

General Terms and Conditions of Pharmalex Italy S.r.l. (2019)

§ 1 Applicability, Definitions

- 1.1 These General Terms and Conditions (“GTC”) govern the business relationship between PharmaLex GmbH and/or its Affiliates (together “PharmaLex”) and any professional client and/or its Affiliates (together “Client”), in particular in respect of the provision of Services subject to individual Work Orders (as defined below). PharmaLex and Client are hereinafter also referred to individually as “Party” and collectively as “the Parties”.
- 1.2 These GTC shall apply exclusively and shall be considered as accepted by Client upon order placement or receipt of Services at the latest. Receipt by PharmaLex of Client’s order or Client’s acknowledgement of PharmaLex’s order confirmation without PharmaLex’s objections to the terms and conditions of Client, or receipt of payments shall not constitute acceptance by PharmaLex of or approval to Client’s terms and conditions. PharmaLex’s failure to object to Client’s additional or conflicting terms does not operate as a waiver of these GTC. PharmaLex specifically rejects any different or additional terms that may have been previously discussed or proposed or agreed by the Parties, are now or hereafter proposed by Client, or are contained in Client’s purchase order or are contained in other documents prepared by Client.
- 1.3 As used in these GTC the following terms shall have the following respective meanings:
 - (a) “Affiliate(s)” of a Party for the purpose of these GTC mean(s) any company, corporation, firm, joint venture, partnership or other entity controlled by, controlling or under common control with such Party. For purposes of this definition, “control” shall mean the ownership of at least fifty percent (50%) of the share capital or voting rights or any other comparable equity or ownership interest.
 - (b) “Information” means all data, know-how, materials and / or other information provided by one Party (“Disclosing Party”) to the respective other Party (“Receiving Party”) in connection with a Work Order in oral, written or any other way and shall include any studies, analyses and / or copies based on such Information.
 - (c) “Services” means the whole scope of consulting and advisory services collectively or individually offered and/or provided by PharmaLex, its Affiliates and/or its sub-contractors, as well as any supplies and performances associated with the provision of such services (including, without limitation, trainings, audits, staff leasing, to the extent they are permitted by law and subject to prior mandatory authorization).
 - (d) “Third Parties” means any legal entity or individual person other than PharmaLex, Client, the Parties’ Affiliates, and PharmaLex’ Staff Members (as defined in § 3.2).
 - (e) “Work Order” means any individual order from Client or any of its Affiliates for the provision of Services to be placed with PharmaLex or any of its Affiliates. The Work Orders shall be issued and confirmed in accordance with these GTC and any additional and individually agreed terms between the Parties.

§ 2 Services, Contact Persons

- 2.1 Services will be performed by PharmaLex on the basis of mutually agreed Work Orders, which shall be binding for PharmaLex only if signed by its representatives. The Work Orders, these GTC, and any additional and individually agreed terms between the Parties constitute the entire agreement of the Parties which supersedes all prior agreements and understandings relating to such subject matter. PharmaLex shall not be obliged to commence performing any Services before a Work Order has been confirmed by PharmaLex. Nothing in these GTC will be construed as to limit PharmaLex' right not to accept or confirm a Work Order.
- 2.2 Each Work Order will set forth the scope and terms and conditions of the particular Services, including a detailed description of the work, deliverables, timelines, and the budget. A Work Order may only be modified or amended in writing signed by a duly authorized representative of each respective Party and specifically referring hereto. Each Work Order shall refer to these GTC and shall be governed by these GTC. Any reference to the Work Order in these GTC shall be a reference to the Work Order inclusive of any and all appendices hereto.
- 2.3 In the event of any conflict between these GTC and a Work Order, these GTC shall govern unless such Work Order specifically refers to these GTC and specifically identifies the Section(s) to be modified in these GTC. Any such amendment shall apply only to such Work Order and shall not act as an amendment of these GTC as they relate to any prior or subsequent provision of Services.

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2.4 In connection with each Work Order, each of Client and PharmaLex may appoint a designee as its representative which shall be the primary point of contact under such Work Order. The representatives will interface regarding the performance of Services arising under the applicable Work Order and must have or promptly be able to obtain sufficient authority to make all necessary decisions in relation to the Work Order.

§ 3 Responsibilities of PharmaLex

- 3.1. When performing the Services according to the Work Order, PharmaLex will comply with the applicable and current legal requirements of the competent health authorities or agencies of the respective countries and states.
- 3.2 PharmaLex shall be entitled to use, at its sole discretion, employees, freelancers and/or sub-contractors (together the "Staff Members") having the necessary and legally required technical expertise and experience for providing the Services under the Work Order.
- 3.3 PharmaLex shall use best efforts to ensure the continuity of the Staff Members assigned to provide the Services. PharmaLex reserves the right to change any assigned Staff Members provided that the replacement personnel shall have substantially equivalent qualifications as the Staff Members being replaced.
- 3.4 PharmaLex will be responsible for the professional quality of the Services to be provided with customary care and using all required methods, means and procedures in its own discretion. PharmaLex will use all commercially reasonable efforts in a diligent manner to perform the Services in accordance with the timing agreed by the parties in the Work Order.
- 3.5. Client shall have the right to inspect and audit PharmaLex and its respective services provided to Client by authorized representatives upon giving reasonable written notice to PharmaLex. PharmaLex provides guided facility access to Client during the time of the audit. PharmaLex's time invested in preparing and attending the audit will be charged to Client at hourly rates depending on the level of expertise required.

§ 4 Responsibilities of Client

- 4.1 To assist PharmaLex to fulfil its obligations under the individual Work Order, Client will at all times cooperate in good faith and at its cost provide PharmaLex with
 - all information and documentation as well as technical preconditions necessary so as to enable PharmaLex render the Services efficiently and in a timely manner,
 - ensure that any information and documentation provided is complete and accurate;
 - promptly notify PharmaLex of any change in the information, documentation and preconditions which may impact the Services as soon as such change becomes known to it,
- 4.2 All personal data provided by Client to PharmaLex shall be exclusively in anonymized form. Nothing herein shall require PharmaLex to perform or verify an anonymization process of the data provided by Client or bear any related costs.

§ 5 Place and Time of Provision of Services

- 5.1 The Services will be conducted at PharmaLex's or Client's premises or at another place as mutually agreed upon. If and as required to fulfil PharmaLex's obligations, Client shall afford PharmaLex full and safe access to its premises as well as to necessary materials and equipment of Client during normal working hours.
- 5.2 The Services will be provided during normal business hours. Services provided outside normal business hours, over the weekend or on public holidays shall be provided only if expressly agreed and subject to a surcharge in accordance with PharmaLex's Service rates. Public holidays at the place where the Services are provided shall be valid.

§ 6 Payment of Fees and Expenses

Client will pay PharmaLex for Service fees and expenses in accordance with the Work Order and these GTC. Unless otherwise agreed in a particular Work Order, the following shall apply:

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- 6.1 Service Fees. The Services will be charged to Client on the basis of performed working hours and PharmaLex's hourly Service rates. The Service rates will be applied depending on the level of expertise required for each project and will be specified in the respective Work Order.
- 6.2 Expenses. Pharmalex shall be reimbursed for any accommodation costs and travelling expenses incurred by rendering the Services as follows:
- (a) **Accommodation cost**: All costs for accommodation of a PharmaLex' Staff Members during a business trip will be charged to Client after prior authorization and following the submission of the corresponding receipts. For all days when PharmaLex staff is on site at Client or traveling on behalf of Client, a standard meal allowance rate per day for each staff member as defined in the Work Order will apply depending on the respective country.
- (b) **Travel expenses** (according to PharmaLex's travel policy):
- Use of private car: In accordance with the local laws and regulations regarding kilometer / mile allowance rates, determined by the government / tax authority.
 - Use of train: Train ticket 2nd class (economy / flexible rate).
 - Short and mid distance flights (up to 5 hours): flight ticket economy class.
 - Long distance flights (over 5 hours): flight ticket premium economy, business class booking requires previous confirmation by Client.
- The choice of transportation is to be agreed upon by PharmaLex and Client before start of the journey. PharmaLex shall obtain Client's approval prior to booking any flight arrangements. Further specifications will be determined in the Work Order.
- (c) Additional extraordinary expenses and pass-through costs, if any, will be agreed on a case by case basis.
- 6.3 Payment and Invoices. PharmaLex will invoice Client on a monthly basis for the Service fees and expenses incurred in performing the Services. If requested by Client, PharmaLex will provide time sheets in which the expended service time is detailed.
- Client shall pay each invoice within thirty (30) days of the date of the invoice or any longer period as set out in the invoice. If any payments due under the Work Order are not received by PharmaLex when due, PharmaLex reserves the right (i) to suspend performance for all Services, and (ii) to charge default interest from the first day after the due date until payment in full is received as required under the Work Order. The date of receipt by PharmaLex of the payment is decisive for its timeliness. 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.
- Client shall have no right to offset any amounts due or to become due, except against claims which are undisputed or have been finally adjudicated upon by the courts. Client shall notify PharmaLex in writing of any amounts disputed within 10 days from receiving the invoice. Such notice must include the invoice number in dispute, the item(s) and amount(s) disputed, and a description of the grounds for disputing the invoice. Notice of any disputed invoice amount shall not release Client from the obligation to pay. Any portion of an invoice not disputed within 10 days shall be deemed accepted by Client.

§ 7 Secrecy obligation, data protection and privacy

- 7.1. The receiving Party shall not disclose any Information to any third party without the Disclosing Party's prior written approval. The confidentiality obligation will survive the term of the Work Order for which such Information was disclosed or of any current Work Order, whichever is longer, for a period of five (5) years.
- 7.2. The receiving Party will treat Information received from the Disclosing Party with the same level of care and attention that it applies to its own confidential information.
- 7.3. The receiving Party will make Information accessible on a need-to-know basis only to those of its Staff Members, Affiliates, consultants, and other third parties who require such Information in order for the Receiving Party to fulfill its obligations under any Work Order. The Receiving Party will execute Non-Disclosure Agreements containing provisions which are at least as restrictive as the ones applicable to the Receiving Party under these

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GTC or under any Non-Disclosure Agreement, prior to granting such access. The Receiving Party is legally responsible for the compliance with the provisions of such Non-Disclosure Agreements by those receiving access to Information from it.

- 7.4. The obligations to confidentiality and restriction of use shall not apply to any particular portion of Information for which the Receiving Party can reasonably demonstrate that: (a) it is available to the public domain, or (b) it becomes available to the public domain (other than as a result of unauthorized disclosure by the Receiving Party); or (c) it was available to the Receiving Party prior to the receipt from the Disclosing Party; or (d) it becomes lawfully available to the Receiving Party on a non-confidential basis from a third party entitled to make such disclosure.
- 7.5. All documents received by a Party shall be returned or destroyed upon the written request of the Disclosing Party after completion or termination of the Work Order, as the case may be.
- 7.6. Each Party recognizes and agrees that nothing contained in the Work Order or these GTC shall be construed, by implication or otherwise, as a grant of any right, option, or license under any intellectual property rights or other proprietary rights. Each Party recognizes and agrees that nothing agreed on in the Work Order or these GTC shall be construed, by implication or otherwise, as an obligation to enter into any further agreements, nor as a restriction to do so.
- 7.7. Client recognizes that the means, methods, techniques, skills, concepts, equipment, algorithms, software (including PharmaLex's commercial software), and any other approaches and tools (the "Working Tools") used to perform the Services are regularly used by PharmaLex for its core business. Therefore, Client recognizes that PharmaLex may use, develop, adapt and/or improve such Working Tools using Information of Client and that such Working Tools will remain the sole property of PharmaLex. PharmaLex will be free to use its developed, adapted and/or improved Working Tools without any restriction or payment of royalties in the future.
- 7.8. This § 7 shall have priority over and replace any non-disclosure or confidentiality agreement entered into by the Parties prior to a specific Work Order.
- 7.9. The Parties agree to handle and process personal data in compliance with any applicable national and European data protection laws, in particular the General Data Protection Regulation (GDPR) (EU) 2016/679, in its most recent version. If the Parties become aware of any breach of any applicable data privacy law relating to the Services, they shall promptly notify the other Party and, if requested, assist the other Party in meeting any obligations under applicable data privacy law to notify data subjects, regulatory authorities or other required parties of such a breach.

§ 8 Publications

Except as otherwise described in the Work Order, PharmaLex undertakes not to use any data generated or any Information received from Client in connection with any Work Order for any kind of publication, except with Client's prior approval.

§ 9 Limitation of liability and warranty

- 9.1. PharmaLex's liability shall be limited to damages and losses suffered by Client and caused by PharmaLex through gross negligent or willful breach of its contractual or legal obligations. PharmaLex shall not be liable for any indirect or consequential damages of any type, such as, without limitation, lost profits or business interruption, due to any breach of any provision of Agreement the Work Order. PharmaLex's liability is limited to damages caused by the breach of key contractual obligations which are essential to the performance of Services and on the fulfillment of which Client reasonably may rely (the "cardinal obligation"). Furthermore, PharmaLex's liability is limited to a maximum amount equal to the sum of all service fees (excluding expenses, travelling, accommodation, and pass-through costs) invoiced to and paid by Client for all Services rendered by PharmaLex to Client under all Work Orders during the respective calendar year.
- 9.2. PharmaLex is not liable for tortious acts or omissions of its Staff Members. Client will indemnify PharmaLex in this regard for all claims arising from Third Parties.

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- 9.3. The limitations of liability stated above shall not apply to damages from injury to the life, limb or health. However, for the slightly negligent infringement of contractual duties the liability is limited to damages and losses typically predictable at the time the contract was concluded.
- 9.4. The limitations of liability stated above also apply in favor of the Staff Members of PharmaLex and any Third Parties appointed by PharmaLex to perform the Services.
- 9.5. The limitations of liability stated above shall cover any and all claims, whether in contract or in tort, which Client may assert against PharmaLex, regardless of their legal basis, without prejudice to the liability arising out of gross negligence, willful misconduct or violation of public policy (in accordance with article 1229 of the Italian Civil Code).
- 9.6. PharmaLex will during the time of any Work Order and for 5 years thereafter maintain at its own costs a liability insurance with an insured sum of maximum € 6,000,000.00 per incident for bodily injury and property damages (including claims to rented property) as part of the General Liability Insurance and an insured sum of maximum € 10,000,000.00 per incident for financial losses as part of the Errors and Omissions Insurance with double aggregated limits per year, respectively. Upon request, PharmaLex will provide Client with a copy of the insurance certificates.

§ 10 Force Majeure

- 10.1. Except for the obligation to pay due invoices, either Party shall be relieved from its obligations under any Work Order and these GTC, if and as long as an event of Force Majeure prevails. As cases of Force Majeure are considered all such events that are beyond a Party's reasonable control including, without limitation, fire, flood, storm, natural disasters, war, military conflicts, strike, industrial disputes, acts of terrorism, cyber-attacks, riot, boycott, embargo, import ban, political sanctions, pu of laws and official directives, or the rejection of sub-contractors to provide supplies with regard to the above circumstances.
- 10.2. The Party claiming relief by reason of an event of Force Majeure shall notify the other Party without delay on the occurrence and cessation thereof. In the event that a party experiences Force Majeure, it shall do its utmost to minimize the effects of the delay, and to adhere as closely to the Agreement and/or any Work Order as reasonably possible.

§ 11 Effective Date, Term, Termination of Work Orders

- 11.1. Work Orders shall come into force upon the effective date as set forth in the respective Work Order and may be terminated at any time by Client upon 30 days' prior written notice to PharmaLex, or by PharmaLex upon 90 days' prior written notice to Client, if not otherwise specified in the respective Work Order.
- 11.2. The termination of an individual Work Order shall not affect the validity of any other current Work Orders, unless they are also terminated in writing according to the respective applicable provisions.
- 11.3. PharmaLex or Client may terminate any Work Order for good cause in particular, but without limitation:
 - (a) In the event that the other Party is in breach of any of its obligations under a Working Order, the non-breaching Party may terminate the Working Order affected by the breach effective on thirty (30) days' prior written notice (which notice shall specify in reasonable detail the nature of such breach and the specific Work Order) to the breaching party; provided that no such termination shall become effective if the breaching party shall have cured such breach within thirty (30) days after its receipt of such notice.
 - (b) In the event a (voluntary or involuntary) petition for insolvency, receivership or any similar proceedings under any insolvency laws has been filed in respect of the other Party, the non-affected Party may terminate any Working Order at any time; provided that no such termination shall become effective if such petition shall be dismissed within thirty (30) days after the filing thereof.
- 11.4. In the event of early termination of any individual Work Order, PharmaLex shall be entitled to invoice and Client shall pay to PharmaLex all fees and other amounts that accrued in connection with such Work Order prior to the effective date of termination. In addition, PharmaLex shall be entitled to invoice and Client shall pay PharmaLex's actual costs reasonably documented and incurred as a consequence of the early termination including, without limitation, costs for non-cancellable obligations and unused resources. PharmaLex shall refund to Client any

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exceeding amounts. The payments shall be made within 14 days after the effective date of termination at the latest.

11.5. The foregoing is without prejudice to the right to claim damages and any other legal rights provided for in the event of breaches of contract by the Client.

11.6. The provisions of § 7, 8, 9, 11, 12 and 13 of these GTC will survive any expiration or termination of any Work Order.

§ 12 Solicitation of PharmaLex Staff Members for Employment

12.1. The Client warrants that it will not hire any PharmaLex Staff Member 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 the Client will entitle PharmaLex to claim damages. In the event that Client or any of its Affiliates, enters into a (full-time or part-time) employment relationship with a Staff Member of PharmaLex with whom Client had contact or who (or whose performance) became known to Client in connection with the Services, PharmaLex shall be entitled to ask for the payment of a contractual penalty equivalent to 100% of the gross annual income of the affected employee.

The term annual gross earnings as used above shall mean the amount paid by Client to the Staff Member excluding ancillary benefits, plus the statutory value added tax in effect at the respective point in time. Client shall undertake to promptly notify PharmaLex of Client's entering into an employment relationship causing a claim for brokerage commission. The brokerage commission shall become due for payment upon establishment of the employment relationship, in no case later than 8 calendar days after the execution of a respective employment agreement.

12.2. Client may prove that the recruitment of the Staff Member is not based on a direct or indirect solicitation by Client as a result of the prior cooperation within the scope of a Work Order with PharmaLex, and that Client has had no contact to, or the Staff Member (or its performance) have not become known to Client in connection with the Services.

§ 13 Miscellaneous

13.1 The business relationship with Client and any Work Order shall be exclusively governed by and construed in accordance with Italian law, excluding the conflict-of-law rules. The place of jurisdiction in case of any claim, dispute or controversy arising out of or in relation to business relationship with Client, including but not limited to the validity, invalidity, breach or termination of a Work Order, is Milano, Italy.

13.2. If any provision of any Work Order or these GTC is or becomes invalid, void or unenforceable, (a) all remaining provisions of such Work Order or these GTC shall remain in full force and effect, and (b) the invalid or unenforceable provision shall be replaced by mutual agreement of the Parties in writing by a provision that is valid and enforceable and that comes closest to expressing the intention of such invalid or unenforceable term or provision.

In accordance with Article 1341, paragraph 2, of the Italian Civil Code, the Client hereby expressly acknowledges and accepts the following clauses: § 6.3, last paragraph – Restriction to set-off right; § 9 – Limitations of liability of Pharmalex, especially in relation to Pharmalex's non liability for tortious acts or omissions of its Staff Members; § 12.1 – Solicitation of PharmaLex Staff Members for employment; § 13.1 – Place of jurisdiction.