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## GENERAL TERMS AND CONDITIONS

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### 1. GENERAL

- 1.1 These General Terms and Conditions for Services (hereinafter "GTC") apply to all Services (cf. Sec. 1.2) provided by the respective AENOVA Member (hereinafter "AENOVA") unless otherwise agreed in writing in the individual case in question between AENOVA and the Customer. These GTC shall only apply if the Customer is an entrepreneur, a legal entity under public law or a special fund under public law.
- 1.2 These GTC shall, in particular apply to all supplies, deliveries, manufacture, developments and other services (hereinafter "Services") by AENOVA regardless of whether AENOVA has manufactured the product concerned itself or has purchased it from any of its suppliers. Unless otherwise agreed, these GTC shall apply in each case in the latest version as a framework agreement for any subsequent agreement with the Customer without AENOVA being under an obligation to refer to the latest version in each individual case.
- 1.3 Any of the Customer's general terms and conditions of business which may deviate from or contradict these GTC are hereby explicitly waived. They will not become part of any agreement unless AENOVA expressly consents in individual cases to their applicability in writing..
- 1.4 These GTC shall also apply if AENOVA unconditionally performs Services despite being aware of terms and conditions of the Customer which contradict or deviate from these GTC.
- 1.5 Any agreements concluded between AENOVA and the Customer for performing Services, in particular the conclusion or amendment of contracts must be made in writing. This also applies to the parties' waiver of the written form requirement.
- 1.6 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 GTCs or explicitly excluded.

### 2. SCOPE OF SERVICES

- 2.1 The scope and the content of any Service shall be defined in the relevant Service Agreement - including but not limited to the Supply Agreement for Pharmaceutical Products and the Development Agreement - the relating specification (if any) and these GTC; each of them forming an integral part of the relevant Service Agreement. The scope and content of Services not covered by any Service Agreement shall be defined in an individual offer issued by AENOVA or the relevant order by the Customer, and these GTC. To the extent the contents of the individual agreement parts contradict each other, the following priority order shall apply: (1) Service Agreement with the relating specifications (if any), (2) individual order and (3) these GTC.
- 2.2 AENOVA shall be entitled to subcontract Services to third parties (subcontractors) to the extent permitted by applicable law.
- 2.3 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 the Customer, including but not limited to, non-compliance with agreed times or special security and safety requirements. In addition, AENOVA shall, in such cases, be entitled to reasonably extend the response times, including delivery times, at its own discretion.

### 3. CONCLUSION OF AGREEMENTS/CONTRACTS FOR SERVICES

- 3.1 All AENOVA offers are non-binding and without commitment. By placing an order, the Customer makes a binding offer to contract the relevant

Service. Customer's offer shall remain valid for acceptance by AENOVA for a period ending on the thirtieth (30<sup>th</sup>) calendar day following the day of the offer.

- 3.2 The order shall be deemed to be accepted by AENOVA either upon acceptance of the order by letter, email or fax, respectively by dispatching the ordered product. The agreement with the Customer shall only become effective upon acceptance by AENOVA.

### 4. PLACE OF PERFORMANCE, DELIVERY, PASSING OF RISK

- 4.1 Unless otherwise agreed the place of performance for all Services is the respective site of the AENOVA Member indicated by the individual agreement or offer. Each delivery of products is "ex-work" (Incoterms 2010). Requisite transportation documents shall be provided by AENOVA.
- 4.2 In the event of the Customer's delay in pick-up or in case of delay in delivery or shipment for reasons for which the Customer is responsible, risk of accidental loss of the goods shall pass to the Customer as of the date on which AENOVA's notification of readiness for shipment is sent to the Customer and AENOVA shall be entitled to invoice the order(s) so affected. AENOVA's invoice shall not constitute a waiver of any such rights or the loss of any other rights or affect any other claims AENOVA may have in this case resulting from the Customer's failure to promptly accept delivery of any product or the Customer's delay in delivery or shipment.

### 5. NON-CONFORMING PRODUCTS, INSPECTION, PERIOD OF LIMITATION

- 5.1 The Customer shall notify AENOVA of apparent defects immediately and, in any event, no later than ten (10) business days after receipt of the product by the Customer. Notification of defect shall be in writing and shall provide evidence of the defect. Hidden defects shall be notified to AENOVA immediately in writing upon detection, i.e. without culpable delay, accompanied by supporting documentary evidence, and, in any event, no later than one (1) year after delivery of any such products or, if so agreed, after acceptance thereof. The supporting documentary evidence shall include a sample of the non-conforming product. The product delivered is otherwise deemed to be approved and accepted in both cases.
- 5.2 If the Customer and AENOVA disagree on the non-compliance of a product, the dispute shall be referred to the Zentrallaboratorium Deutscher Apotheker e.V., Carl-Mannich-Str. 20, 65760 Eschborn (hereinafter "Zentrallaboratorium") for adjudication, or any other mutually agreed testing laboratory; such laboratory acting as an independent expert. The decision handed down by the Zentrallaboratorium or the independent expert shall be binding on both the Customer and AENOVA. If the Zentrallaboratorium or the independent expert deems the product 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 the Customer. The Customer and AENOVA undertake to give the independent expert a maximum of two (2) months to carry out its task.
- 5.3 In the event AENOVA supplied the Customer with non-conforming products, AENOVA shall, at its own discretion, upon the Customer's request to remedy defects and within the agreed time period, either repair or replace the non-conforming products. AENOVA shall do its best efforts to rectify the defects or to make a replacement delivery as soon as possible. Any expenses, fees, and other costs incurred by AENOVA shall be limited to, and shall not exceed, the amount of the individual order value exclusive of costs of active pharmaceutical ingredients.
- 5.4 In the event that AENOVA has failed to repair or replace non-conforming products, the Customer may cancel the respective individual order or may demand a reduction of the price.
- 5.5 The limitation period for all claims in connection with the supply of non-conforming products is one (1) year from the day of delivery or, if an acceptance by Customer is required, the day of acceptance.



## 6. PRICES AND PAYMENT

- 6.1 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 the Customer. The Customer shall return all rental crates to AENOVA. In the event that the Customer fails to comply within four (4) weeks as of the date of delivery, AENOVA shall be entitled to charge the Customer EUR 5.00 (five euros) for each crate.
- 6.2 In the event that AENOVA has agreed to payment after delivery, AENOVA's invoices shall be due and payable by the Customer within thirty (30) calendar days of receipt thereof by the Customer and receipt of the Service. Should the Customer be in default of payment or if it exceeds the period allowed for payment in a mutual commercial transaction, interest will be charged at a rate of nine percentage points (9 %-points) p.a. above the currently valid base rate (Basiszinssatz) of the German Central Bank (Deutsche Bundesbank). AENOVA reserves the right to claim further damages.
- 6.3 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. The Customer shall bear all costs associated with payment by bills of exchange or checks.
- 6.4 The Customer shall have no right of set-off or retention, except to the extent that the counterclaim has not been disputed by AENOVA or been determined by a final and binding decision.
- 6.5 AENOVA reserves the right to use payments to settle the oldest due outstanding accounts plus the default interest and costs accrued thereon; this will be done in the order of costs, interest, due receivables.
- 6.6 AENOVA has the right to refuse performance if after conclusion of the contract it becomes apparent that its claim for payment of Services is jeopardised by the Customer's poor financial standing. This right to refuse performance shall cease once payment has been made or the Customer has put up adequate collateral. AENOVA has the right to set the Customer an appropriate deadline within which the Customer has either to make payment upon tender of delivery, or provide collateral for the delivery. Upon fruitless expiry of the deadline, AENOVA shall be entitled to rescind from the contract. In addition, AENOVA has the right in the aforementioned event of the deterioration of the Customer's assets, to deliver Services only on the basis of advance payment or the provision of appropriate collateral.

## 7. RETENTION OF TITLE WITH REGARD TO PRODUCTS

- 7.1 AENOVA retains legal title to any product supplied until the whole price for the respective product (including but not limited to, VAT, costs for quality control, quality assurance and testing of the products) has been paid in full. The Customer shall be entitled to resell any product delivered by AENOVA subject to retention of title in the ordinary course of business, unless it is in default of payment. The Customer is not, however, entitled to either pledge or assign products not yet paid for in full as security. The Customer assigns to AENOVA all its payment claims against buyers of the products, as well as those claims with regard to the reserved products 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 the Customer. AENOVA accepts this assignment. The Customer is entitled to collect the assigned claims for AENOVA in his own name and on his own account unless such authorization is otherwise revoked by AENOVA. AENOVA shall not be entitled to collect the assigned claims itself as long as the Customer meets its payment obligations.
- 7.2 On the Customer's request, AENOVA shall release the security once their realisable value exceeds the value of outstanding claims against the Customer by more than 10%. In such case, AENOVA may select the security to be released.

## 8. REPRESENTATIONS AND WARRANTIES

- 8.1 The Customer shall perform all of its agreed obligations in full compliance with all applicable Laws. Moreover, the Customer shall hold during the whole term of any business relationship with AENOVA all licenses, permits and similar authorisations required by any governmental authority for the Customer to perform its agreed obligations.
- 8.2 The Customer 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 the 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 the Customer is a party.
- 8.3 AENOVA assumes no warranty for the economic usability of Services or economic success of the Customer's business.

## 9. LIMITATION OF LIABILITY

- 9.1 Except in cases of wilful misconduct and gross negligence or otherwise stated in this Section 9, 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 this Agreement. In the case of gross negligence, AENOVA shall only be liable for foreseeable and typical damage.
- 9.2 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 - subject to approval by AENOVA - of an independent quality guarantee.
- 9.3 Furthermore, AENOVA's liability shall not be limited with regard to any violation of cardinal obligations whose violation jeopardises the purpose of these GTC or the negligent violation of obligations whose fulfillment is essential for the proper execution of these GTC and on which the Customer usually relies. In such case, AENOVA shall nevertheless only be liable for foreseeable and typical damage.
- 9.4 Insofar as the liability of AENOVA is excluded or limited, this also applies to the personal liability of AENOVA's employees, directors, representatives and vicarious agents.

## 10. INDEMNIFICATION AGAINST THIRD-PARTY CLAIMS

- 10.1 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 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 mentioned insurance cover a maximum amount of EUR 30,000,000.00 (thirty million euros) in total per insurance year; and
- (b) if, with regard to products placed on the market in Germany, AENOVA is pharmaceutical entrepreneur pursuant to Section 4 (18) German Medicinal Products Act, German pharmaceutical product liability insurance with insurance cover up to a total maximum amount of 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 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 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 EUR 36,000.00 (thirty-six thousand euros) per insurance year.



10.2 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 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 Section 10.1.

10.3 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.

## 11. FORCE MAJEURE

11.1 Neither party shall be liable for any failure of or delay in performing obligations hereunder, and neither party shall be deemed to be in breach or default of its obligations set forth in any agreement, insofar as, to the extent that, and as long as, such failure or delay is due to any circumstances constituting Force Majeure that are beyond its or its supplier's reasonable control and not to its acts or omissions, including, without limitation, natural disasters, fire, flood, severe storm, earthquake, civil disturbance, riot, order of any court or administrative body, embargo, acts of government, war (whether or not declared), acts of terrorism, strikes and other legal labour law disputes, theft or other similar causes (hereinafter "Force Majeure").

11.2 In the event of the occurrence of a Force Majeure event, the party prevented from or delayed in performing shall promptly give notice to the other party and shall use commercially reasonable efforts to avoid or minimise the delay.

## 12. CONFIDENTIALITY

12.1 Subject to the limitations set forth in Section 12.3 below, the Customer undertakes to maintain confidentiality in respect of all information disclosed by AENOVA, including but not limited to formulations, know-how, business secrets, manufacturing processes and samples (hereinafter "Information") irrespective of its form and medium in which it is contained.

12.2 The Customer hereby undertakes and warrants to maintain confidentiality in respect of all Information and to take due care in ensuring that any Information is only used for the contractually stipulated purpose, to reproduce any Information only to the extent necessary and to pursue the purposes set forth in this agreement, with all such reproductions also deemed to constitute Information.

12.3 The following is not deemed to constitute Information within the meaning of Section 12.1: Information which the Customer can prove:

- (a) it is generally known to the public at the time of disclosure or becomes generally known through no wrongful act by the Customer;
- (b) to have become known to the Customer through a disclosure by sources other than AENOVA having no duty of confidentiality vis-à-vis AENOVA, whether direct or indirect, with all respect to such information and having the legal right to disclose such Information;
- (c) it has been independently gained and without infringing of a duty of confidentiality.

12.4 The Customer may disclose any Information as required by applicable laws, court order or administrative directive, provided that the Customer has submitted prior written notice of such disclosure to AENOVA and takes

reasonable and lawful actions to avoid and/or minimise the extent of the disclosure.

12.5 The Customer may make available the Information to its employees or consultants only to the extent that this complies with the contractual purpose of these GTC and the individual agreement. Moreover, the Customer shall not exploit or otherwise utilise the Information for its own commercial purposes. The Customer agrees that it shall not acquire ownership of or any other right to use the Information by virtue of this agreement or by implied conduct.

12.6 The obligation to maintain confidentiality in accordance with this Section 12 shall remain in full force and effect for as long as AENOVA continues to disclose Information to the Customer, however, unless otherwise agreed, the obligation of non-disclosure or any economic non-use of the Information shall end after the time period of five (5) years after the termination or expiration of any business relations with AENOVA.

## 13. APPLICABLE LAW AND COMPETENT COURTS

13.1 Any contracts entered into between AENOVA and the Customer, including but not limited to these GTC, shall be governed by the laws of the country in which AENOVA has its legal seat under exclusion of the UN Convention on the International Sale of Goods (CISG) and provisions of conflict of laws.

13.2 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. In addition, AENOVA is entitled to file a suit before the competent court of the Customer's place of business.

April 2017