

# GENERAL TERMS AND CONDITIONS OF SALE AND DELIVERY

Organon Pharma B.V. and N.V. Organon

Deposited on 12 June 2024

Chamber of Commerce numbers

75977958 (Organon Pharma B.V.)

&

16032089 (N.V. Organon)

# GENERAL TERMS AND CONDITIONS OF SALE AND DELIVERY OF

# Organon Pharma B.V. & N.V. Organon

# 1. **APPLICABILITY**

Unless explicitly agreed otherwise in writing, these General Terms and Conditions of Sale and Delivery as well as the terms included in Annex I and Annex 2 are applicable as from 12 June 2024 to all verbal and written quotes and agreements and deliveries by Organon Pharma B.V. and N.V. Organon (hereinafter collectively or individually: the "Seller"). The Seller explicitly rejects the applicability of any general terms and conditions of purchase of the recipient or the customer or the buyer (hereinafter: the "Buyer"), which the Buyer accepts.

# 2. **AGREEMENTS**

- 2.1 All price lists, quotes and offers made or issued by the Seller in connection with the delivery of finished products, active pharmaceutical ingredients and/or services, in any form whatsoever, are free of obligation and do not constitute an offer by the Seller.
- 2.2 An order placed is considered an irrevocable offer by the Buyer and can therefore not be cancelled by the Buyer.
- 2.3 The Seller is not bound until the commencement of the filling of an order, unless the filling is or was subject to a reservation.

## 3. PRICES

- 3.1 Unless explicitly agreed otherwise, the prices applied by the Seller on the delivery date, which prices the Seller has published or otherwise communicated, apply to all agreements. These prices are net and exclusive of VAT. The Seller may change these prices at any time. In addition, the Seller may reduce these prices by a discount yet to be determined or agreed, in which event the prices applied by the Seller are merely recommended prices.
- 3.2 The Seller is authorised to levy a surcharge for administrative and shipping costs for orders with an invoice value of less than EUR 1,000.

### 4. **DELIVERY**

- 4.1 The Seller is responsible for the proper shipment of the products ordered by the Buyer. Unless explicitly agreed otherwise, the Seller will bear the costs of shipment. Delivery of the products ordered will be DAP at the delivery address indicated by the Buyer, in accordance with the provisions for this method of delivery in the INCOTERMS® 2020, unless agreed otherwise in writing.
- 4.2 The risk of damage, reduction of value, deterioration and loss of the products passes to the Buyer upon delivery.
- 4.3 The delivery dates given by the Seller are always an approximation and are non-binding. Any failure to meet a delivery date by the Seller does not mean that the Seller is in default as referred to in Book 6, Article 83 of the Dutch Civil Code.
- 4.4 If the goods to be delivered are not collected by the Buyer or if the Buyer does not take receipt of the goods, they will be stored by the Seller at the expense and risk of the Buyer, possibly, at the Seller's discretion, with a third party.

### 5. PAYMENTS

- 5.1 Payment of the purchase price for delivered products becomes due immediately following delivery. Payment must be made without any discount or offset before or on the due date stated on the invoice or, absent such due date, within 30 days after the invoice date, unless agreed otherwise in writing.
- Absent payment in a timely fashion, the Buyer will be in default by operation of law without any prior notice of default being required. From the moment the Buyer is in default, it will owe interest of 1% per month on the outstanding amount or, at the Seller's discretion, statutory interest as referred to in Book 6, Article 119a of the Dutch Civil Code. All extrajudicial costs incurred by the Seller in connection with the collection of sums owed to the Seller (including the costs of legal assistance) will be met by the defaulting Buyer. The compensation for these extrajudicial costs is at least 15% of the amount owed, unless the actual costs are higher.
- 5.3 The provisions above with regard to the payment term notwithstanding, the Seller is at all times authorised to require advance payment or down payment or to require security from the Buyer for payment before the Seller effects delivery. If the required advance or down payment is not effected and/or the security required is not provided to the Seller's satisfaction, the Seller will be authorised to suspend or refuse delivery.
- 5.4 If the Buyer disputes an invoice from the Seller, the Buyer must send a written, substantiated objection to the Seller within eight days after the invoice date. The challenge of an invoice by the Buyer does not suspend its obligation to pay.

### 6. **RETENTION OF TITLE**

- 6.1 The title to the item purchased does not pass to the Buyer until it has complied with all its obligations vis-à-vis the Seller to pay the purchase price for goods delivered or yet to be delivered, services provided or yet to be provided and the related interest, charges and damages due. The Buyer is, however, authorised to dispose of the goods in the course of its ordinary business operations. However, the Buyer is not authorised to pledge the goods or create any other right thereon. The Buyer is required to immediately inform the Seller if third parties assert rights with regard to goods that are still the property of the Seller.
- In the instances referred to in Article 7.1, the Seller is irrevocably authorised, without any notice of default being required, to remove or procure the removal of goods that are still its property. The Seller is authorised either to retain the goods until the purchase sum, including interest, charges and damages, has been paid in full or to sell the goods to third parties, in which event the net proceeds will be deducted from the total amount owed by the Buyer.
- 6.3 The Buyer is required to store the goods delivered by the Seller in such a way that these products can at all times clearly be identified as having been delivered by the Seller. If the Buyer rents a location for the storage of the goods delivered, the Buyer will inform the Seller of the identity and domicile of the lessor upon the Seller's first request.

# 7. **Non-Performance**

7.1 If either of the parties fails imputably in the performance of its obligations, and in the event of an application for bankruptcy, actual bankruptcy, liquidation of the company or if either of the parties has applied for or been granted suspension of payment, the other party will be authorised to terminate the agreement in full or in part unilaterally, with no notice of default being required and without intervention by the court, without being required to pay any damages and without prejudice to all further rights that party may have.

7.2 If one of the instances referred to in the first paragraph occurs in respect of the Buyer, all the Seller's receivables will be immediately exigible in full. In that event, the Seller will be authorised to suspend or terminate all other agreements with the Buyer for the delivery of goods and services.

### 8. Force Majeure

- In the event of force majeure, the Seller will be authorised, at its discretion, to suspend the performance of the delivery agreement for a maximum period of three (3) months or to terminate the agreement in full or in part without intervention by the court, without being obligated to pay damages. Force majeure is understood to include every circumstance which the Seller could not have taken into account when the agreement was entered into and as a result of which the Buyer cannot reasonably require the ordinary performance of the agreement, such as: war or threat of war, regardless of whether the Netherlands is involved directly or indirectly, full or partial mobilisation, state of siege, terrorism or the threat of terrorism, riot, sabotage, epidemics, natural disasters, fire or other destruction and damage in factories or warehouses, sit-ins, strikes, both in the business of the Seller and in companies from which goods, raw materials and/or auxiliary materials are obtained, restrictive government measures of any nature whatsoever, restrictions on or impediments to production and/or the supply of goods, raw materials, auxiliary materials, fuel and/or electricity.
- 8.2 If the Seller is unable to comply with its delivery obligation due to force majeure, the Buyer will be authorised to terminate the agreement in full or in part without intervention by the court, unless this is not justified in view of the duration of the force majeure.
- 8.3 Performance by the Seller in one or more of the situations described in the first paragraph does not diminish its right to use its power to suspend or terminate in subsequent or different instances.

## 9. GUARANTEE & RETURN SHIPMENTS

- 9.1 Products are manufactured and placed on the market by the Seller with due observance of the applicable statutory requirements. Announcements made by or on behalf of the Seller with regard to the quality, composition, treatment in the broadest sense of the word, application options, properties, etc. of the products are only considered guarantees if they are made in writing and explicitly in the form of a guarantee.
- 9.2 Goods that have been delivered may only be returned with the prior consent of the Seller and returned in accordance with the returns policy in <u>Annex 1</u>, unless agreed otherwise in writing.

# 10. BUYER'S DUTY OF CARE & CLAIMS FOR DAMAGES

- 10.1 The Buyer must adequately familiarise itself with the properties (including any side effects) of the products it purchases from the Seller.
- 10.2 The Buyer is required to strictly observe the rules and reasonable instructions given by the Seller with regard to the storage and handling of the products delivered. The Buyer is required to inspect the products and packaging upon receipt or otherwise as soon as possible and to the extent this can be reasonably required of the Buyer and/or in accordance with the Buyer's common practice. Defects to the products and packaging discovered during this inspection, along with the defects not discovered until the product is used or consumed by the Buyer or third parties, must be reported to the Seller within 24 hours after discovery by the Buyer. The Buyer is required to take measures to limit the damage as much as possible. In so doing, the Buyer will in particular follow the instructions given by

- the Seller with regard to the products and packaging. All liability lapses if the Buyer fails to comply with any of these obligations.
- 10.3 The Buyer is responsible for any and all permits and authorisations required to purchase the products from the Seller, sell them on and/or use them. The Buyer must comply with all applicable laws and regulations, including the Guidelines of Good Manufacturing Practice and the Guide to Good Distribution Practice for Medicinal Products and Medical Devices. The Buyer indemnifies and holds the Seller harmless against all claims based on the fact that the Buyer did not comply with the foregoing.
- 10.4 The Buyer will ensure that its records related to the products delivered by the Seller comply with all requirements ensuing from applicable laws and regulations. The Buyer will ensure that the recipients of the products can be traced within a short period. The Buyer will ensure that the products delivered by the Seller remain identifiable and will not be mixed with other products if this leads to the products no longer being identifiable. Upon the first reasonable request by the Seller, the Buyer will cooperate, free of charge, in recalls, campaigns for informing recipients of the products about significant health risks or other, similar campaigns.
- 10.5 The Seller's liability pursuant to an attributable failure in the performance of an agreement with the Buyer is limited to personal injuries or damage to things as referred to in Book 6, Article 190 of the Dutch Civil Code and will never exceed the net sales price or the net invoice amount of the products in question.

### 11. AUDIT RIGHT

- 11.1 The Seller or its authorised representative has the right to inspect at the Buyer from time to time all circumstances, documents and information in relation to the storage and/or use of finished products, active pharmaceutical ingredients and/or services delivered by Seller, during normal working hours and in the presence of an authorised representative of the Buyer. The Seller or its authorised representative shall give the Buyer reasonable advance notice of intended audits.
- 11.2 For the purpose of such audits, the Seller or its authorised representative shall have access to the facilities of the Buyer until three (3) years after the date of final payment by the Buyer to the Seller pursuant to the delivery of finished products, active pharmaceutical ingredients and/or services.
- 11.3 The Seller or its authorised representative shall have access to the Buyer's facilities and to all necessary records and information regarding the delivery of finished products, active pharmaceutical ingredients and/or services, and shall be provided by Buyer adequate and appropriate work space, in order to conduct audits in compliance with this Article.

# 12. INTELLECTUAL PROPERTY RIGHTS

- 12.1 All intellectual property rights related to the products and related materials delivered remain with the Seller or its licensors.
- 12.2 Except in so far as permitted by law, the Buyer is not permitted to remove, modify or conceal, in full or in part, brand and/or identification marks on the products delivered or the packaging thereof or to change or copy the products or any part thereof.
- 12.3 The Buyer will immediately inform the Seller in writing of any claim by a third party in connection with the infringement of intellectual and/or industrial property rights with regard to the products delivered to the Buyer. The Seller will be authorised in that event, also on behalf of the Buyer, to conduct a defence or take legal action against the relevant third

party. The Buyer will at all times lend its cooperation to the Seller should the Seller so request in that respect.

### 13. CONFIDENTIALITY & PUBLICITY

- 13.1 The Seller and the Buyer will treat information and/or data related to the other party's operations which, by nature, are confidential, as strictly confidential and will not disclose same to third parties in any way whatsoever, unless this information and/or data were demonstrably already generally known when the first agreement between the Seller and Buyer was concluded, or if one party has authorised the other party in writing to disclose this information and/or data to a third party/parties.
- 13.2 The Buyer will not refer to agreements, offers and/or deliveries of the Seller in publications or advertising in magazine, newspapers, reports, brochures or otherwise without prior written consent of the Seller.

# 14. ETHICAL BUSINESS/CONFLICT OF INTEREST/BUSINESS BUYER CODE OF CONDUCT/ SELLER EXPECTATIONS

- 14.1 In its performance of agreements and deliveries of the Seller, the Buyer shall adhere to business practices that are in accordance with the letter and spirit of applicable laws and ethical principles as follows:
  - (a) All transactions in connection with the delivery of finished products, active pharmaceutical ingredients and/or services shall be accurately reflected in the Buyer's records, and no funds or other assets shall be paid directly or indirectly to government officials 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 Seller's business.
  - (b) The Buyer shall conduct its activities hereunder so as to avoid loss or embarrassment to the Seller due to any real or apparent conflict of interest, and to require that all third parties involved by the Buyer comply with such policy.
  - 14.2 Seller endeavours to hold itself and Buyer 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 sellers other obligations hereunder, and without conflicting with or limiting any of the warranties, obligations or other provisions expressly set forth elsewhere in these condition, the Buyer agrees that it will endeavour to abide by the letter and spirit of Seller's Business Partner Code of Conduct (the "Code"), as in effect from time to time, a copy of which is available at <a href="https://www.organon.com/about-organon/mission-vision-and-values/business-Buyer-code-of-conduct/">https://www.organon.com/about-organon/mission-vision-and-values/business-Buyer-code-of-conduct/</a>. Buyer agrees that it will provide all documentation reasonably requested by Seller to demonstrate compliance with the Code.
  - 14.3 The Seller shall have the right to terminate agreements and deliveries upon violation of said business practices on the part of the Buyer, its employees, agents, representatives, subcontractors, consultants, or other third parties involved by the Buyer.

# 15. PARTIAL INVALIDITY

15.1 If these General Terms and Conditions are or become partially invalid or non-binding, the parties will continue to be bound by the remainder of the General Terms and Conditions. In such instance, the Seller will be authorised to replace the invalid or non-binding part by

clauses that are valid and binding, the legal consequences of which, in view of the contents and purport of these General Terms and Conditions, correspond with the invalid or non-binding part as much as possible.

# 16. CHOICE OF LAW AND FORUM

- 16.1 Agreements between the Seller and the Buyer are governed by the laws of the Netherlands, such with the exclusion of the Vienna Sales Convention (CISG).
- Any disputes ensuing from or related to an agreement concluded between the Seller and the Buyer regarding the delivery of products by the Seller to the Buyer will, in the first instance, be brought exclusively before the competent judge of the District Court of Amsterdam, on the understanding that the Seller retains the right to bring such a dispute before the court having jurisdiction in the Buyer's domicile.

Registered with the Chamber of Commerce under number 75977958 (Organon Pharma B.V.) and number 16032089 (N.V. Organon) on 12 June 2024.

# **ANNEX 1**

# Returns Policy for Products of Organon Pharma B.V. and N.V. Organon

Seller applies the following rules with regard to returns by Buyer, unless agreed otherwise in writing. These rules apply only to the last delivery of the relevant product, in other instances there is no right of return.

Situation	Conditions	Returns policy and crediting	Comments
<b>1.</b> Products ordered erroneously by the Buyer.	N/A	0% return and 0% crediting.	
<b>2.</b> Products delivered erroneously by the Seller (product A instead of product B).	Reported to the Seller in writing within 24 hours after delivery.	100% return and 100% crediting.	
3. Damaged goods received.	Reported to the Seller in writing within 24 hours after delivery.	100% return and 100% crediting if the damage occurred prior to delivery (see Article 4.2 General Terms and Conditions), otherwise 100% return and 0% crediting.	
<b>4.</b> Complaints related to the product (complaint about quality).	Reported to the Seller as soon as possible in writing.	100% return and 100% crediting, if the complaint is declared valid by a qualified representative of the Seller.	Damage occurring during transport or in the Buyer's warehouse is not covered by quality complaints.
<b>5.</b> Products with a shelf life > than 12 months that are delivered with a remaining shelf life of < 6 months or products with a shelf life $\leq$ 12 months that are delivered with a remaining shelf life of < 3 months.	Reported to the Seller in writing within 24 hours after delivery.	100% return and 100% crediting.	
<b>6.</b> Goods the Buyer has in stock, the shelf life of which has expired.	N/A	0% return and 0% crediting.	There is no compensation for items in stock.

# Contact

# Coordination with:

- customer.service.nl@organon.com

# Return shipment

The Seller will be responsible for the return shipment.

Include a return document with every return shipment.

Please always clearly state the destination on the return.

Also please put a letter containing the following information in the box:

- Your name and address
- Reason for the return
- Include reference on the credit note
- The name of the contact person, if any, with whom you spoke at the Seller.
- The conditions under which the product was stored.

Please wait for the credit note for the return before offsetting this with outstanding invoices.

# **ANNEX 2**

#### PHARMACOVIGILANCE REPORTING REQUIREMENTS:

Should Buyer receive any information involving the Seller's product, device or software application, Buyer must report the pharmacovigilance (PV) information without delay (i.e. Adverse events (AE), Product Quality Complaints, other safety information) via encrypted Email, Phone or FAX via the contact information provided in Appendix 1. Buyer will receive confirmation of receiving the report by the automatic message. If confirmation is not received, then Buyer will contact Seller to determine if the original report needs to be re-sent.

#### An Adverse Event is defined as:

Any 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 unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

# A Product Quality Complaint is defined as:

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. Note: A report of Lack or Limited Efficacy is considered an Adverse Event rather than a Product Quality Complaint.

# Other Safety Information is defined as:

Other reportable information including 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.

# **APPENDIX 1**

# Contact numbers for pharmacovigilance reporting:

Country	Phone Number	Encrypted Email	FAX
Bulgaria	+359 28063030	dpoc.bulgaria@organon.com	+359 28063031
Malta	+357 22866730	dpoc.cyprus@organon.com	+357 22866732
Poland	+48 221055001 or	dpoc.poland@organon.com	+48 221055006
	+48 221055005		
Romania	+40 215272990	dpoc.romania@organon.com	+40 215272991
Slovakia	+421 244889888	dpoc.slovakia@organon.com	+421 233056871