

## BACCINEX SA General Terms and Conditions of Sale for Contract Development and Manufacturing

### 1. Definitions

In this document, the following words and phrases shall have the following meanings :

- 1.1. « *BACCINEX* » : BACCINEX SA, a corporation organized and existing under the laws of Switzerland, whose registered offices are CH-2822 Courroux, rue de la Source n°3, acting by its legal representatives.
- 1.2. « *Client* » : any person or entity to whom or to which BACCINEX SA has to supply or perform «*Services*».
- 1.3. « *General Terms* » : this document («*Baccinex SA General Terms and Conditions of Sale*») and any document annexed.
- 1.4. « *Contract* » : the entire agreement between the parties, constituted by « *General Terms* », « *Particular Conditions* » and all attached documents.
- 1.5. « *Particular Conditions* » : detailed characteristics of each sale.
- 1.6. « *Services* » : what BACCINEX SA has to deliver or to perform, the nature and the purpose of which are specified in the contract.

### 2. Priority of contractual documents

- 2.1. These Conditions and any exhibits hereto supersede any other terms and conditions of purchase of Contractor, even if BACCINEX do not expressly reject them. No modification of any of our Conditions herein shall be valid or binding on either party unless in writing and signed by an authorized representative of BACCINEX.
- 2.2. When BACCINEX SA provides a written estimate, this quotation constitutes the Particular Conditions that complement or amend the General Terms and Conditions.

### 3. Offers and acceptance of orders

BACCINEX offers apply for thirty (30) days from the date of the offer and are made without obligation. All orders placed do not become legally binding until they have been confirmed by BACCINEX in writing. Save where otherwise agreed, these Conditions apply EXW COURROUX (Incoterms 2010, International Chamber of Commerce, Paris January 2011).

### 4. Services

The extent of the Services for a given product or project will be outlined in writing prior to the start of the project between the Client and BACCINEX. Any addition or change must be made in writing.

#### 4.1. Production

Production dates are agreed with the Client in order to reserve the corresponding production capacities in due course. A prepayment is required for the booking of the production slot. Its amount is defined in the BACCINEX offer.

#### 4.2. Development Work

Development work required for performing specific tasks within the scope of our offer range can be performed. This work can for example include, but should not be limited to, laboratory tests, sample production, preparation of production and testing instructions, validations, and similar work which aim at the implementation of a product idea into suitable, cost-effective and competitive production or marketing. Unexpected development costs that are not foreseeable upon issue of the offer will be charged to the Client according to time and expenses.

#### 4.3. Pilot Batches, Risk of Pilot Manufacture

If a pilot batch is asked by the Client, a test batch will be produced under regular operating conditions upon instruction of the Client. The size of the batch shall be chosen to the effect that meaningful findings can be established for the course of the subsequent production. The production risk is at the expense of the Client. Unexpected costs for pilot manufacture that are not foreseeable upon issue of the offer will be charged according to extra expenses. In-process controls as well as quality controls for pilot manufactures are made and charged upon agreement.

#### 4.4. Risk of Production

If it is agreed that the Client provides BACCINEX, without cost, with the quantities of active agents required for the manufacturing of the ordered product the Client shall bear the production risk regarding the provided active agents. Any losses of active agents, for any cause whatsoever, are not at BACCINEX expense. This also applies to any shortfall in yield. If due to production-related losses of active agents or other losses of active agents or any lower yield of active agents for any

cause whatsoever any agreed or planned batch quantities regarding the ordered products cannot be generated, this shall not be at BACCINEX expense.

#### **4.5. Liability for Defects**

Upon performance of the Services, BACCINEX warrants compliance with the agreed processing, treatment, testing and other procedures according to the acknowledged rules of pharmaceutical production technology. BACCINEX does not assume liability for any defects of the starting substances, active agents or other materials provided by the Client and used in the manufacturing process. BACCINEX also does not assume liability for any defect of the finished product caused by defective starting substances, active agents or other materials provided by the Client.

#### **5. Allocation of Responsibility**

Responsibilities with regard to the GMP (Good Manufacturing Practice) regulations shall be allocated – to the extent necessary – in a separate allocation of responsibility contract (Quality Agreement). Such agreement shall be entered into force before the first GMP manufacturing.

#### **6. Warranty and Liability**

BACCINEX shall have no liability with respect to any recommendations or instructions as to handling, use or disposal of any product resulting from a performed Service. BACCINEX's sole and exclusive warranty is that its product complies with the BACCINEX specifications for the said product. BACCINEX makes no other warranties either express or implied, whether with respect to its recommendations, instructions, product, process or otherwise, and specifically disclaims any implied warranties of merchantability, suitability, fitness for a particular purpose, non-infringement, or otherwise. BACCINEX liability to the Client for any and all losses or damages resulting from BACCINEX's breach of this contract or product not meeting specifications, whether in tort or in contract or otherwise, shall be, at the election of BACCINEX, limited to the replacement of a like quantity of product and in no event shall BACCINEX be liable for special, indirect, incidental, consequential or contingent damages, (including, without limitation, loss of anticipated profits, business interruption, loss of use or revenue, cost of capital or loss or damage to property or equipment).

#### **7. Insurance / Liability**

Except to the extent of liability arising solely and directly from any breach of BACCINEX's obligations, the Client assumes full responsibility for any liability arising out of unloading, discharge, storage, handling, use and disposal of any product or container, including the use of such product or container alone or in combination with other substances, compliance or non-compliance with any laws or regulations and damage to or destruction of returnable containers from any cause whatsoever after delivery to the Client (and, if applicable, until their return to BACCINEX). Except to the extent solely and directly caused by any breach of BACCINEX obligations through BACCINEX gross negligence or willful misconduct under this contract, the Client shall defend, indemnify and hold harmless BACCINEX, and their respective representatives and employees, from and against all losses, liabilities, damages, and expenses made against or incurred by BACCINEX, and their representatives and employees, arising out of any claim, suit or proceeding by any governmental agency or any third parties (including, without limitation, any employee or relative of any employee of the Client) which alleges death, personal or economic injury or damages to any private or public property or resources, caused or contributed to by the product resulting from performed Services. All toll materials supplied by the Client shall remain the property of the said Client and, except in the event of BACCINEX's gross negligence or willful misconduct, BACCINEX shall have no liability, and shall assume no risk, for any such materials.

Any material belonging to the Client is stored by BACCINEX without insurance. BACCINEX does not assume any liability for damage and perishing occurring during production or storage, unless such damage has been caused by BACCINEX by intent or gross negligence. Upon request of the Client, BACCINEX takes out a storage insurance against fire, burglary, hail, storm and tap water damage, according to the Client instructions and at its expense, with coverage sums to be agreed.

#### **8. Communication**

During the course of the Service, BACCINEX will remain in communication with the Client. In the case of unusual occurrences, the Client will be informed immediately. If immediate notification is impossible and a delay might have deleterious effects, the Client authorises BACCINEX to take any action in the presumed best interest of the Client.

#### **9. Property Rights**

All results of Services will become exclusive property of the Client. The client will be responsible for all vindications of patents, copyrights or similar claims, unless agreed otherwise.

## 10. Data from the Client

If a Service is subject to disclosure of compositional information or of test results, the Client remains fully responsible for the completeness of this information. BACCINEX takes no responsibility for conclusions derived from incomplete and/ or incorrect information.

## 11. Confidentiality

Except lawful and legitimate authority orders, BACCINEX obligation of secrecy against third parties is guaranteed and includes all information which BACCINEX may have received from the Client for his product and all data which BACCINEX may have obtained about the said product.

On special request, BACCINEX business connection with the Client will be kept confidential insofar that this is possible and warranted.

This confidentiality will remain in effect after completion of the project unless agreed otherwise.

## 12. Price

12.1. BACCINEX prices valid at the time of the contract conclusion shall apply. The prices are strictly net, EXW (Ex-Works). Applicable VAT (Value Added Taxes) is added thereto.

12.2. The Client shall also pay all other taxes, levies, fees and other payments due in accordance with Swiss law or the law of an importing or transit country. BACCINEX reserves the right to assess and re-invoice to the Client freight and handling charges for any special shipment requests, including but not limited to, expedited shipments or special transportation costs.

## 13. Payment

13.1. The remuneration of the Services will be agreed upon prior to its initiation. Depending on the extent and the degree of complexity of the work to be done, the remuneration may either be based on a fixed price contract or on a budget plan. The agreed-upon remuneration will not exceed the original offer without the explicit consent of the Client. Costs not included in the written offer will be charged separately; especially the following:

- Shipping of the test items, samples and documents to BACCINEX and the subsequent return of all remaining test items and samples to the Client upon completion of the Service.
- Shipping of documents and materials by special courier if requested by the Client. Shipping costs include all charges incurred by BACCINEX for shipping and transport of the materials as well as all insurances, custom duties and associated taxes paid by BACCINEX.
- Costs for work to fulfill the Client's specific wishes for special report formats.

13.2. The payment schedule will be stated in the offer in advance and will be either a single amount or payment by installments. The amounts are payable in full as per the agreed value. Payments must be settled in a timely manner. Payments shall be made in the same currency as the offer.

## 14. Cancellation or Postponement of Project

14.1. Should the Client decide not to proceed with the contracted project or to terminate a running Service, BACCINEX reserves the right to charge the Client for all incurred costs. BACCINEX will endeavor to ensure a mutually acceptable and amicable agreement is reached when calculating these costs.

14.2. Should the Client inform BACCINEX that a contracted project is to be carried out at a later date, BACCINEX will endeavor to offer the free capacity to other clients and to carry out the Services at a time acceptable to both the Client and BACCINEX. Otherwise, a compensation for the immobilization of the production capacity will be charged to the Client, as provided for in paragraph 14.1. above (incurred costs).

## 15. Changes and Validity

If, for any reason, a point in a clause of these Conditions becomes invalid, the validity of the remaining points will not be affected. In such case and if necessary, the parties undertake to come together to negotiate in good faith without delay the rewriting of the clause in question, so as to preserve the spirit and the economy of their agreement. All changes and amendments must be made in writing.

## 16. Force Majeure

16.1. BACCINEX or the Client shall not be held responsible for any delay or failure in performance hereunder caused by acts of God or other causes beyond its control and without its fault or negligence, usually recognised as a « force majeure » case by the jurisprudence of Swiss courts, including among other possibilities : violent act of nature, war, terrorism, riot, fire, explosion, accident, flood, sabotage, mechanical breakdown, plant shutdown, BACCINEX inability to obtain fuel, power, raw materials or equipment from its usual sources at prices it deems reasonable, government laws, regulations or orders, labor trouble, strike, lockout or injunction (whether or not

such labor event is within the reasonable control of such party) delays, prevents, restricts, limits, or renders commercially infeasible, the performance of the order or the consumption, sale or use of the product, except as to product already in transit.

16.2. If such contingency occurs, the affected party shall invoke this provision by promptly sending to the other party written notice of the nature and estimated duration of the suspension period.

16.3. The total order quantity shall be reduced by the quantity not delivered during the term of such suspension and the order shall otherwise remain unaffected. In no event shall BACCINEX be required to purchase product or material from other sources to fulfill the order requirements. If any such event occurs, BACCINEX may, without any liability to the Client, keep its available supply of any product for its own use, or distribute it among its customers upon such basis and in such manner as BACCINEX deems fair and practicable.

## 17. Arbitration

17.1. Both parties will use their best efforts to settle all matters in dispute amicably.

17.2. All disputes and differences of any kind related to these conditions, which cannot be solved amicably by the parties, shall be finally settled under the Rules of Conciliation and Arbitration of the International Chamber of Commerce by one or more arbitrator(s) appointed in accordance with the said rules.

- Notice of arbitration shall be given to the party to whom demand therefor is addressed. The arbitral award shall be final and binding for both Parties.

- Judgment upon the award rendered by the arbitrator(s) may be entered in any court having jurisdiction or application may be made to such court for a judicial acceptance of the award and an order of enforcement, as the case may be.

- The location of the arbitration shall be Basel (Switzerland) and the arbitration shall be held in English according to the substantive laws of Switzerland to the exclusion of any rule that would refer the subject matter to another forum or jurisdiction, even in the case of plurality of defendants, the introduction of third parties, emergency proceedings or protective proceedings, by injunction or by petition.

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