decree 231/2002 and section 1224 of Italian Civil Code. The Seller is not entitled to suspend deliveries of the Goods as a result of any sums being outstanding. The payment shall not be deemed as acceptance of the Goods.

**11. CONFIDENTIALITY**

11.1 The Seller shall keep in strict confidence all technical or commercial know-how, specifications, inventions, processes or initiatives which are of a confidential nature and have been disclosed to the Seller by the Company or its agents and any other confidential information concerning the Company's business or its products which the Seller may obtain and the Seller shall restrict disclosure of such confidential material to such of its employees, agents or sub-contractors as need to know the same for the purpose of discharging the Seller's obligations to the Company and shall ensure that such employees, agents or sub-contractors are subject to like obligations of confidentiality as bind the Seller.

**12. THE COMPANY'S PROPERTY**

12.1 Materials, equipment, tools, dies, moulds, copyright, design rights or any other forms of intellectual property rights in all drawings, specifications and data supplied by the Company to the Seller or not so supplied but used by the Seller specifically in the manufacture of the Goods shall at all times be and remain the exclusive property of the Company but shall be held by the Seller in safe custody at its own risk and maintained and kept in good condition by the Seller until returned to the Company and shall not be disposed of other than in accordance with the Company's written instructions, nor shall such items be used otherwise than as authorised by the Company in writing.

**13. HEALTH AND SAFETY REGULATION**

13.1 The Company and the Seller undertake to provide with the provisions of Law 81/2008 (Testo Unico Sicurezza Lavoro), in particular with art. 26, within the limits and to the extent provided therein.

Any failure to comply with the provisions set out in this article, will give the Company the right to immediately terminate the Contract pursuant to art. 1456 of the Italian Civil Code.

The Seller undertakes to comply with laws (e.g. labour or social security laws) concerning the staff that it use for carrying out contractual obligation. Seller shall hold Company harmless against any damages, expenses, claim or action brought by its staff in connection with the performance of the activities.

**14. LAW 231/2001**

14.1 The Seller represents to have examined and to be aware of the content of the Organizational Model adopted by Astellas pursuant to Legislative Decree 231/2001 (hereinafter referred to as the "Model") and its Code of Ethics, which can be found at: <http://www.astellas.it/it/about-us-home/procurement/>.

14.2 The Seller undertakes to fulfill and comply with the provisions and principles set forth in the Model and in the Code of Ethics that have been adopted by Astellas and which enclose the values to which Astellas business activities, purposes and scopes are inspired to, also in order to prevent the relevant crimes set out in Legislative Decree 231/2001 and following amendments.

14.3 If any relevant criminal offence under the Legislative Decree 231/2001 shall be committed and/or if any of the provisions set forth in Article 12 shall be violated, Astellas shall have the right to immediately terminate the Agreement pursuant to art. 1456 of the Italian Civil Code, without prejudice to any other remedies which may be available to it and to the right to claim compensation for further damages. During the term of this Agreement and (one) year thereafter, the Compliance Committee of Astellas is entitled to request the Seller all the information deemed necessary as for the scope and execution of the Agreement, in order to properly fulfill its duty of supervision.

**15. TERMINATION**

15.1 The Company shall have the right at any time and for any reason to terminate the Contract in whole or in part by giving the Seller thirty (30) days written notice whereupon all work on the Contract shall be discontinued. The Company shall pay to the Seller fair and reasonable compensation for work-in-progress at the time of termination but such compensation shall not include loss of anticipated profits or any consequential loss.

15.2 The Company shall have the right at any time by giving notice in writing to the Seller to terminate the Contract forthwith without prejudice to any other rights which it may have if the Seller pursuant to art. 1454 of Italian Civil Code:

a) commits a material breach of any of the terms and conditions of the Contract and fails to remedy the said breach within fifteen (15) days from the receipt of the written notice; or

b) fails to deliver the Goods on the due date and fails to remedy the said breach within fifteen (15) days from the receipt of the written notice.

In such case, the Company reserves the right to refuse to accept any subsequent delivery of the Goods which Seller attempts to make, and/or recover from Seller any expenditure reasonably incurred by the Company in obtaining the Goods in substitution from another supplier, and/or, claim damages for any additional costs, loss or expenses incurred by the Company which are in any way attributable to Seller's failure to deliver the Goods on the due date. The Company shall return to Seller at Seller's risk and expense any Goods already delivered which by reason of the non-delivery of the balance are not reasonably capable of use by the Company in the ordinary course of business, and, the Seller shall immediately refund to Company any money paid by the Company for or in respect of undelivered or returned Goods, and, the Seller shall pay to the Company an amount equal to the excess (if any) over the agreed price for costs reasonably incurred by the Company in buying other goods in place of the Goods, and, the Company shall be under no other liability to the Seller for or in respect of rescission of the Agreement pursuant to the provisions of this article; or

15.3 Pursuant to art. 1456 of the Italian Civil Code, the Company shall have the right at any time by giving notice in writing to the Seller to terminate the Contract forthwith if the Seller makes an arrangement or composition with creditors or enters into a voluntary liquidation except a solvent voluntary liquidation for the purpose only of reconstruction or amalgamation.

15.4 The termination of the Contract, however arising, shall be without prejudice to the rights and duties of the Company accrued prior to termination. The conditions which expressly or impliedly have effect after termination shall continue to be enforceable notwithstanding termination.

**16. REMEDIES**

16.1 Without prejudice to any other right or remedy which the Company may have, if any Goods are not supplied in accordance with, or the Seller fails to comply with, any of the terms of the Contract the Company shall be entitled to avail itself of any one or more of the following remedies at its discretion, whether or not any part of the Goods have been accepted by the Company:

(a) to rescind the Order;

(b) to reject the Goods (in whole or in part) and return them to the Seller at the risk and cost of the Seller on the basis that a full refund for the Goods so returned shall be paid forthwith by the Seller;

- (c) at the Company's option to give the Seller the opportunity at the Seller's expense either to remedy any defect in the Goods or to supply replacement Goods and carry out any other necessary work to ensure that the terms of the Contract are fulfilled;
- (d) to refuse to accept any further deliveries of the Goods but without any liability to the Seller;
- (e) to carry out at the Seller's expense any work necessary to make the Goods comply with the Contract; and
- (f) to claim such damages as may have been sustained in consequence of the Seller's breach or breaches of the Contract.

The above remedies of the Company will be exercised taking always into account the principle of good faith.

**17. INSURANCE**

- 17.1 Seller shall take out and maintain at its own cost an insurance policy with a good standing insurance company, covering appropriately and adequately its obligations and liabilities under the Agreement.

Copy of the insurance policy should be provided to the Company if requested and should be valid and/or renewed covering the whole period of the duration of the Agreement and the Contract.

**18. ASSIGNMENT AND SUBCONTRACT**

- 18.1 The Seller shall not be entitled to assign and/or subcontract the Contract or any part of it without the prior written consent of the Company.

- 18.2 The Company may assign the Contract or any part of it to any person, firm or company, to an affiliate of the Company and it will simply notify to the Seller such assignment.

**19. FORCE MAJEURE**

- 19.1 The Company reserves the right to defer the date of delivery or payment or to cancel the Contract or reduce the volume of the Goods ordered if it is prevented from or delayed in the carrying on of its business due to circumstances beyond the reasonable control of the Company including, without limitation, acts of God, governmental actions, war or national emergency, acts of terrorism, protests, riot, civil commotion, fire, explosion, flood, epidemic, lock-outs, strikes or other labour disputes (whether or not relating to either party's workforce), or restraints or delays affecting carriers or inability or delay in obtaining supplies of adequate or suitable materials.

**20. DATA PROTECTION**

- 20.1 Supplier hereby represents to have received any information relevant to article 13 of Italian Legislative Decree No. 196/03 or any other European Data Protection Act. Supplier hereby acknowledges that it is a Data Controller as per section 29 of Decree abovementioned.

**21. GOVERNING LAW AND JURISDICTION**

- 21.1 The Agreement shall be governed by Italian law. If any dispute or difference arises out of or in connection with this agreement the parties shall seek to resolve the dispute amicably and in accordance with the standards of good faith. If the dispute is not resolved to the satisfaction of both parties within ninety (90) days after it has arisen, either party may initiate litigation and the parties shall submit to the exclusive jurisdiction of the courts of Milan, Italy. For the avoidance of doubt, nothing in this article shall prevent either Company or the Seller from seeking equitable relief at any time.

**22. GENERAL**

22.1 This Agreement, along with the documents referred to therein, contains the entire agreement between the Company and the Seller with respect to the matters to which it refers, and contains everything the Company and the Seller have negotiated and agreed upon within the framework of this Agreement. It replaces and annuls any agreement, communication, offer, proposal, or correspondence, oral or written, exchanged or concluded between the Company and the Seller relating to the same subject matter. No modification of this Agreement will be effective unless made in writing and signed by an authorised representative of each party. The parties warrant and represent that they have the right to enter into this Agreement and that the terms of this Agreement are not inconsistent with other contractual obligations, expressed or implied, which they may have.

22.2 The Seller will perform the obligations under this Agreement consistent with the highest standards of the profession, and to the best of Seller's skill and ability, and in accordance with all applicable current and future laws and regulations.

22.3 The Seller will obtain any and all consents, authorisations, licences and releases necessary for the supply of Goods and/or Services. The Seller undertakes to comply with any relevant codes of practice and specifically to those related to the pharmaceutical industry. The Seller will comply with all applicable standards of safety, taking due regard of and complying with the safety regulations of the Company, and reporting to the Company promptly any incident which could give rise to unsafe working conditions or practices.

22.4 The Seller will comply with any specification supplied by the Company to the Seller, or specifically produced or otherwise agreed between Seller and the Company in connection with this Agreement.

22.5 The Seller will not recruit, solicit or induce any of the Company's employee(s), clients, or customers.

22.6 Any notice in connection with this Agreement must be in writing and in Italian, and shall be validly given with respect to each party if delivered by hand (with written confirmation of receipt), sent by fax, or sent by registered mail or an internationally recognised courier service to the address set out in the relevant Order to such other addressee, fax number or address as one party may notify to the other party in accordance with this clause. Any notice shall be effective upon receipt and shall be deemed to have been received at the time of delivery, if delivered by hand, or, on the next business day in the place to which it is sent, if sent by overnight delivery service or fax (provided, however, that if no confirmation is received within three business days, the notice shall be deemed to have been received on the date such confirmation is received), or on the first business day following the date of posting if sent by registered mail, provided both the sender and the addressee reside in Italy, or three business days (in the place to which it is sent) following the date of posting if sent by registered mail, when either the sender or the addressee does not reside in Italy.

22.7 Each right or remedy of the Company under the Contract is without prejudice to any other right or remedy of the Company whether under the Contract or not.

22.8 If any provision of the Contract is found by any court, tribunal or administrative body of competent jurisdiction to be wholly or partly illegal, invalid, void, voidable, unenforceable or unreasonable it shall, to the extent of such illegality, invalidity, voidness, voidability, unenforceability or unreasonableness, be deemed severable and the remaining provisions of the Contract and the remainder of such provision shall continue in full force and effect.



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TERMS AND CONDITIONS OF PURCHASE

- 22.9 Failure or delay by the Company in enforcing or partially enforcing any provision of the Contract shall not be construed as a waiver of any of its rights under the Contract.
- 22.10 Any waiver by the Company of any breach of, or any default under, any provision of the Contract by the Seller shall not be deemed a waiver of any subsequent breach or default and shall in no way affect the other terms of the Contract.
- 22.11 The Seller will not make any press release, statement or public announcement including by means of advertising or sales promotional materials or any other way that mentions or refers to the Company or the names of its employees without Company's prior written consent and will not publish the results of any of his work hereunder without the prior written approval of Company.
- 22.12 At no time will the Seller act in a manner to prejudice the rights of Company, including by failing to notify Company promptly in writing if Seller becomes aware of any infringement, or suspected infringement, of the rights to the Intellectual Property or any breach of Confidentiality. The Seller will during or after the term of this Agreement and upon the Company's request, assist the Company (at the Company's expense) in obtaining, enforcing and/or maintaining the Company's rights in the Intellectual Property and irrevocably appoint the Company and its authorised representatives as Seller's attorneys for such purpose.