

## **Standard Business Terms of Sale and Service (SBTSS) of the Haupt Pharma Group**

### **Part I: General Provisions**

#### **1. Preface**

1.1. All our deliveries, development and other services are subject to our SBT. Other standard terms of trade do not become part of the contract, even if we do not object them expressly. If we effect a delivery or render a development or other service without explicitly objecting to SBT other than ours, this shall not be considered as acceptance or approval of the other party's standard terms of trade.

#### **1.2. Our SBT apply**

- only towards entrepreneurs and public legal entities
- also to all future commercial transactions with the same customer
- to the delivery of any goods, in particular to medicinal products, foodstuffs, cosmetics and medical devices,
- to the development of medicinal products,
- to other services (contracts of service, contracts of manufacture)

#### **2. Conclusion of Contract, written form**

If an order is considered as a quotation, then this quotation may be accepted by us within a period of two (2) weeks. Offers are not binding unless confirmed by our order confirmation in written form or by our performance without reservation. Written form in terms of these SBT may be fulfilled through facsimile or email also.

#### **3. Documents**

We retain all rights in documents provided to customer in connection with the order. This also applies to written documents which are marked as "confidential". These documents may be passed on to third parties only with our explicit written approval.

#### **4. Confidentiality**

4.1 Any information provided to customer in the course of business are to be treated confidential. This does not apply to information, which was already known to the customer prior to receipt from or on behalf of us or which has become known to it otherwise. In any and all cases our prices and commercial conditions are to be kept secret.

4.2 Unless expressly permitted, customer is not authorized to refer to our business relationship in its advertising material.

4.3 Customer is obliged to obey all statutory provisions on data protection. In particular it has to swear its employees to data protection secrecy according to applicable law.

4.4 Customer shall impose the same legal obligations on its subcontractors.

4.5 Customer shall be liable for all damages sustained by us or any of our affiliated companies arising out of or in connection with the breach of the provisions in sec. 4.1 to 4.4 of these SBT according to statutory law.

#### **5. Intellectual Property**

5.1. Customer has conducted sufficient investigation on the absence of conflicting IP-rights of third parties.

5.2. Customer acknowledges that the development, manufacture, supply and /or use of the product does not infringe Intellectual Property of third parties and is liable for negligent or willful violation of such infringement. Further customer is obliged to indemnify us and hold us harmless from any third parties' claims in connection with such negligent or willful infringement of Intellectual Property and shall bear all judicial and extrajudicial costs and damages

5.3. Customer shall bear any licence fees for 3rd parties' IP rights unless otherwise agreed in writing.

#### **6. No exclusivity**

Exclusivities regarding the development, manufacture or other services have to be agreed separately in writing.

#### **7. Force Majeure**

Force Majeure, including, without limitation, interruption of operations beyond customer's responsibility, lack of energy, or commodities or primary products, collective actions or labour disputes, acts of government authorities, and the like shall suspend the duties from the agreement to the extent and for the duration of the hindrance, its extent and its estimated duration without culpable delay. The affected party shall inform the other party about the manner, extent and the expected duration of the hindrance without undue delay and shall use its best efforts to eliminate it.

#### **8. Termination in cases of insufficient performance**

If due payment by customer is jeopardized (for instance due to substantial economical deterioration or factual hindrances in performance), we reserve the right to either withdraw from- or terminate the agreement. This is considered to constitute a good and just cause for termination.

#### **9. Place of delivery and performance**

Unless otherwise agreed with us, place of delivery and performance for all deliveries and payments to us is our business address.

#### **10. Applicable Law**

The agreement shall be governed by and construed in accordance with the laws of Germany. The provisions of the United Nations Conventions on Contracts for the International Sale of Goods (CISG) shall not apply.

#### **11. Place and venue of jurisdiction**

For all direct or indirect disputes, controversies, or claims in connection with the agreement, the parties submit to the competent courts of our business address. This also applies to complaints with regard to cheques and bills of exchange. However, we may to sue customer at its natural forum or at our natural forum.

#### **12. Severability Clause**

If individual provisions of these SBT should be, on the whole or in parts, invalid, the validity of the remaining provisions shall remain unaffected. The parties undertake to replace the invalid provision by a valid one which serves the intended economic purpose closest in a legally permissible way. This shall not apply to invalidity according to infringement of Book 2, div. 2 of the German Civil Code (BGB) with the title "Drafting contractual obligations by means of standard business terms". In this case statutory law shall replace the invalid provision, unless supplementary interpretation of the contract requires to close the loophole.

### **Part II: Particular provisions with regard to supplies and deliveries**

#### **1. Prices**

##### **1.1 Prices, payment and passing of risk**

Unless agreed otherwise in writing, our prices are valid "ex works" (Incoterms 2000) exclusive of shipping packaging and shipment, VAT or tolls.

1.2 At request of customer, we will ensure adequate transportation insurance prior to each shipment at the expense of customer.

1.3 Unless agreed otherwise in writing payment is due strictly net within 10 (ten) days upon receipt of the invoice and the defect-free goods.

The statutory provisions upon default in payment are applicable.

1.4 Customer shall have rights to offset only with regard to claims acknowledged by final legally binding judgment or to undisputed claims. Further, customer shall only have rights of retention as far as its counterclaim originates from the same contractual relationship. This does not affect the parties' statutory rights of retention between entrepreneurs as they may arise from applicable law.

## **2. Delivery, provision, liability in case of default in delivery**

2.1 Delivery terms and delivery dates are not binding unless confirmed expressly in writing.

2.2 We are bound by our planned delivery dates only if complete documentation and materials to be supplied by customer have been provided DDP (Incoterms 2000) at its own risk and all technical issues have been clarified properly and in due time.

2.3 In case of customer's default of acceptance or breach of any other customer's co-operation obligation, we are entitled to claim any damage incurred, including possible additional expenses. Further claims remain unaffected. We reserve the right to claim further damages.

2.4 Upon customer's default in acceptance, risk of loss and deterioration shall pass to customer.

2.5 Quantity variances of +/- 10 % (plus/minus ten percent) shall be considered as contractual. Any contractual quantity variance shall be taken into account in the respective invoice accordingly.

2.6 If we are responsible for a delay in delivery, we are liable for any damage incurred according to statutory law, but limited to predictable and transaction-typical damage, provided that the contract concerned is a time bargain according to sec. 286 sub. 2 No. 1 German Civil Code or sec. 376 Code of Commercial Law, and if customer is entitled to refer to discontinuance of interest or inasmuch as the default in delivery is caused by the culpable breach of an essential contractual obligation.

2.7 Further, we shall be liable according to applicable statutory law, inasmuch as we have caused the default in delivery by willful or gross negligent breach of contract. As far as the default in delivery is not attributable to willful breach of contract, our liability is limited to the predictable and transaction-typical damage.

## **3. Warranty and contractual Liability for Products**

3.1 We are not liable for the pharmaceutical efficacy or therapeutic correctness, utility or safety of the products, unless they are not manufactured or delivered according to the specifications provided by customer.

3.2 Inasmuch as the products delivered are deficient, we shall, at our choice, have the right to remedy defects by repairing or replacing the defective products.

3.3 After we have failed specific performance twice, the customer may withdraw the respective individual order or claim reduction of price.

3.4 We are liable according to the applicable statutory law for damages caused by the delivery of deficient products, provided that they are attributable to our willful or gross negligent conduct.

3.5 Further, we are liable according to the applicable statutory law if and to the extent damages arise or result from or were otherwise attributable to breach of a essential contractual obligation or warranty; in the latter case our liability shall be restricted to predictable and transaction-typical damages.

3.6 Customer shall inspect the products after delivery to Customer or respectively to the carrier according to applicable law but in no event later than 7 (seven) days upon delivery.. Customer shall further notify us of obvious defects immediately and in no event later than 7 (seven) days after delivery of such products. Hidden defects must be notified to us immediately upon detection without undue delay in writing and providing evidence and in no event later than 1 (one) year after delivery of any such products. Evidence shall include a sample of defective products with the notification or within appropriate time limit.

3.7 The limitation period for all claims in connection with the supply of defective products is 1 (one) year after delivery, unless the applicable mandatory law constitutes longer limitation periods.

3.8 Inasmuch as damage is covered by our liability insurance on its merits our liability shall be limited to the amounts covered. The insurance covers currently no less than accumulated annual

total of 10,000,000 € and a total of 2,500,000 € per occurrence and person.

3.9 In any case, our liability is limited to the amount of the individual order value.

3.10 Liability for culpably caused personal injuries or death as well as for cases of gross negligent conduct as set forth under sec. 309 no 7 b German Civil Code, if applicable, shall remain unaffected as well as the liability according to mandatory applicable Product Liability provisions.

3.11 Unless stipulated otherwise in the preceding provisions any warranties and liabilities are excluded.

All limitations and exclusions of liability shall apply to acts and/or omissions of our employees, personnel, members of staff, statutory and other representatives as well as vicarious agents, auxiliary or similar persons fulfilling similar tasks.

## **4. Other Liability, Expenses, Indemnification and Recourse**

4.1 Any liability beyond the stipulations of the said sec. 3 and 4, irrespective of its legal basis, is excluded; including, but not limited to claims for damages based on violation of "secondary obligations" pursuant to sec. 241 sub. 2 of the German Civil Code and tortious liability.

4.2 The limitation of sec. 4.1 also applies, if customer claims for reimbursement of expenses instead of compensation of damages.

4.3 Customer shall solely and exclusively be responsible and liable towards third parties for all injuries and damages arising or resulting from products brought to the market. Customer waives its rights for indemnification or other legal recourse against us upon first request, for all incidents, injuries, and damages within the scope of application of its medicinal products liability insurance, or of its general product liability insurance whichever is applicable, or for which the respective insurance carrier provides, in fact, coverage. Customer shall inform its insurance company about this waiver of recourse and obtain a written declaration of consent of its insurance company.

4.4 In case a third party claims damages against one or both parties, the following shall apply:

4.4.1 If a third party files a claim against one of the parties, the other party shall be obliged to provide best possible support for the defence against the claim.

4.4.2 Customer shall hold us harmless upon first request from any liability claims of third parties, unless we are liable towards customer for such damages according to this agreement. Holding us harmless shall include but shall not be limited to assume defense, to pay/share our attorney's fees and other defense costs, and to reimburse our counsel.

4.4.3 In any case customer shall hold us harmless upon first request from any liability claims of third parties covered by customer's waiver of rights for indemnification or other legal recourse.

4.4.4 We shall not acknowledge any third party's claim without customer's prior written approval in writing.

4.5 Sections 3.9 (maximum amount), 3.10 (liability for culpable causation of death, personal injuries or gross negligence) and 3.11 of this Part 2 shall apply to all restrictions of liability and indemnification in sec. 4.1 to 4.4.4 accordingly.

## **5. Conditional Sale (Retention of title)**

5.1 We retain title to all products until all outstanding accrued debts and all other claims against customer have been settled. In case of breach of contract by customer we are entitled to exert proprietary rights over our products - specifically the taking back of delivered products. Taking back the products means that we exert our right to withdraw from the contract, which entitles us to utilise and realise the product. The proceeds of realisation will be credited against customer's debts less reasonable charges.

5.2 Customer is obliged to treat delivered, unpaid product carefully; it is in particular held to provide sufficient insurance cover-

age against loss, damage and destruction, as for example caused by water, fire or theft, to the reinstatement value.

5.3 In case of levy of execution or any other third party's intervention, customer shall inform us without undue delay, to enable us to initiate third party proceedings in due time. Insofar as the third party is not able to compensate for court fees and other defence costs, customer shall compensate the costs incurred accordingly.

5.4 Customer is entitled to sell the products in the regular course of business. Customer hereby assigns all claims which result from the resale to its customers or third parties to the amount indicated in the final invoice (incl. VAT if applicable) to us, irrespective of whether the product has been resold without or after being further processed or not. Customer remains generally authorised to collect the outstanding debt, even after the assignment. Our right to collect the debt by ourselves remains unaffected. Upon request, customer discloses the debts assigned and their debtors accordingly, to give the necessary particulars for the collection of debts, to hand out the corresponding documents and to inform the debtor about the assignment. We will not collect the debts until customer is in default of payment or a petition in bankruptcy has been filed.

5.5 Customer's processing or altering of the product takes place in our favour. If the product is mixed with other substances which do not belong to us, we shall be co-owner of the new product according to the proportion of the value of the product to the other items processed at the time of processing. Further, the newly formed product follows the same rules applicable to conditional sale as set forth above.

5.6 If the product was inseparably mixed with other objects not owned by us, we obtain co-ownership of these products according to the proportion of value of the product to the other mixed objects at the time of the intermingling. If the intermingling leads to the result, that the customer is deemed to be the owner of the new object, it is understood and agreed, that customer assigns its respective partial property to us.

5.7 At customer's request, we are obliged to release customer's securities of our choice insofar as the realizable value of our securities exceeds the debts which are to be secured more than 10 (ten) %.

### **Part III: Special terms with regard to development activities**

#### **1. Scope of the development activities**

1.1 In the performance of the development work we observe the applicable pharmaceutical and food stuff laws and regulations and the relevant provisions applicable in the individual case as well as the state of scientific and technical progress, as far as this is part of our development offer. If customer requests that special regulations or guidelines etc. are to be observed, which are not generally known or recognized, customer is to point this out to us in writing.

1.2 We prepare a project plan for the development of pharmaceutical products in coordination with customer, which indicates the individual milestones of development and the time which is estimated to be required. For each defined milestone we will provide customer with an intermediate report. For any other products the respective intermediate steps will be separately agreed with customer.

1.3 We develop the product according to the project plan respectively the individual agreements for- and at cost of customer. The execution of required clinical trials and registration procedures will be in the responsibility of customer, unless it is agreed that the coordination of such activities rests with us.

1.4 We will start the performance of the activities for any next milestone determined in the project plan only after customer has instructed us in each case separately and in writing. If customer withholds such instructions the agreed timelines will be shifted accordingly.

1.5 We shall immediately inform the customer of any delays requiring a shift of the next milestone.

1.6 Changes of the project plan are only effective in writing and signed by both parties. If customer requests changes, we shall inform customer within a maximum of 2 (two) weeks after receipt of the inquiry about whether or not the requested change is feasible and about the impact it will have on the development, especially about the alterations with regard to costs, timing and risk of success of the development. If we suggest a change, customer shall inform us within a maximum of 2 (two) weeks whether it agrees to the suggested change or not, otherwise the change is deemed to be accepted. We will inform customer accordingly separately.

1.7 Customer will, for the purpose of the development of a medicinal product, supply us with a sufficient quantity of active pharmaceutical ingredients (API) free of charge. Customer is in charge of the procurement of the API for the medicinal product to be developed. Customer will further qualify and audit the manufacturer of the API and is responsible for the release of the API. Customer will additionally supply us with API which has gone lost during the development process or reimburse us any costs incurred through substitution, unless the respective loss is caused by our gross negligent or willful misconduct.

1.8 Any raw materials, such as API, provided by customer shall be delivered to us according to DDP (Incoterms 2000). The customer assumes all risk throughout the transport (free ramp) accordingly.

1.9. After completion of the project, we shall provide customer with a final report which contains a summary of the project results.

#### **2. Payment and remuneration**

2.1 For the execution of the development services the customer shall pay us the remuneration indicated in the development offer. If not stated otherwise, VAT is excluded and personnel costs and expenses for internal effort are included. This remuneration is made on estimates which are minimums of the workload and hours needed as per our best understanding and experience. We preserve our right to invoice the services rendered based on the actual time and effort basis. To the extent possible we will give customer notice on substantial cost alterations and further specifications of costs.

2.2 The payment of the due amounts will be effected in partial amounts. If not agreed otherwise, the remuneration is due net on receipt of the invoice and to be effected within 14 (fourteen) days after receipt of the invoice. The statutory provisions of delay in payment apply.

2.3 Potential services regarding stability studies will be charged to customer at least once per calendar year. Services started or terminated in the course of a calendar year will be charged pro rata.

#### **3. Acceptance of performance**

Insofar as the character of the contract is a contract of manufacture (Werk(lieferungs-)vertrag) rather than a contract of service (Dienstvertrag) the acceptance of performance follows the individual working steps as set forth under the development offer. Any working step, about which customer has been informed via intermediate report, is deemed to be accomplished and (physically) accepted as (generally) in accordance with the contract, either through unconditional acceptance of the intermediate working steps or 4 (four) weeks after receipt of the intermediate report, unless customer has explicitly issued a notice of defect. The development is deemed to be accepted as completed by unconditional payment, otherwise or 4 (four) weeks after receipt of the final report, unless customer has explicitly issued a notice of defect. We will instruct customer of the consequences of the expiration of the time limits set forth under the sentences 2 and 3 of this section. Acceptance shall not be withheld by reason of minor defects.

#### **4. Warranty and contractual liability for Products**

4.1 The development will be conducted according to the state of the art. We do not assume any warranty for the economic usability.

ity of the results or for their fitness for the purpose of filing a marketing authorization as medicinal product.

4.2 The period of warranty for defects shall one (1) year upon acceptance (see this sec. 3).

4.3 We are liable according to statutory law, if attributable to our wilful and gross negligent conduct. Further, no liability is assumed for consequential damages, liability, equity and other compensation including e.g. loss of revenues caused by a defective performance of development services.

4.4 Further, we are liable according to the applicable statutory law if and to the extent damages arise or result from or were otherwise attributable to breach of an essential contractual obligation or warranty; in the latter case our liability shall be restricted to the predictable and transaction-typical damages.

4.5 Warranty as well as liability for any damage is excluded if,

4.5.1 the underlying formulations, manufacturing instructions, validation instructions or specifications were likely to be misunderstood, incomplete or incorrect or proved to be technically impracticable and if this had been unrecognizable for us;

4.5.2 a starting material, which has been declared unsuitable, was used following explicit instruction of customer;

4.5.3 product defects result, either in whole or in part, from inappropriate quality of starting materials purchased by us from third party suppliers which had been determined by customer, or which result from starting materials provided by or on behalf of customer; or

4.5.4 manufacturing and testing procedures were carried out following the explicit instructions of customer.

4.6 All aspects set forth under the said sections 3.9 (maximum amount), 3.10 (liability for negligent causation of death, personal injuries or gross negligence) and 3.11 of Part II shall apply to all restrictions of liability (sec. 4.1 to 4.5) accordingly.

## 5. Other liability, Expenses, Indemnification and Recourse

5.1 Any liability beyond the stipulations of the said sec. 4 of this Part III, irrespective of its legal basis, is excluded, including, but not limited to claims for damages based on violation of "secondary obligations" pursuant to sec. 241 sub. 2 of the German Civil Code and tortious liability.

5.2 The limitation of sec. 4.1 also applies, if the customer claims for reimbursement of expenses instead of compensation of damages.

5.3 We do assume only liability, independent from the character of the product that is to be developed, for the execution of the services, but not for the successful outcome of the development project. Customer shall solely and exclusively be responsible for the product developed under its name and undertakes to have available all necessary authorisations and licences and to be authorised to accept delivery of the product.

5.4 In case a third party claims damages against both parties or either of them, the following shall apply:

5.4.1 If a third party files a claim against one of the parties, the other party shall be obliged to provide best possible support for the defence against the claim.

5.4.2 Customer shall hold us (and our affiliated companies as well as their respective directors, officers, employees and agents harmless upon first request from any liability claims of third parties and if they are attributable to

- marketing, sales and supply of the products and their promoting;
- customer's breach of the obligations or responsibilities set forth under this contract;
- negligence or willful misconduct.

Holding us harmless shall include but shall not be limited to assume defence, to pay /share our attorney's fees and other defence costs, and to hire our counsel. In any case customer shall hold us harmless upon first request from any liability claims of third parties covered by customer's waiver of rights for indemnification or other legal recourse (see sec. 6.3 of this Part

III). Customer does not hold us harmless, if we are liable for the respective damages towards it

5.4.3 We shall not acknowledge any third party's claim without customer's prior written approval in writing.

5.5 All aspects set forth under the said sections 3.9 (maximum amount), 3.10 (liability for negligent causation of death, personal injuries or gross negligence) and 3.11 of Part II shall apply to all restrictions of liability (sec. 5.1 to 5.4.3) accordingly.

## 6. Special terms applicable if the product will either be used in clinical trial studies or produced for market volumes or both

6.1 In case any batches manufactured according to this agreement are, whether or not for remuneration, applied to human beings, esp. are brought to the market for the use with end-consumers or are used for clinical trials, the customer shall solely and exclusively be responsible and liable towards third parties for all damages arising or resulting from the product supplied by us.

6.2 Customer confirms to hold sufficient insurance coverage regarding

- its medicinal product liability insurance, or
- its clinical trials insurance, or
- other liability insurance.

6.3 Customer waives its rights for indemnification or other legal recourse against us for which any of its insurance carriers with respect to the insurances set forth under sec. 6.2 provide coverage and holds us harmless from any claims for compensation upon first request according to the provision 5.4.2 of this Part III. Customer shall inform its insurance company and obtain its written consent.

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