

Terms & Conditions of Sale of Norgine Italia S.R.L. - December 2024

1. Interpretation

1.1 Definitions:

Agreement: these Conditions and the terms of the relevant Order (except to the extent that the terms of the Order deviate from Norgine's quotation, accepted Order or are otherwise not agreed by Norgine).

Business Day: a day other than a Saturday, Sunday, a day when banks in Italy are closed for business or a day when Norgine is not open for business in Italy.

Business Hours: the period from 9.00 am to 5.00 pm on any Business Day.

Calendar Day: has the meaning given to in in **Appendix A**.

Conditions: the terms and conditions set out herein as amended from time to time in accordance with clause 11.6.

Contract: a separate executed written contract between Norgine and the Customer for the sale and purchase of the Goods.

Customer: the person which purchases the Goods from Norgine as may be more specifically set out in the Order.

Delivery Location: has the meaning given in clause 4.2.

Force Majeure Event: an event, circumstance or cause beyond a Party's reasonable control including, without limitation, regulatory action, strikes and other industrial disputes (excluding the Customer's obligation to make payments to Norgine hereunder).

Good Industry Practice: means the standards, practices, methods and procedures conforming to the degree of skill, care diligence and prudence which would reasonably be expected from a company in the position of Customer

Goods: products to be manufactured and/or supplied by or on behalf of Norgine to the Customer.

Norgine: Norgine Italia S.R.L incorporated in Italy with Company Number REA No MI-1437987.

Order: a request by the Customer to Norgine for certain Goods in accordance with the Specification (if any), as set out in the Customer's purchase order form (or written request for the supply of Goods) **OR** overleaf **OR** in the Customer's written acceptance of Norgine's quotation, as the case may be.

Order Confirmation: Norgine's written acceptance of the Order.

Party: either the Customer or Norgine (together, the "Parties").

Specification: any specification for the Goods, including any related plans and drawings, agreed in advance in writing by the Customer and Norgine.

Territory: the country and/or countries in which the Customer shall sell, use or make available for purchase the Goods, which shall be Italy.

1.2 A person includes a natural person, corporate or unincorporated body (whether or not having separate legal personality).

1.3 A reference to a Party includes its successors and permitted assigns.

1.4 A reference to legislation or a legislative provision is a reference to it as amended or re-enacted. A reference to legislation or a legislative provision includes all subordinate legislation made under that legislation or legislative provision.

1.5 Any words following the terms including, include, in particular, for example or any similar expression shall be interpreted as

illustrative and shall not limit the sense of the words preceding those terms.

2. Basis of Agreement

2.1 This Agreement shall apply between the Parties to the exclusion of any other terms that the Customer seeks to impose or incorporate, or – to the extent permitted by the applicable law - which are implied by law, trade custom, practice or course of dealing, and shall govern unless otherwise agreed by the Parties in an applicable Contract. In the event of any inconsistency between this Agreement and a Contract, the Contract shall prevail.

2.2 The Order constitutes a binding offer by the Customer to purchase the Goods in accordance with these Conditions. The Customer is responsible for ensuring that the terms of the Order and any applicable Specification are complete and accurate and shall include full details of the Goods to be supplied, the Territory, the quantity of each of the Goods ordered and the full legal identity of the Customer. Each Contract shall come into full force and effect when: (i) Norgine provides an Order Confirmation; or (ii) if Norgine does not provide an Order Confirmation to the Customer, Norgine will be deemed to have accepted each Order upon Norgine doing any act consistent with fulfilling the Order. The placement of any Order or the acceptance of delivery of the Goods shall constitute acceptance by the Customer of these Conditions.

2.3 The Customer waives any right it might otherwise have to rely on any term endorsed upon, delivered with or contained in any documents of the Customer.

2.4 Any samples, drawings, descriptive matter or material produced by Norgine and any descriptions or illustrations contained in Norgine's materials are produced for the sole purpose of giving an approximate idea of the Goods referred to in them. They shall not form part of this Agreement nor have any contractual force.

2.5 A quotation for the Goods given by Norgine shall not constitute an offer. A quotation shall only be valid for a period of twenty (20) Business Days from its date of issue.

2.6 Each Order accepted by Norgine shall constitute a separate contract. There may be more than one Contract between the Parties in force at any one time.

2.7 Norgine retains all rights and title in the intellectual property subsisting in the Goods and hereby grants to Customer a limited, non-exclusive licence to such intellectual property for the purposes contemplated under this Agreement.

3. Goods

3.1 The Customer shall ensure that the Goods are described in the Order.

3.2 To the extent that the Goods are to be manufactured in accordance with a Specification supplied by the Customer, the Customer shall indemnify Norgine against all liabilities, costs, expenses, damages and losses (including any direct, indirect or consequential losses, loss of profit, loss of reputation and all interest, penalties and legal and other reasonable professional costs and expenses) suffered or incurred by Norgine in connection with any claim made against Norgine for actual or alleged infringement of a third party's intellectual property rights arising out of or in connection with Norgine's reliance or use of the Specification. This clause 3.2 shall survive termination of this Agreement.

3.3 Norgine reserves the right to amend the Specification at any time to the extent required by any applicable statutory or

regulatory requirement, and Norgine shall notify the Customer in any such event. In case of amendments to the Specification for any other reason and where such amendment shall materially impact the Customer's use of the Goods, the Parties will agree in good faith terms of such amendments.

3.4 The Customer acknowledges that Norgine as a manufacturer and supplier of medicinal products and medical devices has a legal obligation to monitor patient impact and traceability in relation to use of the Goods. To assist Norgine with compliance with this legal obligation, the Customer shall not, without the prior written consent of Norgine and suitable pharmacovigilance measures in place in the relevant Territory, use, sell or make available for purchase, or allow the use, sale, or making available for purchase of, directly or indirectly, the Goods (i) outside of the Territory, or where the Territory includes a member state of the European Union or European Economic Area, outside the European Union or European Economic Area in any territory or jurisdiction, or (ii) for use other than for the approved indications and in accordance with the terms of the licence for sale for the Goods and/or (iii) on an "off-licence" or "special" (or equivalent) basis. The Customer undertakes not to sell or make available for purchase the Goods to a third party (i) without also obliging such third party to comply with the restrictions set out in this clause 3.4, or (ii) if the Customer knows or has reason to believe that the third party will or could export the Goods from the Territory or, where the Territory includes a member state of the European Union or European Economic Area, outside the European Union or European Economic Area.

3.5 The Customer must specify in each Order the Territory in which it shall sell, use and/or otherwise make available for purchase the Goods.

3.6 If Goods are unlicensed or only available under prescription in the Territory, the Customer shall not, and shall procure that each of its customers, agents, employees, contractors and any other third party providers involved in the sale, use or provision of the Goods shall not, promote or otherwise advertise for sale the Goods at any time and in any manner which may be deemed to be an unauthorised promotion of an off-licence or prescription only pharmaceutical product or medical device.

4. Delivery

4.1 Norgine shall use its reasonable endeavours to ensure that:

- (a) each delivery of the Goods is accompanied by a delivery note that shows the date of the Order, all relevant Customer and Norgine reference numbers, the type and quantity of the Goods (including the code number of the Goods, where applicable), special storage instructions (if any) and, if the Goods are being delivered by instalments, the outstanding balance of Goods remaining to be delivered; and
- (b) if Norgine requires the Customer to return any packaging materials to Norgine, that fact is clearly stated on the delivery note. The Customer shall make any such packaging materials available for collection at such times as Norgine shall reasonably request. Unless otherwise agreed between Norgine and the Customer, returns of packaging materials shall be at Norgine's expense.

4.2 Unless otherwise agreed between Norgine and the Customer, Norgine shall deliver the Goods on an Ex Works (Incoterms 2020) basis to the location set out in the Order (**Delivery Location**) at any time after Norgine notifies the Customer that the Goods are ready for collection. Norgine may use its own third party logistics provider and charge the Customer for delivery of the Goods (in the amount stipulated to the Customer in respect of each Order).

4.3 Delivery is completed by Norgine on the completion of unloading the Goods at the Delivery Location. Norgine shall

deliver the Goods at the nearest entrance to the Delivery Location and at ground floor level only. The Customer shall be responsible for the Goods after delivery, including the movement or transfer of Goods to another location at the Delivery Location.

4.4 Any dates quoted for delivery are approximate only, and the time of delivery is not of the essence. Norgine shall not be liable for any delay in delivery of the Goods that is caused by a Force Majeure Event or the Customer's failure to provide Norgine with adequate delivery instructions or any other instructions that are relevant to the supply of the Goods, including any failure of the Customer (or its third party representative) to make adequate provision for the receipt and storage of Goods on arrival or collection (as the case may be).

4.5 If Norgine fails to deliver the Goods in accordance with this clause, its liability shall be limited to the costs and expenses incurred by the Customer in obtaining replacement goods of similar description and quality in the cheapest market price available, less the price of the undelivered Goods. Norgine shall have no liability for any failure to deliver the Goods to the extent that such failure is caused by a Force Majeure Event or the Customer's failure to provide Norgine with adequate delivery instructions or any other instructions that are relevant to the supply and/or receipt of the Goods.

4.6 If the Customer fails to take or accept delivery of the Goods within one (1) Business Day of Norgine notifying the Customer that the Goods are ready for collection, then, except where such failure or delay is caused by a Force Majeure Event or Norgine's failure to comply with its obligations under this Agreement in respect of the Goods:

- (a) delivery of the Goods shall be deemed to have been completed at 9.00 am on the first Business Day after the day on which Norgine notified the Customer that the Goods were ready for collection; and
- (b) Norgine shall store the Goods until actual delivery takes place, and charge the Customer for all related costs and expenses (including insurance).

4.7 If **ten (10)** Business Days after the day on which Norgine notified the Customer that the Goods were ready for collection the Customer has not taken or accepted actual delivery of the Goods, Norgine may resell or otherwise dispose of part or all of the Goods and, after deducting reasonable storage and selling costs, account to the Customer for any excess over the price of the Goods or charge the Customer for any shortfall below the price of the Goods.

4.8 If Norgine delivers up to and including **five (5)%** more or less than the quantity of Goods ordered the Customer may not reject such Goods on this basis, but on receipt of notice from the Customer that the wrong quantity of Goods was delivered, Norgine shall make a pro rata adjustment to the invoice for the Goods.

4.9 Norgine may deliver the Goods by instalments, which shall be invoiced and paid for separately. Any delay in delivery, defect or other breach in respect of an instalment shall not entitle the Customer to cancel any other instalment and shall be deemed a severable breach of contract.

4.10 Norgine reserves the right to delay or cancel an Order if any payment or amount due from the Customer to Norgine either exceeds any credit limit for credit granted by Norgine to the Customer or has not been made by the required date for payment.

5. Quality

5.1 Norgine warrants that on delivery the Goods shall:

- (a) conform with their description or the Specification; and
- (b) be free from material defects in design, material and workmanship.

- 5.2** Subject to clause 5.3, if:
- (a) the Customer gives notice in writing to Norgine within a reasonable time, and in any event within one Business Day, of discovery that some or all of the Goods do not comply with the warranty set out in clause 5.1;
 - (b) Norgine is given a reasonable opportunity of examining such Goods; and
 - (c) the Customer (if asked to do so by Norgine) returns such Goods in accordance with instructions provided by Norgine and to a location specified by Norgine at Norgine's cost,
- To the extent permitted by the applicable law, Norgine shall, at its option, replace the defective Goods or refund the price of the defective Goods in full. Unless and until Norgine examines and repairs or receives the defective Goods, the Customer shall, at its cost, hold such Goods in a safe and secure location in good condition.
- 5.3** Norgine shall not be liable for the failure of the Goods to comply with the warranty set out in clause 5.1 if:
- (a) notice of the breach was not provided by the Customer to Norgine in accordance with clause 5.2(a);
 - (b) the Customer makes any further use of such Goods after giving notice in accordance with clause 5.2;
 - (c) the defect arises because the Customer has failed to follow Norgine's oral or written instructions as to the storage, use or maintenance of the Goods or good trade practice regarding the same;
 - (d) the defect arises as a result of Norgine following any instructions, requirements, drawing, design or specification supplied by the Customer;
 - (e) the Customer alters such Goods without the written consent of Norgine;
 - (f) the defect arises as a result of wilful damage, negligence, or abnormal storage or working conditions by the Customer; or
 - (g) changes to the Goods have been made to ensure they comply with applicable statutory or regulatory requirements.
- 5.4** Except as provided in this clause 5, Norgine shall have no liability to the Customer in respect of a failure of the Goods to comply with the warranty set out in clause 5.1.
- 5.5** If the Customer makes an invalid claim under the warranty, Norgine may charge the Customer for its fees and costs of dealing with the claim, including examining, testing, storing and replacing any alleged defective Goods.
- 5.6** These Conditions shall apply to any replacement Goods supplied by Norgine.
- 5.7** Except as where expressly provided for within this clause 5, Norgine excludes all other warranties whether express or implied by statute, common law or otherwise, to the extent permitted under applicable law.
- 5.8** Prior to any return of Goods to Norgine by the Customer, the Customer shall first ask the permission of Norgine to return of such Goods. Any return permission request by the Customer shall include the quantity of Goods to be returned, a full description of the Goods and the reason for return (including any supporting evidence). Norgine shall have the right to request further information from the Customer, which the Customer shall provide prior to any return of Goods.
- 5.9** The Customer shall have in place a procedure and system of traceability for the Goods in accordance with Good Industry Practice, which shall include, without limitation, a product recall procedure that enables the Customer to swiftly identify and recall any Goods subject to a product recall (notwithstanding the reason for the recall). Any product recall procedure and system put in place by the Customer shall include the details of all customers of the Customer in connection with the sale of the Goods whether in the Territory or otherwise.
- 5.10** In the event of a recall of any Goods, whether by Norgine or an applicable regulatory authority, the Customer shall provide Norgine and any regulatory authority with reasonable assistance as may be reasonably required. Subject to clause 8, Norgine shall reimburse the Customer for the Goods subject to the recall and any reasonable costs. Norgine shall bear the costs associated with a recall but only to the extent they are incurred as a result of any direct action, or inaction, by Norgine.
- 6. Title and risk**
- 6.1** The risk in the Goods shall pass to the Customer on completion of delivery.
- 6.2** Subject to clause 6.4(d), title to the Goods shall not pass to the Customer until Norgine receives payment in full (in cash or cleared funds) for the Goods and all other sums which are or which become due to Norgine from the Customer on any account under this Agreement.
- 6.3** Until title to the Goods has passed to the Customer, the Customer shall:
- (a) store the Goods separately from all other goods held by the Customer so that they remain readily identifiable as Norgine's property;
 - (b) not remove, deface or obscure any identifying mark or packaging on or relating to the Goods;
 - (c) maintain the Goods in good, saleable condition and keep them insured against all risks for their full price from the date of delivery;
 - (d) notify Norgine immediately if it becomes subject to any of the events listed in clause 9.1(b) to clause 9.1(d);
 - (e) hold the Goods on a fiduciary basis as Norgine's bailee; and
 - (f) give Norgine such information as Norgine may reasonably require from time to time relating to:
 - (i) the Goods; and
 - (ii) the ongoing financial position of the Customer.
- 6.4** Subject to clause 6.5, the Customer may resell or use the Goods in the ordinary course of its business at full market value (but not otherwise) before Norgine receives payment for the Goods. However, if the Customer resells the Goods before that time:
- (a) it does so as principal and not as Norgine's agent;
 - (b) the Customer shall keep the proceeds of sale separate from any money or property of the Customer or third parties;
 - (c) the Customer shall remain responsible for paying to Norgine the full value of the payment due to Norgine; and
 - (d) title to the Goods shall pass from Norgine to the Customer immediately before the time at which resale by the Customer occurs.
- 6.5** At any time before title to the Goods passes to the Customer, Norgine may:
- (a) by notice in writing, terminate the Customer's right under clause 6.4 to resell the Goods or use them in the ordinary course of its business; and
 - (b) require the Customer to deliver up, or make available for collection from a single collection point specified by Norgine, all Goods in its possession that have not been resold, or irrevocably incorporated into another product and if the Customer fails to do so promptly, enter any premises of the Customer or of any third party where the Goods are stored in order to recover them.

- 6.6** The Customer hereby grants to Norgine for Norgine and its agents, staff, officers, employees and contractors, an irrevocable licence to enter for the purpose of recovering possession of the Goods any premises then occupied by or in the ownership or possession of the Customer or the Customer's customer. The Customer shall indemnify Norgine against all claims, losses, damages, liabilities, costs and expenses so arising in exercising its rights under this clause 6.6.
- 6.7** This clause 6 shall survive expiry or termination of the Agreement.
- 7. Price and payment**
- 7.1** The price of the Goods shall be the price set out in the invoice, or, if no price is quoted, the price set out in Norgine's published price list in force as at the date of delivery.
- 7.2** Norgine may, by giving notice to the Customer at any time up to ten (10) Business Days before delivery, increase the price of the Goods to reflect any increase in the cost of the Goods that is due to:
- (a) any factor beyond Norgine's control (including foreign exchange fluctuations, increases in taxes and duties, and increases in labour, materials and other manufacturing costs);
 - (b) any request by the Customer to change the delivery date(s), quantities or types of Goods ordered, or the Specification; or
 - (c) any delay caused by any instructions of the Customer or failure of the Customer to give Norgine adequate or accurate information or instructions.
- 7.3** The price of the Goods:
- (a) excludes amounts in respect of value added tax (**VAT**), which the Customer shall additionally be liable to pay to Norgine at the prevailing rate, subject to the receipt of a valid VAT invoice; and
 - (b) excludes the costs and charges of packaging, insurance and transport of the Goods, which shall be invoiced to the Customer.
- 7.4** Norgine may invoice the Customer for the Goods on or at any time after the completion of delivery.
- 7.5** The Customer shall pay each invoice submitted by Norgine:
- (a) within thirty (30) days of the date of the invoice; and
 - (b) in full and in cleared funds to a bank account nominated in writing by Norgine, and
- time for payment shall be of the essence of the Agreement.
- 7.6** If the Customer fails to make a payment due to Norgine under the Agreement by the due date, then, without limiting Norgine's remedies under clause 9, Norgine may do any or all of the following: (a) charge the Customer interest on the overdue sum from the due date until payment of the overdue sum, whether before or after judgment (interest under this clause 7.6 will accrue according to Legislative Decree no. 231/2002; and (b) suspend the performance of this Agreement and any other agreement between the Parties until payment has been made by the Customer to Norgine in full.
- 7.7** All amounts due under the Agreement shall be paid in full without any set-off, counterclaim, deduction or withholding (other than any deduction or withholding of tax as required by law).
- 8. Limitation of liability**
- 8.1** Subject to clause 5.2, this clause 8 prevails over all other clauses and sets out the entire liability of Norgine and the sole and exclusive remedies of the Customer in respect of performance (or non-performance) of this Agreement or otherwise in relation to this Agreement.
- 8.2** References to liability in this clause 8 shall include every kind of liability arising under or in connection with this Agreement including liability in contract, tort (including negligence), misrepresentation, restitution or otherwise.
- 8.3** Nothing in this Agreement limits any liability which cannot legally be limited, including liability for:
- (a) death or personal injury;
 - (b) fraud or fraudulent misrepresentation or gross negligence;
 - (c) breach of confidential information;
 - (d) in the case of the Customer only, negligence and/or wilful misconduct which may result in a recall of Goods; or
 - (e) defective products under the Consumer Code (Legislative Decree no. 206/2005).
- 8.4** Subject to clause 8.3, Norgine's total liability to the Customer per Order:
- (a) shall not exceed 100% of the total sums paid and payable by the Customer to Norgine under the relevant Order; and
 - (b) for any non-delivery of Goods will be as set out in clause 4.5 and Norgine shall have no other liability for any such non-delivery or failure to deliver.
- 8.5** Subject to clause 8.3, the following types of loss are wholly excluded whether or not such losses were reasonably foreseeable or Norgine (or its authorised third party) was advised of the possibility of the loss being incurred (whether direct, indirect or consequential in each case in connection with (a)-(g) inclusive):
- (a) loss of profits or revenue (whether actual or anticipated);
 - (b) loss of sales or business;
 - (c) loss of operation time;
 - (d) loss of agreements or contracts;
 - (e) loss of anticipated savings;
 - (f) loss of use or corruption of software, data or information;
 - (g) loss of or damage to goodwill or reputation; and
 - (h) any other indirect or consequential loss.
- 8.6** Any action commenced by Customer with respect to the performance, non-performance and/or delay regarding any aspect of this Agreement, including any Order, save and except for third-party claims of intellectual property infringement, must be commenced by the Customer and filed no later than one year from the date Norgine delivered the Goods, work or services concerning the subject matter of the dispute or claim to the Customer. If the Customer fails to file a claim within the one year time period specified in this clause 8.6, the claim shall be deemed time barred and any such rights of action or enforcement waived by the Customer. This provision expressly overrides any statutory not mandatory provision that would otherwise apply.
- 8.7** The Customer will maintain at its own expense appropriate insurance coverage with limits typical to its industry to cover the liabilities under this Agreement.
- 8.8** This clause 8 shall survive termination or expiry of this Agreement.
- 9. Termination**
- 9.1** Without limiting its other rights or remedies, Norgine may terminate this Agreement with immediate effect by giving written notice to the Customer if:
- (a) the Customer commits a material breach of any term of the Agreement and (if such a breach is remediable) fails to remedy that breach within fifteen (15) days of Customer being notified in writing to do so;
 - (b) to the extent permitted by the applicable law, the Customer takes any step or action in connection with its entering administration, provisional liquidation or

- any composition or arrangement with its creditors (other than in relation to a solvent restructuring), obtaining a moratorium (or other form of financial support or freeze), being wound up (whether voluntarily or by order of the court, unless for the purpose of a solvent restructuring), having a receiver appointed to any of its assets or ceasing to carry on business or, if the step or action is taken in another jurisdiction, in connection with any analogous procedure in the relevant jurisdiction;
- (c) the Customer suspends, threatens to suspend, ceases or threatens to cease to carry on all or a substantial part of its business; or
- (d) the Customer's financial position deteriorates to the extent that Norgine, acting reasonably, is of the opinion that the Customer's ability to give prompt effect to the terms of this Agreement is in jeopardy and the Customer fails to duly perform its obligation under this Agreement within fifteen (15) days of Customer being notified in writing to do so.
- 9.2** Without limiting its other rights or remedies, Norgine may suspend provision of the Goods under the Agreement or any other Contract between the Customer and Norgine if the Customer becomes subject to any of the events listed in clause 9.1(b) to clause 9.1(d), or Norgine reasonably believes that the Customer is about to become subject to any of them, or if the Customer fails to pay any amount due under this Agreement on the due date for payment.
- 9.3** Without limiting its other rights or remedies, Norgine may terminate the Agreement with immediate effect by giving written notice to the Customer if the Customer fails to pay any amount due under this Agreement on the due date for payment.
- 9.4** On termination of this Agreement for any reason the Customer shall immediately pay to Norgine all of Norgine's outstanding unpaid invoices and interest and, in respect of Goods supplied but for which no invoice has been submitted, Norgine shall submit an invoice, which shall be payable by the Customer immediately on receipt.
- 9.5** Termination of the Agreement, however arising, shall not affect any of the Parties' rights and remedies that have accrued as at termination, including the right to claim damages in respect of any breach of the Agreement which existed at or before the date of termination.
- 9.6** Any provision of the Agreement that expressly or by implication is intended to come into or continue in force on or after termination of the Agreement shall remain in full force and effect.
- 10. Force majeure**
- 10.1** Neither Party shall be in breach of this Agreement or otherwise liable for any failure or delay in the performance of its obligations if such delay or failure results from a Force Majeure Event. In case a Force Majeure Event occurs, the claimant shall i) notify the other Party as soon as reasonably practicable of the Force Majeure Event and ii) exerts its best efforts to eliminate, cure or overcome any such circumstances and to resume performance of its obligations in a timely manner. In any case, the performance of each Party's obligations shall be suspended during the Force Majeure Event and the time for performance of such obligations shall be extended accordingly. Each Party shall bear its own costs incurred by the Force Majeure Event. If the period of delay or non-performance continues for a consecutive period of three (3) months, the Party not affected may terminate this Agreement by giving no less than fifteen (15) days' written notice to the affected Party. Neither Party shall have any liability in respect of such termination.

- 10.2** In the event that Norgine is obligated to supply the same or similar Goods to more than one customer or market and is prevented from meeting its obligations to the Customer in full as a result of the Force Majeure Event, Norgine may decide at its sole discretion which contracts to perform and to what extent.

11. General

11.1 Assignment and other dealings.

- (a) Norgine may at any time assign, novate, transfer, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with all or any of its rights or obligations under this Agreement and the Customer's consent shall be deemed given by accepting this Agreement.
- (b) The Customer may not assign, novate, transfer, mortgage, charge, subcontract, delegate, declare a trust over or deal in any other manner with any or all of its rights or obligations under this Agreement without the prior written consent of Norgine.
- (c) This Agreement does not give rise to any rights in favour of any third party to enforce any term of this Agreement.

11.2 Confidentiality.

- (a) Each Party undertakes that it shall not disclose to any person any confidential information concerning the business, assets, affairs, customers, clients or suppliers of the other Party, except as permitted by clause 11.2(b).
- (b) Each Party may disclose the other Party's confidential information:
- (i) to its employees, officers, representatives, contractors, subcontractors or advisers who need to know such information for the purposes of exercising the Party's rights or carrying out its obligations under this Agreement. Each Party shall ensure that its employees, officers, representatives, contractors, subcontractors or advisers to whom it discloses the other Party's confidential information comply with this clause 11.2; and
 - (ii) as may be required by law, a court of competent jurisdiction or any governmental or regulatory authority.
- (c) Neither Party shall use the other Party's confidential information for any purpose other than to exercise its rights and perform its obligations under or in connection with the Agreement.

11.3 Compliance.

- (a) Each Party agrees that it will comply with all applicable anti-corruption, anti-bribery, anti-money laundering, anti-slavery or human trafficking, and economic sanctions laws and regulations of the United States, United Kingdom, European Union and United Nations (collectively, the "**Compliance Laws**") in connection with this Agreement.
- (b) The Customer further agrees that it shall not, and it shall procure its employees shall not, pay or cause other person(s) to pay Norgine using any funds that would result in a violation of any of the Compliance Laws by either the Customer or Norgine, or otherwise take any action that would result in a violation of any of the Compliance Laws by either the Customer or Norgine.
- (c) The Customer shall promptly notify Norgine in the event of any violation or failure to comply with any of the Compliance Laws in connection with this Agreement or otherwise, or allegations relating thereto, by the Customer or its customers, directors, officers, employees or agents.

11.4 Pharmacovigilance

- (a) All reports concerning safety related information including Adverse Events (“**AE**”), Device Incidents and Special Situations (as defined in Appendix A) hereafter collectively referred to as “**safety information**” received by the Customer or its representatives on Norgine’s medicinal products or devices, including the Goods, must be transmitted to Norgine within one (1) Calendar Day after receipt. The transmission of information shall be by email or telephone call, in accordance with the contact details set forth in **Appendix A**.
- (b) Information to be reported to Norgine includes, but is not limited to, the following:
- (i) An identifiable report source (name, address, qualification);
 - (ii) An identifiable patient (e.g. initials, date of birth, age group, age or gender);
 - (iii) A suspect Norgine product / device; and
 - (iv) An AE, Device Incident (undesirable side effect) or Special Situation.

Even if all the above information is not available (i.e. the case is non-valid), the Customer must still transmit the report to Norgine in accordance with the timeframes specified above. Following the receipt of the above information, Norgine may request clarifications and/or additional safety information from the Customer and the Customer shall promptly provide such clarifications and/or additional information to Norgine.

- (c) The Customer must clearly communicate to anyone who reports any safety information (the “**Reporter**”) that relates to or implicates Norgine’s medicinal products or devices, including the Goods, that the details of the safety information will be forwarded to Norgine. In cases where safety information has been reported, the Customer will procure that the Reporter and/or other relevant individuals give consent to their name and contact information being forwarded to Norgine. The Customer acknowledges and agrees that Norgine may, at its discretion, contact the Reporter and/or other relevant individuals for further information in order to fulfil the legal requirements of the reporting legislation.
- (d) The Customer shall fully cooperate with Norgine in respect of the gathering, compilation and reporting of safety information and shall promptly implement any corrective actions required by Norgine.
- (e) In no event shall the personally identifiable information of any patient be provided to Norgine in connection with the safety information without consent from the patient. All patient information sent to Norgine by the Customer must be anonymous and in compliance with applicable laws, including data protection laws.

11.5 Entire agreement.

- (a) This Agreement constitutes the entire agreement between the Parties in respect of the Order.
- (b) Each Party acknowledges that in entering into this Agreement it does not rely on any statement, representation, assurance or warranty (whether made innocently or negligently) that is not set out in this Agreement.

11.6 Variation. No variation of this Agreement shall be effective unless it is in writing and signed by the Parties (or their authorised representatives).

11.7 Waiver. Waiver of any right or remedy is only effective if given in writing and shall not be deemed a waiver of any subsequent right or remedy. A delay or failure to exercise, or the single or partial exercise of, any right or remedy shall not waive that or any other right or remedy, nor shall it prevent, diminish or restrict the further exercise of that or any other right or remedy.

11.8 Severance. If any provision or part-provision of this Agreement is or becomes invalid, illegal or unenforceable, it shall be deemed deleted, but that shall not affect the validity and enforceability of the rest of this Agreement. The Parties shall negotiate in good faith to agree a replacement provision that, to the greatest extent possible, achieves the intended commercial result of the original provision deleted as a result of invalidity, illegality or unenforceability.

11.9 Notices.

- (a) Any notice given to a Party under or in connection with this Agreement shall be in writing and shall be delivered by hand (which shall be deemed to include commercially recognisable courier), pre-paid first-class post (or other next working day delivery service) or email to the postal or email address specified on the Order for the purpose of notice or such other postal or email address as that Party may from time to time notify to the other Party in writing regarding the receipt of notice.
- (b) Any notice shall be deemed to have been received:
- (i) if delivered by hand, at the time the notice is left at the proper address;
 - (ii) if sent by pre-paid first-class post or other next working day delivery service, on the second Business Day after posting; or
 - (iii) if sent by email, at the time of transmission, or, if this time falls outside Business Hours in the place of receipt, when Business Hours resume.
- (c) This clause does not apply to the service of any proceedings or other documents in any legal action or, where applicable, any arbitration or other method of dispute resolution.

11.10 Governing law & Jurisdiction. The Agreement, and any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with it or its subject matter or formation, shall be governed by and construed in accordance with the laws of Italy. Each Party irrevocably agrees that the courts of Italy and namely the Tribunal of Rome shall have exclusive jurisdiction to settle any dispute or claim (including non-contractual disputes or claims) arising out of or in connection with the Agreement or its subject matter or formation.

Appendix A

Capitalised terms and expressions used in this Appendix A, and not otherwise defined in the Agreement, shall have the following meanings:

“**Adverse Event**” or “**AE**” means any unfavourable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product;

“**Calendar Day**” means any day including a Business Day, a Saturday, a Sunday, and a company or a public holiday in the relevant country of either Party.

“**Device Incident**” means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect.

“Special Situations” means those situations requiring reporting in addition to routine expedited and periodic reporting and currently detailed in GVP Module VI (Management and reporting of adverse reactions to medicinal products) as:

- All cases of pregnant women who took the medicinal product, regardless of whether there was an AE;
- All cases of pregnant women where the male partner took the medical product regardless of whether there was an AE;
- Reporting of outcomes of use of a medicinal product during breastfeeding;
- Reporting of lack of therapeutic efficacy; and
- Reporting in relation to overdose, abuse, off-label use, misuse, medication error or occupational exposure.

In addition to the situations defined above, Special Situations in this Agreement will also cover:

- Reporting following suspension or withdrawal of the marketing authorisation for safety or commercial reasons;
- Reporting from compassionate/named patient use;
- Reporting of suspected transmission of infectious agents;
- Reporting in the event of a public health emergency;
- Reporting a drug interaction;
- Reporting an unexpected beneficial effect; and
- Reports of falsified drugs.

PV Contact details

Exchange email for reporting AEs: medinfo@norgine.com

For any other safety questions: GPharmacoVigilance@norgine.com / NorginePVAlliances@norgine.com