

**Organon Pharma (Ireland) Limited**  
**Organon (Ireland) Limited**

**CONDITIONS OF SALE FOR SUPPLY OF GOODS AND SERVICES**

**1. DEFINITIONS**

- a) The “Agreement” shall mean the contract between the Buyer and the Contractor, incorporating these terms and conditions and the Buyer’s Purchase Order and any other document referred to in the Buyer’s Purchase Order.
- b) An “Authorised Signatory” shall mean an employee of a party who has authority by virtue of that party’s internal procedure to commit that party to a legally binding contract.
- c) The “Buyer” shall mean the ORGANON entity engaging the Contractor under this Agreement. The relevant entity will be one or more of the following: i) Organon Pharma (Ireland) Limited; or ii) Organon (Ireland) Limited.
  - ii) an affiliated company of any these companies that agrees to apply these conditions of sale.
- d) The “Contractor” shall mean the company, partnership, person or other legal entity supplying the Works to the Buyer.
- e) The “Contract Price” is the price to be paid for the Works by the Buyer.
- f) “Good Practice” shall mean exercising the same skill, expertise and judgment and using facilities and resources of a similar or superior quality as might be expected from a person who:
  - i. is skilled and experienced in providing the Works; and
  - ii. takes all proper and reasonable care and is diligent in performing their obligations.
- g) The “Works” shall mean all the work, goods, services, materials, parts, components, plant, equipment, insurance, transport and all other things which the Contractor is required to provide in order to fulfil its obligations under the Agreement and “Works” shall be construed as any one or more of the above as appropriate.
- h) A “Health Professional” is defined as being any member of the medical, dental, pharmacy, and nursing professions and any other persons, including administrative staff, who in the course of their professional activities may administer, prescribe, purchase, recommend, or supply a medicine.
- i) A “Transfer of Value” is defined as any direct or indirect transfer of value, whether in cash, in kind or otherwise, made, whether for promotional purposes or otherwise.

**2. INTRODUCTION**

- a) These Terms and Conditions apply to and supersede any terms and conditions oral or written referred to, offered or relied on by the Contractor whether in negotiation or at any other time in the dealing between the Buyer and Contractor with reference to the Works to which this Agreement relates.
- b) Without prejudice to the matters above the Buyer will not be bound by any standard, oral, or printed terms or any other terms whatsoever provided by the Contractor in any of its documents or otherwise unless the Contractor specifically states in writing, separately and distinct from such terms that it intends such terms to apply and the Buyer by an Authorised Signatory acknowledges and confirms its acceptance in writing to the Contractor.

**3. ENTIRE AGREEMENT AND VARIATION**

- a) This Agreement cannot be varied except in writing by an Authorised Signatory. This Agreement encompasses the whole accord reached between the parties.

- b) Each party agrees that it has not relied on and shall have no remedies in respect of any representations or warranties (whether made innocently or negligently) that are not set out in the Agreement. Each party agrees that its only liability in respect of those representations and warranties that are set out in the Agreement (whether made innocently or negligently) shall be for breach of contract.
- c) Nothing in this Clause 3 is intended to exclude liability for fraud.

#### **4. WAIVER**

No single nor repeated waiver for any period of time by either party of any of its rights hereunder shall prejudice its ability to enforce any other rights accrued or accruing under this Agreement.

#### **5. SPECIFICATION, DESCRIPTION, SAMPLE**

- a) The Works shall be in conformity with the specifications, drawings, samples or any other description or descriptions of the Works contained or referred to in this Agreement and shall fulfil and comply with any representation made by the Contractor, its agent, sub-contractor, or employees in respect thereof.
- b) It shall be a condition of sale that the Contractor has the right to sell the goods, that the goods are free from any third party encumbrance, that the Buyer shall enjoy quiet possession of the goods and, without affecting the generality of the foregoing, that the Buyer shall have the right to use the goods for any purpose of which the Contractor is, or should be reasonably aware without interference from any third party on the grounds of infringement of any rights in industrial property.

#### **6. QUALITY**

- a) The Works shall be of merchantable quality and free from defects in material or workmanship.
- b) The Contractor will carry out the Works with all due care and attention and in accordance with Good Practice and with applicable laws, regulations, orders, governmental requirements and industry guidelines.
- c) The Contractor will promptly notify the Buyer of any (i) quality deviations, (ii) any deliverable falling outside of specification, or an event which could lead to a deliverable not meeting specification; or (iii) any other occurrence which could or does result in an out of scope deliverable.

#### **7. FITNESS FOR PURPOSE**

The Works shall be fit and sufficient for the purpose(s) for which they were intended, as were expressly made known to the Contractor, or could reasonably have been inferred by it.

#### **8. QUALITY ASSURANCE AND GOOD MANUFACTURING PRACTICE**

- a) The Contractor shall comply with the principles and guidelines of Good Industry Practises in the performance of the Services and where applicable, Good Manufacturing Practice (GMP) set out in Commission Directive 2003/94/EC (implemented by The Medicines (Standard Provisions for Licences and Certificates) Regulations 1971 and as may be amended from time to time).
- b) The Contractor shall ensure that all personnel employed by it to perform the Works shall have received and shall continue to receive appropriate training by qualified persons in the theory and application of the concept of quality assurance and Good Industry Practises, and where applicable GMP (if applicable) and in the provision of calibration and maintenance services and shall have the necessary qualifications and practical experience in the provision of such services. Upon request,

the Contractor shall provide the Buyer with appropriate evidence of the Contractor's compliance with this subclause.

## **9. ORGANIZATION OF EVENTS**

- a) The event shall be held in locations appropriate for the event and for the number of participants as determined by the Buyer. The agency entrusted with the organization of the event shall ensure that all sites for meetings (including without limitation buildings, surrounding grounds and related facilities) comply with the applicable laws and that all required permits and other certificates have been obtained.
- b) The agency shall comply with all indications and timeframes specified in the the Buyer Purchase Order and shall follow the Buyer's instructions. Furthermore, if required, the agency shall, for the benefit of the Buyer, enter into agreements in its own name and for its own account with third parties for the organization of the event and shall use best efforts to negotiate reasonable commercial terms with such third parties (including without limitation price and cancellation conditions) in accordance with the applicable laws, the Buyer policies communicated to the agency and with the requirements of these General Terms and Conditions. Prior to his contracting with any third party, the Buyer may request from the Contractor a list of these third parties. In this case, the Buyer shall have the right to oppose to the use by the Contractor of such third party. The agency shall coordinate with the Buyer on a regular basis. The Buyer's Purchase Order shall specify the detailed budget for the services to be provided for the organization of the event, including the cost related to the services of any third party contracted by the Contractor for the organization of the event.
- c) All services to be performed by the Contractor (including without limitation any invitations, registration packets or any other communication of any type with invitees) shall require the prior written approval of the Buyer prior to any distribution. The agency shall at all times act in accordance with the Buyer's requirements and policies communicated to the agency.

## **10. CREATION/PRODUCTION OF PROMOTIONAL MATERIAL AND PUBLIC RELATIONS SERVICES**

- a) All promotional materials to be provided to the Buyer by the Contractor shall be subject to written approval by the Buyer's Medical/Legal department prior to any use. Promotional materials to be provided by the Contractor which will be distributed by the Buyer and which refer to the Buyer products or therapeutic classes in which the Buyer has products must comply with the applicable laws and regulations on the promotion of medicinal products. Said laws and regulations require that all labeling and promotional material be consistent with the information contained in the scientific product circular of the product concerned. These regulations also impose many other restrictions regarding labeling and promotion of medicinal products.
- b) Any public relations services to be provided to the Buyer by the Contractor shall be carried out by the Contractor subject to prior written approval by the Buyer's Medical/Legal department. Public relations materials to be provided or distributed by the Contractor on behalf of the Buyer need to be pre-approved by the Buyer.
- c) For the reasons set forth under paragraphs (a) and (b), the Buyer may impose and the Contractor shall implement any additions, deletions or modifications in order to comply with any regulations and other medical and/or legal considerations. The Buyer also reserves the right to make and/or request changes that enhance editorial flow and style and lend precision to expression. It is therefore possible that several drafts or rough cuts may be required to secure the Buyer's approval. These drafts and any work associated herewith shall not result in any additional payments due under the Buyer Purchase Order. Payment for any such drafts is included as part of the price set forth in the Buyer Purchase Order.
- d) The Contractor represents and warrants that he has a working knowledge of applicable scientific product package circulars of the Buyer, of the laws and regulations, as well as of the Buyer policies on promotion of medicinal products.
- e) The Contractor shall secure from its staff and/or any third parties all necessary written consents, authorizations, approvals and releases for use of the promotional/public relations material by the Buyer worldwide in any media, including but not limited to rights for use on the Internet, now known or later developed. Except where promotional/public relations material is developed by the Buyer and where applicable intellectual property rights are in the public domain, the Contractor shall obtain such rights with respect to trademarks, copyrights, patents, personal or contractual rights, music, drama, literary, artistic, or similar works or rights which may be necessary for the worldwide production and use by the Buyer of the promotional/public relations materials developed by the Contractor pursuant to the Buyer Purchase Order, including without limitation authors and publishers.

- f) In addition, the Contractor shall secure written consents, authorizations, approvals and releases from any person who is not an employee of the Buyer whose voice, image or name is to be used in any part of the promotional material in view of the worldwide use of this material by the Buyer. If the Contractor is unable to obtain such valid and binding written consent of the persons referred to above prior to final production of the materials, the Contractor must notify the Buyer hereof on beforehand in writing. Copies of any consents, authorizations, approvals and releases provided for in this paragraph shall be provided to the Buyer upon request.
- g) During the period in which the Contractor renders services to the Buyer, the Contractor shall not contemporaneously render services to third parties relating to the same product category or disease area for which it is rendering services to the Buyer.

## **11. CHANGE OF PERSONNEL**

- a) The Contractor is responsible for maintaining reasonable continuity in personnel providing the Works on its behalf, but reserves the right to make changes from time to time. Where substitution of personnel occurs:
  - i. no additional charge will be made for any handover period, and the Contractor remains responsible for Works performed by any individual on its behalf;
  - ii. where the Contractor's charges are on a time and materials basis, it is the Contractor's responsibility to ensure that the relevant skills and experience of any replacement personnel remain commensurate with the fee rates charged;
  - iii. the terms of this Agreement and in particular (but not limited to) the Contract Price and timetable of the project, will remain unchanged, unless otherwise agreed by the parties in writing;
  - iv. the Contractor shall ensure that any substitute personnel shall have the necessary qualifications and experience to fulfil the obligations pursuant to this Agreement; and
  - v. the Contractor acknowledges that the Buyer has the right to refuse to accept the substitute personnel in the event of non-compliance with this clause.
- b) In the event that the Contractor cannot provide either the original personnel or acceptable substitute personnel, the Buyer is entitled to terminate this Agreement immediately.

## **12. PRICE**

- a) The Contract Price shall be a fixed price unless otherwise agreed in writing as between the Buyer and the Contractor (when the Buyer's order is placed). The Contract Price shall not be increased by the Contractor (whether following an increase in the cost of labour or materials or otherwise) unless the Buyer, at its absolute discretion, expressly agrees in writing in advance to such increase.
- b) In addition to the Contract Price, the Contractor may charge the Buyer for agreed expenses providing such expenses are:
  - i. reasonably and properly incurred by or on behalf of the Contractor;
  - ii. invoiced by the Contractor at cost; and
  - iii. the Contractor obtains the Buyer's written approval before incurring any such costs or expenses. Invoices issued by the Contractor to the Buyer covering reimbursement of expenses must be accompanied by relevant receipts.
- c) Further to the provisions of Clause 12(b) (iii), the Contractor agrees to provide and will procure that any third party agency it may work with provides, in the performance of its obligations under these terms, copies of all expenses and pass-through costs related to air travel, local transportation, hotel accommodation, meals, catering and any other travel or hospitality related costs or expenses. The Contractor shall maintain and shall procure that the third parties it works with so maintain all records in accordance with generally acceptable accounting practices.
- d) The Contractor agrees that payment of pass-through costs and expenses submitted for payment without the required information and copies of pass-through costs may be withheld or delayed until the required information has been provided.

- e) The Contractor agrees that for purposes of this Agreement, and its collaboration with the Buyer, that the Buyer will handle all contractual arrangements with Health Professionals. To this end, neither the Contractor nor any of its third party contractors, will contract with any Health Professional for any Transfer of Value.

### **13. PAYMENT**

- a) The Buyer shall pay for the Works within 90 days of the date of receipt of a properly prepared invoice.
- b) Payment for the Works shall only be made against a valid invoice submitted by the Contractor.
- c) All invoices should contain the following information:
  - i. the amount due, net of Value Added Tax (VAT);
  - ii. the amount of VAT payable;
  - iii. the rate of VAT chargeable;
  - iv. any further information required to ensure the invoice is a valid VAT invoice;
  - v. the relevant purchase order number issued by the Buyer.
- d) The Buyer will be entitled to return any invoice and withhold payment of the Contract Price and/or any other amounts charged by the Contractor to the Buyer until an invoice complying with the requirements of this clause is presented to it.
- e) The Buyer may elect to pay for the Works using its corporate payment card (e.g. American Express). Such payment may be made at the point of ordering with the Contractor. The Contractor will supply valid VAT receipts in respect of any such payments.

### **14. DELIVERY**

- a) The Works must be delivered carriage paid to such destination as the Buyer may direct in the Buyer's order. Where applicable, delivery shall be subject to any special conditions or requirements agreed between the parties. If the Works are incorrectly completed the Contractor shall be liable for any additional expense incurred in delivering them to their correct destination.
- b) The Buyer may postpone delivery by informing the Contractor at any time before delivery.

### **15. RISK OF LOSS OR DAMAGE**

- a) Subject to the express provisions of clause 15(b) below, the property and risk in the Works shall remain with the Contractor until they are completed and accepted by the Buyer at the point specified in the Buyer's order.
- b) If the Agreement provides for payment by the Buyer of part of the agreed Contract Price at any time before any work hereunder is commenced by the Contractor and/or if the Buyer pays for the Works or materials being prepared, procured, manufactured, assembled or produced by any means whatsoever whether at the premises of the Buyer, Contractor or any sub-contractor or elsewhere and/or if the Buyer pays part of the agreed Contract Price at various times or stages during the Agreement (whether such payments are made in advance or arrears of given stages in the fulfilment of the Agreement) then such payments are to be regarded as part payments and not deposits of the agreed Contract Price and the property in these Works and materials shall pass to the Buyer upon making the first agreed payment.
- c) Insofar as the property in the Works and materials as set out in 15(b) pass to the Buyer upon making the agreed payment the risk in these goods and materials shall remain with the Contractor until completed and accepted as specified in the Agreement.

## **16. TIME**

- a) The date of completion of the Works shall be that specified in the Buyer's Purchase Order unless otherwise agreed in writing between the Buyer and the Contractor. The Contractor shall furnish such programmes of manufacture, delivery and completion as the Buyer may reasonably require and the Contractor shall give notice in writing to the Buyer as soon as is practicable if such programmes are, or are likely to be, delayed.
- b) Unless otherwise specified by the Buyer, time shall be of the essence.

## **17. INSURANCE**

- a) During the term of this Agreement and for a period of not less than five (5) years thereafter the Contractor shall have in place insurance cover for such risks and for such amounts as a reasonable insurance broker advising a business providing the Works to the Buyer would consider prudent. Unless otherwise agreed in writing by the Buyer, this insurance cover shall include, but not be limited to, Public and Product Liability cover of not less than €5 million, Employers Liability cover of not less than €10 million, and Professional Liability of not less than €1 million.
- b) The Contractor shall deliver to the Buyer, within seven days of the commencement of this Agreement and on request during the Agreement, Certificates of Insurance as evidence that policies providing such coverage and limits of insurance are in full force and effect and with insurers with an AM Best rating of A- or better. The Contractor shall provide not less than thirty (30) calendar days advance notice in writing to the Buyer of any cancellation, termination, or material alteration of said insurance policies.
- c) The Contractor's obligations under this clause 17 shall survive the termination of this Agreement.

## **18. INTELLECTUAL PROPERTY RIGHTS**

- a) Subject to clause 18(b) below the Contractor warrants and represents that the Contractor has the right to use the relevant intellectual property rights in the Works for this Agreement and that the Works will not infringe intellectual property rights of third parties.
- b) Title to and ownership of the Works and any related trademark, copyright or any other intellectual property rights arising out of the Works shall remain the exclusive property of the Buyer. The Contractor hereby agrees to assign all such intellectual property rights to the Buyer absolutely and to execute all documents required to give effect to this intention. For the avoidance of doubt, any such intellectual property rights which belonged to either party or any third party hereto prior to the commencement of this Agreement shall remain the property of that party. The Contractor hereby irrevocably grants to the Buyer for the duration of this Agreement, all licences and permissions, express or implied, necessary for the operation of this Agreement.

## **19. CONTINGENCY PLANNING**

- a) Throughout the term of this Agreement the Contractor must have in place reasonable contingency and disaster planning arrangements designed to minimise any interruption or disruption to the provision of the Works including interruptions and disruptions caused by the loss, damage or destruction of any premises, equipment, infrastructure or records.
- b) The contingency and disaster planning arrangements referred to in clause 19.(a) must be reasonably satisfactory to the Buyer and the Buyer and its representatives may inspect and take copies of the information referred to in clause 19.(a) upon giving 5 (five) days' notice.

## **20. FORCE MAJEURE**

Neither the Contractor nor the Buyer shall be liable to the other for any failure to fulfil its obligations under the Agreement if such a failure is caused by circumstances beyond its reasonable control in which event the obligations of the failing party shall be suspended for the period during which such force majeure operates, provided that

reasonable efforts have nonetheless been made by them to fulfil their obligations under the Agreement, and provided further that the suspended obligations are fulfilled as soon as possible after the force majeure ceases to so operate.

## **21. REJECTION**

- a) If any of the Works does not comply with the purchase order or with any term of this Agreement including quantity, quality or description, the Buyer shall be entitled to reject those Works at any time after delivery or completion irrespective of whether the Buyer has accepted them or made payment for them. Any acceptance of such Works by the Buyer shall be without prejudice to any rights that the Buyer may have against the Contractor, including but not limited to those set out in clause 21(b).
- b) In the event of rejection of Works under clause 21(a), the Buyer may at its absolute discretion;
  - i. seek recovery of sums paid to the Contractor in respect of the rejected Works as a debt, or
  - ii. seek alternative Works from the Contractor which alternative shall in all respects comply with the terms of clauses 5, 6 and 7 hereof, or
  - iii. replace the rejected Works with works carried out by another in accordance with the Agreement as near as practicable to the same specifications as circumstances shall permit. As appropriate the Buyer shall be entitled to return any rejected Works, carriage forward, to the Contractor at the risk of the Contractor.

## **22. NON DELIVERY**

If the Contractor does not complete the Works or any part thereof within the time specified in the Buyer's Purchase Order the Buyer shall be entitled to terminate the Agreement forthwith, complete the Works to the same or similar description to make good such default and recover from the Contractor the amount by which the cost of obtaining such replacement Works exceeds the price which would have been payable to the Contractor in respect of the Works so replaced without prejudice to any other remedy at law.

## **23. LIABILITY AND INDEMNITY**

- a) Without prejudice to any other remedy which the Buyer has against the Contractor, any defective parts, materials or workmanship which shall appear within a period of twelve months following acceptance of the Works shall be replaced or made good by the Contractor at its own expense within a reasonable time of written notification of such by the Buyer.
- b) Nothing in clause 23(a) above shall prejudice the right of the Buyer to enforce any remedy at law which the Buyer may have as against the Contractor for breach of the Agreement
- c) The Contractor shall indemnify the Buyer against all claims, costs, expense, loss or damage (including legal fees and expenses) whether direct or consequential which the Buyer may suffer arising from (1) the supply of the Works to the extent that such claim arises out of the breach, negligent performance or failure or delay in performance of this Agreement by the Contractor, its agents or subcontractors; or arising from (2) any actual or alleged infringement of a third party's intellectual property rights or other rights arising out of, or in connection with, the supply or use of the Works.
- d) Nothing in this clause shall render the Contractor liable for any claim, cost, expense, loss or damage caused by the wrongful act or omission of the Buyer.
- e) To the fullest extent permissible by law, the Buyer shall not be liable for any loss of revenue, anticipated savings, profits, data or for damage to property or for any indirect or consequential loss howsoever arising whether from negligence, breach of contract or otherwise.
- f) Nothing in this Agreement shall limit or exclude liability for death or personal injury resulting from negligence, liability for fraud or liability for any matter for which it would be illegal to exclude or attempt to exclude liability.

## **24. TERMINATION**

- a) The Agreement can be terminated immediately on written notice by or on behalf of the Buyer to the Contractor if the Contractor ceases to conduct business in the normal course, becomes insolvent, makes a general assignment for the benefit of its creditors, suffers or permits the appointment of a Receiver for its business or assets or becomes subject to any proceedings in bankruptcy or for the protection of the rights of its creditors.
- b) Where the Buyer advances monies as a part payment under clause 15(b) then the Contractor shall keep such monies in a separate, distinct and identifiable account in order that should any circumstance outlined in clause 21(a) above occur the Buyer shall be entitled to the immediate return of any such monies unencumbered and without any charge or other lien attaching to it.
- c) Should the Contractor cease to conduct business in the normal course and/or in any of the circumstances as set out in clause 24(a) the ownership and copyright and any other proprietary rights of any computer program(s) and the relevant source code and any other ancillary code pertinent to the usual use of the program(s) and any other propriety right associated with the program(s) in which the Buyer has an interest arising out of this Contract shall vest absolutely in the Buyer forthwith. The Contractor undertakes to execute all necessary documents to give effect to the intention of this sub clause.
- d) The Buyer may terminate this Agreement at any time on giving thirty (30) days' notice. The Contractor shall be entitled to be reimbursed for reasonable expenditure incurred in the execution of this Agreement for work performed on submission of satisfactory proof of such expenditure. Any work shall be the property of the Buyer on payment. Partial payment for incomplete Works shall be at the absolute discretion of the Buyer.
- e) Any licences that the Contractor has under this Agreement to use any intellectual property rights belonging to the Buyer or any of its group companies will immediately end when this Agreement is terminated and this shall include the Contractor's right to supply any products that use or are marked with that intellectual property.
- f) Following the termination of this Agreement the Contractor must immediately return to the Buyer or destroy at the Buyer's request:
  - i. all the property in its possession or under its control that belongs to the Buyer and its group companies; and
  - ii. all copies of any materials and records of any kind that are in its possession or under its control (and in any medium) that contain any part of the Buyer's confidential information except that the Contractor may retain a copy of any confidential information that it reasonably requires for its accounting purposes or to comply with any applicable laws.
- g) Termination of this Agreement does not affect the accrued rights and liabilities of the parties or the enforceability of clauses 17, 18, 21, 23, 24, 27, 31, 32 and any other provisions of this Agreement that are intended to remain in force after its termination.

## **25. PARTIAL INVALIDITY**

If any provision or portion of this Agreement is held to be invalid under any applicable statute or rule of law, it is to that extent to be deemed omitted from the Agreement and shall not affect the validity of the remaining terms and conditions of the Agreement which shall be interpreted as though the invalid clauses did not appear.

## **26. HEADINGS**

The headings used in this Agreement are for convenience only and are not in any way intended to affect the construction of any clause, right or obligation contained in this Agreement.

## **27. CONFIDENTIALITY**

- a) In the course of work done by the Contractor for the Buyer under the terms of this Agreement (including the negotiation of this Agreement) the Buyer may disclose to the Contractor certain confidential information which both parties hereto acknowledge constitutes a valuable trade asset of the Buyer.

- b) The Contractor, its employees, agents or sub-contractors will treat all such information as confidential, will not disclose any information to any third party without the prior written consent of the Buyer and will take all reasonable steps to prevent any such disclosure. The Contractor undertakes not to use any information for the benefit of any third party.
- c) The obligation of confidentiality set out here shall not apply to information which the Contractor is able to prove was already known to him, or information subsequent to disclosure by the Buyer comes into the public domain other than through breach of any duty of confidentiality.
- d) This duty of confidentiality shall survive any termination of this Agreement for a period of ten (10) years from the date of termination.
- e) If in the performance of duties under this Agreement the Contractor utilises any information expressed by the Buyer to be confidential then the Contractor or any body corporate or personal who becomes responsible for the obligations of the Contractor shall not sell, transfer or otherwise deal in any right which he may have in the Works without the Buyer's written consent (such consent not to be unreasonably withheld by the Buyer).
- f) In the event that the party receiving any confidential information is required by judicial or administrative process to disclose any or all of the information, said party shall promptly notify the disclosing party and allow the disclosing party a reasonable time and opportunity to oppose such process before disclosing any information.
- g) Notwithstanding anything in this Agreement, the Buyer shall have the right to disclose any information to a regulatory agency (including but not limited to quality audit reports relating to the Contractor) to the extent required or requested by such agency in connection with any regulatory filing, inspection or otherwise.

## **28. ASSIGNMENT AND SUB CONTRACTING**

- a) The Contractor shall not assign or sub-contract the whole or any part of the Agreement without the prior written consent of the Buyer. Notwithstanding any written agreed assignment or sub contract, the Contractor shall be responsible for all work done and for all materials, goods and equipment supplied by him and by all subcontractors and assignees appointed by him.
- b) The terms and conditions of this Agreement shall be binding upon, and shall inure to the benefit of, the parties hereto and their respective successors and permitted assigns.

## **29. NOTICES**

Any notice required to be served by either party on the other shall be served at the addresses set out on the Buyer's Purchase Order or as otherwise notified by one party to the other.

Notice shall be effective (i), in the case of service by post, at the expiration of two business days after the day of unreturned posting; (ii) in the case of personal delivery, when it is delivered or (iii) in the case of service by email, at the time of transmission. Unless otherwise agreed in writing between the parties, no other form of notice shall be effective as between the parties.

## **30. COUNTERFEIT, DIVERSION OR TAMPERING**

- a) Notifications or concerns of suspected Counterfeit, Diversion or Tampering ("CDT") events are to be reported by email to [cdt.global@organon.com](mailto:cdt.global@organon.com) [cdt.emea@organon.com](mailto:cdt.emea@organon.com) within one (1) business day. ORGANON's Counterfeiting Director and Regional Security Director will make the decision to open a suspect CDT investigation and ORGANON's Global Security Group and/or local legal representative will perform any necessary government agency notifications for confirmed CDT events, in collaboration with the Contractor.
- b) Contractor should also notify ORGANON of events involving major product losses or product thefts via email to [cdt.global@organon.com](mailto:cdt.global@organon.com) [cdt.emea@organon.com](mailto:cdt.emea@organon.com) and utilize ORGANON's Global Security Group as a resource for investigative and intelligence issues.

## **31. PUBLICITY**

The Contractor shall not advertise or otherwise make known to others the existence or the terms of this Agreement or that the Contractor is providing Works to the Buyer. Moreover, the Contractor shall not use or reference in any

advertising, sale promotion, press release or other communication, and the Buyer company, product, or representative name, endorsement, direct or indirect quote, code, drawing, logo, trademark, trade name, specification, or picture without the prior written consent of the Buyer.

### **32. RIGHT OF AUDIT**

Information in the Contractor's files that relates to the business of the Buyer, including but not limited to, invoices received from suppliers, payment of third party invoices, time records of the Contractor covering billing for work on an hourly basis authorised in writing by the Buyer, expense records covering costs billed to the Buyer, and any other source documents and supporting evidence necessary to substantiate charges related to this Agreement shall be open for inspection and examination by an authorised representative of the Buyer at all reasonable times provided that the Buyer gives reasonable prior notice. All examinations of records shall take place at the site at which the records are regularly kept and shall be at the Buyer's sole expense. For the purpose of such audits, inspections, examinations and evaluations, the Buyer or its authorised representative shall have access to said records beginning on the date of this Agreement and continuing until five (5) years after the completion of all Works subject to this Agreement.

### **33. PROPER LAW & FORUM**

This Agreement shall be governed by the laws of Ireland. Each of the parties to this Agreement irrevocably agrees that the courts of Ireland are to have exclusive jurisdiction to settle any dispute arising out of or in connection with this Agreement and, for such purposes, irrevocably submits to the exclusive jurisdiction of such courts. Any proceeding, suit or action arising out of or in connection with this Agreement (the "Proceedings") shall therefore be brought in the courts of Ireland. Each of the parties to this Agreement irrevocably waives any objection to Proceedings in the courts referred to in this clause 33 on the grounds of venue or on the grounds of *forum non conveniens*.

### **34. ETHICS/CONFLICT OF INTEREST**

- a) In its performance of this Agreement the Contractor shall adhere to business practices that are in accordance with the letter and spirit of applicable laws and ethical principles as follows:
  - i. All transactions in connection with this Agreement shall be accurately reflected in the Contractor's records, and no funds or other assets shall be paid directly or indirectly to government officials, Healthcare Professionals or persons acting on their behalf or to representatives of the other businesses for the purpose of influencing government decisions or actions with respect to the Buyer's business
  - ii. The Contractor shall conduct its activities hereunder so as to avoid loss or embarrassment to the Buyer due to any real or apparent conflict of interest, and to require that all sub-contractors comply with such policy in connection with this Agreement.
  - iii. The Buyer shall have the right to terminate this Agreement, without any penalty or obligation to pay damages, upon violation of the business practices mentioned in this clause by the Contractor, its employees, agents, representatives, sub-contractors or consultants.
- b) The Buyer endeavours to hold itself and its Contractor to the highest ethical and compliance standards, including basic human rights, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. Without limiting any of the Contractor's other obligations hereunder, and without conflicting with or limiting any of the warranties, obligations or other provisions expressly set forth elsewhere in this Agreement, including without limitation its obligations under hereof, the Contractor agrees that it will abide by the letter and spirit of the Buyer's Business Partner Code of Conduct (the "Code"), as in effect from time to time, a copy of which is available at [https://www.organon.com/wp-content/uploads/sites/2/2021/05/Business-Partner-Code-Of-Conduct\\_v1.pdf](https://www.organon.com/wp-content/uploads/sites/2/2021/05/Business-Partner-Code-Of-Conduct_v1.pdf)
- c) The Contractor agrees that it will provide all documentation reasonably requested by the Buyer to demonstrate compliance with the Code. In the event of a conflict between the obligations in this clause 34 and the Code, on

the one hand, and any other provision in this Agreement, on the other hand, such other provision of this Agreement shall control (but only to the extent of the conflict).

- d) The Buyer reserves the right, in its sole discretion, to audit the Contractor's operations, books and records to ensure compliance with the Code. The Buyer will provide reasonable advance notice of such an audit, and may conduct this audit on its own or using a third-party auditor of its choosing. The Contractor shall acknowledge receipt of the Buyer's notice as promptly as practicable after receipt of such notice and will confirm the date on which the audit will occur within 14 days after receipt of such notice. The Buyer or its third-party auditor may interview the Contractor's employees as part of or in connection with the audit. This audit right shall be in addition to any other audit rights granted in this Agreement.
- e) In the event an audit identifies a non-conformance by the Contractor with the Code, the Contractor will promptly take corrective action to remedy the non-conformance. The Buyer reserves the right to approve all corrective actions. Corrective actions shall be implemented by the Contractor at the Contractor's expense. The Buyer will endeavour, whenever practicable, to work with the Contractor to remedy the issue and put in place a corrective action plan.
- f) In the event the Contractor refuses to allow an audit, or fails or refuses to take corrective action, then in addition to any other remedy available to it under this Agreement, at law or in equity, the Buyer reserves the right to terminate this Agreement in the event the Contractor fails to cure such refusal or failure within 90 days after written notice from the Buyer.

Without limiting any of the Contractor's other obligations under this Agreement, the Buyer expects that the Contractor will abide by the letter and spirit of the Buyer's Supplier Performance Expectations (<https://www.organon.com/wp-content/uploads/sites/2/2021/04/Organon-Supplier-Performance-Expectations.pdf>) and Business Partner Code of Conduct (the "Code"), copies of which are available at [https://www.organon.com/wp-content/uploads/sites/2/2021/05/Business-Partner-Code-Of-Conduct\\_v1.pdf](https://www.organon.com/wp-content/uploads/sites/2/2021/05/Business-Partner-Code-Of-Conduct_v1.pdf) in its performance of the Agreement.

### **35. RELATIONSHIP BETWEEN THE PARTIES**

- a) The Contractor is engaged as and shall be at all times an independent contractor and the Contractor shall in no sense be considered an employee or an agent of the Buyer, and shall not therefore be able to bind the Buyer in any way nor be entitled or eligible to participate in any benefits, privileges or plans given or extracted by the Buyer to its employees.
- b) The Contractor will not in any way bring into disrepute the business or reputation of the Buyer.

### **36. EXCLUDED ENTITIES**

- a) For the purpose of this clause 36:
  - i. A "Violation" shall mean that either the Contractor, or any of its officers, directors, Key Employees or Key Sub-contractors has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (<http://oig.hhs.gov/fraud/exclusions/authorities.asp>); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<http://oig.hhs.gov/fraud/exclusions.asp>) or the U.S. General Services Administration's list of Parties Excluded from Federal Programs or (3) listed by any US Federal agency as being suspended, debarred, excluded, or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a ( FDA Debarment List (Drug Product Applications) | FDA) (each of (1), (2) and (3) collectively the "Exclusions Lists").
  - ii. A "Key Employee" shall mean any employee of the Contractor who performs any work in connection with the Works.
  - iii. A "Key Sub-contractor" shall mean any individual or other entity which, as a subcontractor or agent of the Contractor, performs any work in connection with the Works.

- b) The Contractor represents and warrants that prior to the date of this Agreement, it has screened itself, and its officers, directors Key Employees or Key Sub-contractors against the Exclusions Lists and that it has informed the Buyer whether it or any of its officers or directors has been in Violation. After the execution of the Agreement, the Contractor shall notify the Buyer in writing immediately if any such Violation occurs or comes to its attention. If a Violation exists with respect to any of the Contractor's officers, directors, Key Employees, or Key Sub-contractors, the Contractor shall promptly remove such individual(s) or entities from performing any service, function or capacity related to the Works. The Buyer shall also have the right, in its sole discretion, to terminate this Agreement immediately in the event of any such Violation.

### **37. DATA PRIVACY AND SECURITY**

- a) Each party shall comply with Data Protection Law in connection with its obligations under this Agreement. For the purposes of this Clause, "Data Protection Law" means any applicable data protection or privacy laws to which either party, as applicable, is subject in connection with this Agreement.
- b) The parties represent and warrant that in the event that either party provides personal data to the other party, including, without limitation, any individually identifiable health information, the party providing the personal data represents and warrants that it has obtained all necessary consents, approvals and authorisations to provide the personal data to the receiving party, and it is not violating any laws, rules or regulations, or the rights of any individual or entity, by providing such personal data. Upon request by the receiving party, the providing party shall provide documentation of any applicable consents, approvals and authorizations.
- c) No personal data, other than the personal data necessary for the Contractor to carry out the Works hereunder, shall be provided by the Contractor to the Buyer under this Agreement.
- d) Data Integrity: Any documentation or data relevant to activities performed, must be attributable, original, accurate, legible, complete, controlled, retrievable, and safe from intentional or unintentional manipulation, loss or unauthorised access. This applies to all documents or data under this agreement, including without limitation those activities or services performed under current GCP, GMP, GDP and other applicable good practice standards. These items are required throughout the retention period of such data / documentation, and the Contractor warrants that it will maintain such protection throughout this period.

### **38. USE OF WOOD PALLETS IN SHIPMENTS**

- a) This clause shall apply only to the supply of GMP materials or products that will be used by the Buyer in manufacturing; wood pallets; and/or non-GMP materials or products where the Buyer has notified the Contractor in advance that compliance with this clause is required.
- b) The Contractor expressly agrees and represents, warrants and covenants that any shipment to a Buyer site or location using wood pallets shall only be done if the wood pallets meet the following criteria:
- i. Certified heat treated wood pallets, in accordance with the International Standards for Phytosanitary Measures (ISPM) 15 "Regulation of Wood Packaging Materials in International Trade", developed by the International Plant Protection Convention (IPPC), as amended; provided, however, that nothing herein or therein shall permit the use of any chemical on wood pallets to be supplied to the Buyer.
  - ii. No additional chemical treatments have been used on such wood pallets, including, but not limited to Methyl Bromide.
  - iii. Contain the heat-treatment certification (stamped "HT"), the country of origin two-letter designator, the regional identifier and a registration number in accordance with ISPM, and such stamp, designator and number will be located on the wood pallet to allow the Buyer to visually inspect the wood pallet, upon receipt.
- c) The Buyer reserves the right to reject any shipment that does not meet the aforementioned criteria and any costs associated with the rejection of such shipment due to a failure to meet these criteria shall be for the sole cost and expense of the Contractor.

**39. TRADE SANCTIONS COMPLIANCE**

The Contractor agrees that no products or technical data supplied under this Agreement will be exported, reexported, sold, distributed, or otherwise transferred to any legal entity listed on a U.S. or EU denied parties list, or any other denied parties list issued by another jurisdiction which is applicable to the products or technical data supplied under this Agreement, as notified by the Buyer to the Contractor from time to time, all of the foregoing collectively referred to as “Denied Parties Lists”, or to any individual person listed on an EU denied parties list. As of the date of this Agreement, the U.S. Denied Parties Lists consist of the U.S. Treasury Department’s List of Specially Designated Nationals and Blocked Persons (<https://www.treasury.gov/ofac/downloads/sdnlist.pdf>), the U.S. Commerce Department’s Denied Persons List (<http://www.bis.doc.gov/dpl/thedeniallist.asp>) and Entity List (<http://www.bis.doc.gov/entities/default.htm>), and the EU denied parties list consists of the Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions ([http://eeas.europa.eu/cfsp/sanctions/consolist\\_en.htm](http://eeas.europa.eu/cfsp/sanctions/consolist_en.htm) Instructions to access EU financial sanctions database.pdf ).

**40. PACKAGING, IMPORT AND EXPORT**

- a) The Contractor shall comply with the specifications and all applicable standards and legal and regulatory requirements concerning the design, manufacture, processing storage, testing and packaging of the Works.
- b) The Works shall be marked in accordance with the Buyer’s instructions or the Buyer’s specifications and all lawful requirements and shall be properly packed and secured for delivery to the Buyer in an undamaged condition.
- c) If the Contractor is to export the Works into the Republic of Ireland the Contractor shall ensure that the goods are not packaged in hay, straw, peat moss or litter. The Contractor shall in addition promptly obtain all necessary export and import licences, clearances and other consents necessary for the export and supply of the Works.
- d) Contractor shall ensure that any materials required by this order that are deemed hazardous will be packaged, marked and shipped by Contractor in a manner which complies with all regulations governing the transport, packaging and supply of such hazardous materials.

Signed by Contractor (name & address): \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Signature: \_\_\_\_\_

Date & Place: \_\_\_\_\_