Supply Agreement for Gene and Cell Therapy

Delivery of the medicinal product xxx

Case number: 20yy/NNN

SYKEHUSINNKJØP

Table of contents

1 General Provisions

1.1 Parties to the Agreement

This agreement is entered into between the following parties:

Health Trust	
Name:	
Organisation number:	

(hereafter referred to as the **"Hospital"**)

and

Hospital Pharmacy	
Name:	
Organisation number:	

(hereafter referred to as the **"Hospital Pharmacy"**)

and

Supplier	
Name:	
Organisation number:	

(hereafter referred to as the **"Supplier"**).

The Hospital, the Hospital Pharmacy, and the Supplier are hereafter jointly referred to as the **"Parties"**.

1.2 Agreement Documents and Interpretation Rules

This agreement regulates the sale, use, and handling of the medicinal product xxx (**"Agreed Product"**) where the Supplier sells the Agreed Product to the Hospital Pharmacy, which resells it to the Hospital that will provide treatment (the **"Supply Agreement"**). The Parties have entered into the Supply Agreement as part of the Framework Agreement to be able to carry out call-offs, so that the terms of the Framework Agreement apply between the Parties. The Supply Agreement consists of the following documents (in addition to the Supply Agreement):

All boxes must be ticked (yes or no)	Yes	No
Appendix 1: Points of Contact		
Appendix 2: Activities and Services Associated with the Product and the Place of Treatment		
Appendix 3: Ordering and Cancellation of Orders		
Appendix 4: Acceptance Form		
Appendix 5: Permits and Documentation		
Appendix 6: Agreement for the Extraction and Export/Transport of Cells (Biological Material) Between the Customer (Hospital) and the Supplier (**"Technical Apheresis Agreement"**)		

Other appendices:		

The documents comprising the Supply Agreement are complementary. In case of conflict between any provisions of the agreement documents, newer documents shall prevail over the older ones. If this does not resolve the conflict, specific provisions shall be given precedence over general provisions, and provisions prepared specifically for the Supply Agreement shall be given precedence over standard terms.

2 Duration of the Supply Agreement, Options, and Termination

2.1 Duration

The Supply Agreement enters into force upon signing, terminates automatically upon termination of the Framework Agreement, and remains in force for as long as there is a valid Framework Agreement (the "Agreement Period").

2.2 Termination

The rights to terminate the Framework Agreement apply correspondingly to the Supply Agreement.

2.3 Expiration of the Supply Agreement

The terms of the Supply Agreement shall apply to all call-off orders of the Customer that are confirmed within the Agreement Period, even if delivery takes place after termination of the Supply Agreement.

3 Preparation, Ordering, and Delivery

3.1 Preparation

If concrete clinical results must be available in order to be able to order the Agreed Product for a specific patient, this must be stated in Appendix 2 to the Supply Agreement (Activities and Services Associated with the Product and the Place of Treatment). The same applies if the use of any equipment is necessary for providing treatment to the patient.

The Supplier is responsible for planning and carrying out the necessary training for designated employees free of charge. The Supplier shall describe what the necessary training implies in Appendix 2 to the Supply Agreement.

For Hospitals, the training shall take place at the treating department during normal working hours, unless otherwise agreed between the Supplier and the treating department. After the designated employees of the Hospital complete the training, they can begin to work with the Agreed Product and treat patients. The Agreed Product can only be prescribed by employees of the Hospital with relevant experience who have undergone the necessary training in handling the Agreed Product.

The employees of the Hospital Pharmacy shall be trained at the place of delivery specified in Appendix 1 to the Supply Agreement (Points of Contact) during normal working hours, unless otherwise agreed between the Supplier and the Hospital Pharmacy. The Agreed Product can only be prescribed/received by employees of the Hospital Pharmacy who have received the necessary training in handling the Agreed Product.

The Hospital and the Hospital Pharmacy are responsible for keeping an overview of the employees who have undergone training and can handle the Agreed Product, which shall be made available to the Supplier. The Hospital Pharmacy is responsible for ensuring that the Agreed Product is only received by an employee who is specifically trained by the Supplier in receiving the Agreed Product.

3.2 Ordering and Order Confirmation

The Hospital Pharmacy shall order the Agreed Product by sending an order to the Supplier in accordance with the ordering process described in Appendix 3 to the Supply Agreement (Ordering and Cancellation of Orders). Orders shall be sent after the Hospital Pharmacy has received a requisition from the Hospital.

The Supplier is obliged to deliver the Agreed Product in accordance with every order and shall confirm the order no later than one business day after the order was sent, unless otherwise agreed.

3.3 Terms of Delivery

The Supplier shall deliver the Agreed Products (including documentation that is required by the applicable law and documentation described in Appendix 5 to the Supply Agreement (Permits and Documentation) at the delivery point specified in the order. The Supplier shall bear all costs until the product is delivered DDP (Delivery Duty Paid) in accordance with Incoterms 2020 and have the necessary permits to be able to perform such delivery. The Agreed Products are considered delivered when they are delivered as described in the order and when the Hospital Pharmacy has conducted the necessary acceptance check and an employee of the Hospital Pharmacy who is authorised to sign documents on behalf of the Hospital Pharmacy has signed Appendix 4 to the Supply Agreement (Acceptance Form).

The employees who have the right to accept delivery of the Agreed Products and sign the acceptance form are listed in Appendix 1 to the Supply Agreement (Points of Contact). The Agreed Products shall be delivered on weekdays between 10:00 a.m. and 14:00 p.m. Norwegian time, unless the Supplier has received a written acceptance from the Hospital Pharmacy allowing the Supplier to deliver the order at another time.

3.4 Time of Delivery

The Agreed Products shall be delivered no later than [XX business days] after the order has been sent. The Supplier shall state the time of delivery in the order confirmation by indicating the date and time (hereafter referred to as the “Delivery Date”).

The Supplier shall immediately notify the Hospital Pharmacies and the Hospital if there is a delay in the delivery of the Agreed Products.

3.5 Place of Delivery

The places that can be used as delivery points for the Agreed Products in accordance with this Supply Agreement are specified in Appendix 1 to the Supply Agreement (Points of Contact).

Points of contact for the Supply Agreement and the Agreed Products that are delivered in accordance with the Supply Agreement are specified in Appendix 1 to the Supply Agreement (Points of Contact).

3.6 Transportation and Handling of the Agreed Products Until Delivery

The Supplier shall ensure that handling, transportation, and packing of the Agreed Products until delivery comply with all requirements of the applicable law and the requirements stipulated by this Supply Agreement. Among other things, the Supplier is responsible for ensuring the Agreed Products are handled, packed, and transported until delivery in a manner that ensures that their quality, storage conditions, and safety are maintained in accordance with the Guidelines on Good Distribution Practice of medicinal products for human use (GDP).

If the Supplier uses a third party for transporting the Agreed Products, the Supplier shall ensure that the carrier has signed an agreement with the Supplier ensuring that the conditions of this Supply Agreement are met. The Supplier is also responsible for ensuring that the carrier has sufficient experience, knowledge, and competence to handle, secure, and transport the Agreed Products in accordance with the requirements of the Supply Agreement and the Framework Agreement. The Supplier shall also enter into a quality agreement with the carrier. Upon request, the Supplier shall provide the Customer with a copy of all agreements related to the transportation of the Agreed Products and other documents related to the validation and quality of the Agreed Products.

4 Cancellation, Re-Delivery, and Crediting of Purchases/Orders

The Parties' obligations and responsibilities in situations where the Agreed Product must be replaced by a new product (re-delivery) or destroyed and/or the order must be cancelled are regulated by the Framework Agreement. The Supplier shall describe its procedures and systems that are used for cancellation, re-delivery, and crediting in Appendix 3 to the Supply Agreement (Ordering and Cancellation of Orders).

The party that discovers that the Agreed Product cannot be used as intended and must be replaced by a new product, or the order/delivery must be changed, or the order must be cancelled (or revoked), is obliged to notify the other parties as soon as possible.

5 Handling of the Agreed Product After Delivery

When handling the Agreed Products after their delivery, the Hospital Pharmacies and the Hospital shall ensure that the Agreed Products are handled in accordance with the summary of product characteristics (SmPC) and training provided by the Supplier.

6 Remuneration and Payment Terms

Remuneration and payment terms of the Supply Agreement are stated in Section 5 of the Framework Agreement.

7 Changes to the Supply Agreement

Changes to the Supply Agreement, including any standard terms and conditions of / belonging to a party, cannot be made by a party alone, but require the consent of all parties. This does not apply to changes of Points of Contact (Appendix 1); in that case, the Parties are responsible for informing one another of any changes. All changes shall be made in writing.

8 General Provisions

8.1 Requirements for the Parties

In exercising their rights and obligations under the Supply Agreement, the Parties shall:

a) ensure compliance with applicable laws and regulations, including anti-corruption laws and regulations;

(b) ensure compliance with all generally accepted and applicable industry standards.

8.2 Processing of Personal Information

8.2.1 Processing Responsibility

The Parties are individually responsible for complying with EU General Data Protection Regulation (EU) 2016/679 ("GDPR") and other applicable rules for the processing of personal data and information security, including the Norwegian Act of 15 June 2018 no. 38 concerning processing of personal data (hereafter, the "Personal Data Legislation"). Each party shall be considered a data controller, cf. Art. 4 (7) and Art. 24 of the GDPR.

The Hospital is a controller of personal data related to its legal responsibility for patient treatment and the provision of specialist health services, as well as its contractual obligations under this agreement. The Hospital transfers necessary/sufficient personal data to the Supplier, which is based in [The Supplier's country], for the purpose of fulfilling contractual obligations, including ordering, production, and delivery of a medicinal product / the Agreed Product from the Supplier to the Hospital Pharmacy at the agreed delivery point. Personal data shall be transferred from the Hospital to the Supplier through an agreed communication/ordering system. (For some contracts, personal data is transferred via the Hospital Pharmacies as an intermediary, in which case the contract should contain a clarification of such transfer).

The Hospital Pharmacies are controllers for the purpose of fulfilling their contractual obligations under this Supply Agreement, including administrative purposes, and their obligations in accordance with the pharmaceutical legislation, etc.

The Supplier is a controller of personal data for the purpose of fulfilling its contractual obligations under this Supply Agreement and its legal obligations as a manufacturer of medicinal products, etc. The legal basis for the Supplier's processing of personal data is [Specify the applicable legal basis, for example Art. 6 (1a) and Art. 9 (2a)] of the GDPR.

If the parties to a contract agree that one party processes personal data on behalf of the other (data processor), a data processing agreement shall be drafted in accordance with the Personal Data Legislation.

8.2.2 General Obligations of the Parties

Each party shall ensure and is responsible for documenting that the processing of personal data, including the disclosure of personal data to the other party/Parties, is done in accordance with the Personal Data Legislation and health legislation.

If the Supplier so wishes, the Hospital shall assist in obtaining consent for the processing of personal data from patients/guardians by signing the Hospital's forms/templates, which shall be sent to the Supplier with the order.

Each party shall, at its own expense, assist the other party in complying with its obligations as a controller, including by providing reasonable assistance, information, and cooperation as required by the Personal Data Legislation to the other party, and, where appropriate, to data subjects.

The Parties shall, within a reasonable time, and no later than [5 days], notify each other upon receipt of any inquiries from data subjects or supervisory authorities, concerning the processing of personal data covered by this Supply Agreement.

Furthermore, the Parties shall notify the other Parties, without undue delay and no later than thirty-six (36) hours after they became aware of, or had reasonable grounds to suspect, a breach of security of the personal data processed in accordance with this Supply Agreement. In the event of a personal data breach, the Parties shall cooperate and provide each other reasonable assistance in performing their respective obligations in accordance with the Personal Data Legislation.

8.2.3 Transfers of Personal Data to Third Countries or International Organisations

Option 1:

The transfer of personal data from the Hospital to the Supplier is regarded as a transfer within the EU/EEA and regulated by the GDPR in general. The Parties will not process personal data in any countries outside the EU/EEA.

Option 2:

The transfer of personal data from the Hospital to the Supplier, or from the Hospital Pharmacy to the Supplier, involves a transfer to the following countries [specify the country(ies)] outside the EU/EEA ("Third Countries") and must be done in accordance with Chapter V of the GDPR.

A transfer of personal data to Third Countries or international organisations may only take place if an adequate level of protection is ensured in accordance with the Personal Data Legislation, cf. Chapter V of the GDPR. Unless otherwise agreed between the Parties, such transfer may only take place pursuant to [tick the relevant legal basis for the transfer]:

☐ The European Commission's decision on whether [a country] offers an adequate level of data protection on the basis of Article 45 of the GDPR;
☐ EU Standard Contractual Clauses for the transfer of personal data to a recipient in a Third Country as specified in Article 46 (2c) or (2d) of the GDPR, cf. Annex [x]; or
☐ Binding Corporate Rules in accordance with Article 47 of the GDPR.

8.3 ICT Security

The Parties agree that the processing of personal and health information in accordance with this Supply Agreement requires a high level of security, cf. the Personal Data Legislation, health legislation, and the Code of Conduct for information security and data protection in the healthcare and care services[1].

The Parties shall implement appropriate technical and organisational measures to achieve a satisfactory level of information security in relation to the nature and scope of the processing, the technical development, implementation costs, and relevant risks to the rights and freedoms of individuals.

The Parties shall individually or, if needed, jointly perform risk assessments to ensure that an appropriate level of security is maintained at all times, including regular testing, analysis, and evaluation of the security measures, especially with regard to the ability to ensure the ongoing confidentiality, integrity, availability, and resilience of processing systems and services, as well as the ability to restore the availability of personal data in a timely manner in the event of incidents.

The Supplier shall have an online ordering/communication system in place that ensures a high standard of communication between the Parties in terms of ICT security and data protection/privacy. The platform must have two-factor authentication of users / ordering users and state-of-the-art encryption technology as a standard.

The Parties shall work proactively to minimise the risk of breaches of personal data security, including unlawful/criminal activities (hacking, etc.) associated with data security. Adequate measures shall be taken to limit the risks, such as pseudonymisation of personal data and the like, which are appropriate for the specific medicinal product, in addition to technical infrastructure that has a high degree of security.

If the Supplier, at the time of entering into the agreement, does not have an acceptable ordering/communication system in place, the Supplier undertakes to develop and implement such system by [date/period]. Until such system has been developed and put into use, any order-related and other communication that involves the transfer of personal data between the Parties shall be encrypted. Encryption must at least meet the following requirements […].

The Supplier shall give an account for, by providing necessary/satisfactory documentation, its ICT security system, processes, and measures to the Hospital and Hospital Pharmacies in Appendix 3 (Ordering and Cancellation of Orders).

[1] https://www.ehelse.no/normen/normen-for-informasjonssikkerhet-og-personvern-i-helse-og-omsorgssektoren

Any additional requirements for ICT security are specified in Appendix 3 to the Supply Agreement (Ordering and Cancellation of Orders).

If the Supplier does not comply with the terms and conditions in this section with any attachments, it shall be considered a material breach of the Supply Agreement.

9 Disputes, Applicable Law, and Legal Venue

This Delivery Agreement is regulated by Norwegian law.

Any disputes that arise between the Parties in connection with the Delivery Agreement should be attempted to be resolved by negotiations.

If negotiations do not succeed, the Parties may try to resolve the dispute by mediation. The Parties may choose to use the Norwegian Bar Association's rules for mediation by a lawyer, with possible modifications as the Parties may wish. The Parties are expected to agree on a mediator with the expertise the Parties believe is best suited to the dispute. The detailed mediation procedure is determined by the mediator, in consultation with the Parties.

If the Parties do not reach an agreement, the dispute shall be brought before the ordinary courts of law. The legal venue for the Delivery Agreement is XXXX District Court, Norway.