

TERMS and CONDITIONS

This document sets out the terms and conditions of trade (**Conditions**) between Organon Pharma Pty Limited (**Organon**) and any person or corporation supplying Goods and/ or Services to Organon.

(Revised 16 October 2023).

1. In these Conditions:

- (a) "Blanket Order" means an Order that provides for the supply of Goods and/or services up to a maximum amount specified by Organon and under which Organon may place in individual Orders as and when required.
- (b) "Confidential Information" means all information in whatever form relating to the business or the affairs of either party which is provided by either party to the other or which otherwise becomes known to either party in connection with an Order, including (without limitation) information relating to either party's business operations, technology, finances, products and any information of a third party that is in either party's possession.
- (c) "Delivery Address" means the ship to address specified in an Order or otherwise notified to Supplier by Organon
- (d) "Goods" means the goods described in an Order in the quantity(ies) specified in an Order.
- (e) "Intellectual Property Rights" means all copyright, inventions (including patent), plant varieties, registered and unregistered trademarks (including service marks), registered and unregistered designs, pdfs, films and plates, confidential information (including trade secrets and know how), circuit layouts and other rights resulting from any intellectual activity in the industrial, scientific, literary or artistic fields.
- (f) "Organon" means Organon Pharma Pty Limited and any related body corporate (within the meaning of the Corporations Act 2001).
- (g) "Order" means an order by Organon for the supply of Goods and/or Services from the Supplier by a document, of which these Conditions form part, or otherwise notified by Organon to Supplier.
- (h) "Order Number" means the number assigned to the Order by Organon and shown in the Order.
- (i) "Price" means (unless otherwise specified in the Order) the total price of Goods and/or Services specified in an Order in Australian dollars, inclusive of packaging, packing, handling, freight, goods and services tax (GST), insurance, delivery of the Goods to the Delivery Address and all other duties, levies and charges.
- (j) "Supplier" means the seller of the Goods or Supplier of the Services specified in an Order.
- (k) "Services" means the services described in an Order.
- (l) "Tax Invoice" has the meaning given in the *A New Tax System (Goods and Services Tax) Act 1999*.

2. Unless an Order provides otherwise:

- (a) the Order and the sale and delivery of Goods and/or Services thereunder shall be governed by these Conditions.
- (b) Organon shall pay the Supplier the Price within Ninety (90) days from the end of the month in which the Supplier's invoice is received, subject to clause 2(c) below.
- (c) Organon is not obliged to pay the Supplier for any part of the Goods and/or Services until the Supplier has:
 - (i) given Organon a correctly rendered Tax Invoice; and
 - (ii) delivered to Organon any Goods and/or Services due to be delivered
- (d) the Order Number must be clearly marked on all documents and invoices relating to the Order; and
- (e) discounts must be shown on the face of the Supplier's invoice.

3. Supplier warrants that:

- (a) all Goods supplied to Organon pursuant to these Conditions are new and in an unused condition;
- (b) the Goods are acceptable in appearance and finish;

- (c) the Goods are safe and durable;
 - (d) the Goods are fit for the purpose for which goods of the same kind are commonly supplied and/or for any other purpose made known by Organon to the Supplier;
 - (e) the Goods are free from all defects in design, materials and workmanship;
 - (f) where the Goods and/or Services are sold by reference to a specification, drawing, description or sample, they will conform to such specification, drawing, description or sample. Any inspection by Organon will not affect this requirement;
 - (g) the Goods and/or Services will comply with all relevant industry standards, applicable laws, rules and regulations including those concerning safety, quality, manufacture, packaging, packing, and delivery;
 - (h) the use by and/or sale of the Goods and/or the output/product resulting from the Services by Organon does not infringe Intellectual Property Rights of third party and Organon shall not be liable for any claim in that regard or for payment of any loss, damages, royalty licence or other monies in respect thereof;
 - (i) it has a good and unencumbered title to the Goods and the Goods will be free from all liens and encumbrances;
 - (j) it will use all due skill, care and diligence when providing the Services;
 - (k) it will perform the Services within a reasonable time, if the time for performance is not otherwise specified in the Order or notified by Organon to the Supplier;
 - (l) it will carry out the Services in accordance with any requirements specified by Organon in the Order or which are otherwise agreed by Organon and Supplier in writing; and
 - (m) it will notify Organon immediately if it becomes aware of any actual or potential breach of warranty set out in these Conditions.
4. Supplier transfers to Organon (at no cost to Organon) the benefit of any applicable manufacturers' warranty or guarantee received by Supplier.
 5. Supplier shall deliver the Goods to the Delivery Address by any delivery date specified by Organon in the Order or otherwise agreed by Organon and Supplier in writing.
 6. All Goods and/or Services shall satisfy Organon's quality control tests and inspection. Any Goods and/or Services which do not satisfy such tests and inspection and/or are found to breach the warranties in Condition 3 shall entitle Organon, without prejudice to its other rights, to:
 - (a) reject the Goods and/or Services and be released from all obligation to pay for them and Supplier shall collect the Goods within seven (7) days after notification of rejection by Organon (Collection Period). If Supplier fails to collect the Goods within the Collection Period, Organon may deliver the Goods to Supplier at Supplier's risk and cost; and
 - (b) purchase like or similar replacement Goods or require the Supplier to re-perform or re-provide the Services and all additional and reasonable cost and expense incurred shall be payable by Supplier to Organon forthwith on demand.
 7. Title to, and risk in, the Goods shall not pass to Organon unless and until it has been established that the Goods satisfy Organon's quality control tests and inspection pursuant to Condition 5, Signed delivery dockets shall not mean acceptance by Organon of Goods delivered, or any terms and conditions included in such delivery dockets, but only of the number of packages or cartons delivered.
 8. If the full quantity of Goods is not delivered or all or part of the Services are not provided in accordance with the requirements specified in an Order or otherwise agreed by Organon and Supplier, Organon shall be entitled without prejudice to its other rights to:
 - (a) cancel the Order in whole or in part; and
 - (b) purchase like or similar replacement Goods and/or Services from another party.
 9. In the event that MSD exercises its right under clause 7(a) then the Supplier must, in addition to any other liability, pay the reasonable costs of removing any Goods which are the subject of that Order from MSD's Delivery Address.
 10. Neither party shall not be entitled to assign or sublet in whole or in part any of its rights, interest or obligations under an Order without approval from the other party which will not be unreasonably withheld.

11. Organon shall be entitled to direct Supplier to suspend, or Supplier may suspend, shipment or performance of the Order where circumstances beyond either party's control render the same desirable or necessary action without being liable for any costs or damages of the other party, provided the suspending party provides prior written notice of the suspension to the other party as soon as reasonably practical.
12. In relation to Blanket Orders:
 - (a) the issue of a Blanket Order by Organon does not in any way oblige Organon:
 - (i) to place Orders totaling the maximum amount specified in the Blanket Order; or
 - (ii) to place any Order(s) under that Blanket Order.
 - (b) Organon has no obligation to cancel a Blanket Order if it intends not to place any Order (or any further Orders) under that Blanket Order.
 - (c) a Blanket Order will specify that it is a Blanket Order or otherwise be notified by Organon to Supplier as such.
13. The Supplier acknowledges that it is critical to Organon which operates in the area of human health products to have reliable supplies of Goods and Services and the Supplier indemnifies and agrees to keep indemnified Organon from and against all liability, costs and expenses (including consequential loss) suffered as a consequence of or arising out of or in any way incidental to breach of a warranty (Condition 3) rejection (Condition 5) or cancellation (Condition 7) except to the extent that such liability, cost or expense are incurred or contributed to by the breach of this Agreement by Organon or the negligence or wilful default of Organon.
14. Subject to Condition 18 these Conditions alone constitute the entire agreement between Organon and Supplier and no agreement, term, condition, arrangement, understanding, warranty or promise shall supersede these Conditions.
15. An Order and these Conditions may only be varied with the prior written consent of both parties.
16. GST
 - (a) In this clause "GST" means goods and services tax under the *A New Tax System (Goods and Services Tax) Act 1999* and regulations thereunder as in force from time to time (**GST Law**) and terms used have meanings as defined in the GST Law.
 - (b) The amount payable for any taxable supply made under or in accordance with this agreement is increased by the amount of any GST levied or imposed on or in respect of such supply provided that it is a precondition of any payment for any taxable supply that the recipient has issued a GST tax invoice or such other document as may be required under the GST Law to enable the payer to obtain an input tax credit.
17. These Conditions shall be governed by the laws of the State of New South Wales.
18. The Supplier must not, without Organon's prior written consent, in any manner advertise or publish the fact that the Supplier is a Supplier of Goods and/or Services to Organon.
19. If Organon and the Supplier execute a formal agreement in relation to the supply of Goods and/or Services the terms of such formal agreement shall, in the event of inconsistency, prevail over these Conditions.
20. By accepting an Order and/or by delivering Goods or supplying services pursuant to an Order, Supplier accepts these Conditions as the sole basis of the sale of the Goods and/or supply of the Services and these Conditions shall supersede any conditions of sale appearing on any document of the Supplier (subject to Condition 18).

Modification of these Conditions expressed in any document of the Supplier does not apply to an Order unless expressly accepted in writing by Organon.
21. Supplier must effect and maintain:
 - (a) Statutory workers compensation insurance;
 - (b) Public liability insurance;
 - (c) Professional indemnity insurance; and
 - (d) Product liability insurance, to cover any and all costs and expenses of whatsoever kind or nature which Organon may suffer or incur as a result of or in connection with any claim, demand, action

or proceeding brought by any party including any officer, employee or sub-contractor of the Supplier in relation to the Goods and/or Services.

22. Organon will own all Intellectual Property Rights in all material created by the Supplier in performing the Services. To facilitate this the Supplier:
 - (a) assigns to Organon all future Intellectual Property Rights in all such material (whether the material is created alone or jointly with Organon); and
 - (b) acknowledges that no additional documentation is necessary to complete the assignment and that by virtue of this clause all such future Intellectual Property Rights will vest in Organon.
23. To the extent that the Services contain existing Intellectual Property Rights, the Supplier hereby grants, and will ensure that relevant third parties grant to Organon an irrevocable, royalty-free, perpetual licence to copy, use and modify same for any purpose required by Organon.
24. In relation to confidential information, the parties agree:
 - (a) to keep the Confidential Information strictly confidential and secret and prevent disclosure to third persons;
 - (b) to use and reproduce the Confidential Information only as strictly necessary for the purposes of supplying Goods and/or Services pursuant to an order
 - (c) to keep the Confidential Information secure and protect it from unauthorised use and disclosure;
 - (d) once Goods and/or Services have been supplied, or upon request by the other party to return or destroy (at the other party's direction) all Confidential Information in material form.
25. Information will not be considered to be Confidential Information if a party can prove:
 - (a) it has been, or is, published otherwise than through the fault of that party;
 - (b) it is independently developed by that party; or
 - (c) it is lawfully obtained by that party from a third party not under a duty of confidence.
26. Ethical Business Practices
 - (a) The parties mutually acknowledge that their respective corporate policies require that their business is to be conducted within the letter and spirit of the law.
 - (b) Both parties agree to perform their obligations under each Order in a manner which is consistent with both law and good business ethics. Specifically, each warrants that it shall not make any payment either directly or indirectly of money or other assets including but not limited to the compensation it derives from an Order to any party where such payment would constitute a violation of any law. In addition, regardless of legality, the parties shall make no payment either directly or indirectly to any officials, officers, agents or representatives of any government or political party if such payment is for the purpose of influencing decisions or actions with respect to the subject matter of an Order or any other aspect of Organon's business.
 - (c) Supplier acknowledges that no employee of Organon shall have authority to give any direction, either written or oral, relating to the making of any commitment by Supplier or its agents to any third party in violation of the terms of this or any other clause of these Conditions.
 - (d) Supplier's failure to abide by the provisions of this clause shall be deemed a material breach of these Conditions. Organon may, in such case, terminate any Order(s) at its sole discretion upon written notice to Supplier and without prejudice to any other remedies that may be available to Organon.
27. Data Privacy and Security
 - (a) In the course of providing goods and/or while performing services pursuant hereto, Supplier agrees that when collecting, accessing or using any personal information that can identify an individual, Supplier will only collect, access, use and disclose the minimum information necessary to enable Supplier to perform its obligations and that it will do so only in accordance with MSD's instructions or where disclosure is required by law; which required disclosure shall be reported to MSD by Supplier in sufficient time prior to any such disclosure as to allow MSD to take any protective action if it deems necessary. Supplier agrees to protect such information from loss, misuse, unauthorised access, disclosure, alteration or destruction and promptly notify MSD of any loss, misuse unauthorised access, disclosure, alteration or destruction to such information of which Supplier becomes aware.

28. Business Partner Code of Conduct

Organon endeavours to hold itself and its Supplier 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 Supplier'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 **clause 3** hereof, the Supplier agrees that it will abide by the letter and spirit of Organon'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/Code-Of-Conduct_v2.pdf.

Organon will provide the Supplier with reasonable notice of any material changes to the Code prior to the date on which those changes take effect,

- (a) The Supplier agrees that it will provide all documentation reasonably requested by Organon to demonstrate compliance with the Code. In the event of a conflict between the obligations in this **clause 28** 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 prevail (but only to the extent of the conflict).
- (b) Organon reserves the right, in its sole discretion, to audit the Supplier's operations, books and records to ensure compliance with the Code. Organon 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 Supplier shall acknowledge Organon'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. Organon or its third party auditor may interview the Supplier'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.
- (c) In the event an audit identifies a non-conformance by the Supplier with the Code, the Supplier will promptly take corrective action to remedy the non-conformance. Organon reserves the right to approve all corrective actions. Corrective actions shall be implemented by the Supplier at the Supplier's expense. Organon will endeavour, whenever practicable, to work with the Supplier to remedy the issue and put in place a corrective action plan.
- (d) In the event the Supplier 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, Organon reserves the right to terminate this Agreement in the event the Supplier fails to cure such refusal or failure within 90 days after written notice from Organon.

29. Supplier Expectation

Without limiting any of Supplier's other obligations hereunder and without limiting any of the express warranties or obligations agreed to elsewhere in this Agreement, including without limitation to its obligations under this **clause 29**, Organon expects that Supplier will abide by the letter and spirit of Organon's **Supplier Performance Expectations**, as in effect from time to time, a copy which is available at <https://vip-organon.com/organon/wp-content/uploads/sites/2/2021/04/Organon-Supplier-Performance-Expectations.pdf>

Organon will provide the Supplier with reasonable notice of any material changes to the Code prior to the date on which those changes take effect, In the event of a conflict between the obligations in this **clause 29** and Organon's Supplier Performance Expectations, on the one hand, and any other provision in this Agreement, on the other hand, such other provision of this Agreement shall prevail (but only to the extent of the conflict).

30. Data Integrity

- (a) Any documentation or data relevant to activities performed, including without limitation any GMP documentation, must be attributable, original, accurate, legible, complete, controlled, retrievable, and safe from intentional or unintentional manipulation or loss. These items are required throughout the retention period of such data / documentation.

31. Reporting adverse events and Quality complaints

- (a) Whereas applicable, Supplier will transmit any Adverse Events (AEs), Product Quality Complaints (PQCs), and other reportable information (including without limitation, local law reporting requirements, health authority reporting guidance etc.) related to Organon medicinal product or medical device within one (1) business day or three (3) calendar days, whichever is shorter, upon receipt from any source.

- (b) Supplier and Organon will agree on the mode of transmission for safety information, which will be documented in a mutually agreed upon agreement (ie: PV plan, PV agreement, protocol, safety management plan) prior to the commencement of activities.
- (c) In situations where collection of adverse events are outside the scope of the services but the Supplier learns of any Adverse Event or Product Quality Complaint related to Organon product, the Supplier agrees to report the Adverse Event to Organon's local Designated Point of Contact (DPOC) as outlined below:

Country	DPOC Phone Number	Email	Fax
Australia	1800 023 135	dpoc.anz@organon.com	1800 353 013
New Zealand	0800 111 700	dpoc.anz@organon.com	0800 349 300

- (d) An adverse event is untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product or medical device, whether or not considered related to the medicinal product or medical device.
- (e) A Product Quality Complaint (PQC) is any communication that describes a potential defect related to the identity, strength, quality, purity, or performance of a product identified by an external customer. This includes potential device or device component malfunctions.
- (f) Other reportable information includes but not limited to worsening of existing symptoms, new disease, abuse, misuse, overdose, accidental exposure, medication errors, off label use and drug exposure during pregnancy.