

Terms and Conditions

§ 1 Applicability, Definitions

- 1.1 These General Terms and Conditions (“GTC”) govern the business relationship between PharmaLex Ireland Limited (“PharmaLex”) and/or its Affiliates (together “PharmaLex”) and Client and/or its Affiliates (together “Client”), in particular in respect of the provision of Services by PharmaLex to Client, 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 to arrangements between Client and PharmaLex. These GTC shall be considered as accepted by Client upon counter-execution of any Work Order (as defined below), order placement, or permitting PharmaLex to carry out Services, whichever is the latest. Receipt by PharmaLex of Client’s order or payments without PharmaLex’s objections to the terms and conditions of Client, shall not constitute acceptance by PharmaLex of 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 hereby 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, training 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, personnel leasing).
 - (d) “Third Parties” means any legal entity or individual person other than PharmaLex, Client, the Parties’ Affiliates, and PharmaLex’ Staff Members (as defined in clause 3.2).
 - (e) “Work Order” means (a) any statement of project agreement or quotation issued by PharmaLex to Client or any of its Affiliates to which Client indicates acceptance and/or proceeds on such basis; and/or (b) 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 these GTC shall apply to 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, representations 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 to Client. 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 description of the work, deliverables, timelines, and the budget/Service fees. If during the course of PharmaLex’ engagement by Client, additional work arises which is beyond the scope of that contained in any proposal or Work Order as accepted, or which could not reasonably have been foreseen by PharmaLex in making the proposal, PharmaLex will endeavor to indicate to Client the likely cost of this additional work. If this is accepted by Client, this work will be undertaken as part of the Work Order/overall assignment/project as applicable and costs will be altered accordingly.
- Each Work Order 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 or amendments thereto.
- 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 clause(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.
- 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, PharmaLex will comply with applicable Irish and European Union law and the requirements of the relevant competent health authorities.
- 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 technical expertise and experience for providing the Services under the Work Order.
- 3.3 PharmaLex shall endeavor 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 appropriate qualifications.
- 3.4 PharmaLex will be responsible for the provision of the Services with due care and diligence, using methods, means and procedures determined in its own discretion. PharmaLex will endeavor 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
- (a) all information and documentation as well as technical preconditions necessary so as to enable PharmaLex to render the Services efficiently and in a timely manner;
 - (b) ensure that any information and documentation provided is complete and accurate; and
 - (c) 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. A day is defined as eight working 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 observed by PharmaLex.

§ 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:

- 6.1 **Service Fees.** The Services will be charged to Client on the basis of PharmaLex's daily Service rates, unless otherwise agreed. Hours in excess of a standard day or for part of a standard day will be charged pro rata at the daily rate, unless otherwise agreed. 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 and travelling expenses incurred by rendering the Services as follows:
- (a) **Accommodation cost:** All costs for accommodation of PharmaLex Staff Members during a business trip will be charged, at cost, to Client.
 - (b) **Travel expenses:**
 - Travel time is charged at 75% of the daily rate.
 - Travel by private car: mileage, and any applicable tolls, shall be recoverable by PharmaLex Staff Members at a rate of €0.79/km.
 - Travel by air/train: charged at cost. Flights of 5 hours or more shall require business class ticket.
 - (d) For days when PharmaLex staff is on site at Client or traveling on behalf of Client, vouched subsistence charged at cost, shall apply.

- (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 a log of hours showing Service provision.

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 immediately suspend performance for all Services, and (ii) to charge interest in accordance with European Communities (Late Payment in Commercial Transactions) Regulations 2012, until payment in full is received. The date of receipt by PharmaLex of the full payment is decisive for its timeliness.

Payment of invoices shall be made by Client in full without set-off, deduction or counterclaim of any kind including limitation, no withholding for or on account of, any current or future taxes, levies, import duties, charges or other deductions or withholdings levied in any jurisdiction from or through which payment is made or where the payer is located unless such deduction or withholding is required by applicable law. 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 PharmaLex. Any portion of an invoice not disputed within 10 days shall be deemed accepted by Client.

Upon completion of the Service provision, PharmaLex will issue a final invoice to Client for work undertaken.

- 6.4 The following penalties shall be payable on cancellation of any Work Order by Client following confirmation of engagement but prior to any commencement of Service:
- (a) Within two weeks of date: 50% of projected costs
 - (b) Within one week of date: 75% of projected costs

§ 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 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 clause 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

- 8.1. 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.
- 8.2. Information contained in any proposals made by PharmaLex should not be disclosed under any freedom of information requirements. This is because PharmaLex proposals contain confidential, proprietary, competitive and/or commercial information regarding working methods and fee rates.

§ 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 negligence or willful breach of its contractual or legal obligations. PharmaLex shall not be liable for any indirect or consequential damages, costs, expenses or losses of any type, such as, without limitation, lost profits or business interruption, due to any breach of any agreement or Work Order. PharmaLex's liability is limited to damages caused by the breach of key contractual obligations. PharmaLex shall have no liability for any losses resulting from reliance on any estimates, forecasts, projections, representations or recommendations. PharmaLex endeavors to fulfil the agreed requirements of any Work Order. In the event that circumstances outside PharmaLex's control make it impossible to meet the objectives of any Work Order, including but not limited to reasons of force majeure,

PharmaLex can accept no liability for any such failure once the agreed time allocation for any Work Order has been utilised.

- 9.2. Notwithstanding any other provision of these GTC, PharmaLex's liability to Client 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.
- 9.3. PharmaLex shall not be liable for tortious acts or omissions of its Staff Members. Client will indemnify PharmaLex in this regard for any and all claims arising from Third Parties.
- 9.4. Neither Party excludes or limits its liability for fraud or death or for personal injury arising from its negligence or any liability to the extent the same may not be excluded or limited as a matter of law.
- 9.5. The limitations of liability stated above shall cover any and all claims of whatever nature which Client may assert against PharmaLex, regardless of their legal basis.
- 9.6. 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.
- 9.7. PharmaLex will maintain appropriate insurance in respect of its obligations to Client under any Work Order. Upon request, PharmaLex will provide Client with a copy of its relevant 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, changes 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 to any Work Order as is 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 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:
 - (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 exceeding amounts. The payments shall be made within 14 days after the effective date of termination at the latest.
- 11.5. The provisions of clauses 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. In the event that the Client, during the course of Service provision by PharmaLex or within a period of 6 months after the completion of such Service, engages as an employee of the Client or as a consultant to the Client, any person or persons who had been supplied by PharmaLex in the course of providing Services, then and in any such event the client will pay to PharmaLex a sum of money equivalent to 6 month's gross salary/remuneration then being paid by PharmaLex to the person or persons in question.

§ 13 Miscellaneous

- 13.1 It is acknowledged by the Client that PharmaLex will be free to undertake activities and offer the same or other services at

the same time or otherwise to other parties. PharmaLex and the Client confirm that there is no conflict of interest of which either Party is aware that would prevent PharmaLex from delivering the Services as outlined in any Work Order.

- 13.2 Please complete, sign and return the attached Client set-up form for accounts purposes which includes details of purchase order number, Client VAT number and country of residence. As indicated therein, please provide a copy of VAT 13B Exemption Certificate if applicable.
- 13.3 PharmaLex is not required to commence providing Services until a PO is received by PharmaLex from Client. If a PO is not received within six weeks of a scheduled training delivery date, or within four weeks of a scheduled audit/inspection/gap analysis/other Service, then delivery of Service is at the discretion of PharmaLex and is not guaranteed.
- 13.4 The relationship between the Parties is that of independent legal parties and nothing in any arrangement or Work Order shall be construed as being a partnership, joint venture, employment or agency relationship.
- 13.5 All Work Orders, arrangements and agreements of whatever nature between PharmaLex and Client shall be exclusively governed by and construed in accordance with Irish law, including any non-contractual disputes. The place of exclusive jurisdiction in the event of any claim or dispute of whatever nature arising out of or in relation to matters between the Parties, including but not limited to the validity, invalidity, breach or termination of a Work Order, is Ireland.
- 13.6 If any provision of this Agreement is found by any Irish court, tribunal or administrative body to be wholly or partly illegal, invalid, void, unenforceable or unreasonable it shall, to the extent of such illegality, invalidity, voidability, unenforceability or unreasonableness, be deemed severable and the remaining provisions of this Agreement and the remainder of such provision shall continue in full force and effect.