General Terms and Conditions of Business for Customers of ratiopharm Arzneimittel Vertriebs-GmbH ("ratiopharm")

1. General

1.1 ratiopharm shall make deliveries and provide its services based solely on the following General Terms and Conditions of Business unless otherwise agreed upon in the individual case in question between ratiopharm and the Customer.

1.2 The German version of ratiopharm's General Terms and Conditions of Business shall apply even when the legal transaction in question has been concluded in a language other than German. Any version in another language shall be for information purposes only.

1.3 Any terms of business employed by the Customer shall not be accepted unless ratiopharm has expressly consented to the application thereof in writing in the individual case in question.

2. Delivery Terms and Conditions

2.1 ratiopharm shall not be obliged to deliver when there are still receivables outstanding from the Customer from an earlier legal transaction.

2.2 The dispatch of the goods on the delivery date is sufficient for compliance with validly agreed delivery dates. ratiopharm is entitled to make partial deliveries.

2.3 In the event of delivery being delayed due to circumstances attributable to ratiopharm, the Customer shall be entitled to declare its withdrawal from the agreement in writing after granting a grace period of at least 4 weeks. Such grace period shall start to run from the date on which the Customer's notice of withdrawal is received by ratiopharm. Delivery delays of up to 10 days must be accepted by the Customer anyway without giving rise to any claims for compensation or any right of withdrawal.

2.4 If it has been agreed upon with the Customer that the item is to be called by the Customer within a certain period of time, and if this call date has been exceeded, then ratiopharm shall be entitled to withdraw from the Agreement, in full or in part and without granting any grace period, and claim compensation up to the amount of the production costs at least.

2.5 Quotes issued by ratiopharm shall be subject to confirmation. They shall only become binding once a written order confirmation is sent by ratiopharm (by fax, email or post) or if its delivery has been effected. Unless otherwise agreed to the contrary in writing, delivery terms shall be DAP (Delivered At Place) pursuant to the latest version of the ICC INCOTERMS.

2.6 In Austria, ratiopharm shall only deliver medicinal products to parties entitled to acquisition pursuant to Section 57 of the Austrian Medicinal Products Act. By ordering the medicinal products, the Customer declares that it is authorised under the Austrian Medicinal Products Act and that it has fulfilled all obligations arising thereunder with respect to the documentation of storage and supply in accordance with the applicable laws, in particular with Section 22 of the Regulation on Operating Instructions for Medicinal Products and Section 8 of the Pharmacy Working Regulations. ratiopharm hereby reserves the right to verify information and/or reject orders. The Customer shall be required to provide ratiopharm with written proof of its eligibility to acquire immediately upon request and to provide copies of the relevant documentation.

3. Defect Notifications

3.1 The Customer shall be required to inspect the item immediately following receipt and to notify ratiopharm of any discernible defects within eight days, at the latest, in writing and with specific details. Otherwise the item supplied shall be deemed approved. Where ratiopharm determines that an item reported by the Customer is indeed defective, a replacement item free from defects shall be sent only in exchange for the return of the defective item.

3.2 Only those defects which could not be discovered within the period specified in clause 3.1, in spite of careful examination, shall be exempt from the Customer's obligation to notify. Such defects shall be deemed to have been approved if not reported to ratiopharm by the Customer in writing immediately following their discovery, but no later than within 60 days following the item's arrival at the agreed destination, with precise details of the defect.

3.3 The assertion of warranty claims or claims for compensation, and the right to avoidance on the grounds of error due to defects shall be excluded in cases of approval in accordance with clauses 3.1 and 3.2. The defect complaint must be verifiably received by ratiopharm.

3.4 At ratiopharm's request, the Customer shall be required to send ratiopharm samples of the defective item or equivalent evidence of the defective nature thereof at its own expense.

3.5 After a defect is determined by the Customer, any further use of the item, in particular further distribution thereof or any (further) handling or processing shall be prohibited without ratiopharm's express, written consent otherwise all claims shall be forfeited.

3.6 Items about which a complaint has been made may only be returned upon request or with ratiopharm's prior written consent. Acceptance of such returns shall not constitute any acknowledgement of the claimed defects.

3.7 Unless otherwise agreed to the contrary, notices of defects made by the Customer shall not release it from its payment obligations.

3.8 Returns

Subject to the Purchaser's other rights under clause 3 herein, expired medicinal products shall be taken back for up to 6 months following the expiry date visible on the packaging in exchange for a credit for the invoice value of the delivery, less 40% discount. The return of pharmaceutical specialities with an expired expiry date is accepted once per calendar quarter and must be reported to ratiopharm by the Customer. This registration must be made at bestellung@ratiopharm.at and must include a scan of the return delivery note (in particular with notification: material, quantity, batch, expiry date, reason). ratiopharm will then organise the collection. The following shall be excluded from this right to return: narcotics and psychotropic substances; serums and vaccines; refrigerated items; oncological drugs; unregistered items supplied upon clinic request; packaging that has become unsightly during storage; medicinal products marked as "no longer available" in the product directory; packaging provided free of charge (e.g. medical samples, clinical trial samples etc.). ratiopharm shall not accept any liability for goods returned outside these regulatory guidelines. In particular, ratiopharm hereby reserves the right to refuse to accept such returns or to destroy such goods without replacement.

4. Warranty and Liability

4.1 ratiopharm hereby warrants that the products it supplies comply with all applicable Austrian and EU rules governing medicines and have all the characteristics generally required.

4.2 In the case of a justified defect notice submitted correctly, ratiopharm hereby reserves the right to either grant an appropriate price discount, rectify the defect or provide a replacement, or to take back the defective item in exchange for reimbursement of the purchase price. Throughout the entire duration of the warranty period, the onus shall be on the Customer to prove that the item was already defective at the time of delivery.

4.3 Any claims by the Customer against ratiopharm for compensation shall be limited to the invoice value of the item about which a complaint was made. In any case, ratiopharm's liability shall be limited, insofar as legally permissible, to cases of wilful acts or gross negligence on its part or attributable to it. ratiopharm's liability for lost profit, indirect damages or consequential damages shall be excluded in all cases. In the case of injury to life, limb or health caused by, or attributable to, ratiopharm, or in cases covered by the Product Liability Act, the statutory liability shall apply.

4.4 The limitation period for compensation claims, regardless of the legal grounds thereof, shall be one year. This shall not apply if ratiopharm can be accused of wilful acts or gross negligence, or where the latter are attributable to it, or in the event of culpably caused injury to life, limb or health. The limitation period shall commence upon delivery of the goods. Otherwise, the statutory provisions regarding the start of the limitation period and the suspension and recommencement of deadlines shall remain unaffected.

4.5 The Customer shall be required to pass on ratiopharm's liability limitations, as stated herein, to any distribution partners to ensure that the validity of the limitation of liability is guaranteed up to the last distribution partner of the Customer.

5. Retention of Title

5.1 ratiopharm shall retain ownership of the goods supplied until such time as the purchase price has been paid in full, including all ancillary costs. Invoking the retention of title shall only involve a withdrawal from the Agreement where this has been expressly declared.

5.2 The Customer shall be entitled to resell the item delivered to it by ratiopharm during the ordinary course of business. The Customer hereby assigns all claims arising for it against a third party due to the resale to ratiopharm up to the invoice amount and undertakes to make a corresponding note in its books of account or on its invoices. ratiopharm hereby accepts this assignment. The Customer shall be entitled to collect on the claim after the assignment. ratiopharm hereby reserves the right to collect on the claim itself as soon as the Customer fails to properly fulfil its payment obligations and falls into payment arrears. In this case, the Customer shall immediately upon request inform ratiopharm of the assigned claims and its debtors, hand over all documents necessary for collection of the claims and disclose the assignment of the claim to its customers. The Customer must agree with its customers that they will not acquire ownership of the goods delivered to them until proper payment has been made. If a customer only makes partial payments to the Customer, then ratiopharm's claim must first be satisfied from the amount received.

5.3 The Customer shall not be entitled to pledge goods under retention of title or to assign them as security. In the case of court-ordered pledging, confiscation or other dispositions or interventions of third parties in connection with these goods the Customer must notify ratiopharm thereof immediately and support the latter in invoking its retention of title accordingly.

6. Reporting Requirements (Pharmacovigilance, Quality Defects)

The Customer shall report to ratiopharm any indications during the course of its business of (i) suspected side effects or (ii) off-label use, or (iii) lack of expected efficacy, or (iv) inadequate withdrawal periods, or (v) frequently observed improper use and serious abuse, or (vi) quality defects in medicinal products.

7. Non-Assignment Clause and Ban on Offsetting, no retention right

The Customer shall only be entitled to assign rights and obligations, as well as claims – whether in full or only in part – and to pledge to third parties with ratiopharm's prior written consent. This shall not include the Customer's cash receivables. The Customer may only offset undisputed or legally established claims, the exercise of a right of retention is excluded.

8. Reduction by More than Half

The legal remedy of reduction by more than half (laesio enormis) shall not be available to the Customer.

9. Data Protection and Data Storage

9.1 Data of the Customer, which ratiopharm receives with the order, the conclusion of a purchase contract and its processing, is collected, stored and processed by ratiopharm in accordance with the statutory provisions (in particular the Data Protection Basic Regulation, DSGVO, Regulation (EU) 2016/679, and the Data Protection Act, DSG, BGBl 1999 I/165, as applicable). ratiopharm refers in this regard in detail to its data protection declaration, which can be accessed under the following link: https://www.ratiopharm.at/datenschutz.html.

If the Customer employs employees whose personal data is made available or disclosed to ratiopharm within the scope of fulfilling the contract, the Customer shall inform the employees concerned accordingly and provide them with the data protection declaration valid for ratiopharm.

9.2 ratiopharm passes on the data to the wholesalers commissioned to deliver the goods as well as to the credit institutions commissioned to process payments and to other companies of the Teva Group in Europe, the USA or Israel.

9.3 ratiopharm also transfers the data to service providers commissioned by ratiopharm to process an order. They can also send the Customer information about their products (by post, fax or e-mail) on behalf of ratiopharm. If the Customer does not agree with these information mailings, it can object to these mailings and the use of its data for this purpose.

9.4 ratiopharm assures that it will not pass on the Customer's personal data to third parties unless ratiopharm is legally obliged to do so or the Customer has expressly consented in advance.

10. Compliance (TEVA's Ethical Standards, Anti-Corruption)

10.1 The Customer who concludes this Agreement with ratiopharm understands that the parent company of the Teva Group, Teva Pharmaceutical Industries Ltd., headquartered in Israel, including all of its subsidiaries and affiliated companies, including ratiopharm Arzneimittel Vertriebs-GmbH, (collectively "Teva"), is subject to the applicable anti-corruption laws and principles, in particular the United States Foreign Corrupt Practices Act, the U.K. Bribery Act and the laws of Israel.

10.2 The Customer, as a Third Party Representative of Teva (the "Third Party Representative"), acknowledges by entering into this Agreement that it is also subject to and must comply with these laws in all respects when co-operating with Teva, acting on behalf of Teva or providing services.

10.3 By entering into this Agreement, Customer further agrees to Teva's Ethical Standards, which are available at all times below:
http://tevanet.teva.corp/BusinessUnits/GlobalCompliance1/Policies%20and%20Procedures/Policies/Ethical%20Business%20Clauses.doc.

10.4 The Ethical Standards include the Customer's obligation to comply with all applicable anticorruption laws, to ensure adequate and lawful payment methods, to maintain accurate financial books and records and to grant Teva the right to audit the Customer's books and records for a period of five years after the conclusion of this Agreement.

10.5 In addition, Customer undertakes by entering into this Agreement to ensure that all third parties (including but not limited to subcontractors) engaged by Customer to provide services and/or sell goods related to Teva also comply with Teva's Ethical Standards as agreed by Customer herein.

10.6 Customer shall indemnify and hold Teva harmless from and against any and all claims and actions arising out of or in connection with the performance of any of its obligations under this clause 10. This applies in addition to Teva's other rights and remedies. Teva reserves the right to claim any additional damages; damages paid to Teva will be set off against the additional damages suffered by Teva.

11. Final Provisions, Applicable Law and Venue

11.1 Austrian law shall apply to the exclusion of any collision regulations. Application of the United Nations Convention on the International Sale of Goods (Federal Law Gazette 1988/96) is hereby expressly excluded.

11.2 The courts of Vienna, Austria, where ratiopharm is headquartered, shall have jurisdiction. ratiopharm shall be entitled, however, to transfer jurisdiction to a different venue, e.g. In the Customer's location.

12. Validity

These General Terms and Conditions of Business apply from 01-01-2019. They also apply to new, future business relationships, unless they are replaced by new General Terms and Conditions.