

General Terms and Conditions of Contracts and Orders of Saneca Pharmaceuticals a. s.

The General Terms and Conditions of Orders (hereinafter referred to as "**GTCO**") of Saneca Pharmaceuticals a.s. company (ID No. 46833323) (hereinafter referred to as "**Saneca Pharmaceuticals**" or "**the Customer**") lay down the basic terms and condition under which Saneca Pharmaceuticals and the other contractual party (hereinafter referred to as "**the Supplier**"; the Customer and the Supplier jointly also referred as "**Contractual Parties**") undertake to conclude and perform the contractual relationship. The GTCO constitute an integral part of each Customer's order and become binding for both Contractual Parties once the Supplier accepts the order.

1. The Supplier shall confirm the order in writing to the registered office address, or as a scan by electronic mail (e-mail) to the e-mail address stated in the order. The order is binding for a period of 14 (fourteen) days as of the date of its delivery to the Supplier. Should the Customer not receive confirmative acceptance of the order in the above manner from the Supplier within this deadline, it shall be assumed that the order was not accepted, except for cases when the Customer immediately shall inform the Supplier in writing that also late acceptance of an order shall still be considered proper acceptance of the order. The Customer reserves the right to withdraw the order prior to the expiry of the deadline for its acceptance whereas the order withdrawal comes to the Supplier before confirmative acceptance of the order is delivered to Customer.
2. Confirmative acceptance of an order, which contains changes of the original order or reservations or additions, shall be deemed a rejection of the order and a proposal for a new order. However, acceptance of the order is a reply, which defines the contents of the order in different words if a change to the contents of the order does not arise from the reply.
3. The contract between the Contractual Parties is concluded at the moment when the order proposal acceptance (including these GTCO) from the Supplier is received by the Customer.
4. Any ensuing changes of the contract are permissible only on the basis of agreement both Contractual Parties in writing which can be included or in one document or it can be in the form of writing proposal for the change of the order by one party and its acceptance in writing by the other party.
5. In the case of baseless rescission of the contract or the order, the Customer shall pay to the Supplier demonstrable accrued, reasonably expended expenses. In the event of rescission of the contract or the order by the Customer due to delivery failure of the contract subject or the order, or breach of obligations from the Supplier's side, the Customer is entitled to reimbursement of demonstrable damage accrued, whereby the Supplier is to the reimbursement obliged.
6. The document for drawing up and subsequent payment of the relevant invoice for rendering the subject matter of the delivery (hereinafter referred to as "the Performance") is (i) the order accepted by Supplier in the manner stated in Article 1 above, (ii) on the basis of the order rendered duly, promptly with professional care and according to the Customer's requirements, or its relevant agreed part, confirmed by Customer or its empowered third party by the delivery note, confirmation of acceptance or acceptance protocol or other similar document signed without any reservations and remarks by the Customer.

7. The invoice shall contain the order number, ID No., Tax ID No., the Supplier's bank details and further particulars of a tax and accounting document as well as the all necessary requisites according to Act No. 222/2004 Coll. on VAT. Should the invoice not contain all the above-mentioned data or the correct data, the Customer shall be entitled to return it to the Supplier. In such a case, the original period of its maturity shall be suspended and a new maturity period shall commence with the delivery of the corrected or a newly drawn up invoice to the Customer. Unless stated otherwise in the order, the period of maturity for individual invoices shall be **60 (sixty) days** as of the date the invoice is drawn up. In case the counterparty is municipality or state subject, invoice maturity is 30 (thirty) days at most pursuant to the Art. 340b of the Slovak Commercial Code (Act No. 513/1991 Coll.).
8. The obligation to pay the price is fulfilled on the date the relevant sum is debited from the Customer's account to the Supplier's account stated in the invoice.
9. Should the individual agreement in writing on the price of the delivery not be agreed between the Contractual Parties, the last previous price charged by the Supplier shall be the agreed price.
10. Should the Customer default payment of a validly drawn up invoice, the Supplier in accordance with these GTCO shall be entitled to demand from the Customer a 0.05% (five hundredths per cent) default interest for each defaulted day of payment. Should the Supplier not observe the dates of the Performance in the orders, the Customer shall be entitled to withdraw from the contract or demand from the Supplier payment of a contractual fine corresponding to 0.05 % (five hundredths per cent) of the price of the relevant the Performance for each defaulted day including any only commenced defaulted day. The Customer's entitlement to full damage compensation shall not hereby be affected.
11. Should special delivery terms and conditions, technical or testing terms and conditions, packaging, marking and transport instructions be included in an order, these shall be considered a part of the order and shall become binding for both Contractual Parties at the moment of the Supplier's confirmative acceptance of the order.
12. The Supplier shall submit all documents for performance that apply to the subject of the Performance, especially the delivery note, quality protocol, health and fire technical documentation, letter of guarantee, and all the documents which are demanded according to the relevant legal regulations as well as the documents which are demanded for the Performance utilization and the documents which are ordinarily supplied together with the Performance and always according to the type of the Performance rendered.
13. In case the Performance is delivered in returnable packaging, this fact shall be stated in the delivery note and invoice accordingly. The costs of returning the packaging shall be charged to the Supplier's account, unless the Contractual Parties agree otherwise.
14. Special arrangements applying to electric motors, metallurgical material, spare parts, fuel, technical material and chemical raw materials and material:
Each packaging unit must be clearly marked with a label containing the following information – material name, batch number, production date for continuous production, quality, gross, net, tare weight.
The Supplier shall arrange a date of expiry or retesting with the producer, which shall be marked on the relevant analytical certificate.
The Supplier shall state the following clause in the invoice "The goods in this invoice originate from".

The Supplier shall attach a preferential certificate of origin of goods delivered from countries outside the EU.

Material is accepted on working days from 6.30 a.m. to 2.00 p.m.

The Performance shall take place in accordance with ISO 14000+ class norms

15. Special arrangements applying to expert opinions:

An expert opinion shall mean an opinion in CTD format in the English language under the requirements of EU directives, Commission notice "Notice to applicants, volume 2B, Presentation and content of the dossier CTD, May 2002", for the Customer's drug products. The expert opinion shall meet the following particulars, unless the relevant order states or the Contractual Parties agree otherwise:

- minimum of 30 (thirty) pages, containing 40-100 quotes, with the Supplier's CV and a complete collection of full versions of quoted articles and/or literary sources;
- a legal foundation for registration based on documents delivered by the Customer (i.e. generic application or application with a reference);
- meeting the requirements for the format of the quotations in the text based on the document Uniform Requirements for Manuscripts Submitted to Biomedical Journals (standard norm for format of the contributions to biomedical journals);
- drawing up an opinion in one written copy and soft (electronic) copy in Microsoft Word (with personal signature and possibly the signature of a "contributing" expert) and a list of the bibliography;
- an integral part of the expert opinion shall be a complete collection of full versions of the quoted articles and/or literary sources;
- approval of the processing of personal data in line with Act No. 122/2013 Coll. of Personal Data Protection as amended.

The Supplier shall amend expert opinions based on the comments of the registration authority during the course of registration proceedings as part of the negotiated the Performance. If required, the Customer shall provide the Supplier with the results of its own clinical trials carried out on the studied medicinal product.

The Supplier shall be responsible for papers, records, documents that he accepts from the Customer and acquires in connection with the negotiated the Performance and shall ensure that they are protected against damage, any misuse, loss, destruction, misappropriation in any way and not find their way into the hands of unauthorized persons. Once the activity ends, the Supplier shall return all accepted documents and documentation to the Customer.

16. Once the Customer accepts the Performance or its part the Customer shall become sole and unrestricted owner of the subject of the Performance or its part provided such subject of the Performance or its part is fit to be the subject of ownership rights.
17. The place of the Performance shall be the Customer's registered office, unless stated in the specific contract or agreed between the Contractual Parties otherwise. The Performance shall be provided within 3 (three) working days as of the date of the order's confirmative acceptance, unless the relevant order states or the Contractual Parties agree otherwise.
18. The Supplier shall render the Performance at its own costs and risk. It shall be fully responsible if using third person to render the Performance as if the Performance supplies itself.
19. The period of warranty for the Performance delivered by the Supplier shall be 24 (twenty-four) months as of the date when the subject of the Performance is duly handed over by the Supplier and taken over by the Customer unless in the specific case the Supplier provides or

the relevant legislation specifies a longer guarantee period or the Contractual Parties negotiate in writing a shorter guarantee period. The Supplier shall always deliver the letter of guarantee together with the relevant delivery to the Customer.

20. For the supply of buildings, building modifications and installation work, the Supplier shall provide the warranty for 36 (thirty-six) months from their duly hand over by the Supplier and take over by the Customer, unless in specific case the Supplier will provide another period of warranty, which shall be specified in the contract, or from relevant legal regulations does not result longer period of warranty.
21. The Supplier shall remedy the defects arisen during the period of warranty, as follows:
 - the defects preventing the Client's business activity, within one working day (putting into operation provisionally) as of the date of defects notification in written form as far as the technological process of defect removing allow it
 - relevant, reciprocal local verification for defect acknowledgement shall be made within 2 (two) working days of its notification
 - for other defects, up to 1 (one) month after the defect notification in written form, unless otherwise stated in writing by both Parties.
22. The Supplier shall eliminate the defects either on the site or defective supply will be replaced. If the Supplier, even despite of the Customer request, will not eliminate the defects or he will not eliminate them properly and on time, the Customer alone is entitled to secure the defects elimination, and fully at expense of the Supplier, while his rights under the warranty remain untouched.
23. The Supplier shall provide after warranty service for payment on the basis of the contract of service activity concluded between the Customer and the Supplier in the case when the Customer will require such activity. If the Supplier does not provide warranty service and after warranty service for the subject of delivery, the Supplier shall bound to notify to the Customer the service organization that takes over this activity of the Supplier by contract with respective rights and duties.
24. The Supplier is responsible for the conformity of the ordered the Performance (including its packing, the way of delivery) and for the conformity of accompanying documents together with Slovak legal regulations or technical norms valid in the area of the Slovak Republic which relate to the ordered material or goods.
25. The Customer's information the Supplier encounters when rendering the Performance, shall be deemed confidential. The Supplier shall maintain the confidentiality and take all necessary precautions so this confidential information is not disclosed to third persons without the Customer's prior written consent. Likewise, the Supplier shall protect against such information being leaked, published or disclosed without authorization to other third persons. The Supplier shall also bind its employees to the duty of confidentiality and its authorized persons who came or encounter information being subject to the duty of confidentiality, and shall ensure that these persons maintain the duty of confidentiality, at least to the same extent as the Supplier itself is bound thereby. Under this Article the Supplier shall be bound by the duty of confidentiality even after the termination or expiry of the contractual relationship. Should this duty be breached the Supplier shall pay the Customer a contractual fine of EUR 2.000 (two thousand euros) in each individual case of its breach. The Customer's right for compensation of any damage shall not be affected by the payment of a contractual fine.

26. The work shall be duly handed over by the Supplier and duly taken over by the Customer on the basis of proper installation or site diary and duly record of the work hand over, even if in the record of hand over and take over will present the defects and unfinished work, which themselves nor in conjunction with others do not prevent to the proper, smooth and safe use of the work, and if in corresponding record of work hand over the Supplier undertakes to remove listed defects and unfinished work within by client specified period. In the event, that the deadline for defects and unfinished work elimination from the Supplier's side will not be met, the Supplier is obliged to pay the Customer a contractual fine of 33,- EUR (thirty-three euros) per each day of removal delay of each individual defect or unfinished work, to maximum of 1.660,- EUR (one thousand six hundred and sixty euros) for each individual defect or unfinished work. By the payment of contractual fine is not affected the Customer's right to ensure the elimination of defects and unfinished work at the expense of the Supplier at third party.
27. The Supplier shall not be responsible for defects caused by improper handling with the subject of delivery, he also is not responsible for defects caused by the use of documents and items provided by the Customer, when the Customer could not nor at making any effort and professional care to detect their unsuitability or he warned the Customer but he insisted on their use. The Supplier shall be bound always to warn the Customer to potential unsuitability
28. The Supplier shall be bound to proceed at the Performance of the subject of the contract or the order with professional care. The Supplier undertakes to observe technical norms and other conditions contained in this document (unless otherwise agreed in the contract) and generally binding regulations. The Supplier undertakes to manage himself with initial documents, requirements and instructions of the Customer, minutes and with confirmations agreed by authorized personnel of Contractual Parties.
29. In the case of measuring instrument repair the Supplier shall be bound attach a registration of ÚNMS (Office for Standardization, Metrology and Testing of the Slovak Republic) according to law no. 142/2000 Coll. on Metrology, as amended.
30. Mandatory provisions of relevant legal regulations governing liability for defects, the claiming the defects are not affected by the provisions of this article.
31. The Supplier shall test all machines, apparatuses and equipment, with respect to their functionality and quality prior to the delivery. The Supplier shall hand over technical documentation and confirmation of such tests to the Customer. Confirmation shall include the date of testing its methodology, duration and description and finally result and the declaration of capability to meet all required parameters, technical standards and provisions of all legal regulations. In the case of the Customer's requirements for special tests of equipment before their delivery to destination, the Customer shall specify these tests in the contract or in the order. The costs of realization such specific tests shall be reimbursed by the Customer.
32. For purposes of these GTCO, the force majeure will occur in such circumstances that will arise after the mutual conclusion of the contract due to unexpected and unusual events which the Supplier could not prevent with the expending all effort and professional care or to predict them, such as for example natural disasters, war, government measures and the like. The Supplier who due to force majeure can not to fulfil contract commitments is bound to inform the Customer of such circumstance immediately in writing, especially when such

circumstance occurred or ended eventually, and he shall evidence that such circumstance has had an essential impact to fulfilment of respective delivery (commitment).

33. The defects, unfinished works, complaints, late deliveries and strikes are not considered to be force majeure. In such cases, the Supplier shall not be entitled to claim an extension of stipulated delivery period.
34. The Supplier is aware that the Customer is a holder of Environmental Management System Certificate No. EMSC 1222, and as such, he is bound to ensure the Performance which is fully in compliance with applicable law and standards concerning to environmental protection.
35. The Supplier undertakes to execute the subject of the contract or the order only by way that meets all the requirements of relevant legal regulations and other norms for environment protection. In the case of repeated violation of this commitment, despite the Customer written warning, the Customer has the right to withdraw from the contract or the order without further.
36. The Supplier takes over all responsibility for consequences of possible non-compliance by him carried out realization of the subject of the contract or the order with relevant legal regulation and norms for environment protection.
37. In the cases defined by the Customer, the Supplier's representative or persons authorized by the Supplier shall attend the input training in area of ensuring the protection of the environment in the customer premises before the start the subject of the contract or the order, what the Supplier agrees to unsure.
38. The Supplier and his employees or other personnel, or subsuppliers are, what the Supplier undertakes to ensure, obliged:
 - a) to adhere strictly the instructions of the Customer's responsible employee that is stated in the contract or the order or the employee charged to manage supply organization based on mandate contract (hereinafter referred as responsible employee).
 - b) all the waste incurred at realization the Performance of the subject of the contract or the order to dispose at own expense or under the provisions of the Contract. If the waste is determined as hazardous, in accordance with the Act on waste, it must be about this fact drawn up the record and responsible employee must be familiar with this. The Customer reserves the right to request from the Supplier the confirmation of ecological disposal this waste.
 - c) at the occurrence, any event which might affect negatively the environment at customer premises, to notify the accrued situation to responsible employee immediately who is bound to solve it in accordance with the Customer's internal regulations. In the case, the event will occur in the days of public holidays or during the afternoon or night shift, when the Customer's responsible employee is not present, the Supplier shall inform the commander of a guard duty (tel. no. 1142), or fire commander (tel. 2222), and to write the record about the event into construction diary or installation diary.
39. For the Supplier and his employees and other employees or sub suppliers is prohibited:
 - a) to execute any maintenance or repair of own devices whereat may come to a discharge of substances jeopardized the environment in the customer's premises
 - b) to use the energy and media provided by the Customer on basis of the contract or the order uneconomic or in conflict with the Customer instructions

The Supplier shall be bound to comply with the provisions of this article and to ensure their compliance by his employees and other employees or sub suppliers.

40. The Supplier shall bound to ensure the measures from the point of view safety at work and fire protection and to ensure their observance by the Supplier's employees, sub suppliers and other workers:
- the Supplier shall be bound to observe valid safety, sanitary and fire regulations at the Customer's workplaces in close cooperation with professional employees of the Customer
 - the Supplier shall be bound to provide own supervision over work safety under the Act No. 124/2006 Coll., as amended, and permanent control of safety at work at activities in the Customer's workplace
 - the Supplier shall be bound to observe internal regulations and instructions valid at the Customer's premises in terms of safety at work and fire protection
 - the workers determined by the Supplier are bound to participate at initial trainings from the area of safety at work and fire protection in the Customer's premises, before begin the work, what the Supplier undertakes to ensure.
 - the Supplier shall be bound to equip himself and his employees with equivalent personal protective equipment by the professions, activities and risks in the Customer's workplaces.
 - the Supplier shall be bound to familiar himself with hazards at the Customer's workplaces, he will warn his workers about hazards and he will determine the ways of protection and prevention against injuries and other damage of the health
 - the Supplier shall be bound to notify the Customer in writing all circumstances that might lead at his activities at the Customer's workplaces to threat of life and health of the Customer's workers or other persons and to threat of the operation or the safe state of technical equipment and premises
 - the Supplier is aware that under the provisions of § 421 and Act. 40/1964 Coll., the Civil Code, as amended, he is also responsible for damage caused by circumstances that have the origin in the nature of the device or other things that have been used at performance of commitment and he cannot rid this responsibility.
 - in the case of injury of the Supplier's worker, the Supplier's manager shall be bound to investigate it and write down the record of injury and transmit this record to the responsible employee of the Customer.
41. The Supplier shall be bound to ensure that his employees and other workers or sub-suppliers will observe regime measures valid in the Customer's area with which the Supplier has been familiarized, in particular:
- he secures that his employees and other personnel or sub-suppliers will remain only in areas designated for execution of the subject of the contract or the order or in areas designated for them (dressing rooms, washrooms, canteen, etc.). The employees and other workers, sub-suppliers of supplier are not eligible to enter and move in other areas of Saneca Pharmaceuticals's Hlohovec site
 - he will instruct his employees and other workers or sub-supplier that they are entitled to bring in the Customer's area only things that employees usually bring to the work and that those personal things as well as working tools or materials are bound to store in places designed for this purpose
 - he shall be bound to secure by record in installation diary or site diary that they were demonstrably familiar with the system and regime of fire protection valid in the customer's area and that they will subordinate to this regime unconditionally
 - he shall be bound ensure that all welding jobs with arc or by open flame will be carried out by a person only with a valid welding certificate and permission issued and signed by the Customer's fire protection engineer and the safety engineer

- he shall be bound to notify to the Customer's representative the number and location of welding sets and duly will mark the placement
 - all employees and other personnel or subsuppliers will be demonstrably familiar with the SOP 5320 for movement of persons, vehicles and materials in Saneca Pharmaceuticals seat in Hlohovec.
42. Both Contractual Parties are aware that the Customer who is holder of GMP certificate is bound to ensure the Performance that is entirely in accordance with the regulations concerning to Good Manufacturing Practices. The Supplier shall be bound to observe valid internal regulations GMP in the Customer's campus relating to hygiene, regime and other measures serving to ensuring the compliance of GMP principles. The Supplier shall ensure that the selected workers will take the training GMP which within reasonable range will cover the necessary knowledge in this area, prior beginning the work, in the campus of customer (it can provide the Customer after the agreement).
43. Different provisions in the contract shall prevail over these GTCO.
44. The contractual relationship based on an order and its confirmative acceptance shall be governed by Slovak law and order, especially by Law. No. 513/1991 Coll., the Commercial Code, as amended, excluding the UN Convention on Contracts for the International Sale of Goods. Disputes arising from contracts arbitrate the Slovak courts, unless the contract otherwise specified.
45. By accepting the order, the Supplier confirms that the Supplier has become acquainted with these GTCO, agrees with and undertakes to observe them.
46. If the Supplier violates legislation on illegal employment, in particular, but not limited to Act No. 82/2005 Coll. during a contractual relationship with the Customer and consequently as a result of this violation, any sanction by the courts, public authorities, supervisory and control bodies or other competent bodies is imposed on the Customer, the Supplier undertakes to pay the Customer the compensation of all costs, including, but not solely the sums of paid fines arising due to the imposition of any sanctions on the Customer by the abovementioned authorities as a result of this violation.

Revision of GTCO dated 1.1.2017