

Terms & Conditions of Sale of Norgine SAS/Norgine Pharma SAS – January 2025

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 France are closed for business or a day when Norgine is not open for business in France.

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 including, with respect to Goods comprising of medicinal products or medical devices, any wholesaler-dispatcher, pharmacy and equivalent status (including any grouping of pharmacies), health care facility (except as otherwise provided by the French Public Procurement Code with respect to public health care facilities) or any other authorised person, organisation or company.

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, PROVIDED ALWAYS that the claimant i) notifies 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.

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

Norgine: Norgine Pharma SAS - 29, rue Ethé Virton, 28100 Dreux, France (RCS Chartres n° 825 034 259), or Norgine SAS - 23, rue François Jacob, 92500 Rueil-Malmaison, France (RCS Nanterre n° 552 019 689, numéro unique ADEME FR205778_01TBAD), as applicable.

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 technical documentation, 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 metropolitan France (including Corsica), overseas territories (DROM-COM) and Monaco.

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 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 Agreement 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 ; and in either case of (i) and (ii) above, for each Agreement for the supply of Goods comprising of medicinal

products to Customers that are hospital pharmacies or pharmacies that supply to a hospital (each a "Hospital Pharmacy Customer"), the Agreement will come into full force and effect provided the Hospital Pharmacy Customer proves the fulfilment of the requirements of Article L 5126-4 of the French Public Health Code ("Article") in the form of a copy of the authorisation as mentioned in section I. of said Article. The Hospital Pharmacy Customer shall inform Norgine immediately of the expiry or termination of such authorisation. Where such authorisation has expired or terminated, both the entitlement to supply and the entitlement to payment shall lapse. With respect to pharmacies supplying hospitals, such Hospital Pharmacy Customer may only supply the Goods acquired under each Agreement to hospitals within the scope of its supply contracts. Any supply to other pharmacies, wholesalers or intermediaries is expressly prohibited. The placement of any Order or the acceptance of delivery of the Goods shall constitute unqualified 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 that is inconsistent with these Conditions.

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 Each Order accepted by Norgine shall (together with these Conditions) constitute a separate Agreement. There may be more than one Agreement between the Parties in force at any one time.

2.6 Norgine shall be free to accept or reject any Order placed by the Customer. Norgine's acceptance of an Order shall not be deemed to result solely from Norgine's receipt of the Order. In particular, Norgine may refuse an order :

- if the Order is for an amount less than (i) €300 exclusive of VAT for a wholesaler-dispatcher, (ii) €149 exclusive of VAT for a pharmacy and equivalent status or (iii) for a private or public health facility, the minimum Order amount provided for in the Contract (these Terms and Conditions remaining otherwise applicable). In the event that an Order for an amount less than these thresholds is accepted by Norgine, a flat-rate invoice for administrative costs, packaging costs and delivery costs of €20 exclusive of VAT will be applied, or
- if the order does not comply with the packaging conditions communicated by Norgine for each Good, or
- if Norgine is aware of a failure by the Customer to comply with the rules

relating to the storage and distribution of medicinal products, or

- depending on Norgine's stocks and production capacities (it being understood that in this case Norgine may choose to proceed by partial deliveries).

NO COMPENSATION OF ANY KIND WHATSOEVER MAY BE CLAIMED BY THE CUSTOMER IN THE EVENT OF A SHORTAGE OF PRODUCTS OR A LIMITATION OF DELIVERIES JUSTIFIED BY THE ORGANISATION OF THE SUPPLY OF PRODUCTS IN FRANCE.

In addition, Norgine may subject the acceptance of an Order to the provision by the Customer of a warranty of payment.

2.7 Norgine retains all rights and title in the intellectual property subsisting in the Goods and hereby grants to the 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 on 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 for any reason, including to the extent required by any applicable statutory or regulatory requirement, and Norgine shall inform the Customer in any such event.

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, in any territory or jurisdiction outside the European Union or European Economic Area, and/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, even where it is allowed under the laws of the concerned territory or jurisdiction. 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 outside 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 the 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 unauthorized promotion of an off-licence or prescription only medicinal 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** For deliveries in metropolitan France, unless otherwise agreed between Norgine and the Customer, Norgine shall deliver the Goods to the Customer using its own third party logistics provider, at the location set out in the Order (Delivery Location).
- 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 the Goods to another location at the Delivery Location.
- 4.4** For deliveries to overseas territories (DROM-COM), unless otherwise agreed between Norgine and the Customer, Norgine shall deliver the Goods on an FCA (Incoterms 2020) basis at the Delivery Location set out in the Order.
- 4.5** 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. No reasonable delay in delivery shall entitle the Customer to refuse the Goods, to claim damages or to suspend any payment whatsoever.
- 4.6** 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.
- 4.7** Norgine may reject an Order if the Order is not submitted as standard carton or bundle (such information being provided by Norgine for each Good) or if it otherwise doesn't comply with the required commercial conditions.
- 4.8** Norgine may deliver the Goods by instalments, which shall be invoiced and paid for separately. Each instalment shall constitute a separate contract (even where a number of instalments are included in the same Agreement). 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.
- 4.9** 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 granted by Norgine to the Customer or has not been made by the required date for payment.
- 4.10** All deliveries must be inspected on delivery. In the event of a missing, open or damaged package, it is the Customer's responsibility to make specific and handwritten reservations on the transport document, and to confirm them within 3 days to the carrier or freight forwarder who made the delivery, in accordance with article L.133-3 of the French Commercial Code. Any error by Norgine concerning the nature or quantity of the Goods ordered by the Customer must be notified in writing, to the shipping address or any other address indicated on the invoice, within 3 days of receipt. IN THE EVENT OF AN ERROR BY NORGINE, AND BY EXPRESS AGREEMENT, NORGINE SHALL ONLY BE LIABLE FOR THE COST OF REPLACING THE PRODUCTS. In the absence of a declaration made under the conditions of this paragraph, the entire delivery will be deemed to have been made in accordance with the Order and will be deemed correct in all respects.

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 seven 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,

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 obtain the express written permission of Norgine to return 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. Save where Norgine made a mistake as to the type or quantity of Goods delivered to the Customer, the return costs shall be borne by the Customer. No expired Good may be returned to Norgine.

- 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 6.5(d), title to the Goods shall not pass to the Customer until Norgine receives payment in full including applicable taxes (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. UNDER NO CIRCUMSTANCES MAY THE CUSTOMER PLEDGE OR USE THE PRODUCTS AS A WARRANTY.

- 6.3** Subject to clause 6.5, 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** For the supply of Goods comprising of medicinal products alone, Customers may only offer, (re)sell or dispense with the Goods in their unaltered original packaging as received by them from Norgine. Sale of such Goods in partial quantities or part of a clinic pack are not permitted.
- 6.5** Subject to clause 6.6, 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 full 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.
- 6.6** 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 6.5 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.
- 6.7** 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 6.7.
- 6.8** 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 Order Confirmation or, if no price is quoted, the price set out in Norgine's published price list in force as at the date of the Order.
- 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 request by the Customer to change the delivery date(s), quantities or types of Goods ordered, or the Specification; or
 - (b) 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 sixty (60) days (save as otherwise provided by law) of the date of the invoice (or, for deliveries in overseas territories (DROM-COM), from the date of customs clearance of the Goods at the port of final destination, and
 - (b) in full and in cleared funds to a bank account nominated in writing by Norgine.
- 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 (at a rate equal to the interest rate applied by the European Central Bank (ECB) to its most recent refinancing operation, plus ten (10) percentage points); (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 and (c) withdraw the Customer's authorization to sell the Goods before full payment pursuant to clause 6.5. The Customer will furthermore be automatically liable to pay a fixed debt collection charge of forty (40) euros.
- 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 caused by negligence;
 - (b) fraud or fraudulent misrepresentation;
 - (c) property infringements;
 - (d) breach of confidential information;
 - (e) in the case of the Customer only, negligence and/or wilful misconduct which may result in a recall of Goods; or
 - (f) pursuant to the French Product Liability Act (*Loi n°98-389 du 19 mai 1998 relative à la responsabilité du fait des produits défectueux*).
- 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 failure to deliver the Goods, will be as set out in clause 4.6 and Norgine shall have no other liability for any such 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 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 (including failure to pay any amount due under this or any other Agreement) and (if such a breach is remediable) fails to remedy that breach within ten (10) days of Customer being notified in writing to do so;
 - (b) 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.
- 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** 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.

9.4 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.

9.5 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 (excluding the Customer's obligation to make payments to Norgine hereunder) if such delay or failure results from a Force Majeure Event. 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 delay or failure continues for a consecutive period of three (3) months, the non-affected Party may terminate this Agreement by giving no less than fourteen (14) 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.
- (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 to any third Party in accordance with the principle of the relative effect of contracts referred to in article 1199 of the French Civil Code.

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 medical 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 medical 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 France. Each Party irrevocably agrees that the courts of Paris 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 medical 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 medicinal 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