

# PharmaLex Standard General Terms and Conditions

Version 1

February 2018

## 1) Definitions

Affiliate(s): means any corporation, company, partnership, joint venture or firm which controls, is controlled by or is under the common control of PharmaLex GmbH. For purposes of this definition, “control” shall mean the ownership of at least fifty percent (50%) of the voting share capital of such entity or any other comparable equity or ownership interest.

Contract(s): means all agreements, business transactions between PharmaLex and a principal.

GTCs: means PharmaLex’s General Terms and Conditions for the Services

Parties: means PharmaLex Italy S.r.l. , a subsidiary of PharmaLex GmbH (GERMANY), and Principal.

PharmaLex: means PharmaLex Italy S.r.l.

Principal: means the buyer, customer/client or other purchaser.

Services: means products and services provided by PharmaLex, its affiliates and/or its sub-contractors.

Third Parties: means legal or natural business entities, sub-contractors or not, which has not originally been an active party to the contract/agreement between PharmaLex and a Principal.

## 2) Scope

(1) In addition to the individual contractual covenants and the statutory provisions, the Services by PharmaLex or the Affiliates shall be exclusively subject to these GTCs. They shall apply to all business transactions between PharmaLex and the Principal. Any contradicting or deviating terms of purchase, terms and conditions of performance and all other conflicting general terms and conditions of the Principal shall not be acknowledged by PharmaLex unless PharmaLex did in fact expressly consent to their applicability in writing. Such terms and conditions shall also not become integral components of the Agreement as a result of an order having been accepted.

(2) These GTCs shall also apply in the event that PharmaLex, being aware of terms and conditions of the Principal that contradict or deviate from these GTCs, performs the contractual obligation for the Principal, accepts payments or renders Services without raising objections. The absence of any related feedback from PharmaLex shall not constitute PharmaLex's acknowledgement of the applicability of any such terms and conditions. At the latest upon acceptance of Services provided by PharmaLex, the Principal shall be deemed to have expressed Principal's consent with these GTCs.

(3) If these GTCs have become integral components of agreements with the Principal as a result of their integration into the legal business transaction, they shall continue to apply to any future agreements arising from continued business relationships between PharmaLex and the Principal without having to be newly integrated into such agreements and shall apply until PharmaLex issues new GTCs.

(4) All agreements that have been made or will be made between PharmaLex and the Principal have been documented in writing in the attached cost estimate and in these GTCs. Deviations from the former shall principally require written documentation in the interest of better verifiability.

### **3) Service Content**

(1) The type and scope of performance owed by PharmaLex shall be governed by the agreements made, whereby the aforementioned shall be based on the provisions in effect at the time of conclusion of the contract unless express covenants to the contrary have been agreed upon.

(2) If PharmaLex performs any obligations, it shall only owe the Services as such, not their success unless express covenants to the contrary have been agreed upon.

(3) In the event that modifications to the provisions, in particular the technical policies (e.g. GMP, GCP, GVP), should be made while the obligations are performed, this shall not result in any alterations of the Services owed by PharmaLex. However, during the time period that these obligations are being performed, the Contracting Parties shall, if at all possible and known, brief each other on any intended or already implemented changes. Any expansion or alteration of the Services owed by PharmaLex as a result of such changes shall be mutually agreed upon between the Contracting Parties.

(4) The Principal shall be required to take any and all actions required for the contract compliant rendering of the Services by PharmaLex in due time and shall make all declarations and provide any required documentation accordingly (this shall also include notifications on, for instance, technical prerequisites that have to be in place).

(5) Unless otherwise expressly agreed upon between the Contracting Parties, PharmaLex shall have the right to involve sub-contractors and its affiliates for the fulfillment of its obligations as they arise from the agreements covered by these GTCs.

### **4) Changes, Test Parameters**

(1) Any necessary changes to the Services by PharmaLex that the Principal can be reasonably expected to tolerate, shall be permitted.

(2) In the event that the Principal should fail to provide information or the provided

information is false, PharmaLex reserves the right to reasonably amend the content of the Services. Any resulting disadvantages, in particular, those that are cost or damage related, shall be for Principal's account.

(3) For any tests designated to be subject to specific measuring or control values or any other test parameters, the respective testing methods shall be defined prior to the start of deliveries and shall be subject to the acceptance by both Parties. If such definitions are not made, test methods and parameters utilized by PharmaLex shall apply.

## **5) Information, Property of Documentation**

(1) Information on Services or products of PharmaLex, in particular information found in its flyers, catalogs, marketing brochures, leaflets, other documentation and electronic media, e.g. on the Internet, specifically pertaining to the suitability and utilization of its Services and products, as such do not contain any assurances and shall be non-binding, unless they have been expressly designated as binding in PharmaLex's quotation or in an order confirmation and provided the usability for the contractually intended purpose is contingent upon exact compliance with the former. Such information shall not relieve the Principal from the obligation to conduct in-house tests and experiments. In particular, the Principal shall not be relieved from the obligation to verify the suitability of Services, products and recommendations provided by PharmaLex for the intended and all other purposes of use. This shall specifically apply for the compliance with statutory and government agency imposed provisions for the use of the Services and products of PharmaLex.

(2) Reports, evaluations, analysis results and other documentation as well as models, samples and any other objects (hereinafter summarily referred to as "documentation"), which the Contracting Parties provided to each other for the performance of the order, shall remain the property of the Contracting Party providing the documentation and shall be returned to the former upon request. Return of any documentation from PharmaLex to the Principal shall be at the Principal's expense. To that end, the providing Contracting Party shall reserve all inherent rights, in particular any copyrights unless otherwise agreed upon in the individual contractual provisions. Documentation shall not be made accessible to any third parties or

used beyond the purpose for which the respective other Party has provided the documentation. This shall in particular also apply to such documentation that has been marked as confidential. Prior to sharing any documentation with any third Parties, the express written consent of the Contracting Party, who has provided the documentation, shall be obtained.

(3) It shall be the Principal's responsibility to ensure that Principal has acquired all rights inherent in the documentation handed over to PharmaLex and that they do not infringe upon any third-party rights, in particular copyright, brand/trademark rights or patent rights and that there are no other obstacles to use the documentation caused by commitments or legal prohibitions. The Principal shall hold PharmaLex harmless from and indemnified against any third-party claims or government agency interventions related to the contractual use of the documentation provided to PharmaLex.

#### **6) Service Provision Times and Due Dates**

(1) Service provision times shall begin upon PharmaLex's receipt of the written acceptance of the quotation by the Principal; however, they shall not ever begin until all details of the order have been completely clarified and all information or documentation to be delivered by the Principal has been received; the same shall apply accordingly to delivery objectives. In the event of mutually agreed upon modifications of the subject matter of the purchase order, the delivery target shall be null and void and shall be newly agreed upon.

(2) The initiation of the agreed service provision time shall be contingent upon the complete clarification of all significant circumstances for the rendering of the Services. In particular, compliance with the performance obligations by PharmaLex shall be subject to timely and proper fulfillment of the obligations of the Principal. In all other cases the service provision time shall be reasonably extended.

(3) The service provision times specified by PharmaLex shall be approximate unless a concise binding due date has been expressly agreed upon.

## 7) Remuneration

- (1) Prices shall be governed by the cost estimate. Any Services to be provided by PharmaLex shall be subject to the current service rates; the respective rate scales may be requested by the Principal from PharmaLex unless other arrangements have been made in the individual agreements.
- (2) In addition to the agreed upon prices, the Principal shall also be required to absorb any ancillary costs related to the Services (e.g. travel expenses, costs of translations, government agency imposed fees, etc.) as well as the statutory sales tax due at the time the Services are provided.
- (3) PharmaLex shall have the right to reasonably adjust the agreed upon price if, prior to or on the occasion of the performance of the order changes should become necessary because the information and documentation provided by the Principal contained errors or if the Principal desires to make any other changes. Fee rates will be subject to an annual review on January 1 and price adjustments may be made at the time of the review arising out of cost variations due to inflation.
- (4) Upon conclusion of the contract, PharmaLex shall have the right to demand the disbursement of a reasonable advance payment. This advance payment shall not earn any interest.
- (5) Unless otherwise agreed invoices shall be due for payment within 30 days after the invoice date. They shall be due without any deductions. In the event of non-payment, the Principal shall be in default of payment immediately after the due date; no further reminder shall be required. Default interests shall apply from the first day after the due date. The amount of the default interests shall be established in accordance with Legislative Decree 9 October 2002, No. 231 in its current version and/or in accordance with any applicable Law in relation to late payments. Any further rights of PharmaLex for damage claims in case of late payments shall remain unaffected.
- (6) All bank charges should be borne by the Principal.

## 8) Purchase Contract or Contract-for-Work-and-Materials Services

In the event that PharmaLex should provide Services based on an express covenant in purchase contracts or contract-for-work-and-materials, the following provisions shall additionally apply:

(1) PharmaLex'quotations and offers shall be subject to change. PharmaLex reserves the right to make technical modifications within the scope of what is considered reasonable. As far as online Services are concerned, PharmaLex shall have the right to make changes and deviate from its portfolio if the customer's contractual purpose is not impaired or only minimally hampered.

(2) When placing an online order, the Principal makes a binding commitment to acquire the goods. If the Principal uses electronic means to place the order, PharmaLex shall promptly confirm the receipt of the order. The confirmation of receipt shall, however, not constitute a binding acceptance of the order. However, the confirmation of receipt may be sent simultaneously with the declaration of acceptance.

(3) The contract between Principal and PharmaLex shall be concluded once the offer to enter into a contract made by the Principal has been accepted by PharmaLex or upon receipt of the ordered goods or the online contract confirmation by the Principal.

(4) If the Principal uses electronic means to place the order, the contract copy shall be archived by PharmaLex and provided to the Principal via e-mail upon request along with these General Terms and Conditions.

(5) To any case of Pharmalex' deficient, late or non-performance of its obligations arising from a single order, also if resulting from a late, deficient or non-performance of PharmaLex' suppliers, art. 12 shall apply.

(6) PharmaLex shall deliver the goods to the address provided by the Principal in the

order. As a matter of principle, delivery dates shall always be non-binding. PharmaLex shall have the right to make partial deliveries within a reasonable scope.

(7) Claims for deficiencies caused by transportation damages or incomplete deliveries shall be filed with PharmaLex in writing immediately and no later than within ten days as of the date of delivery to the Principal. In case of deficiencies caused by transportation that could not reasonably be expected to be revealed in occasion of an adequate incoming inspection, the 10-days-period shall commence upon the date in which the deficiency has actually been revealed. In addition, any further provisions of section 10 that follows shall apply.

(8) For all purchases involving shipping, the risk of accidental loss or decline of the quality of the goods shall transfer to the Principal upon hand-over of the goods to the logistics enterprise, freight forwarder or any other individual or entity entrusted with the transportation of the goods.

(9) Until all accounts payable from the current business relationship have been paid in full, the delivered goods shall remain the property of PharmaLex. Hence, the utilization rights shall also not transfer until complete payment for all accounts payable has been made. The delivered goods shall be handled with care. The Principal shall undertake to immediately notify PharmaLex in writing of any third party access to the goods or any other damages or the loss of the goods. The Principal shall promptly notify PharmaLex in the event of Principal's change of domicile.

(10) In the event of deficiencies of the goods, PharmaLex shall initially, at PharmaLex's discretion, meet the warranty set forth in art. 1490 of the Italian civil code through remedial action or compensation delivery of replacement goods. If, for the purpose of remedial fulfillment, deficiency free goods should be delivered, the Principal shall be required to return the deficient goods.

If the remedial action should fail, the Principal shall have the right, at Principal's discretion, to principally reduce the price or demand the termination of the contract. Termination shall not be possible if the deficiencies are only minor.

The Principal shall notify PharmaLex in writing of any deficiencies of the delivered goods within a time period of ten days after their delivery. In case of deficiencies that could not reasonably



be expected to be revealed in occasion of an adequate incoming inspection, the 10-days-period shall commence upon the date in which the deficiency has actually been revealed. Any failure of timely notification of deficiencies shall result in the forfeiture of warranty entitlements. The burden of proof for all claim prerequisites shall be solely on the Principal, in particular for the deficiencies as such, for the time the deficiencies were discovered and for the timeliness of the deficiency claim.

For goods purchases, the warranty period shall be one year as of the delivery date of the goods; the Principal's rights regarding deficiencies that have been notified to PharmaLex before expiry of the warranty period and in accordance with the foregoing provisions remain unaffected. Damage claims of the Principal shall be covered by the liability provisions set forth in Sections 11 (Force Majeure) and 12 (Limitations of Liability).

Any retroactive fulfillment measure, such as a remedial action or compensation delivery regarding the defective goods, shall not result in a re-initiation of the warranty period; they shall merely inhibit the warranty period that applies to the goods subject to the original delivery for the time it takes to complete the retroactive fulfillment measures. Further, the performance of the retroactive fulfillment measure shall not constitute an acknowledgement of any non-performance by PharmaLex.

## **9) Terms of Use for Services in Conjunction with the Electronic System (E- System)**

(1) Principal's access to the online portals shall be provided under password protection, i.e., the Principal shall use the personal access data assigned to the Principal (username and password).

(2) The Principal shall undertake to keep the access data (username and password) confidential and shall prevent their unauthorized use by third parties. The Principal shall ensure that the authorized users working for the Principal shall also comply with this obligation. The Principal shall be held liable for any abuse.

(3) Through reasonable technical means, PharmaLex shall strive to ensure that user accounts are protected against unauthorized access and that the confidentiality of the data is

warranted. However, PharmaLex shall not assume any guarantees. Misuse of the data by third parties, data reading or modification, regardless of intended or unintentional cannot be ruled out due to the use of the Internet. The Principal shall take note of this without having any option to file liability claims against PharmaLex.

(4) For technical reasons or because of interruptions of the Internet PharmaLex has no control over, the availability of the online portals may be limited on occasion and access may not be possible.

(5) The Principal shall obtain the technical requirements for the use of the online portals at Principal's own expense and shall be responsible for the procurement and maintenance of the required hardware, operating system software, Internet connection, current browsers, software, etc. PharmaLex shall not assume any responsibility for costs or other obligations in this context. If the software used for the operation of the online portals or any other technical components should be changed or further developed, it shall be Principal's responsibility to make any necessary adaptations to Principal's hardware and software. The Principal shall undertake to implement the precautions required to back-up Principal's system and data.

(6) The Principal shall undertake not to use the online portals to access data other than the data PharmaLex has compiled for the Principal.

(7) The minimum term for such a usage license shall be 12 months. The term of the usage license shall be automatically extended by another 12 months unless it is terminated in writing giving 6 weeks' advance notice prior to the end of the subscription period. This shall be without prejudice to the right to terminate extra-ordinarily. PharmaLex shall in particular have the right to terminate extra-ordinarily the contract if the Principal misuses the E-System or if a third party uses the system without authorization or if accounts receivable due from the Principal to PharmaLex remain outstanding, in accordance with the provisions of art. 15 section 6. The usage license shall end automatically upon termination of the contract. Principal's access data shall be blocked and the username shall be deleted.

## **10) Set-Off, Retention Rights**

(1) The Principal shall have the option to set payments off exclusively against those due receivables that are undisputed, acknowledged or that have been found legally effective by a court of law.

Set-off shall occur in the event that the receivables of the Principal and PharmaLex are mutual, liquid, certain and payable.

(2) The assignment of any claims against PharmaLex shall be subject to the latter's former's consent.

(3) The Principal shall have retention rights only to that end that the counter claim is based on the same contractual transaction and has been acknowledged, is ready for decision or has been found legally effective by a court of law or if PharmaLex has significantly breached any obligations arising from the same contractual transaction despite written notices and if no reasonable collateral has been offered. If the service provided by PharmaLex is undisputedly deficient, the Principal shall have the right to withhold only to the extent that the retained amount is reasonable based on the deficiencies and the anticipated costs of remedying such deficiencies. The limitations regarding Principal's right to present objections as set forth in the present section does not apply with regards to the objections of invalidity (artt. 1418 ss. Italian Civil Code), declaration of nullity (artt. 1425 ss. Italian Civil Code) or termination (artt. 1447 ss. Italian Civil Code) of the contract.

## **11) Force Majeure**

(1) Incidents of force majeure as well as significant, unforeseeable hindrances that are beyond the sphere of control of PharmaLex, such as strikes, lockouts, exceeded delivery times or failures to deliver by sub-suppliers, operating, sales or utility supply interruptions due to energy, commodity or workforce shortages, difficulties with the procurement of modes of transportation, traffic problems, ordinances and orders issued by government or executive powers, at PharmaLex or at its suppliers' end, shall relieve PharmaLex of its respective contractual obligations for the duration of any such measures or hindrances.

(2) PharmaLex shall also not be considered responsible for the above-described circumstances if they occur during any existing default.

The start and end date of such measures and hindrances or the non-availability of the subject matter to be delivered shall be communicated to the Principal immediately.

(3) If as a result of such measures and hindrances, deliveries should be delayed by more than 4 weeks, the Contracting Parties shall have the right to rescind the Agreement. In the event of rescission, the remunerations shall be reimbursed. Any further entitlements shall be excluded.

## **12) Limitations of Liability**

(1) Pharmalex' liability in case of damage claims shall be limited to:

(a) liability based on Pharmalex' acts of willful misconduct and gross negligence;

(b) liability based on Pharmalex, its employees or any other of its auxiliary person's breach of obligations arising from public policy (*ordre public*);

(c) liability based on the provisions on product liability (art. 114 ss. Italian Law Decree n. 206/2005);

(d) liability in cases if loss of life, personal injury or health damages of an individual.

Any further liability of PharmaLex, its employees or other auxiliary persons shall be excluded;

(e) other cases in which according to the applicable law Pharmalex' liability for damages cannot validly be excluded and/or limited by the Parties.' agreement..

(2) The limitation of liability pursuant to Section 1 shall apply to any damage claims of Principal, o regardless of its legal grounds, in particular to damage claims for deficiencies of PharmaLex' products and/or services, for the breach of any other of PharmaLex' contractual or pre-contractual obligations and for the breach of extra-contractual obligations. They shall also apply to any claims for reimbursement of expenses that incurred in vain and to those based on impossibility and default of PharmaLex' performance of its contractual obligations.

(3) Notwithstanding PharmaLex' unlimited liability in the cases cited in above Section 1, any of Principal's deficiency-based rights, shall be contingent to (a) Principal's conduction of an adequate incoming inspection of the delivered goods and (b) to PharmaLex' notification of the

revealed deficiency without undue delay after the incoming inspection. Deficiencies that cannot be detected even if the greatest care is exercised during the incoming inspection must be reported immediately after their discovery; any processing or other work being done on the deficient object must immediately be suspended. The burden of proof for the fact that a deficiency could not have been discovered in an earlier moment shall fall on Principal..

(4) Any Services and works shall be subject to the provisions of the above section 3 accordingly. The submission of a claim for deficiencies shall not relieve the Principal from compliance with Principal's payment obligations.

### **13) Data Storage and Archiving**

(1) The data received from the Principal due to a business transaction shall be stored by PharmaLex for the sole purpose of processing the transaction. The Contracting Partner shall submit any personal data to PharmaLex exclusively in anonymous formats. Any inbound data checks by PharmaLex would generate a significant amount of additional work and shall therefore not be performed.

(2) Any and all materials submitted or sent by the Principal, in particular templates, data and data media, shall be archived beyond the date the final product has been handed over or the service or works project has been completed only subject to a written agreement and in exchange for payment of separate remuneration. The only exception shall be data and documentation that is subject to a statutory retention or archiving mandate. If such items should require insurance coverage, the Principal shall be responsible for obtaining such coverage unless a pertinent agreement on other arrangements has been made. Notwithstanding PharmaLex' unlimited liability in the cases cited in art.12, section 1, any liability of PharmaLex for damages to or the loss of such data regardless of the grounds shall be excluded.

#### **14) Takeover/Solicitation of Employees**

Principal hereby warrants that it will not hire any PharmaLex personnel during this agreement and for a period of at least 1 (one) year from the termination of this Agreement. Any infringement of this provision made by Principal will entitle PharmaLex to claim damages. In the event that the Principal should designate an employee of PharmaLex to transition into an employment arrangement with the Principal as a result of unfair solicitation practices, the Principal shall be required to pay a contractual penalty equivalent to 100% of the gross annual income of the affected employee.

#### **15) Place of Jurisdiction, Governing Law, Place of Fulfillment, Severance, Data Privacy**

(1) For any and all disputes arising between the Parties from the contractual relationship, the Parties herewith agree that the sole local and international place of jurisdiction shall be Milano, Italy. This shall also apply to disputes concerning certificates, bank drafts or checks. However, PharmaLex shall also have the right to file suit against the Principal at the Principal's domicile.

(2) The contractual relationships with the Principal shall be governed exclusively by the laws of Italy. However, the provisions of the UN Convention on the International Sale of Goods (CSIG) shall not apply.

(3) In the event that one of the provisions of these GTCs and of any other agreements made should be or become ineffective, this shall not affect the effectiveness of the remaining Agreement. The Contracting Parties shall strive to replace the ineffective clause, taking into account the statutory provisions that apply in this case, with a different clause that meets the business purpose and the legal intentions of the original wording as closely as possible.

(5) PharmaLex shall store personal data of the Principal generated in conjunction with the business relationship using electronic data processing means in compliance with local and European data protection law, in particular the European Data Protection Act (European Regulation no. 67/2016 - GDPR), in its most recent version.

(6) Unless otherwise stated in the contract, each party shall have the right to terminate the contractual relationship by giving termination notice at any time for good cause and good cause for termination shall be deemed to exist, in particular, in the following events:

- a. a severe violation of statutory obligations or of obligations resulting from this Agreement by the other party;
- b. the complete or partial or substantial discontinuation of the other party's business activity including the ability to render the services stipulated in this Agreement for a term of more than eight (8) weeks.

**Signature of the Client for acceptance:**

---

**The Client hereby declares to have carefully read and to expressly accept, in particular, the following Sections of these GTSs:**

- **Section 4.1 (Changes to Pharmalex' services);**
- **Section 7.3 (Adjustment of Prices);**
- **Section 8.1 (Changes to Pharmalex' quotations and offers);**
- **Section 9.7 (Automatic extension of the usage license' term);**
- **Section 10.2 (Assignment of claims against Pharmalex);**
- **Section 10.3 (Principal's retention rights);**
- **Section 11.1 and Section 11.2 (Limitations of Pharmalex' liability in case of force majeure);**
- **Section 12 (Limitation of Pharmalex' liability)**
- **Section 14 (Takeover/Solicitation of Employees);**
- **Section 15.1 (Place of Jurisdiction).**

**Signature of the Client for acceptance:**

---