

## Introduction

This document is in force from January 2023

### 1. General considerations

Unless a separate and specific contract has been entered into with Boehringer Ingelheim Italia S.p.A. or Boehringer Ingelheim Animal Health Italia S.p.A. or Bidachem S.p.A. (hereinafter "**Purchaser**" or "**BI**") for the Goods or Services covered by the Purchase Order, these General Conditions of Purchase (hereinafter, the "**General Conditions**") will apply. For the sake of clarity, it should be noted that these General Conditions shall not apply to contractual relationships concerning: i) services falling within the scope of application of Art. 24 of Legislative Decree 81/2008, as they involve the performance of services of a nature other than intellectual services and the permanent presence of the Supplier's employees on the Purchaser's premises, such as, for example, the maintenance of plants and buildings, ii) Continuing Medical Education (CME) events and courses, iii) scientific consultancy and/or services involving the appointment of public employees pursuant to Legislative Decree 165/2001, (iv) clinical and observational studies, (v) research contracts, and (vi) scholarships.

Notwithstanding any contrary statement contained in the conditions of sale of the Supplier, the Supplier agrees that acceptance of the BI Purchase Order: constitutes a) express waiver of its terms of sale, and b) acceptance of these General Conditions.

### 2. Definitions

"**Agreement**" or "**Contract**" means these General Conditions, together with the Supplier's Offer, the Purchase Order and the Order Confirmation, if any, as well as any amending and/or additional agreements subsequently agreed in writing between the Parties in accordance with these General Conditions.

"**Purchaser**" means the company Boehringer Ingelheim Italia S.p.A. and/or the company Boehringer Ingelheim Animal Health Italia S.p.A. and/or Bidachem S.p.A., as the case may be, which places an Order to purchase Goods or obtain Services from the Supplier.

"**Goods**" means the movable property indicated on the BI Purchase Order and in Technical Documentation (if any).

"**Restricted Good/Service**" means any Good/Service subject to Trade Restrictions under the laws, legislation, orders, directives, rules and regulations, whether international, supranational, federal, state, local, issued by any Italian, European, U.S. or other public authority (such as, but not limited to, treaties, regulations, directives and decisions of the European Union) that provide for Trade Restrictions.

"**General Conditions of Purchase**" or "**General Conditions**" means these general conditions.

"**Technical Documentation**" means any technical specification, instruction, drawing, graphic representation or design the Goods or Services must comply with, such as agreed and approved in writing by both Parties.

"**Supplier**" means the natural or legal person or entity that supplies the Goods and/or Services.

"**Purchase Order**" or "**Order**" means the Order submitted by the Purchaser to the Supplier.

"**Supplier Offer**" means the offer sent by the Supplier to Purchaser.

"**Accepted Purchase Order**" means the BI Purchase Order accepted by Supplier by written notice or by commencing performance.

"**Party/Parties**" means the Purchaser or the Supplier, or both as the case may be.

"**Trade Restrictions**" means any restrictions on trade transactions such as, but not limited to, the need to apply for permits or make notifications, embargoes, Sanctioned party lists, prohibitions, etc.

"**Sanctioned party list**" means a list of persons and companies for which there are particular prohibitions or restrictions relating to the exercise of commercial activities under the Laws.

"**Services**" means the services described in the BI Purchase Order and Technical Documentation (if any).

"**Transaction**" means any form of export, re-export, transfer, disclosure, supply or similar activity, regardless of the type of transfer.

### 3. Contract Documents and Priority Order

3.1. The Contract is concluded with the acceptance of BI's Purchase Order by the Supplier. Acceptance of the Purchase Order by the Supplier must be sent in the manner and to the address indicated in the Purchase Order. However, any other method of acceptance of the Order, even for conclusive facts, such as the shipment of the Goods to the Purchaser, shall constitute acceptance of the Order by the Supplier.

3.2. Any counter-offer by the Supplier must be considered rejected, unless expressly confirmed in writing by BI by sending an amendment to the Purchase Order.

3.3. In case of conflict between these General Conditions, the Supplier's Offer, the Purchase Order and the Technical Documentation (if any), such documents shall prevail, with reference to the conflicting provisions, in the following order:

- these General Conditions;
- the Order of BI;
- Contractor's Bid.
- Technical Documentation (if any).

3.4. The Electronic Invoices, issued in accordance with the regulations in force, bearing the Order number and the recipient code ZS100U1 must be in the name of the Purchaser. In the case of persons who are not obliged to issue the Electronic Invoice in XML format, invoices must be sent in PDF format to the email address: [PDF-invoices.it@boehringer-ingelheim.com](mailto:PDF-invoices.it@boehringer-ingelheim.com).

Each email must contain only one invoice in PDF format. The same will be paid only after the inspection of the Goods and/or the verification of due execution of the Services, even by testing the Goods (if requested in the Order).

### 4. Technical specifications and compliance with procedures

4.1. Without prejudice to the provisions of Art. 12, being aware of the nature of BI's production business and of the fundamental importance for BI of the proper functioning of the factory and/or offices, the Supplier undertakes to supply first quality Goods and Services, and precisely Goods and Services (described in the Purchase Order) which

- (i) strictly comply with the quality and technical specifications detailed in the Purchase Order and/or in the Technical Documentation (if any) and with all other technical requirements/documents, as agreed in writing between the Parties, as provided for, referred to or attached to the Order, or to the relevant Supplier's Offer referred to in the Order;
- (ii) are suitable for the use for which they are intended by BI (such use as indicated in the Product specifications or otherwise inferable from the nature of the Goods and/or the business carried on by BI); and
- (iii) comply with technical, safety and environmental standards, both national and EU, which are in any case mandatory, as well as with the provisions of laws and regulations in force in the country where the Goods are manufactured and in the country where they are delivered, or where the Services are provided, with reference to all rules on manufacturing, wrapping, packaging, safety, consumer protection, respect for the environment.

If the Supplier is the manufacturer of the Goods, it shall also manufacture them in a workmanlike manner, according to the general state of the art and science.

4.2. The Supplier shall have all of the authorisations, licenses and permits required by applicable law to produce and/or supply the Goods and Services.

4.3. If the Supplier is responsible for the installation and/or testing of the Goods, or parts thereof, at BI's factory or offices, he shall comply with applicable regulations during performance of such services, expressly including all the applicable rules on health and safety at work, with particular reference to the provisions of Legislative Decree 81/2008, the regulations and standards of good practice issued by the relevant bodies (ISO, CEN, CENELEC, UNI, EN, etc.), as well as the Internal Procedures (SOP) of BI, which may have been provided by BI prior to the commencement of services at the plant or offices. In the event

any changes are made to the technical specifications or standard procedures previously agreed between the Parties, where such changes were not requested by BI, the Supplier shall inform BI prior to delivery of the Goods and BI may, at its discretion, confirm the purchase or withdraw freely, without any further costs, expenses or obligations of any kind to be borne by it, except for compensation for damages.

4.4. The Supplier may not transfer or subcontract this Contract, even partially, without BI's prior written consent. In the case of authorised subcontracting, the effectiveness of the authorisation is subject to the Supplier duly following occupational health and safety legislation, subcontractors regularly making social security contributions, and any other applicable rules on the subject, as well as the production, by the subcontractor, of all the documentation required by current regulations, even with regard to social security and accident prevention.

The Supplier retains ownership and possession of any wastes produced by it in the performance of the services subject hereof, and is required to scrupulously comply with current legislation on wastes, bearing the related costs of removal and disposal. If requested by BI, the Supplier shall demonstrate compliance with the above-mentioned regulations, by producing the forms and the loading and unloading registers.

## **5. Intellectual Property and Confidentiality Obligation**

5.1. The Supplier warrants that the provision of the Goods and/or Services to the Purchaser does not infringe upon any third-party intellectual property rights.

5.2. The Supplier acknowledges that the Purchaser is the owner of the Technical Documentation (if any) and of the result of the service carried out by the Supplier accepted by the Purchaser, and that it is the exclusive owner of any commercial, technical, financial and economic information regarding its products and/or services, of which the Supplier may have become aware during execution of the Contract, or in any case in connection with it (the "**Confidential Information**").

5.3. The Supplier undertakes to keep all the Confidential Information strictly confidential and not to use it for purposes other than the execution of the Contract, even after its expiry or termination. The Supplier undertakes to impose the same obligations of confidentiality and secrecy on its employees, associates, and third parties who have the necessity to access the Confidential Information during performance of their duties, and remains jointly and severally obliged with them even in the event of their breach of the confidentiality obligations. Upon termination of the Contract, the Supplier also undertakes to promptly return all the Confidential Information to the Purchaser at the Purchaser's request, or destroy it. The confidentiality constraints above will not apply to information which is in the public domain or which must be disclosed by order of the judicial authorities.

5.4. In case of transmission of Confidential Information via email between Supplier and Purchaser, the Supplier undertakes to use the encryption system required by the procedures of the Boehringer Ingelheim Group, using the appropriate application available at the following address <http://guides.boehringer-ingelheim.com>.

5.5. If the Supplier intends to make information public, including information other than Confidential Information, that concerns the contractual relations between it and the Purchaser, it shall ask the Purchaser's prior written approval from time to time.

## **6. Packaging, transport and transfer of ownership (where applicable)**

6.1. The Supplier shall transport the Goods to the address provided in the Purchase Order. Unless arranged otherwise, transport costs are borne by the Supplier.

6.2. The Supplier shall bear the risks of possible damage to or loss of the Goods during transport, and in any case until they are delivered to the address indicated in the previous point. Ownership of the Goods shall pass to the Purchaser upon delivery thereof to the delivery address indicated in the Purchase Order.

6.3. The Goods must be packaged so as to be clearly identifiable. The packaging must be suitable for the type of goods. In case of hazardous goods, the transport must be carried in compliance with ADR regulations. No charge for the packaging of the Goods shall be borne by BI, as the cost shall be included in the price agreed for the purchase of the Goods. Any special containers and packaging provided by BI shall remain its property and may be used by the Supplier only in accordance with their intended use.

6.4. The Services will be provided at the address specified in the Purchase Order.

6.5. Unless otherwise agreed, the Goods shall be delivered in accordance with the "DDP" (Incoterms 2020) clause to the Purchaser at the address specified in the Purchase Order. In the case of technical systems and installations, the transfer of risk cannot take place until the corresponding formal acceptance and functional test are completed, nor until the Company has signed the relevant minutes of verification/testing for acceptance.

6.6. The Supplier must ensure that all the packaging and declarations (in accordance with any applicable legal requirements) are suitable and adequate for transport. The Parties agree that the use of wooden products (in particular pallets) that have been treated or come into contact with substances that may have a negative impact on the quality of the goods to be supplied/processed (in particular: phenolic halogenated preservatives) is prohibited throughout the entire supply chain. The Supplier is obliged to impose the relevant obligations in favour of BI on its approved suppliers and/or subcontractors.

6.7. The imposition of such obligations shall have no effect on the Supplier's liability to BI. Unless otherwise agreed, the Supplier shall carry adequate insurance cover for loss, damage and/or theft of the Goods during transport. No transport insurance costs will be charged to BI.

## **7. Delivery of Goods and Performance of Services**

7.1. The Supplier shall deliver the Goods and perform the Services within the terms indicated in the Purchase Order. The Supplier acknowledges and accepts that the timeliness of delivery of the Goods and execution of the Services is of fundamental importance, and that therefore the delivery times and terms of execution agreed and indicated in the Order shall always be considered binding and essential in the interest of BI pursuant to Art. 1457 of the Civil Code and, with respect to these, early or late deliveries are not permitted, unless specifically and expressly approved in writing by BI.

7.2. It is the Supplier's obligation to ensure that delivery of the Goods takes place during working and opening hours of BI's factory or at another place of delivery indicated in the Order. BI shall therefore be exempt from any liability for, and shall not be obliged to incur for any reason, any extra costs arising from the impossibility of delivering the Goods before or after the opening hours of the Purchaser's factory and/or offices and/or to the place of delivery indicated in the Order. Arrangements for delivery of the Goods must be made in advance with BI, particularly if special arrangements are required for unloading operations, or if the Goods are to be awaited at their destination before or after the Purchaser's usual office opening hours.

7.3. Unless otherwise agreed or required by the nature of the Service, Services requested by Purchaser shall be performed during Purchaser's usual office opening hours.

7.4. Any acceptance by the Purchaser of late or inconsistent deliveries (such as, for example but not limited to, inconsistencies in the quantity or quality of the Goods) shall not and cannot be deemed to be a waiver by BI of its rights to damages or other remedies under the Contract and/or under the law.

7.5. Upon arrival of the Goods at its factory and/or offices, BI shall check for damage and the number or quantity of packages and/or Goods. In case of obvious anomalies in the packaging or in the delivered goods, BI will have to sign the transport document "subject to checking", highlight the reason (e.g.: severely damaged or missing package) and inform the Supplier within 3 (three) working days from receipt of the goods.

7.6. Taking the Goods, as well as any use thereof, shall not constitute acceptance of them by BI.

Acceptance of the Goods shall in any event be subject to and conditional upon inspection of the Goods by BI in order to verify the conformity of the Goods to the agreed specifications, the absence of defects and faults, the proper functioning (if relevant to the specific nature of the Goods), the completeness and regularity of the supply of the Goods. BI shall provide notice of any discrepancies, defects and faults within 90 (ninety) days from delivery of the Goods to the Factory or, in the case of hidden defects or malfunctions, within 15 (fifteen) days from discovery.

7.7. Where the Goods are subject to testing/checking for proper functioning, acceptance of the Goods shall in any event be subject to and conditional upon the Goods passing the tests/checks performed by Supplier or any third party appointed by Supplier. Where the Goods by their nature are subject to quality controls (e.g. incoming tests pursuant to GMP) or to more detailed inspections and controls on incoming goods during the ordinary course of BI's normal

operating procedures, the acceptance of the Goods shall in any case be subject and subordinate to the performance of the above-mentioned controls by BI in order to verify their conformity to the product specifications. The Parties agree that the above checks shall be carried out within 90 days from delivery of the Goods.

7.8 If the Supplier fails to supply the Goods or execute the Services within the period specified in the Purchase Order or in the relevant Offer referred to in the Order, the Purchaser may, without prejudice to its right to terminate the Contract according to law, request payment of a penalty for delay only equal to 1% (one percent) of the price of the Goods or Services concerned for each calendar day following the date originally scheduled for delivery of the Goods or execution Services, without prejudice to the right to further damages. At the Purchaser's choice, this amount shall be deducted from any future payments, or shall be refunded by the Supplier.

7.9 In the event of delivery of the Goods and/or performance of the Services before the agreed date, Purchaser reserves the right to accept or return the Goods or, as the case may be, to refuse early performance of the Services, with any costs to be borne by Supplier.

7.10 The Goods shall be delivered in the quantities specified in the Order. Unless otherwise agreed in writing between the Purchaser and the Supplier, the Purchaser will not accept any margin of tolerance in respect of the quantity of Goods delivered or Services rendered. Where the quantity of Goods delivered is in excess of the quantity ordered in the Order, BI shall be entitled to refuse, in whole or in part, delivery of the excess Goods, with the consequent obligation of the Supplier to arrange for (at its own expense) immediate collection of the refused Goods. If the Supplier fails to collect the aforementioned Goods within 15 days from BI's collection request, BI shall be entitled to return the Goods to the Supplier at the Supplier's expense. If the quantity of Goods delivered is less than the quantity stated in the Order, BI shall promptly notify the Supplier and the Supplier shall promptly deliver the missing quantities, by no later than 3 working days or a different term agreed in writing between the Parties. In the event of shortages, BI shall in any case be entitled to procure the goods from a third party and any extra costs shall be charged to the Supplier.

7.11 Without prejudice to Art. 7.6, when the Supplier is entrusted with installation and testing of the Goods, or parts thereof, at BI's factory and/or offices, the above services shall be carried out by the Supplier within the terms respectively agreed in the Order or in the Supplier's Offer referred to in the Order, or within any different terms subsequently agreed in writing between the Parties.

7.12 When the Supplier is entrusted with the installation and testing/checking of the Goods at BI's premises and/or offices, the supply shall be deemed to be completed when (i) all the testing/checking operations provided for in the technical documents attached to the Order or in the Offer referred to therein have been successfully carried out; and (ii) the testing/checking reports have been signed for acceptance by BI.

In any case, the signing for acceptance of the aforementioned reports shall not release the Supplier and shall not prevent BI from subsequently demanding from the Supplier, pursuant to Art. 8, the elimination of defects and deviations relating to the parts of the supply already checked and/or tested which had not previously been noticed or found.

7.13 The delivery of goods that are classified as hazardous for the environment, health and/or safety (CLP Regulation No. 1272/2008 EC and subsequent amendments and integrations or Directive 67/548/EC and subsequent amendments and integrations) must necessarily be accompanied by the Safety Data Sheet as provided for in Regulation 1907/2006, as amended by Regulation No. 453/2010 and subsequent amendments and integrations. Should the Supplier deliver the goods in the absence of the relevant Safety Data Sheet or with a Sheet that does not comply with the regulations in force, the Purchaser reserves the right to refuse the goods at no charge to it.

7.14 The Supplier, which is exclusively responsible for the management, control and supervision of its personnel, shall ensure that the personnel who will render the services in the performance of the individual Services entrusted to it, are always present in an adequate number to perform the contractual services in a workmanlike manner. In case of unavailability, for whatever reason, of one of the persons assigned to the Services, the Supplier shall ensure the continuity of the contractual services. If, on the other hand, the Services are interrupted, the Purchaser will be authorised to suspend any payment immediately and to request, as a penalty, the payment of 5% of the Contract price, multiplied by each day of interruption of the service up to a maximum of ten days, without prejudice to compensation for greater damages.

Once this term has passed without the Services having been duly resumed, the Supplier reserves the right to terminate the Contract, pursuant to and for the purposes of Art. 1456 of the Italian Civil Code.

7.15 In case of replacement of the Supplier's employees rendering the Services, the Supplier shall inform the Purchaser immediately at the time of the change, unless this is objectively impossible for reasons beyond the Supplier's control, in order to allow the Purchaser to activate all of the internal procedures related to access and security permissions. In this case, the communication shall be given as soon as the Counterparty becomes aware of the need for replacement. Under no circumstances will the replacement of personnel originally assigned to the Services entail additional costs for the Purchaser.

7.16 The Supplier declares, under its own responsibility, that all personnel employed for the purposes of fulfilling this agreement are employed by it and that, for the same personnel, the legal contributions are regularly paid. It shall also be the Supplier's responsibility to send the Purchaser a document showing the personal details and professional qualifications of the persons providing the Services. The aforesaid document must be delivered to the Purchaser's Manager prior to the start of the Services.

7.17 Under no circumstances shall the Supplier's personnel be integrated into the Purchaser's organisation, nor shall any direct relationship result from this. The Supplier will appoint its own contact person with the task of Coordinator, who can make and receive all communications relating to the activities provided for in this contract. This name must be communicated in writing. Failure by the Supplier to comply with the above shall result in a de facto breach of contract and due to the negligence of the Supplier.

7.18 The Supplier is fully responsible for the safety of its employees in the performance of their duties, in accordance with the provisions of Legislative Decree 81/2008 as amended, as well as applicable legislation in general.

## **8. Payment Terms**

8.1 The Supplier shall, after the Delivery Date, issue an invoice for the Price (or, in the case of delivery in several instalments, for part of it as applicable to each such instalment).

8.2 Each invoice (unless otherwise specified in the Purchase Order or other written document of the Purchaser) will be in Euro and will clearly indicate the Purchase Order number, all data required by law and any other information needed for the Purchaser to request a VAT refund.

8.3 Subject to the Purchaser's rights under Article 8.5 and without prejudice to any other rights of the latter under the Contract, the Purchaser shall, unless another date for payment has been agreed, make the payment within 60 (sixty) days from the invoice date, provided that the Supplier has fulfilled its obligations under the Contract.

8.4 Unless arranged otherwise, payments will be made by bank transfer to the Supplier's bank details provided by the Supplier in writing beforehand.

8.5 The Purchaser shall be entitled (without prejudice to any other rights it may have) to offset any amount due to it at any time by the Supplier with any amounts due to the Supplier for the Goods or Services covered by the Contract.

8.6 The eventual payment of the Goods by BI shall in no way prejudice its right to reject the Goods pursuant to Art. 7 of these General Conditions, or its right to compensation for any damages suffered.

## **9. Insurance**

9.1 The Supplier is fully responsible for the safety of its employees and/or associates in the performance of the task carried out by them and is liable for all damages that they may suffer during the task itself.

9.2 The Supplier is obliged to take out a general and third-party liability and product liability policy, at its own expense for the entire duration of the contract signed with the Purchaser, and the sum insured must be the market value and appropriate to the risk, and in any case:

- a) not less than the sum of EUR 3 million for third-party liability per claim and EUR 2.5 million for Employee Civil Insurance per injured person (including coverage against incidental damages) for service contracts with interference.

b) not less than EUR 1 million for third-party liability per claim, for service contracts without interference.

9.3 Such a policy shall cover losses caused by the Supplier, its employees or representatives as a consequence to the goods delivered. BI may require the Supplier to provide adequate confirmation of insurance cover from the Supplier's insurance company. The Supplier shall provide such proof of insurance cover without delay upon request of BI. The Supplier shall also be in charge of any renewals of the policy during the contractual relationship, sending the Purchaser a copy of such renewals.

#### 10. Right of audit

10.1 The Purchaser may periodically carry out, for the duration of the Purchase Order and for the three years following it, some audits, including financial audits and, where applicable, audits relating to compliance with legislation on the protection of personal data, in order to verify the production processes, quality systems, good administrative practice and any other data that may affect the correct and timely performance of contractual services, agreeing on the dates with the Supplier, with 5 days' notice, during normal working hours, by requesting documents (including invoices, receipts, contracts with third parties, expense reports, receipts, etc.), also at the premises of the Supplier, through its staff or consultants expressly appointed for this purpose. The Supplier undertakes to cooperate fully and unconditionally, providing the necessary support, as well as all of the documents and information requested, with the sole exception of documents and/or information relating to industrial secrets and/or intellectual property rights of the Supplier. If, as a result of the audit carried out, it emerges that the Purchaser has been charged for costs that exceed their actual value, the Supplier shall reimburse the Purchaser for such costs within 30 days of receipt of the audit report.

10.2 All information acquired during the above inspections and audits shall be governed by Art. 5 of these Conditions.

#### 11. Force Majeure

11.1 The Parties shall not be liable, or be deemed to be in default, for any failure or delay in performing any of their obligations under these General Conditions, due to circumstances beyond the reasonable control of either party, such as national strikes, fire, explosion, flood, earthquake or other natural disaster ("Force Majeure").

11.2 The Supplier, in case of delays due to Force Majeure, shall send written notification to the Purchaser with an estimate, as precise as possible, of the duration of the effects of the Force Majeure conditions. However, since the Purchaser will not be able to make use of the Services or Goods under the Agreement during the Force Majeure conditions, Purchaser reserves the right to purchase the Services or Goods from third parties.

#### 12. Guarantees and Responsibilities

12.1 The Supplier declares and warrants to the Purchaser:

- (a) that the Services provided in a workmanlike manner will be provided exclusively by personnel duly qualified and educated, trained and informed in relation to work risks and safety regulations, using the utmost care and professional diligence;
- (b) that the Goods supplied shall also be free from defects and faults, suitable for use, free from third-party rights of any kind, provided with the certifications, marks (including the CE mark), instructions and documents that are necessary or required from time to time, and comply with all Italian and EU standards applicable to them, without exception;
- (c) that the Goods supplied are (i) marketable; (ii) free from defects in material and workmanship; (iii) free from defects in design when designed by the Supplier; (iv) compliant with any applicable specifications, designs and performance requirements; (v) fit for their intended purpose; and (vi) free from constraints and restrictions on title;
- (d) that the Goods will comply with all of the terms and conditions of the Purchase Order and generally accepted standards of technology, the relevant statutory provisions and the regulations and directives of public authorities, trade and professional associations, including in relation to health, safety and the environment.

12.2 All the Goods consisting of machines, plants, tools or equipment shall be deemed to be supplied with the guarantee of good functioning set forth in art. 1512 of the Italian Civil Code, for a period of not less than 24 months, unless otherwise provided for.

12.3 The Supplier also provides full warranty for eviction and claims pursuant to Art. 1476, paragraph 3, of the Italian Civil Code.

12.4 The guarantee given by the Supplier shall also cover the goods and the work of any subcontractors involved.

12.5 Notwithstanding the provisions of the law, the deadline for reporting defects and lack of quality is 90 (ninety) days from delivery, or 15 (fifteen) from the discovery of the defect or lack, if hidden.

12.6 If at least two partial deliveries referring to the same Purchase Order of the same Supplier are found to be lacking/defective, in whole or in part, BI may cancel the entire Purchase Order.

12.7 In the event of defects, faults or deviations from the agreed specifications, other applicable technical requirements or deviations in accordance with Art. 4.1, BI may, at its discretion, require the Supplier to

- (i) promptly replace defective Goods or, where feasible, make all necessary modifications and/or remedies to eliminate the defects, at the Supplier's expense; or
- (ii) refund the purchase price already paid within 30 (thirty) days from the notification of the defects, and collect the defective Goods within the same period;
- (iii) or, as the case may be, properly supply the Services again.

In any event, and without prejudice to any other rights and remedies provided by law or contract, BI shall also be entitled to compensation for any damages suffered as a result of delivery of the defective Goods (such as, without limitation, any costs of shipping, rework, labour, assembly and disassembly, materials, inspections and testing).

12.8 If requested by BI pursuant to Art. 12.7 above, Supplier shall eliminate the defects or replace the defective Goods with new and conforming Goods or, as the case may be, repeat the Services as soon as possible and, in any case, no later than 5 (five) working days from the notification of the flaws/defects or within any other term agreed between the Parties in writing. If the Supplier is obliged to eliminate the defects and/or make subsequent deliveries of replacement goods, the elimination of the defects, the delivery of the replacement goods and/or the rework will restart the limitation period afresh. In cases involving the replacement of components/revamping, the above will apply to the replaced parts.

12.9 If Supplier fails to promptly eliminate any flaws and/or defects on the defective Goods or, as the case may be, to repeat the Services, after a request to do so by BI in accordance with Art. 12.8 above, BI may, in order to avoid greater damages, directly carry out or have a third party carry out, any appropriate correction of the defect, and charge the relevant costs to the Supplier. In order to avoid interruptions in production, BI may eliminate minor defects without first consulting the Supplier, and then invoice the Supplier for the expenses incurred in this regard, without this having any effect on the Supplier's obligations under the law.

12.10 It is understood and agreed between the Parties that the non-conformity of the Goods to the Specifications or to the other technical requirements of the rules of good manufacturing practice or other applicable technical regulations, as agreed or however applicable, shall constitute a lack of quality pursuant to Art. 1497 of the Italian Civil Code.

12.11 If BI disputes the supply for any reason, it shall have the right to suspend the related payment until the Parties, or the Judge, have ascertained the grounds for the disputes.

12.12 Further, BI may offset the sums claimed from the Supplier as compensation for damages with any sums due to the same for Goods or Services under the Contract.

#### 13. Indemnity

13.1 The Supplier shall hold BI harmless and indemnified against any liability to third parties (including the Purchaser's customers) for damages arising out of the failure, or the partial or delayed failure by the Supplier, its employees, sub-contractors, suppliers and/or auxiliaries, to comply with any obligation or warranty arising out of the Contract, or provision contained therein.

13.2 In particular, and inter alia, the Supplier shall indemnify and hold harmless the Purchaser against any liability to third parties (including the Purchaser's customers) for damage arising

(i) from late supply or delivery of the Goods, even if the delay is the result of defects or lack of quality of the Goods delivered or failure of the Goods to meet the specifications and/or technical requirements requested by the Purchaser. In such case, the Supplier shall also bear all costs and expenses, including the costs of any lawsuits; and/or

(ii) from defects, flaws, or lack of quality of the Goods (supplied by the Supplier), or from the lack of conformity of the same to the Product Specifications and/or the technical requirements agreed with BI and/or the regulations applicable to the Goods due to their nature or the use for which they are intended or the requirements set out in Art. 4.1.

#### **14. Withdrawal, Suspension and Termination, Express termination clause**

14.1 The Purchaser is entitled to withdraw from the Contract, at any time and for any reason, by sending a written notice via registered letter with at least 30 (thirty) days' notice, stating that it wishes to enforce this clause.

14.2 Each Party will also have the right to withdraw from the Contract by providing the other with notification in writing with immediate effect, if the other Party is subject to liquidation, or if part or all of its assets are subject to assignment in favour of creditors.

14.3 The Purchaser reserves the right to require the Supplier to suspend deliveries in the event of a strike, lock-out, fire, accident or interruption in the Purchaser's business or production that prevents or impedes the use of the Goods or the enjoyment of the Services. In each of the aforesaid cases, payment will be postponed until the moment in which the delivery of the Goods or the provision of the Services is resumed.

14.4 The Purchaser's waiver to assert its claims in case of breach by the Supplier of these General Conditions or of the conditions in the Purchase Order and/or in the Technical Documentation (if any), shall not be understood as a systematic waiver, also in the event of further breaches of the terms and conditions set forth in the aforesaid documents or other provisions.

14.5 The total or partial non-fulfilment of the obligations provided for one Party by these General Conditions shall imply the right of the other Party to terminate the Contract, subject to a warning to fulfil according to Art. 1454 of the Civil Code, whose term shall not be less than 15 (fifteen) days; and without prejudice to the right of the other Party to compensation for any and all damages deriving from the non-fulfilment, or from the incorrect fulfilment.

14.6 Without prejudice to any right or remedy that the Purchaser may have under the law and without prejudice to compensation for damages, without determining any kind of liability on the part of the Purchaser, the Purchaser shall have the right to terminate the Purchase Order, or part of it, with immediate effect pursuant to art. 1456 of the Italian Civil Code, subject to providing a written notice to the Supplier if:

(a) the Supplier infringes or fails to comply with:

- the obligations regarding confidentiality as per art. 5;
- the obligations concerning Export Control regulations as per art. 17;
- the obligations provided for in art. 10 of the Right of Audit;
- the obligations provided for art. 15.2 of Transfer of contract – Change of control
- the obligations provided for in art. 20 Code of Conduct, Suppliers' Code of Conduct

(b) insolvency, bankruptcy, restructuring or compulsory liquidation proceedings against the Supplier.

#### **15. Transfer of contract - Change of Control**

15.1 The Purchaser shall have the right to transfer, without requiring the Supplier's consent, all or part of the Contract, the Purchase Order and the Technical Documentation, as well as the rights and commitments contemplated therein, to any company belonging to its group.

15.2 The Supplier may not transfer, in whole or in part, the Contract, the Purchase Order, the Technical Documentation, including the rights, obligation and credits deriving from them, without the prior written consent of the Purchaser.

15.3 The Purchaser may immediately terminate the Contract by written notice to the Supplier pursuant to art. 14.6 in the event of a change of control of the Supplier or transfer of the branch of the Supplier's business within which the Contract also falls or in the case of unauthorized transfer pursuant to previous art. 15.2.

#### **16. Processing of personal data**

The Parties undertake to comply with applicable laws regarding the protection of personal data and processing the personal data of the other Party and their employees, associates, consultants and persons in any capacity involved in the execution of this Contract and/or the Purchase Orders relating to it in compliance with such regulations. In particular, the Parties mutually undertake to ensure that the data provided under this Contract and/or the related Purchase Orders are processed in order to fulfil the obligations arising from the Contract (Art. 6.1 b EU Regulation 679/2016 GDPR). The Supplier may at any time access BI's Business Partner Privacy Policy, available and updated at the following link:

<https://www.boehringer-ingelheim.it/privacy/privacy/informativa-sulla-privacy-dei-business-partners-visitatori-rappresentanti-dei-media?>

In the event that, while executing this Contract and/or the related Purchase Orders, the Supplier processes, collects or uses personal data on behalf of BI in accordance with Article 28 of the EU Data Protection Regulation 2016/679, the Supplier shall enter into such agreements as are deemed necessary under the applicable law, in particular in the case of transfers of data to recipients outside the European Union. These agreements may include (i) BI's appointment of an external data processor and/or (ii) European Union standard contractual clauses for the transfer of personal data to data processors and/or (iii) any other agreements that the relevant data protection authorities have declared to be mandatory or acceptable in order to comply with their obligations under applicable data protection law.

#### **17. Export control and anti-corruption regulations**

The Supplier declares that it is not on any Sanctioned party list and that not more than 50% of it is controlled by a person on a Sanctioned party list, and undertakes to inform the Purchaser immediately if there is a change in this situation.

The Supplier acknowledges that the Goods/Services supplied to the Purchaser may be subject to Trade Restrictions. The Supplier shall, in this case, comply with all the Laws, as defined in point 2 above, establish whether the Goods/Services covered by the Purchase Order are subject to restrictions and, if so, identify the specific control/restriction on trade the Goods/Services are subject to.

Before proceeding with a Transaction concerning the Goods/Services subject to restriction, the Supplier shall notify the Purchaser of the Trade Restrictions to which the Goods/Services are subject, specifying in which list they are present (e.g. the U.S. Commerce Control List) and which Trade Restriction applies to the specific Transaction concerning the Goods/Services subject to restriction.

The Supplier undertakes to obtain and maintain at its own expense any authorisation, approval, request for authorisation, permit or licence necessary to carry out the Transaction concerning the Restricted Goods/Services.

The Supplier shall cooperate with the Purchaser and provide, upon its request, information and any other assistance needed to classify the Restricted Goods/Services (e.g. inclusion in the US Export Control List), and submit export documents, export licenses etc.

The Supplier declares and guarantees, also for its employees and subcontractors, that it will act in full compliance with the laws and regulations in force regarding anti-corruption, and in compliance with professional and industrial codes and that it will not offer or promise benefits or advantages of any kind to

any person or entity, such as, by way of example and without limitation, to public officials, as defined below, in exchange for direct or indirect advantages of any kind. In particular, the Supplier may not offer, promise or make payments in order to (i) obtain or maintain the requirements to comply with regulations, (ii) perform any type of activity including commercial transactions to which BI is a party. The Supplier may not request, accept or receive for itself or for a third party any payment, benefit or advantage from any natural or legal person in exchange for advantages in business activities, the supply of goods or other services. If in doubt about a particular transaction, the Supplier must seek advice and approval from BI.

For the purposes of this clause, "public official" means any official or employee of a local or foreign government or of a department or agency thereof or of a public international organisation, as well as persons acting in an official capacity for or on behalf of such governments, departments, agencies or on behalf of or in the name of a public international organisation, or health care professionals working in public or accredited health care institutions. Irrespective of the type of transaction, the Supplier shall not be allowed to transfer valuables to a public official.

The Supplier shall notify BI of any suspected actual or potential violation of the preceding paragraph. In case of doubt as to whether a certain action constitutes a breach of the above obligations, the Supplier shall contact BI and delay the decision before taking such action.

#### 18. Applicable law and place of jurisdiction

These Conditions are governed by Italian law. In case of dispute between the Purchaser and the Supplier, the Court of Milan shall have exclusive jurisdiction.

#### 19. Separation of provisions

If any provision of these General Conditions is or becomes unlawful, invalid or unenforceable under any applicable law, such provision shall be deemed to be omitted from these General Conditions, if it can be omitted, and shall in no way affect the validity or enforceability of the remaining provisions.

#### 20. Code of Conduct, Suppliers' Code of Conduct

20.1 BI has adopted its own Code of Conduct (pursuant to Legislative Decree 231/2001), which is available on the website [www.boehringer-ingelheim.it](http://www.boehringer-ingelheim.it) and contains, among other things, principles and rules concerning relations with the Public Administration, Public Officials and/or Persons in Charge of a Public Service. If the Supplier has also adopted its own code of conduct it will send it to BI or communicate to it where this can be found.

In carrying out the services governed by these General Conditions, the Supplier undertakes to comply fully with the principles and rules set forth in the BI "Code of Conduct".

20.2. BI has also adopted a Suppliers' Code of Conduct, which can be viewed on the website [www.boehringer-ingelheim.com/it/chi-siamo/il-purchasing/codice-di-condotta-dei-fornitori](http://www.boehringer-ingelheim.com/it/chi-siamo/il-purchasing/codice-di-condotta-dei-fornitori). In carrying out the services governed by these General Conditions, the Supplier undertakes to fully comply with the principles and rules established by the BI "Suppliers' Code of Conduct", which is inspired by the following fundamental principles of business ethics and transparency (such as, by way of not exhaustive example: fight against corruption and direct or indirect rejection of all crimes against the Public Administration; fight against corruption among private individuals and transparency in business transactions; fight against infiltration of organised crime and fight against terrorism; protection and defence of the environment; health and safety in the workplace; respect for the principles of fair competition; protection of personal data).

20.3. All reports relating to compliance and ethics issues may be sent to the following email address [risk&compliancengmt.mil@boehringer-ingelheim.com](mailto:risk&compliancengmt.mil@boehringer-ingelheim.com). In the event that the Supplier observes behaviour by BI associates that constitutes a violation of the law or ethics or of the rules and principles of the Code of Conduct, it may also report such behaviour through the Whistleblowing channel of Boehringer Ingelheim called Speak- Up, which can be accessed through the website [www.boehringer-ingelheim.it](http://www.boehringer-ingelheim.it)

20.4 Both the acceptance of the Purchaser's Purchase Order by the Supplier, in the manner and at the address indicated in the Purchase Order itself, and any other method of acceptance of the Purchase Order, also for conclusive facts, such as the shipment of the Goods to the Purchaser, implicitly imply the Supplier's commitment to comply with the principles and rules of the "Code of Conduct" and the "Suppliers' Code of Conduct" of BI.

#### 21. Pharmacovigilance

BI is required by law to monitor all reports on the tolerability of its products and to report them to the competent Health Authorities. In order to allow BI to fulfil its pharmacovigilance obligations, the Supplier must promptly (and in any case within 24 hours) report to the BI pharmacovigilance service any adverse event, including special situations such as: off-label, abuse, misuse, occupational exposure, overdose, exposure during pregnancy and lack of efficacy and therapeutic error, suspected transmission of infectious agents, non-valid waiting times and environmental problems (as defined in the current European Pharmacovigilance Guidelines - GVP Annex I and the current European Veterinary Pharmacovigilance Guidelines EudraLex Volume 9B) that are concomitant with the use of BI medicinal products of which it becomes aware, as well as follow-up information related to them.

Should it be necessary, upon the Supplier's prior request, BI will provide the list of the medicinal and veterinary products of Boehringer Ingelheim Italia S.p.A. and Boehringer Ingelheim Animal Health Italia S.p.A.

The communication to Boehringer Ingelheim Italia S.p.A. shall be made by the Supplier to the following e-mail address: [PV\\_local\\_Italy@boehringer-ingelheim.com](mailto:PV_local_Italy@boehringer-ingelheim.com), specifying at least the following information:

- Patient data (gender and/or age or date of birth and/or patient's initials)
- Contact of the reporter
- Adverse event(s) or special situation
- Medicinal product of Boehringer Ingelheim Italia S.p.A. (trade name or active ingredient)

The communication to Boehringer Ingelheim Animal Health Italia S.p.A. shall be made to the following email address: [farmacovigilanza-AnimalHealth@boehringer-ingelheim.com](mailto:farmacovigilanza-AnimalHealth@boehringer-ingelheim.com), providing at least the following information:

- Contact of the reporter
- Data of the animal (species, breed, sex, weight, age) or of the human patient (gender, age or date of birth, patient's initials)
- Adverse event(s) and/or special situation
- Medicinal product of Boehringer Ingelheim Animal Health Italia S.p.A. (trade name or active ingredient)

The Supplier assures that its personnel will be trained in accordance with this clause, to the extent applicable.

The communication to BI of such information should not be considered to replace the provisions of current legislation in terms of pharmacovigilance for the reporting of adverse events to the Health Authorities by health operators (Ministerial Decree No. 143 of 23/06/2015 OJ No. 143 of 23/06/2015 and Legislative Decree No. 193 of 06/04/2006).

#### 22. Prohibition of exploiting the business relationship for advertising purposes

The Supplier may not refer to its existing business relationship with BI, in any information or advertising material, nor use the name, company logo or trademarks of BI for advertising purposes without the prior written consent of the latter.

#### 23. Health, safety, environmental protection and sustainability policy

The Supplier declares to have read, understood and to fully accept the principles contained in the "Health, safety, environmental protection and sustainability policy", available at [www.boehringer-ingelheim.it](http://www.boehringer-ingelheim.it), which contains the fundamental principles of health, safety, environmental protection and sustainability and applies to all employees of Boehringer Ingelheim Group companies in Italy.

#### 24. Installation and Testing

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Where the supply of goods and/or services so requires and/or is specifically indicated in the Purchase Order or is understood from written agreements between the Parties, the Supplier guarantees the installation and testing of the same. These installation and testing services must be provided in strict compliance with all the occupational health and safety provisions, with the adoption and implementation of all the necessary protective and preventative measures, including with regard to handling, where provided for.

In the case of goods to be tested or inspected to verify their proper operation, the Company will check the operating conditions/proper functioning of the goods following their assembly/installation within an appropriate period of time of accepting the same. These tests will be performed in the presence of a person designated by the Supplier. In the event of the absence of a person designated by the Supplier, the test report/certificate of proper operation shall nonetheless be deemed valid by the same. The person tasked with checking the proper functioning of the goods or the tester/inspector may accept or reject the goods supplied based on the tests performed and the results thereof. In the event of rejection, a new deadline will be established for testing/verifying the proper functioning of the goods. Goods supplied that are defective, non-compliant or that do not conform to the technical specifications, the generally accepted professional standards or the samples provided when sending the Offer/Purchase Order may be rejected. In such cases, the Supplier shall be required to rectify, at its own expense, any defects and to bring the goods into line with the stipulated requirements, within the time limits agreed with the Company. The goods then supplied will be subject to further testing/inspection. The goods rejected following a negative test result or a report by the Company of any defect, quality or operational issue will be made available to the Supplier for collection for a maximum period of 10 days as of receiving the report or notification of rejection. Upon expiry of this period, the Company shall be entitled to store the defective or non-conforming goods, including in a location other than that to which they were delivered, at the expense and risk of the Supplier.

With the issue of a positive test report/certificate of proper operation, the goods are deemed accepted. The transfer of ownership will occur on the date of the test report/certificate of proper operation of the goods supplied.

Pursuant to and for the purposes of art. 1341 and 1342 of the Italian Civil Code, the Supplier also declares that it specifically approves the clauses contained in the above mentioned Conditions set forth in the following points: (Technical Specifications and Compliance with Procedures), (Packaging, Transportation and Transfer of Ownership (where applicable)), (Delivery of Goods and Performance of Services), (Payment Terms), ( Right of audit),(Force Majeure), (Guarantees and Responsibilities), (Indemnity), (Withdrawal, Suspension and Termination, Express Termination Clause), (Applicable Law and place of jurisdiction) and (Code of Conduct, Suppliers' Code of Conduct).

**For all contractual relationships arising from the purchase of Goods or Services (as defined above) by the company Bidachem S.p.A. and the production site of Noventa Padovana (individually the "Site"), in addition to the above, further General Conditions apply:**

#### **REACH Regulation**

If the registered office of the Supplier is located within the European Union or if the Supplier is represented within the European Union by an "Exclusive Representative" (an "ER") in accordance with Article 8 of the EU REACH Regulation 1907/2006, which entered into force on 1 June 2007 ("REACH Regulation"), with regard to the substances supplied to the Site, substances contained in the goods supplied to the Site or emitted by such goods, the Supplier and/or its subcontractors and/or sub-suppliers within the supply chain shall be obliged to carry out pre-registration, registration and/or authorisation in accordance with the Regulation. To this end, the Supplier guarantees that it will contact the Sites and request information about which applications it is required to register for the Site alongside its registration. The Supplier shall refer to the contact person at the Site who is responsible for matters relating to the REACH Regulation. In the event that the Supplier has not pre-registered/has not registered the substance in question, it is understood that the Supplier has taken steps to ensure that it is informed without delay of any failure in terms of pre-registration, registration and/or authorisation for the substance and that, in turn, it will inform the Site without delay when it becomes aware of any failure in terms of pre-registration, registration and/or authorisation for the substance, while refraining from supplying other goods to the Site that contain or release such substance. Where the Supplier breaches its obligations under this clause, this will entitle the Site to terminate the contract and/or cancel the purchase order.

#### **Metals as potential by-products in supplied substances**

The Supplier shall provide the Sites with all information related to the substances supplied that are necessary for the production of pharmaceutical and chemical products at the Site in order to comply with EMEA Guidelines 4446/2000 [GUIDELINES ON SPECIFIC LIMITS FOR THE RESIDUES OF CATALYSERS AND METALLIC REAGENTS] and the US Pharmacopoeia, Chapter 232 [Impurities of Elements - Limits].

#### **Good Manufacturing Practice (GMP)**

To the extent that the products ordered from the Site are used for the production of medicines and/or medical and/or cosmetic and/or food products, the Supplier must ensure compliance with (latest applicable version) the "Quality, Packaging and Transport Requirements for Active Principles and Excipients for the Pharmaceutical Industry", specified by the World Health Organisation (WHO).

Each delivery should, where possible, come from a single batch, i.e. constitute a homogeneous unit. The batch number must be indicated on each packaging unit as well as on the accompanying document. If the delivery consists of two or more batches of the same product, all of the batch numbers must be indicated on the packaging units and on the accompanying document.

In all cases of continuous manufacturing processes where batch products cannot be taken into account, the Supplier must ensure that the quality complies with the specifications. Each packaging unit must be permanently and clearly labelled, and indicate the name of the product, net weight, tare weight, batch number and any possible risks and information relating to storage.

The Supplier shall be liable for any losses and costs resulting from failure to comply with these rules. The Supplier is also responsible for the compliance of its subcontractors with these rules.

If, due to any failure to comply with these rules, the Site is unable to accept the supplies, the Supplier shall collect the delivered goods within 20 days after the Site's declaration of non-acceptance of the goods; during this period, the Site shall store the goods at the Supplier's expense and risk. In this case, the Site may verify the contents and condition of these supplies.

#### **Changes to products and processes**

The Supplier shall inform the Site without delay, in writing and in advance, of any changes to the products and/or manufacturing processes or analysis methods. The term "Changes to products" will be intended to include, for example, changes in product quality, the quality and source of raw materials, synthesis pathway including the typical substances used, the size and type of production line, the production site, significant increases in batch size (exceeding 30%) and any outsourcing of production phases and/or analysis activities.

#### **Rights to the work product and relevant publication**

Should the services performed by the Supplier in accordance with this Contract give rise to know-how or material subject to protection pursuant to intellectual property legislation, the Supplier shall transfer unlimited right to use such know-how or material to the Site, free of charge, for the exclusive global use of the Site.

All the data generated during the course of the supply of goods and any product of the work resulting from this supply are the property of the Site. The Supplier grants the Site any rights whatsoever under copyright law, individual privacy laws and registered trademark laws, as well as any other rights

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associated with the items of goods produced by the Supplier, including all conceivable legal rights with regard to drawings (technical drawings, drafts, concepts). The Site may only exploit such data and work products; the Site's rights in this regard are not subject to any geographical or temporal restrictions.

Should protectable inventions derive from works carried out by the Supplier, the latter shall notify the Site of this without delay. Where the Site is interested in claiming rights to such invention, it will immediately inform the Supplier. The Site shall have the sole right, in its own name and at its own expense (referring to the inventor/s), to request the protection of intellectual property rights based on the rights assigned to it, and shall also have the sole right to use the invention. To the extent necessary, the Supplier shall support the granting and maintenance of such intellectual property rights by providing such declarations as may be required by the Site from time to time.

The Supplier warrants that it is the exclusive owner of the rights to the proprietary items provided in the performance of the Contract, and that it has not made any provision in conflict with any such transfer of rights to the Site. The Supplier shall fully indemnify and hold harmless the Site against all claims made by third parties based on any breach of intellectual property rights or copyright as a result of the contractual supply of goods by the Supplier.

**Ownership of materials provided by the Site**

The diagrams, models, tools, films, materials, raw materials, etc. (collectively referred to as 'Materials Provided by the Site'), which have been supplied or produced by the Site in order to allow the Supplier to process the Purchase Order, including the related documentation, remain (unless otherwise agreed) the property of the Site, even if they remain in the possession of the Supplier. All maintenance expenses relating to the Materials Provided by the Site shall be borne by Supplier during the term of the Contract, and the Supplier shall use the Materials Provided by the Site solely for the purpose of performing the Contract for the Site. The Supplier agrees to label the Materials provided by the Site as "Property of the Boehringer Ingelheim Group", to store them properly and separately, to treat and keep them with due care and to insure them against loss, and will not move them from the location referred to in the Purchase Order without the prior written consent of the Site. Upon request, the Supplier shall deliver to the Site such Materials provided by the Site without undue delay.

**Ownership of the documents**

The Supplier shall provide the Site, in a timely and spontaneous manner, with all of the types of documents required by the Site for its use, creation, assembly, processing, operation, service, inspection, maintenance and repair of contractually defined goods. The most recent version of standards and guidelines listed on the Site will be applicable in any case.

**Supplier's own materials**

The Site shall not assume the risk of loss, damage or other deterioration of materials brought to the Site by the Supplier or its personnel for the purposes of assembly, maintenance, inspection, etc.