



**STANDARD BUYING TERMS AND
CONDITIONS OF
PFIZER LUXEMBOURG SARL,
organizačná zložka**

VERSION: MARCH 1ST, 2016

PREAMBLE

These standard buying terms and conditions (the 'SBTC') are prepared in accordance with Act no. 513/1991 Coll., the Commercial Code, as amended (the 'Commercial Code'), and other rules of the legal order of the Slovak Republic and are binding in respect of any business done between **PFIZER LUXEMBOURG SARL**, Avenue J.F. Kennedy 51, L-1855 Luxembourg, with its business establishment **PFIZER LUXEMBOURG SARL, organizačná zložka**, with its registered office at Pribinova 25, 811 09 Bratislava, Slovak Republic, ID No.: 35 885 696, registered in the Commercial Register of the District Court Bratislava I, Section Po, Insertion 1164/B (hereinafter referred to as the 'Customer') and any legal entity supplying the Customer with goods or services (the 'Supplier').

1. CONCLUSION OF CONTRACT

1.1 The Customer's purchase orders shall be governed by these SBTC unless the application of these SBTC or part thereof is excluded or these SBTC are modified and/or supplemented by the Customer in his purchase order and/or the contract entered into between the Customer and the Supplier.

1.2 The SBTC together with all its appendices form an integral part of purchase orders of the Customer and/or contracts entered into by and between the Customer and the Supplier and any amendments to such purchase orders or contracts.

1.3 Unless the Customer and the Supplier agree otherwise, the Customer is not bound by any terms and conditions of the Supplier that are in conflict with or supplement these SBTC in any manner.

1.4 Unless the parties agree otherwise, each purchase order of the Customer shall contain the following data:

- (a) Purchase order number;
- (b) Supplier data (address, telephone, fax, company ID, and tax registration ID);

- (c) Correspondence address of the Customer (address, telephone, fax, and contact person);
- (d) Billing address of the Customer (address, telephone, and fax); and
- (e) Specification of the goods and/or services (description, quantity, unit price, total price, date of delivery, and purpose).

1.5 The Supplier shall reject in writing any purchase order of the Customer that misses any of the data required under point 1.4.

1.6 The Supplier shall be entitled to reject in writing any purchase order of the Customer and, along with sending his rejection notice to the Customer, send the Customer his binding offer that contains all the data required under point 1.4 above. If the Customer accepts such an offer, he shall send the Supplier a written acceptance confirmation. For the purpose hereof, a 'purchase order' shall also mean a binding offer of the Supplier which has been accepted by the Customer under this provision.

1.7 The Supplier shall send a purchase order acceptance/rejection notice, and a binding offer under 1.6 if applicable, to the contact person in charge of contractual matters on part of the Customer and the contact person who issued the purchase order on behalf of the Customer. For the avoidance of doubts a purchase order acceptance/rejection may be made also electronically.

1.8 The Customer and the Supplier have agreed that in case of amendments and/or comments of the Supplier to the purchase order, the purchase order is not accepted and is considered to be rejected.

1.9 Once a purchase order acceptance by the Supplier is delivered to the Customer or a binding offer acceptance by the Customer is delivered to the Supplier, this results in the creation of (i) a purchase agreement between the Customer as the buyer and the Supplier as the seller if the purchase order is placed for goods or (ii) an agreement on the provision of services if the purchase order is placed for services; the rights and obligation of the parties shall be governed by the purchase order and these SBTC including its appendices (hereinafter also as the 'Supplier Contract'). The Supplier shall not be entitled to supply goods and/or services prior to the execution of the Supplier Contract.

1.10 Unless the Customer receives in writing from the Supplier a purchase order acceptance or a binding offer under 1.6 by the 15th (fifteenth) day following after the date shown in the purchase



order as the date thereof, such a purchase order shall extinguish unless the Customer and Supplier agree otherwise. Such extinguishment of a purchase order shall constitute no entitlement to damages for the Supplier.

2. RIGHTS AND OBLIGATIONS OF PARTIES

2.1 The Supplier agrees to supply goods and/or render services to the Customer in due manner and time, in accordance with these SBTC and under the Supplier Contract and do so with adequate professional care, and the Customer agrees to pay the Supplier such purchase price for the goods duly supplied and/or such consideration for the services duly rendered as stipulated in the Supplier Contract in accordance with these SBTC.

2.2 For the avoidance of doubts the parties represent that the Customer shall be bound by no obligation to issue purchase orders, accept offers of the Supplier and/or take any goods/services from the Supplier and shall be entitled to take goods and/or services from third parties.

3. REPRESENTATIONS AND OBLIGATIONS OF THE SUPPLIER

3.1 The Supplier agrees to follow the specifications stipulated in the Supplier Contract in manufacturing and supply of the ordered goods and/or rendering services to the Customer. The Customer shall accept goods and/or services from the Supplier provided that such goods and/or services meet the requirements of the Customer specified in the Supplier Contract and are fit for the agreed purpose.

3.2 The Supplier agrees to ensure that the supplies of goods and/or services under the Supplier Contract are in full accordance with the valid legal and administrative rules and regulations and all ethical codes of conduct related to the Customer's business and products (Ethical Codex of the Slovak Association of Research and Development Oriented Pharmaceutical Companies, the Ethical Codex of the Advertising Practice of the Advertising Standards Council and published findings of ASC or the ASC's Arbitration Committee) and in connection with the promotion of medicines also with the instructions and recommendations of the State Institute for Drug Control, and, in respect of goods, any directives and regulations of the European Union regulating design, production, putting into operation and use of industrial products (the CE mark). The Supplier shall be

obligated to compensate the Customer for any damage arising from violation of this provision.

3.3 The Supplier represents that he will only use duly qualified, trained and experienced persons for the supplies of goods and/or the rendering of services specified in the Supplier Contract. The Supplier shall ensure that his employees, agents and any other person the Supplier may use in connection with the supplies of goods and/or the rendering of services specified in the Supplier Contract exercise such a standard of due care to which the Supplier is bound in the Supplier Contract and these SBTC. For discharging his obligations resulting from the supplies of goods and/or the rendering of services the Supplier shall only be entitled to use third parties upon a prior written consent of the Customer; even where such a consent is granted, the Supplier shall be liable for due supply of goods and/or rendering of services and observance by the third party of all the terms and conditions of the Supplier Contract and these SBTC as if the Supplier himself supplied the goods and/or rendered the services. The Supplier agrees to immediately replace any third party taking part in performing the Supplier Contract where the Customer requests such replacement.

3.4 In discharging his obligations resulting from the Supplier Contract the Supplier shall act with due professional care and in accordance with the instructions issued by the Customer and all internal policies and the (general) terms of business and these SBTC that the Customer may communicate to the Supplier from time to time.

3.5 The Supplier represents that he is qualified to supply the goods and/or render the services specified in the Supplier Contract, has the relevant approvals and registrations, meets qualification requirements for doing business, has obtained all necessary permissions, consents, authorisations and registrations, has made the relevant notifications necessary for the discharging of the obligations resulting from the supply of goods and/or the rendering of services, and that such permissions and consents are fully valid and effective. The Supplier represents that supplying goods or rendering services under the Supplier Contract is in no conflict with other obligations of the Supplier.

3.6 The Supplier declares that no claim, suit, proceedings, or investigations by state bodies exists, nor is the Supplier aware that any such claim, suit, proceedings, or investigations by state bodies is imminent that could have a deleterious effect on the Supplier's ability to perform his



obligations according to the Supplier Contract or which would cause the invalidity or unenforceability of this Supplier Contract.

3.7 The Supplier represents that the executing of the Supplier Contract under these SBTC is in no conflict with the terms and conditions stipulated in any contract or agreement entered into by the Supplier with a third party, the delivering of the Supplier Contract by the Supplier will not result in violating a third party's rights, ethical codes of conduct, applicable legal rules or generally binding or internal rules of the Supplier, rulings, orders (including minister's orders) or regulations of superior bodies or the Supplier's employer, or other rules and directions by which the Supplier is required to abide, as applicable. The Supplier also represents that the discharging of the Supplier Contract under SBTC and the payment of price/remuneration by the Customer under the Supplier Contract is no means of persuading or motivating into using or prescribing products nor manipulating results of clinical trials nor exercising direct or indirect influence on adopting any decision concerning the Customer or his products. For the purpose of this paragraph products shall be understood to be any products of the Customer or the entities directly or indirectly controlling the Customer or those controlled by the Customer or those under common control of the Customer.

3.8 The Supplier agrees to enable the Customer to check due use of the monetary performance provided under the Supplier Contract; the Supplier shall do so especially by:

- (a) Providing, on a regular basis, invoices with a detailed description of the goods and/or the services provided by the Supplier;
- (b) Providing documentation pertaining to all the expenses the Supplier requests to be refunded and notifying the Customer of any extraordinary expenses in writing beforehand. The Customer shall approve in writing any extraordinary expenses before they are incurred; and
- (c) Providing the Customer's internal and/or external auditors, during the Supplier Contract and for three (3) years following after the last payment under the Supplier Contract, with access to accounting entries, documents and records of the Supplier related to the goods and/or the services provided under the Supplier Contract; such access is to be provided during business hours and following a prior notice made in due time beforehand.

3.9 The Supplier agrees not to carry out any off-label promotion of the Customer's products in the Slovak Republic.

3.10 The Supplier represents and warrants that any information provided to the Customer in connection with Pfizer's anti-corruption due diligence is complete, truthful and accurate and the Supplier agrees to inform the Customer if any responses in the due diligence questionnaire with respect to the Supplier or any individuals identified in the due diligence questionnaire or their Family Relatives, as defined therein, change during the performance of the Supplier Contract under these SBTC.

3.11 The Supplier undertakes to immediately notify the Customer if, in connection with the execution and performance of the Supplier Contract, the Supplier obtains any information of the possible occurrence of an undesirable or reportable event (see Appendix 3 to the SBTC).

3.12 If personal data are collected, processed or kept in connection with the supplies of goods or the rendering of services under the Supplier Contract, the Supplier agrees to act in accordance with Act No. 123/2013 Coll., the Personal Data Protection Act, as amended, i.e. including technical and organisational security measures in respect of access to such data, and to ensure that all data that may be provided for the Customer are anonymous unless the parties agree in writing otherwise. The rights and obligations of the Supplier as the data processor and the Customer as the data controller are governed by Appendix No. 4 hereto.

3.13 The Supplier agrees to make or issue, during the Supplier Contract and for 12 months following the termination thereof, a statement of the existence and subject-matter of this contractual relation with the Customer any time the Supplier writes an article or delivers a speech on any professional, business or other matter which is subject to the Supplier Contract or relates to the Customer.

3.14 The Supplier represents that:

- a) is registered for VAT payer in the Slovak Republic,
- b) is liable to pay VAT, as a supplier under the Law on Value Added Tax, listed on any invoice issued under or in connection with the Supplier Contract, and especially declares that the Supplier is not unable to pay such Tax. Furthermore, in this context the Supplier declares that the Customer as a VAT payer is unaware and cannot be aware

Comment [A1]: If provision of services or supply of goods will not include personal data processing, this part of the provision including Appendix No. 4 should be removed completely.



of any outstanding unpaid VAT, and in this context, especially Supplier declares that:

- counter value for the transactions listed on any invoice issued under or in connection with the Supplier Contract may not be excessively high or excessively low, especially price/remuneration agreed in the Supplier Contract,
- no reasons on deregistration in accordance with § 81, par. 4, point b) the second point of the Law on Value Added Tax occurred by the Supplier or,
- the Supplier has not been published in appropriate list of persons maintained by the Financial Headquarters of the Slovak Republic.

- 3.15 If the Supplier in connection with the supply of goods and/or rendering of services to the Customer pursuant to the Supplier Contract, as a third party pursuant to Act no. 362/2011 Coll. On Medicines and Medical Devices, provides directly or indirectly any monetary or non-monetary transfer of value to any healthcare professional or healthcare provider, the Supplier shall without any delay (within 30 days at the latest after the provision, within 10 days for provisions in months June and December, unless any legal regulations require shorter term) provide the Customer information required under the above mentioned act in electronic form by an e-mail and in hardcopy (signed by the authorized representative with stamp of the Supplier) via mail using the predefined form which will be provided to the Supplier by the Customer upon request. If the Supplier breaches this obligation (including provision of inaccurate, untruthful and incomplete information), the Supplier shall indemnify the Customer for any and all fines for administrative sanctions imposed on the Customer in connection with breach of this Supplier's obligation.

4. REPRESENTATIONS AND OBLIGATIONS OF THE BUYER

4.1 The Customer shall provide the Supplier with the cooperation necessary for the Supplier to duly fulfil his obligations resulting from the Supplier Contract.

4.2 The Supplier declares that he is capable of executing the Supplier Contract, that he has obtained all necessary permits and approvals for

the signing of the Supplier Contract and for the performance of the obligations arising from it, and that these permits and approvals are valid and applicable in their full extent.

5. PURCHASE ORDER ATTACHMENTS

5.1 All technical specifications, drawings, notes, instructions and other information referred to in the Supplier Contract or contained in the appendices thereto shall be an integral part of the Supplier Contract.

5.2 The Supplier shall check any instructions and/or documents provided to him by the Customer for the delivery of the Supplier Contract and inform the Customer immediately of any discrepancy and/or error that the Supplier has identified or suspects. If the Supplier breaches the obligation to inform the Customer, the Supplier shall be held liable for the defects of goods or services that may be caused by the use of wrong or inappropriate instructions and/or documents provided to him by the Customer.

6. TERM OF DELIVERY

6.1 The Supplier agrees to deliver the goods or render the services to the Customer in due manner and in the term of delivery stipulated in the Supplier Contract. The term of delivery is the date on which the ordered goods are to reach the place of delivery and/or the rendering of the ordered services is to be commenced.

6.2 If a delay in supplies is expected, the Supplier agrees to notify the Customer of such a delay in writing as soon as the Supplier becomes aware of such a delay.

6.3 Apart from force majeure events or where an event of default is attributable to the Customer, if the Supplier fails to supply in due manner and/or time or fails to supply in due quantity or amount or a delay in supplies is likely to occur, then the Customer reserves the right to withdraw from the entire Supplier Contract and/or that part thereof which is yet to be performed and/or the right to agree with the Supplier on a new term of delivery. The rights reserved above shall be without prejudice to the Customer's right to demand from the Supplier compensation for direct or indirect damage suffered in connection with delayed supplies and/or failure to supply to the agreed place.

7. SUPPLIES

7.1 Unless agreed otherwise, all supplies of goods and/or services shall be delivered to the registered office of the Customer.



7.2 Partial supplies of goods and/or services are not allowed without the prior written consent of the Customer.

7.3 After goods are dispatched to the place of delivery the Supplier shall deliver the Customer a goods dispatch notice by post, fax and/or e-mail to the address shown in the Customer's purchase order. The goods dispatch notice must show the purchase order number, the quantity of goods and the delivery address.

7.4 Each supply of goods must include a bill of delivery (two copies) which must show the same data as does the goods dispatch notice, otherwise the goods shall be returned to the Supplier at his expense.

7.5 The Supplier agrees to follow the Customer's instructions, especially those in connection with marking goods and issuing accompanying documents.

7.6 Goods/services are understood to have been supplied once accepted by the Customer. By attaching his signature to the bill of delivery and filling in the date of supply, the Customer – his employee, agent or representative authorised to accept goods – confirms the acceptance of a supply but this constitutes no approval as to the standard of the goods supplied.

8. PACKAGING AND TRANSPORT

8.1 Unless the Customer requires otherwise, goods must be prepared and packed in a manner befitting the nature of the goods, the chosen method of transport and the place of delivery.

8.2 Unless agreed otherwise, the transport and dispatch documents are to be prepared by the Supplier. The Supplier shall pay the dispatch costs. The dispatch costs include all costs, especially those of packaging, loading, placing, insurance and the costs of transport related to the supply of goods.

8.3 Packing and transport of goods are at the risk of the Supplier.

9. INSPECTION AND ACCEPTANCE OF GOODS

9.1 The Supplier shall inspect the goods prior to dispatch. In accepting the goods/services the Customer shall check the contents of the supply against the bill of delivery and make a standard control acceptance of the goods / assessment of the services rendered and mark in the relevant bill of delivery all the defects identified in the acceptance inspection.

9.2 If the goods/services show defects in the acceptance procedure, the Customer shall be entitled to:

- (a) Refuse to accept the goods/service and return them to the Supplier at the Supplier's expense and demand that any payments already made be refunded; or
- (b) Demand that the goods in question be replaced, any missing goods be supplied or the services be rendered in due manner; or
- (c) Demand that defects be removed by repairing the goods if they are repairable defects; or
- (d) Demand adequate price discount;
- (e) Withdraw from the Supplier Contract.

10. PRICES

10.1 For goods and/or services duly supplied and/or rendered by the Supplier under the Supplier Contract the Customer shall pay the Supplier a price/remuneration to the amount as agreed and always shown in the Supplier Contract. The price/remuneration set like this shall be final, binding and complete and not subject to change unless otherwise stipulated in the Customer's purchase order and shall cover all and any fees, taxes, costs related to checks, dispatch, transport etc. and any administrative, travel, customs, insurance of other costs related to delivering the goods and/or rendering the services unless the parties agree otherwise. No exchange rate fluctuation shall entitle the Supplier to make a change to the agreed price.

11. INVOICING

11.1 The Customer shall pay the price for the goods and/or the remuneration for the services on the basis of invoices duly made out by the Supplier in accordance with applicable laws and delivered to the Customer without undue delay after the due supply of goods or the due rendering of services to the Customer; invoices for the price for goods and/or services shall be payable within 60 days after its delivery to the Customer. A detailed description of the goods supplied and/or the services rendered by the Supplier and specified in the relevant Supplier Contract must be attached to each invoice.

11.2 The invoices issued by the Supplier for the supply of goods and/or the rendering of services and submitted to the Customer must show the purchase order number, the designation of the goods supplied and/or the services rendered, the



quantity of items of the goods supplied or the specification of the services rendered, the price for the goods supplied and/or the remuneration for the services rendered, the bank account of the Supplier and other essential details required to be shown in a valid accounting and tax document.

11.3 Invoices/tax documents issued by the Supplier in association with the Supplier Contract shall contain all necessary essential information of a tax document according to valid legal regulations, particularly Act No. 235/2004 Coll. on value-added tax, as amended (hereafter the 'Value Added Tax Act'). In the event that any invoice issued by the Supplier should contain incorrect or incomplete information or does not contain requirements mandated by the appropriate legal regulations, particularly the Value Added Tax Act, the Customer shall be entitled to return such a tax document to the Supplier. In such case the Supplier shall be required to correct the invoice or issue a new one. The new or corrected invoice/tax document shall fall due on the 60th day of when it reaches the Customer without the Supplier being entitled to demand any late payment interest on the payments so postponed.

11.4 If the situation specified under Section 69, Subsection 14 of the Value Added Tax Act occurs, i.e. the Supplier fails to pay or is not able to pay the value added tax, the Supplier shall immediately inform the Customer of this fact. In the aforementioned case and also in case conditions for cancellation of registration of the Supplier according to Section 81 Subsection 4 Letter b), second article of the Value Added Tax Act have been met or the Supplier was listed in the relevant list of the Financial Headquarters of the Slovak Republic - Pfizer is entitled to decrease the fee to be paid to the Supplier according to the Schedule 2 of this Agreement or according to the applicable Performance Agreement in the amount of VAT that was not paid.

12. PAYMENT

12.1 The prices for the goods supplied and/or the services rendered by the Supplier shall be payable in accordance with these SBTC unless agreed otherwise.

12.2 Unless agreed otherwise, the Customer will make no payments in cash upon the delivery of goods or the rendering of services.

12.3 Any price additions or changes (modified prices) accepted by the Customer shall be paid along with the final payment of the price.

12.4 Unless the goods supplied and/or the services rendered by the Supplier to the Customer

comply with the Supplier Contract or these SBTC, the Customer reserves the right to postpone the payments for such goods and/or services until the Supplier discharges his obligations in a due manner, without prejudice to any other terms and conditions stipulated in the Supplier Contract. No payment so postponed shall constitute entitlement of the Supplier to late payment interest.

12.5 The Customer is entitled to set off at any time any of its claims on the Supplier owed to the Customer against the claims owed by the Customer to the Supplier that have resulted from the supply of goods and/or the rendering of services. The Supplier is entitled to set off its claims against claims of the Customer only if agreed in writing.

12.6 If the Supplier shall pay any amount of money from which the interests are paid, the Parties expressly agree that in such cases the interest payments on interests (compound interest) can be required. The Parties also agreed that if the Customer becomes entitled to payment of an interest of delay from the Supplier, the interest of delay becomes an integral part of the owed amount, which the Supplier is obliged to pay to the Customer.

13. TRANSFER OF THE OWNERSHIP TITLE

13.1 The title to goods and risk of damage to goods shall pass to the Customer once the goods are accepted by the Customer. The Customer reserves the right to refuse to accept goods and return the same to the Supplier at the Supplier's expense if the Supplier supplies the goods prior to the date of delivery stipulated in the Supplier Contract. The Supplier shall notify the Customer immediately of anything that might cause delay in the Supplier discharging his obligations out of the Supplier Contract.

14. WARRANTIES

14.1 The Supplier undertakes and warrants that the goods supplied by him exactly meet the requirements and the specifications stipulated in the Supplier Contract and are free of any legal or other defects; the Supplier especially undertakes and warrants that:

- (a) The goods supplied are free of defect in material, workmanship, design and manufacture and meet all technical, technological or other certificates, such as those concerning health safety;



- (b) The goods supplied comply with the instructions, specifications, drawings and samples referred to in the Supplier Contract;
- (c) The goods are fit for the purpose stipulated in the Supplier Contract or the regular purpose if no specific purpose is stipulated.

14.2 The Supplier undertakes and warrants that the services rendered by him meet the requirements and the specifications stipulated in the Supplier Contract and are free of any defect; the Supplier especially undertakes and warrants that:

- (a) The services are rendered in a due manner, with professional care and in accordance with all legal rules or internal regulations of the Customer referred to in the Supplier Contract or these SBTC;
- (b) The services rendered comply with the requirements and specifications under the Supplier Contract and/or the SBTC.

14.3 The Supplier grants the Customer a guarantee period of 24 (twenty-four) months from when the Customer accepts the goods/or services to make claims in respect of defective goods/or services unless otherwise stipulated in the Supplier Contract.

14.4 The Customer shall be entitled to make the following claims in respect of defective goods and/or services:

- (a) Demand that defects be removed by supplying replacement goods, any missing goods be supplied, legal defects of the goods be removed and/or the defective service be rendered again or the missing service or part thereof be rendered;
- (b) Demand that defects be removed by repairing the goods if they are repairable defects;
- (c) Demand an adequate price discount; or
- (d) Withdraw from the Supplier Contract.

14.5 The Supplier agrees to make remedy in the warranty period granted by him under 14.3 above immediately or without undue delay depending on the specific case but no later than by the 30th (thirtieth) day from when the Customer reports such a defect to the Supplier, whichever remedy the Customer may choose:

- For the Supplier to supply replacement goods at his own expense or repair at his own expense the defective or inadequate goods and/or the part thereof which is found defective or supply the missing

goods or part thereof or grant a discount on the purchase price for the goods in question or remove the legal defects of the goods;

- For the Supplier to render again at his own expense any service which is found defective or grant a discount on the price for the service in question or remove the legal defects of the service.

14.6 The Customer shall be entitled to damages and contractual penalty in addition to his entitlements under point 14.3.

14.7 The Supplier shall be liable to the Customer, the Customer's contractual partners and third parties for any damage that the Customer, the Customer's contractual partners and/or a third party may suffer as a result of defective goods and/or defective service supplied and/or rendered by the Supplier.

14.8 If the Supplier has been in delay in respect of discharging his warranty-related obligations or has defaulted on the same, the Customer reserves the right to repair or remove immediately the defects and/or errors, or have the same done, at the expense and the risk of the Supplier without any prior notice to the Supplier.

15. ANTI-BRIBERY AND ANTI-CORRUPTION PRINCIPLES

15.1 The Supplier represents that it has not and will not in the future directly or indirectly offer or pay, or authorize the offer or payment, of any money or anything of value in an effort to influence any Government Official (as defined in Appendix 1) or any other person in order for the Customer to improperly obtain or retain business or to gain an improper business advantage, and, has not accepted, and will not accept in the future, such a payment.

15.2 In relation to sub-clauses 3.2 and 15.1 of the Supplier Contract, the Supplier confirms by entering into the Supplier Contract to have been provided with a copy of Pfizer's Anti-Bribery and Anti-Corruption Principles, which form Appendix 1 to the SBTC and that the Supplier has communicated such Principles to all persons acting on its behalf in connection with work for Pfizer, including agents or subcontractors. The Supplier undertakes to submit to Pfizer upon each anniversary of the signing of this Agreement a duly signed Pfizer's International Anti-Bribery and Anti-Corruption Principles – Regular Annual Confirmation, in the form attached in schedule 7 to this Agreement.

Comment [A2]: This provision applies only in case when the Supplier is classified in the category „transaction with *enhanced control*“ or “transaction with *basic control related to a PIGO*“.



16. INSURANCE

16.1 The Supplier agrees to take out an insurance policy so that the rights and the interests of the Customer resulting from these SBTC and a confirmed purchase order would be sufficiently secured in case of any damage suffered.

16.2 At the Customer's request the Supplier shall present the Customer with a certificate issued by the Supplier's insurer to certify a policy taken out that covers the insured risks under the provisions referred to above.

16.3 The Supplier agrees to maintain such a valid policy until the end of the warranty period under 14.3 above.

17. COPYRIGHT AND RELATED RIGHTS

17.1 If on the basis of this Agreement the product of an activity is created which is subject to copyright or any right connected to copyright (the "Work"), the Supplier hereby grants to the Customer exclusive right, free of charge, unlimited in respect of time, place, function, quantity or in any other respect, to exercise such right and use such Work (i.e. a license) and an unlimited right to sublicense it to any third party. The Customer is not obliged to use such license and is entitled to assign it to any third party without the Supplier's further consent. The Customer is also entitled to, make copies, publish a publicly spread the Work or its copies by sale or other form of transfer of its ownership, lease or loan, modify, amend and otherwise deal with the Work including its adaptation, include the Work in a set of works (in Slovak: súborné dielo), connect the Work to another author's work, process the Work or translate it into another language, exhibit it publicly or to broadcast it. The Customer is entitled to change the name of the Work and present it to public as its own. The Customer is entitled to any of the activities stated above free of charge.

17.2 If the Supplier carries out the Services and other activities under the Supplier Contract which are subject to protection under the act no. 618/2003 Coll., Copyright Act (the "Copyright Act"), the Supplier will be obliged to obtain, in accordance with the Copyright Act, all rights of the authors, artists and manufacturers of audio and audio-visual records, whose works, products, records and images are used during the supply of goods and/or performance of the services and other activities under the Supplier Contract, to such extent and for such types of use as to allow the performance of the subject matter of the Supplier Contract, particularly the granting of a

license to the Customer under sub-clause 17.1. The Supplier is also obliged to ensure that no obligation or liability of the Customer will arise towards any author, artist or manufacturer of audio or audio-visual record unless the Parties agree otherwise in writing.

17.3 If, as part of the supply of the goods and/or rendering the services, the Supplier provides any promotion, works, products, records, images or other activities subject to the Copyright Act, the Supplier is responsible for compliance with the rights connected to the use of such work, products, records and images which the Supplier provides and guarantees that no third party will raise any claim arising from a breach of its rights related to any such use against the Customer. In the case of a breach of this obligation, the Supplier will reimburse all damages, material and immaterial harm to the Customer, including the harm to goodwill and the costs of legal representation and any other costs expended in relation to a claim raised by a third party.

18. SAFETY AND ENVIRONMENTAL PROTECTION

18.1 The Supplier undertakes to supply the Customer goods and/or services that are in full accordance with valid safety and environmental rules, otherwise the Customer shall be entitled to withdraw from the Supplier Contract. In addition, the Supplier shall ensure that a supply of goods and/or services is in accordance with the safety and environmental rules applicable to the place of the delivery of the goods and/or the rendering of the services.

18.2 The Supplier undertakes to inform the Customer if the nature of his goods and/or services is of specific character in terms of safety and environmental protection.

18.3 The Supplier shall be fully liable to the Customer, the end buyer/consumer and third parties for any damage suffered as result of the Supplier breaching a statutory duty in respect of safety and environmental protection.

19. CONFIDENTIALITY OBLIGATION

19.1 The Supplier pledges that for the term of duration of this Supplier Contract and after its termination he shall maintain confidentiality and shall not share or make available any information shared by the Customer whether or not it has been explicitly designated as confidential, and related to the contents or purpose of the Supplier Contract, the terms of business created in connection with the Supplier Contract (including



the SBTC), in the wording of their applicable amendments and including all Appendices, as well as all associated documents, records, or other information media whether in material, electronic, or other format, including any information about the commercial activities of the Customer, his employees, products, business relationships and contacts, internal organization of sales activities and internal guidelines, technical equipment or other associated data (hereafter the ‘**Confidential Information**’) and shall use it solely for the purposes of performance of the Supplier Contract. Confidential information shall be protected at least as (i) trade secrets in the sense of the Civil Code and/or (ii) personal information in the sense of Act No. 122/2013 Coll. on the protection of personal data and the amendment to certain laws, as amended, provided it is Confidential Information related to an individual and if the Confidential Information has the character of personal data according to this act. The Supplier shall ensure that his employees, representatives and other persons, with whom he shares the Confidential Information in the course of performing the Supplier Contract, handle this Confidential Information in the manner stated above.

19.2 Upon termination of the validity of the Supplier Contract the Supplier shall do the following without undue delay:

(a) Submit and deliver to the Customer all written materials, data media, and other materials or media which capture or contain the Confidential Information that has been made available to him or provided by the Customer including all originals and copies, without retaining any copy or duplicate thereof; and

(b) Submit and deliver to the Customer, or as instructed by the Customer to destroy all translations, statements or notes in written, printed, or electronic format or materials in a format readable by electronic devices or any other material, data or information derived from the Confidential Information, without retaining any copy or duplicate thereof.

Fulfilment of these obligations may not be conditioned by payment of compensation or fulfilment of other responsibilities by the Customer.

19.3 The Supplier undertakes not to refer to or connect the Customer, under any circumstances without prior written consent of the Customer, with any information during any communication with third parties including but not limited to press releases, internet pages, bids, negotiations,

or discussions. However, this limitation shall not restrict the right to inform, to the extent necessary for discharging the Supplier Contract, the employees or other persons engaged for the performance of obligations in accordance with the conditions of the Supplier Contract and the SBTC.

19.4 The Supplier undertakes to provide all information related to these SBTC, the Supplier Contract, purchase orders and offers and the performance thereof and the performance of the Supplier Contract and/or goods and/or services only to the persons on the Customer’s side authorised therefore. Without the prior written consent of the Customer the Supplier shall not be entitled to advertise or publish any goods or services supplied or rendered by the Supplier to the Customer, such as articles, photographs, films, advertising banners or web sites. Should the Supplier breach this obligation, the Customer reserves the right to remove any advertising or publication at the expense of the Supplier.

20. TERMINATION

20.1 Both parties have the right to terminate the Supplier Contract regulating the provision of services even without indicating a reason, via a one (1) month written notice to the other party; the notice period begins to run on the first day of the calendar month following the month in which notice reaches the other party.

20.2 The Supplier shall be entitled to withdraw from the Supplier Contract by delivering the Customer a written notice becoming effective as of its delivery in the event of material breach by the Customer of the Supplier Contract and/or these SBTC; the following are understood to be a material breach:

(a) The Customer breaches the Supplier Contract and/or these SBTC and does not remedy such a breach within thirty (30) days after receiving a written notice from the Supplier with a description of the breach and a request that such a breach be remedied (if the breach cannot be remedied, the request is not required); or

(b) A decision on the declaration of bankruptcy against the assets of the Customer or a ruling on liquidation is issued; or

(c) The Customer files a debtor’s petition for commencement of insolvency proceedings.

20.3 The Customer shall be entitled to withdraw from the Supplier Contract by delivering to the Supplier a written notice becoming effective as of its delivery in the event of material breach by the Supplier of the Supplier



Contract and/or these SBTC; the following are understood to be a material breach:

- (a) The Supplier breaches any obligation stipulated in 3.2, 3.6, 3.9, 3.10, 3.11, 3.12, 3.13, 15.1, 15.2 or 19.1 of these SBTC;
- (b) The Supplier breaches any other obligation (except those under (a) of this paragraph above), declaration, or guarantee stipulated in these SBTC and does not arrange a remedy within thirty (30) days following the receipt of a written notice from the Customer with a description of the breach and a request that such a breach be remedied (if the breach cannot be remedied, the request is not required); or
- (c) The Customer has established that the Supplier or a person acting on the Supplier's behalf in connection with supplying the goods and/or rendering the services provides or has provided on behalf of the Customer unauthorised payments for a government official or other person; or
- (d) The Customer has established that the Supplier or a person acting on the Supplier's behalf has received in connection with the performance provided on the Customer's behalf any payment, gift or benefit of whatever value in order to award, approve or retain business for a person or gain unauthorised business advantage from any other person or entity or grant the same to such a person or entity; or
- (e) The Supplier has been in delay in respect of completing any individual phase of the required supplies of the goods and/or the services according to the deadline announced by the Customer in comparison to any deadline thus established unless there are circumstances excluding liability that apply to such a delay; or
- (f) A decision has been adopted to reorganise the Supplier or the Supplier's business has been sold; or
- (g) The Supplier assigns his rights and obligations from the Supplier Contract to a third party without the prior written consent of the Customer; or

- (h) the Supplier enters into liquidation proceedings and/or files a debtor's motion to commence insolvency proceedings or authorizes the official receiver to draw up a restructuring opinion or files a motion to allow restructuring or insolvency proceedings are commenced against the Supplier or insolvency is declared or restructuring is allowed on the basis of a motion filed by a third party and the Supplier, in the Customer's opinion, fails to sufficiently prove to the Customer that such third party claim for declaration of bankruptcy or insolvency or claim for allowing restructuring is unjustified.

In these instances the Customer shall be entitled to have another entity to discharge the outstanding obligations of the Supplier at the Supplier's expense irrespective of the Customer's entitlement to demand damages from the Supplier.

20.4 For the purpose of 20.3 a material breach by the Supplier shall also mean any breach by any employee or agent of the Supplier or any third party engaged by the Supplier in connection with providing goods and/or services under the Supplier Contract.

20.5 The rights to terminate the Supplier Contract as specified under sub-clause 20.1 through 20.3 shall be without prejudice to any other right of the parties in relation to the indicated possible breach or any other breach of these SBTC (especially the rights to a contractual penalty and damages).

21. DAMAGES; CONTRACTUAL PENALTY

21.1 If the Supplier breaches any liability or obligation regulated in these SBTC, the Supplier Contract or the purchase order and such breach fails to be remedied by the fifth (5th) day following after the receipt of the Customer's notice with a request that such breach be remedied, the Customer shall be entitled to demand from the Supplier a contractual penalty at 10% of the selling price for those goods supplied and/or of the remuneration for that service rendered which are affected by the breach, but no less than EUR 3.200 (three thousand two hundred Euro) for every event of breach. The fixed amount shall also relate to an event of breach in respect of which no value of the goods supplied and/or the service rendered can be derived or which event of breach does not relate to any goods and/or service. The Supplier shall pay the contractual penalty by the tenth (10th) business day following after the



Customer's written notice, to the account as specified by the Customer. Payment of any contractual penalty shall bear no influence on the requirement of compensation for damages caused by the violation of the obligation or requirement.

22. CIRCUMSTANCES EXCLUDING LIABILITY

22.1 If either party fails to discharge its contractual obligations in full or in part and relies in this respect on circumstances excluding liability in the meaning of section 374 of the Commercial Code, such a party shall inform the other party by a registered post letter immediately after such circumstances arise, specifically within 48 (forty-eight) hours after such circumstances arise at the latest. Once the circumstances excluding liability cease to have effect, the party which relied on such circumstances shall inform the other party in writing of the exact date when the circumstances excluding liability ceased to exist and of the effect such circumstances had on the discharging of obligations and of why such circumstances occurred and, as may be applicable, such a party shall attach to such communication any relevant certificate issued by the relevant central government authority, etc.

22.2 If any interruption in the Supplier discharging his contractual obligations has persisted for more than 6 (six) weeks as a result of circumstances excluding liability, the Customer reserves the right to withdraw from the Supplier Contract under article 20 above.

22.3 No effect of circumstances excluding liability shall be taken account of in respect of supplies of standard goods and the goods the Supplier can arrange from anywhere else in the term of delivery stipulated in the Supplier Contract.

23. RESOLUTION OF DISPUTES; APPLICABLE LAW

23.1 The parties undertake to deal amicably with any dispute that may arise in connection with the Supplier Contract and/or these SBTC, whatever nature or cause of such a dispute. If such amicable agreement should not be possible, all disputes shall be resolved by the appropriate court of the Slovak Republic. All purchase orders, offers, Supplier Contracts and these SBTC shall be governed by the laws of the Slovak Republic.

23.2 As soon as the Customer notifies the Supplier of a claim or an action made by a third party that relates to the ordered goods or services, the Supplier shall arrange for defence for the

Customer against such a claim and cover the costs, expenses and damages associated with such a claim and the defence against it. If a final decision is delivered, forbidding the Customer to use the ordered goods or the rendered services because of breach of patent rights or copyright or if, as the Customer may conclude, the use of such goods or services could result in an action for breach of such rights, the Supplier shall, at the Customer's request and at the Supplier's expense, either obtain for the Customer the right to continue the use of such goods or services or replace or change such goods or services so that the use thereof would constitute such a breach no longer.

23.3 In the event that any provision of the Supplier Contract or these SBTC is or becomes invalid, ineffective, or unenforceable, such provision shall be considered severable from the other contents of the Supplier Contract and shall have no effect on the validity, effect, or enforceability of the Supplier Contract or the terms and conditions as a whole. In such an event the parties undertake to replace such an invalid, ineffective, or unenforceable provision with a different provision that corresponds to the purpose of the contract and the terms and conditions and will be in terms of its content closest to the invalid, ineffective, or unenforceable provision.

24. COMMON PROVISIONS

24.1 All notices and communication under the Supplier Contract and these SBTC shall be delivered to the relevant party by hand or sent by registered post or fax to the respective addresses or fax numbers as specified in the Supplier Contract. If an act is to be effected in writing, it is sufficient if effected by electronic mail unless agreed or stipulated in these SBTC otherwise.

24.2 The Supplier shall not be entitled to include in his promotional, business or other material any reference to the Customer as the Supplier's business partner without a prior written consent of the Customer.

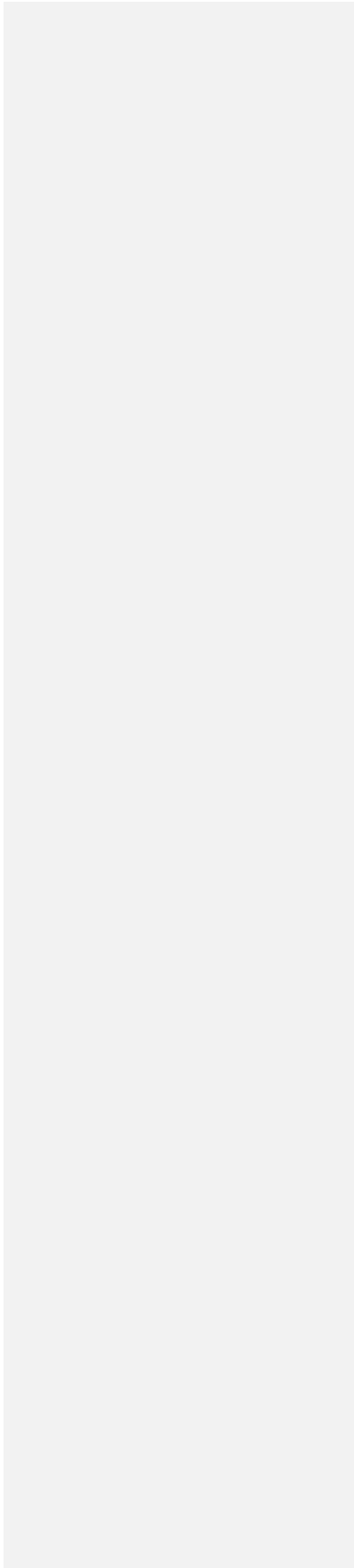
24.3 The Customer and the Supplier explicitly agree that, in the event of significant changes of circumstances, which may give rise to gross disproportion between the parties, namely due to the disproportionate increase of costs of performance or disproportionate decrease of the value of the subject matter of the performance or due to other reasons, neither party will insist on new negotiation on conditions of their commercial relationship.



**25. ACCEPTANCE OF STANDARD
BUYING TERMS AND CONDITIONS
OF THE BUYER**

25.1 By accepting the Customer's purchase order or submitting a binding offer the Supplier represents that he has duly read and understood these SBTC and accepts all the provisions thereof.

25.2 If the Supplier has accepted the SBTC, these SBTC shall also apply to any other goods or services supplied or rendered by the Supplier to the Customer.





Appendix No. 1 Pfizer Anti-Corruption Principles

Pfizer has a longstanding corporate policy that prohibits colleagues or anyone acting on Pfizer's behalf from providing any payment or benefit to any person or entity in order to improperly influence a government official or to gain an unfair business advantage. Pfizer is committed to performing with integrity, and acting ethically and legally in accordance with all applicable laws and regulations, including, but not limited to, anti-bribery and anti-corruption laws. We expect the same commitment from the consultants, agents, representatives or other companies and individuals acting on our behalf ('Business Associates'), as well as those acting on behalf of Business Associates, in connection with work for Pfizer.

Bribery of Government Officials

Most countries have laws that forbid making, offering or promising any payment or anything of value (directly or indirectly) to a government official when the payment is intended to influence an official act or decision to award or retain business. In full compliance with s. 127 and sections 331 – 334 of Act No. 40/2009 Coll., the Criminal Code, under Pfizer's policies, 'government official' is broadly interpreted and includes: (i) any selected or appointed public administration officer, such as ministry of health employees or other officers; (ii) any employee or person acting for or on behalf of a public administration officer, an officer of a body or an entity exercising the powers of public administration; (iii) any political party, candidate running for a public office, officer, employee or person acting on behalf of a political party or a candidate running for a public office; (iv) any employee of a public international organisation, such as the UN, or any person acting on behalf of such an organisation. 'Government' is meant to include all levels and subdivisions of governments (i.e., local, regional, or national and administrative, legislative, or executive). Because this definition of 'government official' is so broad, it is likely that Business Associates will interact with a government official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by government-owned hospitals would be considered 'government officials' under Pfizer's policies. The U.S. Foreign Corrupt Practices Act of 1977 (the 'FCPA') prohibits making, promising, or authorizing the making of a payment or providing anything of value to a non-U.S. government official to improperly or corruptly induce that official to make any governmental act or decision to assist a company in obtaining or retaining business, or to otherwise obtain an improper advantage. The FCPA also prohibits a company or person from using another company or individual to engage in any of the foregoing activities. As a U.S. company, Pfizer must comply with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Business Associate.

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Governments and Government Officials

Business associates are required when interacting with governments and government officials to adhere to the following principles:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any government official to induce that government official to make any governmental act or decision to help Pfizer obtain or retain business. Business Associates, and those acting on their behalf in connection with work for Pfizer, may never make a payment to or offer a government official any item or benefit, regardless of value, as an improper inducement for such government official to approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or take other improper steps to benefit Pfizer's business activities.
- Business Associates, and those acting on their behalf in connection with work for Pfizer, need to understand whether local laws, regulations, or operating procedures (including requirements imposed by



government entities such as government-owned hospitals or research institutions) impose any limits, restrictions, or disclosure requirements on compensation, financial support, donations, or gifts that may be provided to government officials. Business Associates, and those acting on their behalf in connection with work for Pfizer, must take into account and comply with any applicable restrictions in conducting their Pfizer-related activities. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions, or disclosure requirements with respect to interactions with government officials, that Business Associate should consult with his or her primary Pfizer contact before undertaking their activities.

- Business Associates, and those acting on their behalf in connection with work for Pfizer, are not permitted to offer 'facilitation payments'. A 'facilitation payment' is a nominal, unofficial payment to a government official for the purpose of securing or expediting the performance of a routine, non-discretionary governmental action. Examples of facilitation payments include payments to expedite the processing of licenses, permits or visas for which all paperwork is in order. In the event that a Business Associate, or someone acting on their behalf in connection with work for Pfizer, receives or becomes aware of a request or demand for a facilitation payment or bribe in connection with work for Pfizer, the Business Associate shall report such request or demand promptly to his or her primary Pfizer contact before taking any further action.

Commercial Bribery

Bribery and corruption can also occur in non-government, business to business relationships. Most countries have laws which prohibit offering, promising, giving, requesting, receiving, accepting, or agreeing to accept money or anything of value in exchange for an improper business advantage. Examples of prohibited conduct could include, but are not limited to, the provision of inappropriate gifts or hospitality, kickbacks, or investment opportunities offered to improperly induce the purchase of goods or services. Pfizer colleagues are not permitted to offer, give, solicit or accept bribes, and we expect our Business Associates, and those acting on their behalf in connection with work for Pfizer, to abide by the same principles. Pfizer colleagues are not permitted to offer, give, solicit or accept bribes, and we expect our Business Associates, and those acting on their behalf in connection with work for Pfizer, to abide by the same principles.

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Private Parties and Pfizer Colleagues

Business associates are required when interacting with private individuals and employees of the Pfizer corporation to adhere to the following principles:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any person to induce that person to provide an unlawful business advantage for Pfizer.
- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly, solicit, agree to accept, or receive a payment or anything of value as an improper inducement in connection with their business activities performed for Pfizer.
- Pfizer colleagues are not permitted to receive gifts, services, perks, entertainment, or other items of more than token or nominal monetary value from Business Associates, and those acting on their behalf in connection with work for Pfizer. Moreover, gifts of nominal value are only permitted if they are received on an infrequent basis and only at appropriate occasions.

Reporting Suspected or Actual Violations



Business Associates, and those acting on their behalf in connection with work for Pfizer, are expected to raise concerns related to potential violations of these International Anti-Bribery and Anti-Corruption Principles or the law. Such reports can be made to a Business Associate's primary point of contact at Pfizer, or if an Associate prefers, to Pfizer's Compliance Group by e-mail at corporate.compliance@pfizer.com or by phone at 1-212-733-3026.



Appendix No. 2
SAFETY REPORTING CONDITIONS FOR PFIZER PRODUCTS

1. INTRODUCTION

1.1 Pfizer has a legal and corporate responsibility to comply with applicable regulations governing the collection and reporting of potential Adverse Events (“AE(s)”), At Risk Scenarios (“ARSs”), Unexpected Therapeutic Effects (“UTEs”), Medical Device Complaints (“MDC(s)”) and Product Quality Complaints (“PQC(s)”) associated with Pfizer medicinal and nutritional products and/or Medical Devices (which may be separate from, or a component, of a Pfizer medicinal product) all collectively referred to as “Product(s)”, as these terms are defined below. The party providing the services to Pfizer under this Agreement (“Vendor”) shall at all times adhere to the procedures set out below.

2. DEFINITIONS

2.1 **Adverse Event:** an adverse event (AE) is any untoward medical occurrence in a patient administered a Pfizer Product. The event need not necessarily have a causal relationship with the treatment or usage. This includes, but is not limited to:

- Abnormal test findings
- Clinically significant symptoms and signs
- Changes in physical examination findings
- Hypersensitivity
- Progression/worsening of underlying disease
- Lack of drug efficacy
- Drug abuse
- Drug dependency
- Signs and symptoms resulting from drug withdrawal and drug interactions

2.2 **At Risk Scenarios:** circumstances where the report does not include an AE per se, but nevertheless needs to be reported to Pfizer. These circumstances include:

- Medication errors
- Exposure during pregnancy
- Exposure during breastfeeding
- Overdose
- Misuse
- Extravasation
- Occupational exposure
- Off-label use

2.3 **Unexpected Therapeutic Effect (“UTE”):** a beneficial therapeutic effect of a Product aside from the use for which it had been given.

2.4 **Product Quality Complaint:** is any written or oral expression of dissatisfaction relative to the physical properties, condition, labeling, potency and/or packaging of a Product, including whether a Product is suspected or confirmed to be counterfeit.



- 2.5 **Medical Device:** Any instrument, apparatus, appliance, material or other article, intended by the manufacturer to be used for human beings and which does not achieve its principal intended action in or on the human body by pharmacological, immunological, or metabolic means, but which may be assisted in its functions by such means.
- 2.6 **Medical Device Complaint:** is any written or oral expression of dissatisfaction relative to the appearance, identity, quality, durability, reliability, safety, effectiveness, or performance of a medical device or a product with a medical device component.
3. **VENDOR RESPONSIBILITIES**
- 3.1 If Vendor personnel become aware of potential AE(s), ARSs, UTEs, MDC(s), or PQC(s) that may be associated with a Pfizer Product, the Vendor shall inform Pfizer in accordance with the procedures for AE, ARS, UTE, MDC and PQC reporting included in this Exhibit and as may be updated and provided to the Vendor in the future by Pfizer.
- 3.2 The Vendor shall ensure that all employees providing services under this Agreement shall comply with requirements as outlined in this Exhibit.
- 3.3 In the event the Vendor engages a subcontractor to perform services related to this Agreement, the Vendor shall request fulfillment by that subcontractor of these safety reporting requirements on substantially the same terms as those outlined in this Exhibit, unless it is established that there is no possibility that the subcontracted services will involve receipt or handling of potential AE, ARS, UTE, MDC or PQC reports by the subcontractor.
4. **SAFETY TRAINING**
- 4.1 The Vendor agrees to comply with Pfizer's standards and training on Pfizer's AE, ARS, UTE, MDC and PQC reporting procedures ("Reporting Procedures"). The Vendor will require that all employees and, if applicable, subcontractors' employees, responsible for performing the Services under this Agreement must successfully complete the most current version of Pfizer's AE Training Program which will be provided by Pfizer, and any other safety related training requested by Pfizer, ("Training Program"). Training must be completed by an employee before performing the Services under this Agreement, with retraining of the employee on an annual basis. An employee's attendance and successful completion of a Training Program must be documented by signature of confirmation of training certificates ("Training Certificates") which will be provided by Pfizer with the Training Program.
- 4.2 The Vendor shall maintain (and provide to Pfizer upon request) copies of all Training Certificates for a period of ten (10) years after the expiration or termination of this Agreement [or, if applicable, the last SOW in effect, whichever occurs later].
5. **REPORTING PROCESS**
- 5.1 Reporting Time-Frames: In accordance with Pfizer's Reporting Procedures, the Vendor shall report all potential AEs, ARSs, UTEs, MDCs and all PQC(s) to Pfizer within twenty-four hours of awareness, Reporting responsibilities are the same for all AEs, irrespective of the seriousness of the event or whether or not it was caused by the product. All MDCs, ARSs, UTEs and PQC(s) should be reported, whether or not there is an associated AE.
- 5.2 AEs, MDCs, ARSs, UTEs and PQC(s) should be reported to SVK.AEreporting@pfizer.com.



- 5.3 Case Documentation: The Vendor shall document all potential AEs, ARSs, UTE,s MDCs, and PQC's received in the following format: identifiable patient (if applicable), suspect product, adverse event or other reportable situation and any further relevant information provided by the reporter. Documentation shall include, where possible, the name, address, and telephone number of the reporter, and whether consent has been given by the reporter to be re-contacted by Pfizer if further information is required. The Vendor will maintain a record of each AE, ARS, UTE, MDC and PQC report received and a record of each AE, ARS,UTE, MDC and PQC reported to Pfizer for a period of ten (10) years after the expiration or termination of this Agreement [or, if applicable, the last SOW in effect, whichever occurs later] and, if requested, will provide these and any other information requested by Pfizer, to support regular reconciliation and quality checks.
- 5.4 Data Privacy: In forwarding AE, ARS, UTE, MDC or PQC reports on Pfizer Products to Pfizer, the Vendor shall comply with all applicable privacy and data protection laws, rules and regulations on the protection of individuals with regard to the processing of personal data and the free movement of such data. The Vendor shall collect, use and disclose any personal data obtained in the course of performing the safety related activities under this Agreement solely for the purposes of complying with the regulatory obligations as described in this Agreement, or as otherwise required by law or by a court order.
- 5.5 Information Technology: To the extent that the Vendor utilises information technology systems to identify and report potential AEs, ARS, UTE,s MDCs, and PQC's to Pfizer, the Vendor shall conduct regular functionality checks to ensure the systems are operating effectively.

6. **AUDIT**

Pfizer shall have the right, at its cost, with reasonable advance notice, during regular business hours, to audit the facility used by the Vendor and to monitor the Vendor activities in order to review compliance with the safety requirements set out in this Exhibit.

COMPANY NAME: _____

Name and Surname: _____

Position: _____

Date: _____

Signature: _____



Schedule 3
PERSONAL DATA PROCESSING

Pfizer acting in the position of the data controller hereby appoints the Supplier in the position of the data processor for processing of personal data, which will take place within provision of Services by the Supplier hereunder. When processing personal data for the purpose of or within the framework of providing Services under this Agreement, the Supplier shall observe the terms and conditions for personal data processing as specified in Schedule 9 hereto. Pfizer acting in the position of the data controller hereby represents and warrants that in the process of selection of the Supplier as the data processor Pfizer took into consideration the professional, technical, organizational and personal qualification of the Supplier and its capability to ensure safety of the processed personal data through measures pursuant to § 19(1) of the Act No. 122/2013 Coll., Personal Data Protection Act, as amended.

Terms of processing

1. The Processor shall process the personal data exclusively in the extent necessary to proper provision of the Services for the purpose of provision of the Services, i.e. in the extent of:
 - *Contact data of physicians (title, name, surname, phone number to work, private phone number, address of the place of work, address of domicile)*
 - *Data about health conditions of patients in the extent specified in the project (schedule xy of the Agreement)*
Etc.
2. The Processor shall process personal data related to the following category of persons:
 - *Pfizer employees*
 - *Pfizer contractors*
 - *Physicians*
 - *Etc.*
3. The personal data will be processed within the following filing systems exclusively for the following purposes:
....
4. The Processor shall ensure obtaining the consent of data subjects to their data processing prior to obtaining the data and in the form that allows proving that such consent was given. Such consent shall be obtained for the purpose and period as it is necessary for purposes of providing Services hereunder and pursuant to applicable laws and regulations. Consent of the data subject shall be obtained by the Processor in *a written form/in the form of an audio record*, kept for the period of this Agreement and at the time of termination hereof, handed over to Pfizer. The evidence of the provision of the consent by the data subject shall contain mainly the information regarding the person which gave the consent, to whom the consent is given to, for what purpose, the list or scope of personal data and the term of the validity of the consent, while in case of a written form of the consent it must contain own signature of the data subject.
5. Whilst obtaining the consent and prior to its granting the Processor shall inform the data subject in the extent specified in Section 15 of the Act No. 122/2013 Coll., Personal Data Protection Act, as amended (hereinafter referred to as „Act“). The Processor shall upon request of Pfizer provide Pfizer with a written evidence containing an own signature of the data subject or a audio or audio-visual recording that shall prove the performance of the obligation to inform the data subject by the Processor.

Comment [A3]:

Unless the provision of services and/or supply of goods involve personal data processing, this appendix no. 3 needs not to be adapted and you shall remove it before you send the SBTC to the Supplier.

CONTRARY TO that

If the provision of services and/or supply of goods involve personal data processing, this appendix no. 3 must be adapted pursuant to individual comments below and just after this adaptation the SBTC shall be sent to the Supplier.

Comment [A4]:

It is always necessary to outline the extent of the processed data through by making a list of such data or at least indicating categories of such data (data about health condition, contact details, job position related data, etc.) together with making a reference to a document, from which the specific data/detailed extent of processed data or data which may be eventually processed, is evident.

Comment [A5]:

It is always necessary to outline the extent of persons in question, i.e. group of persons the personal data of which will be processed.

Comment [A6]:

Indicate the names of individual information systems in which the data will be processed. For each information system indicate the purpose for which the data will be processed in it.

Comment [A7]:

Choose the option which applies in your particular case.

Comment [A8]:

Shall apply only in case if the Supplier shall collect the data from data subjects, their consent is required and Pfizer has not obtained such consent yet.

Comment [A9]:

Shall apply only in case if the Supplier shall collect the data from data subjects, their consent is required and Pfizer has not obtained such consent yet.



6. The Processor shall ensure pursuant to Section 16 of the Act that the data is accurate and up-to-date. The Processor shall ensure destruction of the data pursuant to Section 17 as well as notify changes to third persons pursuant to Section 18 of the Act upon Pfizer's request (in a form allowing to prove that it was made) and according to Pfizer's eventual instructions.
7. The Processor shall inform Pfizer without undue delay, but within 24 hours at the latest, about each request/claim raised by a data subject related to processing of their personal data and ensure that each such request/claim is responded in line with Pfizer's instructions so that the right of the data subject is properly satisfied without undue delay.
8. The Processor shall ensure appropriate safeguards of processed data against its illegal disclosure to third persons, loss, destruction, leakage, theft, illegal publishing or any other illegal handling with this data, through measures taken at least in the extent and by means as set forth in Section 19 and following of the Act and its implementing legal acts, including but without limitation the Regulation of the Personal Data Protection Authority, No. 164/2013 Coll., on the extent and documentation of safety measures.
9. The Processor shall proceed with personal data processing under this Agreement always in strict compliance with all applicable laws, especially the Act and legal acts adopted for its implementation, also with the instructions of Pfizer and fulfil properly all obligations of the processor ensuing from these legal acts and this Agreement.
10. The Processor is entitled to start processing the personal data from the day that this Agreement was signed by all of the parties.
11. In case the personal data that can be processed by the Processor were obtained before the Processor was entrusted with the processing thereof, the Processor shall inform without any delay the data subjects in question that the Processor was entrusted with the processing thereof, at the latest within the first contact of the Processor with the data subject.
12. In case the Processor has knowledge that Pfizer is in breach of the Act in connection with the processing of the personal data, the Processor shall notify Pfizer in writing without any delay and provide Pfizer with the necessary cooperation in order to remedy such breach. In case the Processor had or should have had knowledge about such breach of Law and did not notify Pfizer until the time when the breach could have been remedied, the Processor shall indemnify and hold Pfizer harmless for any claim, liability, fine, penalty, loss or damage connected with such breach.
13. The Processor is / is not entitled to subcontract the obligation to process personal data to the following subjects:

(the "**Sub-supplier**" or the "**Sub-suppliers**").

The rights and duties of the Processor shall apply in the same extent also to the Sub-supplier / the Sub-suppliers while the Processor is fully responsible for the actions / omissions of the Sub-supplier / the Sub-suppliers.
14. If the personal data are to be transferred abroad, the Processor shall provide Pfizer with all necessary cooperation in order to fulfil all requirements imposed by the section 31 and following of the Act (i.e. mainly, but not limited to, obtain necessary consent of the data subjects, adopting adequate safeguards, ensure security during the transfer, etc.).

List of allowed processing operations:

Comment [A10]:

Choose the alternative which applies in your case.
In case there's a subcontractor used by the Supplier for processing the data, you must indicate also its identification (name, seat, ID No., entry in the commercial or any other registry).



The Processor shall be allowed to perform within personal data processing when providing Services under this Agreement exclusively the following processing operations, unless resulting otherwise from the specification of services in schedule 1 to the Agreement:

- obtaining
- collecting
- recording
- combining
- grouping
- re-grouping
- using
- providing to Pfizer/*other person*
- cross boarder transfer
- storage
- inspecting
- changing
- publishing
- blocking
- destruction

Comment [A11]:

Choose from this list those particular operations that should be performed actually by the Supplier within processing the data. And specify these operations, e.g. how the Supplier can use the data, to whom the Supplier may transfer the data and under what conditions, when the Supplier is allowed to block the data, etc.