



GENERAL TERMS AND CONDITIONS FOR SERVICES REST OF WORLD

1. SCOPE OF APPLICATION

- 1.1 The AENOVA Group consists of a large number of companies that are affiliated (hereinafter individually referred to as “**AENOVA Member**”). These General Terms and Conditions for Services (hereinafter “**GTC**”) of the AENOVA Group shall apply to (a) all supply, delivery, and/or manufacturing services concerning pharmaceutical products or any other deliverables (hereinafter “**Deliverables**”), and (b) all development, documentation, auditing, consultancy and other services, whether subject to an acceptance procedure or not (the services comprised in (a) and (b) altogether hereinafter “**Services**”) provided by an AENOVA Member, regardless of whether such AENOVA Member has rendered the Services itself or has procured them from any of its suppliers. Unless otherwise agreed, only the AENOVA Member offering the respective Services (hereinafter “**AENOVA**”) becomes a contracting party. With placing an order upon receipt of AENOVA’s offer as per Clause 3.2, or, at the latest, by accepting the Services provided by AENOVA, the customer or other contracting entity indicated in such offer (hereinafter “**Customer**”) accepts the exclusive applicability of these GTC, and they shall become an integral part of each such agreement concluded in accordance with the above procedures (hereinafter the “**Agreement**”). These GTC shall only apply in relation to entrepreneurs’ legal entities under public law or special funds under public law.
- 1.2 Any deviating or additional conditions, or general terms and conditions of purchase of Customer, or special license conditions (also for software including open source software) shall only be applicable subject to written confirmation by AENOVA. A general reference to any document containing the said deviating general terms and conditions does not constitute AENOVA’s acceptance of the applicability of such conditions. These GTC shall also apply if AENOVA unconditionally performs Services despite being aware of terms and conditions of Customer which contradict or deviate from these GTC.
- 1.3 Unless otherwise agreed, these GTC shall apply to any subsequent business with Customer in the respectively current version at the date of AENOVA’s offer, or acceptance, without AENOVA being under an obligation to refer to the latest version in each individual case. In this respect, the version valid at the time of the conclusion of the future Agreement is decisive.
- 1.4 Individual agreements between AENOVA and Customer shall take precedence over these GTC. For the purpose of proof of content, a written agreement with AENOVA and/or written acceptance by AENOVA shall be decisive.
- 1.5 Any legally relevant statements and notifications by Customer, including but not limited to, setting deadlines, issuing reminders, notices of termination or withdrawal shall require the written form, unless otherwise specified in these GTC. If “written form” is required in these GTC, or if it is stipulated in these GTC that declarations of the parties are to be made “in writing”, then (i) signed original documents, (ii) transmission of these original documents by fax and/or (iii) the transmission of electronic documents protected against editing (e.g. PDF files), even if they are not signed by hand or provided with a signature stamp or another printed or scanned signature maintain the agreed written form. However, the sending of a simple e-mail or other electronic message does not comply with the agreed written form.
- 1.6 If the nature of AENOVA’s Services or an Agreement requires an explicit acceptance, any reference in these GTC to a delivery shall be understood as to refer to such Acceptance instead.

- 1.7 Any references to the application of statutory provisions shall be for clarification purposes only. Even without such clarification, statutory provisions shall apply unless they are modified in these GTC or explicitly excluded.

2. SCOPE OF SERVICES

- 2.1 For the purpose of AENOVA preparing the offer in accordance with Clause 3, the parties will define the scope and content of any Service in detail (hereinafter the “**Scope of Service**”). In the context of defining the Scope of Service, Customer will disclose to AENOVA (a) all standards and specifications relating to the Services in respect of (i) the manufacturing process (including testing) to be applied when manufacturing a Deliverable and/or (ii) the pharmaceutical parameters which will be tested and confirmed in a certificate of analysis (hereinafter the “**Specifications**”), and/or (b) a complete definition of the expected Service with respect to type, quantity, quality, functionality, compatibility, and interoperability, and concerning all other relevant characteristics of the Service, as well as (c) all other information essential for the use intended on the part of Customer under the respective Agreement. Where the parties have concluded an agreement for the provision of Services by AENOVA to Customer – including but not limited to a Supply Agreement or a Development Agreement – the Scope of Service, notwithstanding the preceding sentences of this Clause 2.1, shall be agreed upon between the parties in accordance with the provisions of that agreement.
- 2.2 Requirements other than those disclosed in the context of the definition of the Scope of Service on the part of Customer pursuant to Clause 2.1, and expressly contractually agreed between the parties in accordance with Clause 3 with regard to type, quantity, quality, functionality, compatibility, interoperability, and other relevant characteristics of the Service shall only be relevant for the determination of AENOVA’s performance obligations if and inasmuch as they (a) have been agreed in writing between the parties after the conclusion of the Agreement in the context of an amendment of the original Scope of Service, or (b) are already included in these GTC. AENOVA advises that an examination of delivered raw materials with regard to possible contaminations or the exceeding of certain limit values for contaminants will take place only if corresponding inspection and test procedures have been expressly agreed within the Scope of Service, and that possible contaminations or the exceeding of certain limit values for contaminants in such raw materials cannot be detected by AENOVA without the performance of respectively agreed inspection and test procedures; Clause 4.2 remains unaffected. The preceding sentences 1 and 2 of this Clause 2.2 shall not apply if and inasmuch as Customer can prove that the Scope of Service expressly agreed in the Agreement was incomplete or ambiguous due to objective requirements, in particular with regard to quantity, quality and other characteristics of the Services, including their durability, functionality, compatibility and security, through no fault of Customer.
- 2.3 AENOVA shall be entitled to subcontract Services to third parties (subcontractors), unless such subcontracting would be unreasonable for Customer to accept.
- 2.4 AENOVA shall be entitled to invoice surcharges for higher Service expenses and efforts if such higher Service expenses and efforts are caused by circumstances attributable to Customer, including but not limited to, (a) Customer’s non-compliance with agreed times or special security and safety requirements, (b) Customer’s failure to provide AENOVA with correct and comprehensive Specifications or other information pertaining to the Scope of Service (including, without limitation, due to changes in component specifications concerning size, inventory, copies of printed components or the like) in accordance with Clause 2.1, whether to the components themselves or to the assumptions on which component pricing is based, and changes in order quantities; or (c) Customer’s request(s) concerning changes with regard to AENOVA’s obligations or the Specifications, instructions,



procedures, assumptions, processes, test protocols, test methods, analytical requirements, or other information pertaining to the Scope of Service initially agreed under the Agreement. In addition, AENOVA shall, in such cases, be entitled to reasonably extend the response times, including delivery times.

3. CONCLUSION OF AGREEMENTS / CONTRACTS FOR SERVICES

- 3.1 All AENOVA offers shall incorporate these GTC. All AENOVA offers are nevertheless non-binding and without commitment. Customer nevertheless undertakes to immediately check AENOVA's offer for recognizable errors, ambiguities (in particular with respect to Customer's subjective requirements), incompleteness as well as, notwithstanding Clause 6.1 sent. 2, an unsuitability of the Scope of Service for the use intended per the Agreement, and to (a) inform AENOVA immediately of any necessary changes or clarifications of the offer in order for AENOVA to be able to re-issue a still non-binding offer that is corrected with respect to Customer's subjective requirements, or (b) place a corrected order in accordance with Clause 3.2. Clause 2.1 and Clause 2.2 shall apply accordingly in the cases described in the preceding sentence. Oral subsidiary agreements to the order shall be recorded in in writing.
- 3.2 By placing an order, Customer makes a binding offer to enter into an Agreement concerning the relevant Service. Customer's order shall remain valid for acceptance by AENOVA for a period ending on the thirtieth (30th) calendar day following the day of Customer's order.
- 3.3 Customer's order shall either be accepted by AENOVA upon explicit acceptance of the order in writing, or respectively shall be deemed accepted by rendering to Customer the ordered Services. An Agreement between the parties shall only become effective upon acceptance by AENOVA.
- 3.4 A joint and several liability towards Customer of any other AENOVA Member not involved in the Agreement shall be excluded.

4. MATERIALS AND PACKAGING

- 4.1 Where and to the extent required by applicable laws or as agreed between the parties, AENOVA shall, at its own cost, procure the active pharmaceutical ingredient(s) and all other materials (including packaging materials) required for the Services, provided that such materials are not tolled materials supplied by Customer according to Clause 4.2. AENOVA shall ensure that these materials are of suitable quality as required according to the agreed Scope of Service.
- 4.2 With regard to (a) materials supplied by Customer, and (b) materials supplied by AENOVA upon Customer's selection of the respective manufacturer or supplier, the following shall apply: (i) Customer shall be responsible for the quality and the continuity of supply of materials, and the compliance of the supplier and the material with applicable laws, including inspecting/qualification of the supplier; (ii) Customer assures that no special regulations for safe handling apply to such materials, except for the regulations of which Customer has duly notified AENOVA, by giving a written advance notice that gives AENOVA a reasonable time to carry out the required examination and training processes; (iii) Customer shall provide a material safety data sheet where so required by law, or where such material safety data sheet would be deemed appropriate; and (iv) AENOVA shall not be liable for any defects or deviations of the Services inasmuch as these result, in whole or in part, from such materials, unless such defect or deviation is caused by AENOVA's failure to properly perform any testing required by the Specifications or otherwise agreed as part of the Scope of Service, or by AENOVA's failure to properly handle or store such materials according to the Specifications or other provisions agreed as part of the Scope Work. In case of such defect or deviation of such materials, Customer shall, at its sole expense, provide AENOVA with Materials free of any defects, and shall further compensate AENOVA

for all costs and damages pertaining or relating to the use of defective materials.

- 4.3 With regard to packaging, Customer shall bear all costs related to the preparation of packaging materials according to Customer's requirements or related to changes of artworks. To the extent applicable to the Services, Customer shall be responsible for reviewing and approving final artwork and packaging of the Deliverable(s). Unless requested otherwise by AENOVA, Customer shall be obliged to (a) submit to AENOVA any requirements or changes regarding artworks at least 8 (eight) weeks prior to the agreed date of delivery; and (b) have clarified the amended artwork on a "ready-for-print"-basis at least 6 (six) weeks prior to the agreed date of delivery.
- 4.4 Customer shall return all rental crates to AENOVA. In the event that Customer fails to comply with such obligation and does not return the rental crates within a maximum of four (4) weeks as of the date of delivery, AENOVA shall be entitled to charge the Customer with a replacement compensation in the amount EUR 5.00 (five euros) for each crate.
- ### 5. PLACE OF PERFORMANCE, DELIVERY, PASSING OF RISK
- 5.1 Unless otherwise agreed, the place of performance for all Services is the respective site of the AENOVA Member indicated in the Agreement.
- 5.2 Each delivery of Deliverables shall be done "ex works" (EXW according to Incoterms 2020). Required transportation documents shall be provided by AENOVA. A delivery date shall only be binding upon AENOVA if explicitly agreed in the Agreement.
- 5.3 Customer acknowledges and agrees that AENOVA's ability to render the Services may be dependent on the timely provision of materials or other deliveries by AENOVA's suppliers. Hence, and notwithstanding Clauses 4.2, 14 and 15 of these GTC, AENOVA shall not be liable for its failure to meet an agreed delivery date where (a) such failure is due to the failure of AENOVA's supplier to deliver on time, and AENOVA has concluded a congruent covering transaction, or (b) neither AENOVA nor its supplier is or are at fault. However, AENOVA shall (a) without undue delay inform Customer about the nature of the obstacle and its impact on its ability to render the Services, and (b) use all reasonable endeavors to mitigate the adverse effects of such obstacle on its ability to render the Services. If AENOVA determines that it cannot render its Services within a reasonable period of time, AENOVA may withdraw the respective Agreement with Customer, and it shall reimburse to Customer all charges for the outstanding Services already paid to AENOVA, if any. All other statutory rights of Customer in case of AENOVA being in delay shall remain unaffected; however, Customer shall always be obliged to issue a written warning prior to any claim for damages due to AENOVA's delay.
- 5.4 AENOVA shall be entitled to partial deliveries in reasonable quantities. Quantity variances of plus or minus ten percent (+/- 10%) shall usually be considered as in accordance with the agreed quantity, unless such variance would be unreasonable for Customer to accept. Any admissible quantity variance shall be taken into account in the respective invoice.
- 5.5 Upon Customer's delay in pick-up or in case of delay in delivery or shipment within Customer's responsibility, risk shall pass to Customer upon receipt by Customer of AENOVA's notification of readiness for shipment, and AENOVA shall be entitled to invoice the order(s) so affected. AENOVA's invoice shall not affect any other claims AENOVA may have resulting from Customer's failure to promptly accept delivery of any Deliverable(s). AENOVA's rights as per this Clause 5.5 shall be in addition to any other statutory rights of AENOVA in the event of Customer's delay in pick-up or in case of delay in delivery or shipment within Customer's responsibility.



6. NON-CONFORMING SERVICES, INSPECTION, PERIOD OF LIMITATION

- 6.1 AENOVA shall manufacture the Deliverables and render all Services according to (a) the agreed Scope of Service, (b) to the extent applicable to the Deliverables, the objective requirements, namely, notwithstanding Clause 2.2 sent. 3, (i) the rules concerning good manufacturing practices of pharmaceutical products in their current version that are applicable to the manufacture of the Deliverable as such rules are promulgated from time to time by the European Union, the European Medicines Agency or any other competent regulatory authorities (“GMP”), (ii) applicable laws (each (i) and (ii) as applicable at the place of performance as per Clause 5.1), and (c) according to any further provisions of the Agreement. Except as expressly set out in this Clause 6 or otherwise in the Agreement, AENOVA does not make any representations or warranties of any kind to Customer, neither expressly nor by implication, with respect to the Deliverables or other Services, and/or to any intellectual property rights or other rights or results of the activities under the Agreement, and/or any other subject matter of the Agreement, including (a) any therapeutic or pharmacological effects, results, characteristics, or quality of Deliverables or other Services; (b) Customer’s marketing and distribution of the Deliverable(s); or (c) the Deliverable(s)’s merchantability or fitness for a particular purpose. Samples or models of Deliverables provided to Customer by AENOVA or by third parties prior to the conclusion of the Agreement shall only be decisive for the contractual quality of a Deliverable instead of the expressly agreed Scope of Service or in addition to the expressly agreed Scope of Service if AENOVA expressly informs Customer thereof at the time of or after providing the sample or model; otherwise, such samples or models are merely non-binding examples of a possible Scope of Service.
- 6.2 Where the Services consist of, contain or comprise the supply or delivery of certain Deliverables to Customer, concerning such Deliverables Customer shall notify AENOVA of obvious defects immediately and in no event later than ten (10) business days after receipt of the Deliverable(s) by Customer. Notification of defect shall be in writing and shall provide evidence of the defect. Hidden defects shall be notified to AENOVA immediately upon detection, i.e. without culpable delay, in writing, accompanied by supporting documentary evidence, and in no event later than one (1) year after delivery of any such Deliverable(s). Where so required or useful for AENOVA to verify the non-conformity, the supporting documentary evidence shall include a sample of the non-conforming Deliverable. Deliverables for which no notification of defect has been received by AENOVA in accordance with the preceding sentences, shall be deemed to be accepted by Customer, unless and except to the extent AENOVA has maliciously concealed a defect. If and to the extent Customer notifies AENOVA of any obvious or hidden defect(s) in or associated with Deliverables that consist of, contain or comprise pharmaceutical products, AENOVA shall quarantine any such Deliverables immediately.
- 6.3 Where Clause 6.2 does not apply, and where the Services require Customer’s Acceptance, Customer shall initiate the necessary testing without undue delay upon receipt of a written notification of completion issued by AENOVA (hereinafter “**Acceptance Notification**”). AENOVA may at its discretion, whilst taking into account Customer’s reasonable interests, in particular the complexity of conducting an Acceptance procedure against the agreed Scope of Service, communicate to Customer in the Acceptance Notification a due date for declaring Acceptance or informing AENOVA about any defect of the Services (hereinafter “**Acceptance Period**”). Customer may object to and request a reasonable prolongation of such Acceptance Period only by providing respective information to AENOVA in writing within three (3) business days upon receipt of the Acceptance Notification. If Customer neither declares Acceptance of the Services, nor notifies AENOVA in writing about any significant defect of the Services until expiry of the Acceptance Period, Acceptance of the Services shall be deemed to be declared upon expiry of the Acceptance Period.
- 6.4 Where neither Clause 6.2 nor Clause 6.3 of these GTC apply to the Services, Customer shall inform AENOVA in writing about any defect of the Services without undue delay upon its detection.
- 6.5 If the parties disagree on the non-conformity with the Agreement of a Deliverable that consists of, contains or comprises pharmaceutical products, the dispute shall be referred to the Zentrallaboratorium Deutscher Apotheker e.V., Carl-Mannich-Str. 20, 65760 Eschborn, or any other mutually agreed testing laboratory, such laboratory being an independent expert. The independent expert’s decision shall be binding on the Parties. If the independent expert finds the Deliverable in question to be non-conforming, the fees and expenses incurred in connection with the testing shall be borne by AENOVA. Otherwise, the fees and expenses of the testing shall be borne by Customer. The parties undertake to give the independent expert a maximum of two (2) months to carry out its task.
- 6.6 In the event AENOVA provided Customer with non-conforming Services, AENOVA shall, at AENOVA’s choice, upon Customer’s request to remedy defects, and within a reasonable time period, either rectify the defective Services or replace the non-conforming Services. Without undue delay upon AENOVA’s request, Customer is obliged to provide any defective good to AENOVA for the purpose of subsequent performance.
- 6.7 After AENOVA has failed to rectify a defect or replace the non-conforming Services, or has failed to do so within a reasonable period of time, Customer may, where either Clause 6.2 or Clause 6.3 of these GTC apply to the Services, (a) withdraw the respective individual order, unless the remaining non-conformity of the non-conforming Service is only of an immaterial nature, or (b) claim an adequate reduction in price.
- 6.8 Customer’s right to claim damages shall remain unaffected. However, any monetary claim of Customer, in particular any claims for damages or the reimbursement of expenditures resulting from the non-conformity of a Service provided by AENOVA shall be limited in accordance with Clause 12 of these GTC.
- 6.9 For the avoidance of doubt, Customer shall not be entitled to any claims resulting from the non-conformity of a Service, if and inasmuch as (i) AENOVA can prove that such non-conformity results from (a) Customer’s and/or a third party’s (hired by or acting on behalf of Customer) engagement in or attempt to remove alleged defects of a Service on their own without AENOVA’s prior approval, and/or (b) materials supplied by Customer, or procured by AENOVA from suppliers selected by Customer, or incorrect or incomplete documents or information provided by Customer, and/or (c) Customer’s own acts or omissions other than the afore-mentioned, (ii) Customer knows or is grossly negligent in not knowing such non-conformity at the time of conclusion of the Agreement or (iii) Customer violated its obligations as per Clause 6.2.
- 6.10 The limitation period for all claims and/or remedies of Customer in connection with the provision of non-conforming Services is one (1) year from the day of delivery, or, if an Acceptance by Customer is required, the day of Acceptance.

7. PRICES AND PAYMENT

- 7.1 AENOVA’s prices are valid as of the time of each order and are net prices exclusive of statutory VAT and sales tax, shipping costs and any additional services, including but not limited to, transfer services. Any customs duties and similar public charges shall be borne by Customer.
- 7.2 Customer shall be responsible for all sales, use, value added, excise and similar taxes imposed by any government or governmental agency with respect to Customer’s receipt of any Service(s) under an Agreement, except for any such taxes based upon the general business operations,



capital, property, corporate franchise, existence, or income of AENOVA and any taxes or amounts in lieu thereof paid or payable by AENOVA. Any taxes, levies or other duties paid or required to be withheld under the appropriate tax laws by one party (the "**Withholding Party**") on account of monies payable to the other Party under an Agreement shall be deducted from the amount of monies otherwise payable to the other party under the Agreement. The Withholding Party shall secure and send to the other party within a reasonable period of time proof of any such taxes paid or required to be withheld by the Withholding Party for the benefit of the other party. The parties shall cooperate reasonably with each other to ensure that any amounts required to be withheld by either party are reduced in amount to the fullest extent permitted by applicable laws. No deduction shall be made if the other party furnishes a document from the appropriate tax governmental authorities to the Withholding Party certifying that the payments are exempt from taxes or subject to reduced tax rates, according to the applicable convention for the avoidance of double taxation.

- 7.3 AENOVA's invoices shall be due and payable by Customer within thirty (30) calendar days of receipt thereof by Customer and, where the Parties have agreed on payment after delivery, receipt of the Service or, in case of Clause 4.2, Customer's receipt of AENOVA's notification of readiness for shipment. Where Customer is in default of payment, AENOVA may charge interest at the then applicable statutory interest rate, and AENOVA may claim for a compensation of its expenses incurred by such default in accordance with applicable law. AENOVA reserves the right to claim further damages.
- 7.4 AENOVA reserves the right to use all payments by Customer to settle the oldest due outstanding accounts of Customer plus the default interest and costs accrued thereon, if any; AENOVA will use Customer's payments in the order of costs, interest, due receivables.
- 7.5 AENOVA is under no obligation to accept any non-cash means of payment (e.g. bills of exchange, checks). Checks and bills of exchange are only accepted on account of performance and will only be accepted in lieu of performance by AENOVA upon the respective encashment in the full amount. Customer shall bear all costs associated with payment by bills of exchange or checks.
- 7.6 AENOVA has the right to refuse performance if, after conclusion of an Agreement, it becomes apparent that its claim for payment of Services is jeopardized by Customer's poor financial standing. This right to refuse performance shall cease immediately, once payment has been made or Customer has put up adequate collateral. AENOVA has the right to set Customer an appropriate deadline within which Customer either has to make payment upon tender of delivery, or provide collateral for the delivery. Upon fruitless expiry of the deadline, AENOVA shall be entitled to withdraw the affected Agreement. In addition, in such cases, AENOVA shall be entitled to let deteriorate materials supplied by Customer, and to make provision of further Services to Customer dependent on Customer's advance payment or provision of appropriate collateral.

8. RETENTION OF TITLE WITH REGARD TO DELIVERABLES

- 8.1 AENOVA retains legal title to any Deliverable supplied until the whole price for the respective Deliverable (including but not limited to, VAT, costs for quality control, quality assurance and testing of the Deliverable) has been paid in full. Save any provision in the Agreement that further limits Customer rights to the Deliverables (in particular any license terms as regards Deliverables), Customer shall be entitled to resell any Deliverable delivered by AENOVA subject to retention of title in the ordinary course of business, unless it is in default of payment. Customer is not, however, entitled to either pledge or assign Deliverable not yet paid for in full as security. Customer assigns to AENOVA all its payment claims against buyers of the Deliverable, as well as those claims with regard to the reserved Deliverable against its

buyers or third parties (including but not limited to all claims in tort and claims for insurance benefits) as security for AENOVA's claims against Customer. AENOVA accepts this assignment. Customer is entitled to collect the assigned claims for AENOVA in its own name and on its own account, unless such authorization is otherwise revoked by AENOVA. AENOVA shall not be entitled to collect the assigned claims itself as long as Customer meets its payment obligations.

- 8.2 Upon Customer's request, AENOVA shall release the security once their realizable value exceeds the value of outstanding claims against Customer by more than 10%. In such case, AENOVA may select the security to be released.

9. INVENTIONS, INTELLECTUAL PROPERTY RIGHTS

- 9.1 Each party's intellectual property rights, (i) which are owned by or licensed to that party prior to the effective date of the Agreement or (ii) which following the effective date of the Agreement are in-licensed by that party or invented, generated, derived or discovered by that party independently and not in the course of the performance of the Agreement (hereinafter "**Background IP**") are and shall remain owned by or licensed to that party. Except as expressly agreed to the contrary, neither party shall acquire any right, title or interest whatsoever in or to any of the other party's Background IP and nothing herein shall constitute or grant any implied license or ownership in proprietary rights or permission to file any intellectual property rights to either party under the other party's Background IP. Customer grants to AENOVA and AENOVA accepts for the purpose of pursuing the activities under the Agreement a non-exclusive, worldwide, sublicensable, royalty-free, fully paid-up license to use the Background IP of Customer solely for the performance of AENOVA's obligations under the Agreement.
- 9.2 All inventions and intellectual property rights solely discovered, invented, generated or derived by Customer or its affiliates in the course of the performance of an Agreement ("**Customer Foreground IP**") shall be the exclusive property of Customer. Customer grants to AENOVA and AENOVA accepts for the purpose of pursuing the activities under the Agreement a non-exclusive, worldwide, sublicensable, royalty-free, fully paid-up license to use the Customer Foreground IP solely for the performance of AENOVA's obligations under the Agreement. All inventions and Intellectual Property Rights discovered invented, generated or derived by AENOVA or another AENOVA Member in the course of the performance of an Agreement ("**AENOVA Foreground IP**") shall be the exclusive property of AENOVA or the respective other AENOVA Member. Customer shall have no rights therein, except in such processing-related AENOVA Foreground IP that is required for the manufacturing of a product by Customer, its affiliates and/or its licensee(s) or designee(s); where this is the case, Customer shall be granted by AENOVA, a worldwide, perpetual, non-exclusive, transferable, royalty free, fully paid-up license solely for the manufacturing of such product(s).
- 9.3 Should a party become aware of any pending or threatened infringement of any third party intellectual property rights by the performance of activities under an Agreement or relating to a Deliverable, the manufacturing processes, or any other Services, such party shall immediately notify the other party thereof.

10. REPRESENTATIONS AND WARRANTIES OF CUSTOMER

- 10.1 Customer represents and warrants vis-à-vis AENOVA that it will comply with all applicable laws applicable to Customer's performance under an Agreement and its use of any Deliverable provided by AENOVA to Customer under an Agreement.
- 10.2 Moreover, Customer represents and warrants vis-à-vis AENOVA that it has and will maintain throughout the term of any business relationship with AENOVA all permits, licenses and other forms of governmental authorization(s) and approval(s) as required by applicable laws that are



applicable to Customer in order for Customer to conduct its business and to execute and deliver the Agreement and to perform its obligations thereunder in accordance with all applicable laws that are applicable to Customer.

- 10.3 In addition, Customer represents and warrants vis-à-vis AENOVA that it will discharge all its agreed obligations according to the state of the art, that it has the power and authority to conduct its business as currently being conducted and as contemplated in any Agreement with AENOVA, and that none of its manufacturing formulation, processes or methods expressly specified by Customer to be used by AENOVA violate or will violate or infringe any intellectual property rights of any third party worldwide or constitute a breach or default under any material contract to which Customer is a party.

11. RECALL

- 11.1 In the event AENOVA believes a recall, withdrawal of a Deliverable, or any other corrective action (altogether "**Recall**") may be necessary with respect to any Deliverable provided under an Agreement, AENOVA shall notify Customer immediately in writing. AENOVA will not act to initiate a Recall without the express prior written approval of Customer, unless otherwise required by or advisable under applicable laws or GMP. In the event Customer believes a Recall may be necessary with respect to any Deliverable provided under an Agreement, Customer shall immediately notify AENOVA in writing and AENOVA shall provide all necessary cooperation and assistance to Customer.
- 11.2 The cost and expenses of any Recall shall be borne by Customer. Customer shall reimburse AENOVA for its costs and expenses, including, by way of example, costs for external personnel and labor costs, incurred in connection with any Recall, in each case unless and to the extent such Recall is caused by AENOVA's negligent or willful breach of its obligations under the respective Agreement, in which case such cost shall, subject to Clause 12, be borne by AENOVA.

12. LIMITATION OF LIABILITY

- 12.1 Except for cases of willful misconduct or gross negligence, or as stated to the contrary in this Clause 12, AENOVA's liability shall be excluded or limited as set forth hereinafter. In addition, nothing in these GTC shall, to the extent applicable, limit AENOVA's liability for a violation of life, body or health of a person, the breach of material obligations or claims under applicable Product Liability Laws, applicable Medicinal Products liability Laws or - where explicitly so declared by AENOVA - of an independent quality guarantee.
- 12.2 Save Clause 12.1 above, AENOVA shall not be liable for any indirect, special, incidental, consequential, punitive or exemplary damages, whether foreseeable or not, that are in any way related to an Agreement.
- 12.3 Furthermore, in cases of slight negligence and in the absence of an individual agreement between the Parties on a fixed liability cap, AENOVA's liability shall be limited to the violation of cardinal obligations, i.e. obligations which are essential for the proper performance of the Agreement and the violation of which jeopardizes the purpose of the Agreement and, and upon which the Customer, thus, may reasonably rely. In such case, AENOVA shall nevertheless only be liable for the foreseeable and typical damage.
- 12.4 All other liability on the part of AENOVA shall be excluded regardless of its legal and factual foundation.
- 12.5 Insofar as the liability of AENOVA is excluded or limited, this also applies to the personal liability of AENOVA's legal agents, assistants, employees, staff members, personnel, directors, representatives and vicarious agents.

13. INDEMNIFICATION AGAINST THIRD-PARTY CLAIMS

- 13.1 AENOVA has and shall maintain, at its own expense,
- (a) general business and product liability insurance with insurance cover up to a maximum amount of no less than EUR 10,000,000.00 (ten million Euros) per insured event, limited to two insured events per insurance year. For personal injury and damage to property, the insurance covers, in addition to the insurance as per the preceding sentence, cover a maximum amount of no less than EUR 30,000,000.00 (thirty million Euros) in total per insurance year; and
- (b) if, with regard to Deliverables placed on the market in Germany, AENOVA is pharmaceutical entrepreneur pursuant to Paragraph 4 (18) German Pharmaceutical Products Act, German pharmaceutical product liability insurance with insurance cover up to a total maximum amount of no less than EUR 120,000,000.00 (one hundred twenty million Euros) per insurance year or, in the case of annuity payments, up to a total maximum amount of no less than EUR 7,200,000.00 (seven million two hundred thousand Euros) per insurance year, limited to insurance cover for one person up to a maximum amount of no less than EUR 600,000.00 (six hundred thousand Euros) per insurance year and, in case of annuity payments, limited to insurance cover for one person up to the maximum amount of no less than EUR 36,000.00 (thirty-six thousand Euros) per insurance year.
- 13.2 The Customer shall indemnify, defend and hold harmless AENOVA, its employees, directors, representatives and vicarious agents on first demand from and against any and all third-party claims to the extent such claims are arising out of, or resulting from, the distribution, marketing, sale, import and any other use of AENOVA's Services by the Customer insofar as the third-party claim exceeds compensation according to AENOVA's general business and product liability insurance or German pharmaceutical product liability insurance pursuant to Clause 13.1.
- 13.3 The Customer shall indemnify, defend and hold harmless AENOVA, its employees, directors, representatives and vicarious agents on first demand from and against any and all third-party claims arising out of, or resulting from, any infringement of intellectual property rights of third parties resulting from the use of AENOVA's Services by the Customer. AENOVA currently has no insurance covering the infringement of intellectual property rights of third parties. Should AENOVA take out insurance in future covering the infringement of intellectual property rights of third parties, the Customer shall indemnify AENOVA, its employees, directors, representatives and vicarious agents on first demand against any and all third-party claims insofar as the third-party claim exceeds compensation according to AENOVA's insurance.
- 13.4 Customer's indemnification obligations in accordance with Clause 13.2 and 13.3 above, shall be dependent on AENOVA (a) informing Customer of any such claim of a third party within due time, (b) reasonably cooperating with Customer in the defense of such claims, and (c) granting permission to Customer to largely control the defense and settlement of such claims, however notwithstanding AENOVA's rights to intervene where, in AENOVA's discretion, such intervention would be required to safeguard AENOVA's business interest, customer relations, or overall reputation in the market. AENOVA shall not acknowledge any such third-party claim without Customer's prior approval.
- 13.5 To the extent that claims are the subject of Customer's indemnification obligation according to this Clause 13, Customer shall bear all judicial and extrajudicial costs and damages of AENOVA in connection with such violation of third-party claims.

14. FORCE MAJEURE

- 14.1 Upon the occurrence of force majeure conditions, including, without limitation, extreme weather conditions, natural disasters, fire, floods,



earthquakes, interruption of operations beyond the affected party's responsibility, unavailability of energy, or commodities or materials, collective actions or labor disputes, pandemics, acts of government authorities, and other conditions beyond the reasonable control of the affected party (hereinafter "**Force Majeure**"), the obligations of the affected party shall be suspended to the extent and for the duration of the hindrance. The affected party shall inform the other party of the Force Majeure event, the extent and estimated duration without culpable delay. The affected party shall endeavor to eliminate the Force Majeure event. A Force Majeure event occurring at any of AENOVA's suppliers shall be deemed a Force Majeure event of AENOVA.

14.2 If, due to Force Majeure, a party is prevented from contractual performance for a period of more than eight (8) weeks, the respective other party shall be entitled to extraordinary termination of the Agreement.

15. COVID-19

15.1 If, at the effective date of an Agreement, the Covid-19 disease ("**Corona**") is still considered a pandemic by the World Health Organization, the following shall apply.

15.2 The parties agree that in case AENOVA is unable to render the Services to Customer due to one or more of the following events occurring in connection with Corona:

- (a) AENOVA's facility, wholly or partially, performs a shutdown due to a governmental and/or administrative order, or the then current applicable laws or regulations applying at AENOVA's location, or based on AENOVA's own risk management or judgement, or
- (b) a considerable number of the AENOVA employees suffer from Corona, or need or elect to stay in quarantine, or
- (c) AENOVA cannot procure the material(s) needed for Customer's requested volumes of Deliverables due to shortages on the market or in transportation capacities, or otherwise, or
- (d) any other hindrance,

then AENOVA's obligations under the respective Agreement shall be suspended for the duration of the respective event and no fault and/or liability of AENOVA can be derived from any such event and/or AENOVA's actions related thereto. In particular, the parties agree that AENOVA may reject Customer's forecasts and/or orders, in the latter case, irrespective of any forecasts already in place, and shall not be bound to contemplated or confirmed delivery dates. Based on the foregoing, any claims for damages, penalties and/or compensation of Customer shall explicitly be excluded regardless of the legal nature of any such claim.

16. CONFIDENTIALITY

16.1 Subject to the limitations set forth in Clause 16.3 below, Customer undertakes to maintain strict confidentiality in respect of all Confidential Information (as defined in Clause 16.2 below) disclosed by or on behalf of AENOVA, irrespective of the form and manner of disclosure, and the medium in which such Confidential Information may be contained.

16.2 "**Confidential Information**" within the meaning of these GTC shall mean all information, including, but not limited to, inventions, innovations, specifications, processes, techniques, business processes and procedures, formulas, manufacturing information, marketing strategies or information, research, development, products, finances, customers, assets, and/or plans and programs related to the business and/or operations of AENOVA, other AENOVA Members, and/or business collaborators, which is or was made available to Customer and/or its representatives by or on behalf of AENOVA either verbally; or in writing; or electronically; or in any other form in connection with an Agreement, if such information (a) is clearly marked as confidential,

is described as such or is otherwise recognizable as such; or (b) is to be regarded as confidential because of its content. Information disclosed by an AENOVA Member respectively by its management, employees, authorized persons or advisors shall be considered as disclosed on behalf of AENOVA.

16.3 The term Confidential Information does not include such information which (a) is or enters into the public domain, or is or becomes generally available when Customer was provided with such information (except by reason of any breach of this Clause 16 by Customer or any of its representatives); or (b) was already legitimately in the possession of Customer and not subject to a duty of confidentiality before Customer received the information from AENOVA; or (c) Customer had received from a third party that was entitled to disclose this information without restriction; or (d) Customer has developed independently without making use of any Confidential Information of AENOVA.

16.4 Customer agrees (a) to keep all Confidential Information strictly confidential; (b) not to disclose any Confidential Information to third parties, with the exception of such of its representatives to whom this Confidential Information has to be disclosed in the process to evaluate or carry out the Agreement ("**need-to-know-principle**"); (c) to take due care in ensuring that any Confidential Information (i) is only used for the purposes of the Agreement, and (ii) is not in any case exploited or otherwise utilized for Customer's own commercial purposes; and (d) to reproduce any Confidential Information only to the extent necessary and to pursue the measures set forth in these GTC also concerning such reproductions. In order to ensure that the Confidential Information is kept confidential, Customer agrees to take all reasonable measures in order to prevent any unauthorized use or any unauthorized disclosure of Confidential Information received from AENOVA. Customer agrees to ensure that all its representatives are bound by and comply with equitable confidentiality provisions as set forth in this Clause 16, in as far as permitted under applicable law.

16.5 In the event that Customer or one of its representatives is subject to a statutory obligation or a lawful court or official requirement to disclose any of AENOVA's Confidential Information, Customer shall (a) notify AENOVA in writing by fax or by e-mail of this obligation and, upon request by AENOVA, assist AENOVA as far as reasonable in protecting the Confidential Information or having it protected through the courts; and (b) to the extent that no other protective measures are taken, disclose only such Confidential Information which must be disclosed by reason of any legal requirements and use its best endeavors to ensure that the Confidential Information disclosed is treated as far as possible in accordance with this Clause 16.

16.6 All rights to the Confidential Information shall remain with AENOVA. No provision in these GTC shall be interpreted expressly or by implication as the transfer of any rights or the grant of any licenses in relation to the Confidential Information.

16.7 Customer is obliged, at the written request of AENOVA, (a) to return to AENOVA all Confidential Information, whether written or in any other form, without undue delay and together with all reproductions and copies thereof or to destroy all such information; and (b) at the same time to return or destroy all other materials, including materials produced by Customer itself, which contain Confidential Information; with respect to (b), it shall be a matter for Customer to choose whether such materials are destroyed or returned. Customer may retain those parts of the Confidential Information which it is required by law or generally accepted standards of professional conduct to document its involvement in the Agreement; Confidential Information contained in routinely saved data and/or contained in data saved due to internal standard backup procedures, does not have to be deleted when undue effort is required; provided that the confidentiality obligations provided in this Clause 16 shall continue to apply to such retained Confidential Information until its destruction or deletion. This includes that



Customer may retain one copy of the Confidential Information it has received in a safe, separate file.

- 16.8 The obligation to maintain confidentiality in accordance with this Clause 16 shall remain in full force and effect, and shall apply with respect to Confidential Information disclosed in connection with an Agreement during the term of the Agreement and for a term of five (5) years after the effective date of a termination or expiration of such Agreement.

17. DATA PROTECTION

- 17.1 Customer undertakes to ensure at all times that the respectively applicable data protection laws (such as the GDPR) are complied with and that any personal data of AENOVA's employees is processed exclusively for the performance of the Agreement, unless any other processing is legally permissible. Furthermore, Customer shall undertake to delete the data after the purpose associated with the processing has been fulfilled, insofar as no legal obligations to provide proof or to retain data apply.
- 17.2 At AENOVA's request, Customer shall conclude further agreements on the protection of personal data if AENOVA is of the justified opinion that these are legally necessary, in particular also in cases in which personal data is transferred to countries outside the EU or the EEA. These further agreements may include (i) AENOVA's standard agreement on commissioned processing in accordance with Art. 28 of the GDPR, (ii) the EU standard contractual clauses for the transfer of personal data to processors and/or (iii) other agreements.

18. COMPLIANCE

- 18.1 Customer shall comply with all applicable laws, rules and regulations as well as standards and orders in connection with the performance of an Agreement, including all respectively applicable laws, rules and regulations on international trade, such as export bans, import and export controls and sanctioned party lists (lists which list all persons and companies with whom no trade may be conducted) and in particular all applicable anti-corruption and minimum wage laws. In addition, Customer undertakes to comply with the 10 principles of the UN Global Compact available under (<https://www.unglobalcompact.org/what-is-gc/mission/principles>), which include principles on respect for human rights, environmental protection, labor, or the prevention of corruption.

19. RIGHT OF RETENTION AND OFFSET

- 19.1 In case of Customer's delay of payment of an individual order, AENOVA shall not be obliged to accept orders, and shall be entitled to refrain from production and shipment of all Deliverables and/or provision of all other Services, unless Customer agrees to and executes advance payments for these outstanding orders upon receipt of respective invoices from AENOVA.
- 19.2 Notwithstanding the foregoing, the parties shall have rights of retention and rights to offset only with regard to claims acknowledged by final legally binding judgment or to undisputed claims. This does not affect the parties' statutory rights of retention under applicable law.

20. APPLICABLE LAW AND COMPETENT COURTS

- 20.1 Any Agreement entered into between AENOVA and the Customer, including but not limited to these GTC, and any non-contractual obligations arising out of or in connection with an Agreement, shall be governed by and construed in accordance with the laws of the country in which AENOVA has legal seat under exclusion of the UN Convention on Contracts for the International Sale of Goods ("CISG") and provisions of conflict of laws.
- 20.2 In the event of any controversy or claim arising out of or relating to any provision of an Agreement, the parties shall first try to settle those

conflicts amicably between themselves. If the Customer is an entrepreneur, a legal entity under public law or a special fund under public law, the courts competent at AENOVA's legal seat shall have exclusive jurisdiction in respect of all disputes arising out of or in connection with the relevant Agreement, which cannot be settled amicably. In addition, AENOVA is entitled to file a suit before the competent court of the Customer's place of business.

21. CONCLUDING PROVISIONS

- 21.1 These GTC are made in the English language. For the avoidance of doubt, the English language version of these GTC shall prevail over any translation of these GTC.
- 21.2 An Agreement may be amended only by an instrument in writing; this also applies to any amendment to this written form clause.
- 21.3 The invalidity or unenforceability of any provision of an Agreement or any loophole in an Agreement shall not affect the validity or enforceability of any other provision thereof.
- 21.4 Unless otherwise provided for herein, an Agreement may not be assigned or transferred by either party hereto without the prior written consent of the other party. The aforesaid shall leave unaffected that each party, without consent of the other party, (a) may assign an Agreement to any of its Affiliates, provided that such assignment to an Affiliate shall not relieve such party of its responsibilities and liabilities thereunder and such party shall remain liable to the other party for the conduct and performance of its Affiliate, and/or (b) may assign any monetary claim under an Agreement to a third party, provided that, unless the assigning party reveals the assignment to the other party, this other party may execute a payment with debt-discharging effect to the assigning party despite such assignment.

January 2022