Framework Agreement for Gene and Cell Therapy

Delivery of the medicinal product xxx

The Norwegian Hospital Procurement Trust would like to point out that this is only a translation of the Norwegian Framework Agreement with annexes, and that it is the Norwegian version that will be signed and made applicable during the agreement period. This means that in the event of a contradiction, the Norwegian version will take precedence over the translated one

Case number: 20yy/NNN

SYKEHUSINNKJØP

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1 General Provisions

1.1 Parties to the Agreement

This agreement is entered into between:

Customers	Organisation number:
South-Eastern Norway Regional Health Authority (Helse Sør-Øst RHF)	991 324 968
Western Norway Regional Health Authority (Helse Vest RHF)	983 658 725
Central Norway Regional Health Authority (Helse Midt-Norge RHF)	983 658 776
Northern Norway Regional Health Authority (Helse Nord RHF)	883 658 752

(hereafter referred to as the **Customers**)

and

Supplier	
Name:	Organisation number:
Email:	

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

The Customers and the Supplier are hereafter jointly referred to as the parties.

The Norwegian Hospital Procurement Trust, Pharmaceutical Division (Sykehusinnkjøp HF, divisjon legemidler) is the Customer's advisor and contract manager (hereafter, the **"Contract Manager"**) and can be contacted regarding contractual matters related to the framework agreement.

Point of contact: Contract Management
Email: avtaleforvalter.legemidler@sykehusinnkjop.no

Contact information of the Supplier for contractual matters related to the framework agreement:

Point of contact: Supplier	
Email:	Tel.:

Each party is responsible for archiving a copy signed by both parties.

1.2 The Purpose of the Agreement and Definitions

This agreement (the **"Agreement"**) is a framework agreement between the Customer and the Supplier on the right to purchase medicinal products stated on the front page of this agreement and described in more detail in Appendix 1 (the **"Agreed Product"**).

Health trusts that have the right to accede to the agreement are listed in Appendix 2 (Administrative Provisions). The same applies to hospital pharmacies (the **"Hospital Pharmacy"**) that serve the relevant health trusts. A health trust is a state enterprise that is owned by one of the four regional health authorities and provides specialist health services. A Hospital Pharmacy is a state enterprise that is owned by one of the four regional health authorities and serves the health trusts by providing them with, among other things, medicines and pharmacy services. To accede to the Agreement, the Supplier, the Hospital Pharmacy, and the individual health trust must enter into a Supply Agreement in accordance with Appendix 3. The Customer can therefore only place an order (call-off) after the

conclusion of the Supply Agreement, which takes the form of the Hospital Pharmacy buying the Agreed Product from the Supplier and selling it on to the health trust. The Agreement shall therefore also become binding on the Supplier, the Hospital Pharmacy, and the individual health trust when the Supply Agreement (see Appendix 3 below) is entered into.

The term "Customers" (hereafter referred to in the singular as "the Customer") is meant to encompass a representative of the Customer or someone the Customer is responsible for, such as a health trust, the Contract Manager, or the Hospital Pharmacy that serves the relevant health trust.

Each Customer is legally and financially responsible for the orders placed in accordance with the Agreement.

The Agreement gives the Customer the right to purchase the Agreed Product that is covered by the Agreement within the scope and duration of the Agreement, but no obligation to purchase a specific volume/quantity. The Supplier is obliged to supply the Agreed Product after the conclusion of the Supply Agreement.

1.3 Agreement Documents and Interpretation Rules

The Agreement consists of the following documents (in addition to the Agreement):

All boxes must be ticked (yes or no)	Yes	No
Appendix 1: Agreed Product		
Appendix 2: Administrative Provisions		
Appendix 3: Supply Agreement Between the Supplier, the Hospital Pharmacy, and the Health Trust (**"Supply Agreement"**) with appendices		
Appendix 4: Contract Requirements for Ethical Trade		
Appendix 5: Price and Price Regulations		
Appendix 6: Protocol of Changes		
Appendix 7: Data Processing Agreement		
Other appendices:		
Appendix x:		

The documents comprising the Agreement are complementary. In case of conflict between any provisions set out in 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 Agreement shall be given precedence over standard terms.

Matters not covered by the Agreement shall be governed by the Act of 13 May 1988 no. 27 on the sale of goods (the Sale of Goods Act).

The cooperation agreement that exists between the regional health authorities and the Association of the Pharmaceutical Industry in Norway ("LMI") constitutes a part of the Agreement. More information about the cooperation agreements is available here.

1.4 Decision to Introduce the Medicinal Product

Decision of the National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway ("Beslutningsforum") with any clarifications/conditions shall be stated here.

1.5 The Relationship Between the Supplier and the Hospital Pharmacy

The Supplier is also a wholesaler of the Agreed Product which is covered by the Framework Agreement. The Supplier must have a valid wholesale distribution license for medicinal products, cf. the Regulation on Wholesale Distribution of Medicinal Products, including import authorisation.

Ordering of goods, invoicing, and payment shall be done via the Hospital Pharmacy as specified in Appendix 2 (Administrative Provisions).

The payment terms for the Hospital Pharmacy shall be a minimum free month of delivery plus 30 days.

1.6 Assignment of the Agreement

The Customer may assign its rights and obligations under the Agreement to another public body in Norway, for example in the event of restructuring of the health trusts, change in ownership of the health trusts, change in the regional structure, and so forth. The body to which the rights and obligations are assigned shall be entitled to corresponding terms and conditions, provided that the rights and obligations under the Agreement are assigned jointly.

The Supplier may only assign its rights and obligations under the Agreement with the written consent of the Customer. The same shall apply if the Supplier is merged with another company, de-merged into several companies, or if the assignment is to a subsidiary or another company within the same group. Such consent shall not be unreasonably withheld. Such consent must be made available as soon as possible before the assignment is scheduled to take place. Any assignment constitutes a change and shall be stated in Appendix 6 (Protocol of Changes).

If the Supplier can no longer sell the Agreed Product to the Customer because the Agreed Product is transferred to a third party (or because of other structural changes at the Supplier as listed above) and the conditions for written approval of the assignment to a new supplier are not met, the Agreement will continue to apply. In such case, the Supplier undertakes to reimburse the Customer in the remaining contract period for the additional cost that the Customer incurs as a result of the failure to assign the Agreement.

Any other structural changes in the Supplier's business, including changes in marketing authorisations or insolvency, shall be immediately notified to the Customer in writing. The Supplier shall, at the request of the Customer, provide detailed information on the new terms and whether the Supplier is able to fulfil the obligations under this Agreement in the future. The Customer shall then decide whether the Agreement shall continue to apply despite the changed circumstances of the Supplier.

2 Duration of the Agreement, Options, and Termination

2.1 Duration

The Agreement shall enter into force upon signing. The start date of the Agreement is DD.MM.20YY, and the initial duration is four (4) years (the **"Agreement Period"**), which shall be automatically extended until a new active substance has been acquired and new framework agreements have been entered into.

2.2 Termination

Neither Party has the right to terminate the Agreement during the first three (3) years of the Agreement Period, except as provided below. After this, the Parties may terminate all or part of the Agreement upon three (3) months' prior written notice at the end of a calendar month, provided that there are valid reasons for the termination. Prioritising other markets (sales to countries other than Norway) is not considered a valid reason.

The Customer has the right to terminate all or part of the Agreement with immediate effect if there is repeated or prolonged delivery failure of the Agreed Product. Prolonged delivery failure shall mean four weeks of delivery failure after the delivery date stated in the order confirmation.

The Customer has the right to terminate all or part of the Agreement with immediate effect if the Supplier is unable to deliver the Agreed Product from the start date of the Agreement.

Both Parties are entitled to terminate all or part of the Agreement with immediate effect if medical information emerges indicating that the Agreed Product cannot be used as intended. Any termination of the Agreement must be in writing and substantiated.

The Supplier is obliged to facilitate the termination of the Agreement in such a way that any new supplier is not prevented from fulfilling its obligations.

2.3 Expiration of the Agreement

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

3 Delivery

3.1 Implementation of the Agreement

The Supplier must ensure that the Agreed Product is available for order at the start of the Agreement.

3.2 Terms of Delivery

The Supplier shall deliver the Agreed Product to the Hospital Pharmacies in accordance with Appendix 3 (Supply Agreement), and at minimum in accordance with the terms of this Agreement.

3.3 Ordering

The Supplier shall deliver Agreed Products in accordance with the order from the Hospital Pharmacy(ies). Within a reasonable time after receipt, all orders must be confirmed by an order confirmation stating at least the delivery date, item number in Farmalogg, and the amount to be delivered. At the time of delivery, Agreed Products shall be accompanied by a packing slip containing

at least the item number and the order number. The ordering process is described in more detail in the Supply Agreement.

3.4 Lead time

The Supplier shall as a main rule adhere to a lead time (the time from the receipt of an order (or from the moment the Supplier gains access to the patient's autologous cells) to the delivery of the Agreed Product) of four (4) to seven (7) weeks after order confirmation. However, the Parties recognise that the production process for the Agreed Product may depend on a number of factors (and in some cases conditions beyond the Supplier's direct control, such as the quality and growth capacity of the received cells), which may affect the lead time. Detailed regulation of lead time will therefore be included in the Supply Agreement (Appendix 3) and Appendix on Technical Apheresis Agreement.

3.5 Place of Delivery

The Agreed Product is to be delivered directly to the Hospital Pharmacy as agreed in Appendix 3 (Supply Agreement), unless another place of delivery is explicitly stated.

3.6 Deliverability

The Supplier shall ensure that the sufficient production capacity for the Agreed Products is available to the Customer at all times.

The Supplier shall notify the Hospital Pharmacy and the Contract Manager of any deviations from the Hospital Pharmacy's orders via an order confirmation.

3.7 Delayed Delivery or Non-Delivery

In the event of delay or non-delivery, the Supplier shall immediately notify the Customer, the Hospital Pharmacy, and the Contract Manager in writing. This also applies to incidents that could potentially lead to future deviations in delivery. The information shall contain the reason for the deviation, what measures are taken, expected delivery time and quantity per item number. The contact information is set out in section 5 of Appendix 2 (Administrative Provisions).

In the event of a delay, the Customer acting through the Contract Manager may claim daily fines and compensation from the Supplier, cf. Section 6 on sanctions in the event of the Supplier's default.

If a delay results in the Agreed Product not being able to be used within the agreed period of use, the

Customer acting though the Hospital Pharmacy may cancel the order. This also applies to a notified delay in the first paragraph.

3.8 Destruction of the Agreed Product

In cases where the Agreed Product cannot be used for patient treatment, regardless of the reason, the Hospital Pharmacy may destroy the Agreed Product. The Hospital Pharmacy must obtain written consent from the Supplier prior to destruction. As an alternative to destruction, the Supplier has the right to ask the Hospital Pharmacy to return the Agreed Product to a Norwegian subsidiary of the Supplier or a corresponding wholly owned Norwegian company in the Supplier's group, to the extent that such subsidiary or company exists. In cases where destruction does not follow the Hospital Pharmacy's standard procedures, the Hospital Pharmacy may invoice the Supplier a minimum fee of NOK 3500 to cover the costs of destruction.

The Hospital Pharmacies can provide documentation for the destruction process at the request of the Supplier.

4 Requirements Applicable to the Parties

4.1 Requirements Applicable to the Customer

The Customer must fulfil its obligations under the Agreement, see in particular Appendix 3 (Supply Agreement).

4.2 Requirements Applicable to the Supplier

4.2.1 General Requirements

The Supplier is obliged to comply with the terms and conditions set out in Appendix 3 (Supply Agreement) and Appendix 1 (Agreed Product). If the Supplier, after entering into the Agreement, wants to start using or change a subcontractor, written consent from the Contract Manager is required. The Supplier's contractual obligations to the Customer are not changed by the use of a subcontractor.

4.2.2 Requirements for Necessary Permits

The Supplier is obliged to adhere to the EU Commission's guidelines on good distribution practice (GDP) and must ensure that it has the necessary permits to produce, import, and distribute the preparations covered by the Agreement within EU/EEA. The permit(s) shall be valid for the entire Agreement Period, and the Supplier must submit documentation in accordance with Section 3.6 of the Supply Agreement.

4.2.3 Requirements for Participation in the Verification System (The Falsified Medicines Directive)

The Supplier undertakes to pay a fee to Nomvec AS (The Norwegian Medicines Verification Company) for operation of the medicines verification system during the Agreement Period. Documentation of the paid fee shall be provided to the Contract Manager upon request.

4.2.4 Membership of the Drug Liability Association

The Supplier undertakes to be a member of the Drug Liability Association for the Agreement Period, cf. Chapter 3 of the Act of 23 December 1988 no. 104 on Product Liability (the Product Liability Act). Documentation of the membership shall be provided to the Contract Manager upon request.

4.2.5 Environmental Requirements

Throughout the Agreement Period, the Supplier shall work actively and preventively with environmental and climate concerns in mind. This involves having in place at least an environmental policy, measurable and time-defined goals, a procedure for reporting environmental impact, and a procedure for setting environmental requirements for its own suppliers/manufacturers. There must also be a person responsible for the environmental work and the goals must be monitored at least once a year.

In accordance with current regulations, the Supplier undertakes to have and maintain membership of a return scheme or to comply with this requirement through its own return scheme for final processing of packaging where the excess packaging is handled in an environmentally friendly way (Grønt Punkt Norge AS or a similar arrangement). Foreign suppliers that are not able to obtain

membership of Grønt Punkt Norge AS or a similar arrangement will participate in the Hospital Pharmacy's return scheme during the Agreement Period.

At the request of the Customer, the Supplier shall document that the requirements in this section have been met.

4.2.6 Requirements for the Products

The Supplier undertakes to make sure that the Agreed Products meet the requirements of applicable laws and regulations. Reference is especially made to the Act of 4 December 1992 no. 132 on medicines, etc. (the Medicines Act) with associated regulations.

4.2.7 Requirements for Shelf Life

The Supplier undertakes to deliver the Agreed Products which, at the time of delivery to the Hospital Pharmacy, have a shelf life equal to, or longer, than that agreed in Appendix 3 of the Supply Agreement.

If the Supplier receives an order for Agreed Products and only has the Agreed Product whose remaining shelf life is shorter than that agreed in Appendix 3 of the Supply Agreement, the Supplier shall notify the Hospital Pharmacy and await acceptance of the shelf life before confirming the order and carrying out the delivery.

4.2.8 Requirement for Reporting on Deliverability

The Supplier undertakes to keep a report on deliverability and any deviations from delivery of the Agreed Product, cf. Section 3.6 (Deliverability). Reports shall be sent to the Contract Manager upon request.

4.2.9 Requirement for Notification of Changes

The Supplier undertakes to notify the Contract Manager if the Supplier makes, or is about to make, such organisational changes as changes to organisation number, name, and the like.

The same applies if the Supplier wants to make changes as set out in Section 6.1 (Changes to the Agreement) or Section 1.6 (Assignment of the Agreement) or changes that are otherwise of significance to the content of the Agreement.

4.2.10 Requirements for Training

The Supplier shall assist with the necessary training of the personnel of the Customer, the Hospital, and the Hospital Pharmacy(ies) as further described in Appendix 3 (Supply Agreement). Training shall be arranged at a time that would allow the Customer to use the Agreed Products from the start date of the Agreement. The Supplier shall also assist with the necessary training of the personnel of the Customer, the Hospital, and the Hospital Pharmacy(ies) in case of any changes that may affect handling, storage, receipt, and distribution of the Agreed Product.

Meetings related to training shall be conducted in accordance with the Customer's guidelines and the cooperation agreements as set out in Section 1.3.

4.2.11 Social Responsibility

The Supplier shall ensure compliance with fundamental requirements relating to human rights, employee rights, and the environment. The goods delivered to the Customer shall be manufactured under conditions that are compatible with the requirements set out in Appendix 4 (Contract

Requirements for Ethical Trade). These requirements are based on key UN conventions, ILO conventions, and national labour legislation at the production site.

The requirements describe minimum standards. Where conventions and national laws and regulations address the same subject matter, the highest standard shall always apply. If the Supplier uses subcontractors to fulfil the Agreement, the Supplier is obliged to pass on the requirements to the subcontractors and contribute to their compliance with the requirements.

4.3 Common Obligations

4.3.1 Cooperation

The parties shall cooperate in good faith on the implementation of the Agreement.

The parties are obliged, without delay, to notify each other about matters that they understand or should understand may affect the implementation of the Agreement.

4.3.2 Communication and Meetings

Communication regarding the Agreement shall be directed to the parties' points of contact. Inquiries shall be answered without undue delay.

The Contract Manager shall in cases where this is deemed appropriate conduct a minimum of one annual status and evaluation meeting with the Supplier. Additionally, a party may, in writing, summon the other party to meet with at least 5 (five) business days' notice to discuss matters arising in connection with the implementation of the Agreement, including progress and status.

4.3.3 Data Processor

To the extent that the delivery implies that the Supplier shall process health and personal information on behalf of the Customer, the Supplier acts as a data processor. The Customer is a data controller. The Customer must carry out an independent risk assessment before entering into a data processing agreement. The Data Processing Agreement is attached as Appendix 7 (Data Processing Agreement). Regulations for processing of health and personal information are set out in Section 8.2 of the Supply Agreement.

Health and personal information cannot be processed before a data processing agreement is concluded between the Supplier and the Customer.

The content of the data processing agreement and the risk assessment may vary and allow for different interpretations and conclusions from one health trust to another. This is partly due to the fact that the health trusts may have different types of information security infrastructure and privacy protection needs.

5 Remuneration and Payment Terms

5.1 Remuneration

All prices are indicated as pharmacy purchase prices (LIS-AIP) in Norwegian kroner excluding VAT and including delivery to the Hospital Pharmacy in accordance with DDP (Delivered Duty Paid, as stated in Incoterms 2020) as further described in the Supply Agreement. Prices are indicated in

Appendix 1 (Agreed Product) and Appendix 5 (Price and Price Regulations). The price includes all activities or services performed in connection with this Agreement. If any training, equipment, or tests are necessary for providing treatment to the patient, which the Customer does not normally perform, the costs shall be covered by the Supplier.

5.2 Price Adjustment

5.2.1 General Rule

With the exception of price regulation described in Section 5.2.2, prices are fixed for the entire Agreement Period.

5.2.2 Price Regulation as a Result of Government Decisions

The Supplier undertakes to inform the Contract Manager immediately upon receipt of notification of a change in the maximum pharmacy purchase price (hereafter, "AIP") for the Agreed Product.

If during the Agreement Period the Agreed Product's AIP is reduced to lower than the contract price, the contract price shall be adjusted to equal to or lower than the maximum AIP.

5.3 Changes to the Agreement

The Customer can, within the parties' reasonable expectations at the time they entered into the Agreement request changes to the Agreement. Requests for changes shall be made in writing.

No significant changes can be made to the Agreement.

The Supplier may only deregister an Agreed Product by agreement with the Customer. A request for deregistration shall be addressed to the Customer through the Contract Manager.

New packages can be added to the range during the Agreement Period based on the same prices and other conditions as for the Agreed Products.

If medical knowledge emerges that is significant for prescribing practices, for example through summaries of product characteristics, studies, or study summaries, the Customer's use of the Agreed Product may change, including an increase or a decrease in usage, but it shall not be regarded as a change to the Framework Agreement according to this section.

5.4 Renegotiation of the Agreement

In the event of changes in medical therapy and changes resulting from product development, the Customer acting through the Contract Manager may demand renegotiation of the Agreement by giving a 3 months' notice. The parties may also call for renegotiation of the Agreement if significant changes occur in the market framework conditions during the Agreement Period.

A request for renegotiation must be submitted in writing.

6 Breach of Contract on the Part of the Supplier

6.1 Defects

6.1.1 What Constitutes a Defect

Defects exist where the Agreed Product does not conform to the requirements stipulated by the Framework Agreement, the Supply Agreement, or the guarantees provided by the Supplier, and this is due to circumstances for which the Supplier is responsible. The same applies if the Agreed Product does not serve a specific purpose that the Supplier was or should have been aware of when the Agreement was entered into. If the Supplier does not fulfil other obligations stipulated by the Framework Agreement and the Supply Agreement, this shall also be considered a defect.

Unless otherwise agreed, there is also a defect if the Agreed Product does not conform to the public requirements stipulated by law or public decisions made according to law at the time of the order.

6.1.2 The Customer's Deadline for Complaints

The Customer shall notify the Supplier of the defect within a reasonable time after the Customer discovered or should have discovered such defect. If a defect in the Agreed Product is discovered after the inspection upon delivery, the Customer shall notify the Supplier within the deadline specified in Appendix 3 to the Supply Agreement.

No complaint deadline applies in case of wilful misconduct or gross negligence on the part of the Supplier or someone the Supplier is responsible for.

If the Customer or the Contract Manager contacts the Supplier about a breach of the Agreement, the Supplier shall follow up the inquiry without undue delay.

6.1.3 Withholding of Payment

If the Supplier breaches the Agreement, the Customer may withhold the payment, but such withholding may not be significantly greater than what is necessary for securing the Customer's claims arising from the defect.

6.1.4 Remedy and Re-Delivery

The Customer may demand that the Supplier remedies the defect by rectification or re-delivery, unless the costs of the remedy is disproportionately large in relation to what the Customer can achieve. Remedy shall take place within a reasonable time after the Customer has complained about the defect and the Supplier has been given the opportunity to remedy the defect.

The Supplier is entitled to have the defect remedied if the remedy can be done without causing significant inconvenience to the Customer, and the Customer has no particular reason to oppose the remedy of the defect. Such particular reason may, for example, exist if the Supplier has previously made unsuccessful attempts of remediation.

If the defect is significant, the Customer may demand re-delivery.

Remedy and re-delivery are done at the Supplier's expense. The Supplier shall cover the costs of remediation and re-delivery, including expenses for ascertaining the defect, expenses related to access, and other expenses that are a direct and necessary consequence of the remedy or re-delivery.

6.1.5 Price Reduction

If a defect is not remedied in accordance with Section 6.1.4 (Remedy and Re-Delivery), the Customer may demand a price reduction. However, this does not apply if the Customer refuses a remedy that the Supplier has the right for, cf. Section 6.1.4 (Remedy).

The price reduction shall be calculated so that the difference between the reduced and agreed price corresponds to the difference between the value of the delivered goods in defective and contractual condition at the time of delivery.

6.1.6 Cover Purchase

If the Agreed Product has a defect that the Supplier has not remedied in accordance with Section 6.1.4 and the Customer needs the Agreed Product urgently, the Customer has the right to cancel the order and make a cover purchase from another supplier if such product is available (as named and specified in the Supply Agreement), at the Supplier's cost. The cover purchase shall be made responsibly and within a reasonable time. The nature and characteristics of the cover purchase shall be equivalent to those of the Agreed Product, and it shall be introduced by Beslutningsforum. The Customer may claim compensation for the price difference between the agreed price and the price after the cover transaction.

6.1.7 Cancellation of an Order

The Customer may cancel all or part of an order with immediate effect in case of a material breach.

6.1.8 Termination of the Agreement

If there is a material breach on the part of the Supplier, the Customer may, after giving the Supplier written notice and a reasonable time to rectify the matter, terminate the Agreement with immediate effect.

If the Supplier is subject to debt settlement, receivership, or bankruptcy proceedings, or any other form of creditor management takes place, the Supplier shall immediately notify the Customer of such proceedings in writing, and the Customer has the right to terminate the Agreement with immediate effect.

If the Supplier is in breach of its obligations to one of the participating Customers and such breach provides grounds for termination of the Agreement, the termination of the Agreement may apply to all Customers.

6.1.9 Cover Purchase in the Event of Termination

If the Agreement is terminated or an order is cancelled in whole or in part, the Customer can make a cover purchase from another supplier. The cover purchase shall be made responsibly and within a reasonable time after termination/cancellation. The nature and characteristics of the cover purchase shall be equivalent to those of the cancelled purchase. The Customer may claim compensation for the price difference between the agreed price and the price after the cover transaction.

6.1.10 Settlement in Case of Cover Purchases

If the Customer makes a coverage purchase from a substitute supplier that does not agree to share its unit price with the Supplier, and provided that the substitute supplier's unit price is subject to the duty of confidentiality pursuant to Section 13, first paragraph, item 2 of the Act of 10 February 1967 relating to procedure in cases concerning the public administration (the Public Administration Act), the Customer acting through the Contract Manager will ask the Supplier:

a) whether the claim for compensation for the Customer's direct loss will be accepted as submitted, or
b) whether an independent auditor's review of the basis for the calculation of the compensation claim is to be ordered, including the time period, volume, and price, where the third party shall be subject to the duty of confidentiality to the extent necessary for protecting the information about the substitute supplier's unit price. The Supplier shall bear the necessary costs associated with the third party's inspection.

6.1.11 Compensation for Defects

The Customer has a right to compensation for the loss it incurred as a result of the defect.

The Customer can claim compensation for indirect losses it incurred as a result of the defect if such defect is due to negligence on the part of the Supplier. This includes losses incurred due to any operational interruptions, including expenses and work related to error correction and repair, as well as losses incurred due to additional work caused by the defect.

Indirect losses are losses described in Section 67, second paragraph of the Sale of Goods Act of 13 May 1988 no. 27.

No compensation shall be claimed if delivery problems were caused by regulatory, patent-related or patent-related technical reasons, requirements of the Norwegian Medicines Agency that prevent/stop the delivery, or Force Majeure.

6.2 Delay

6.2.1 What Constitutes a Delay

There is a delay if the Supplier does not fulfil its obligations under the Agreement at the agreed time (delivery date stated in the order confirmation), and this is not due to circumstances the Customer bears the risk of or circumstances described in Section 9 (Force Majeure).

6.2.2 The Supplier's Duty of Notification and Duty to Mitigate the Delay

If the Supplier understands or has reasons to believe that a delay will occur, the Supplier shall, without undue delay, notify the Customer in writing and state the reasons for and the expected duration of the delay. The Supplier shall at its own expense take reasonable measures to mitigate the delay and keep the Customer continuously informed of the measures the Supplier is implementing to mitigate the delay.

If the Supplier believes that the obligations were not fulfilled at the agreed time due to circumstances on the Customer's side or other circumstances the Supplier does not bear the risk of, cf. Section 9 (Force Majeure), the Supplier shall notify and document this without undue delay.

6.2.3 Withholding of Payment

The Customer has the right to withhold an amount of the payment that covers the Customer's claims arising from the delay.

6.2.4 The Customer's right to uphold the Agreement

The Customer can uphold the Agreement and demand that the Supplier delivers the goods, including in cases of delay.

6.2.5 Cover Purchase

In the event of a delay, the Customer has the right to cancel the order or some of its parts and purchase the Agreed Product from another supplier, at the Supplier's cost. The cover purchase shall be made responsibly and within a reasonable time. The nature and characteristics of the cover purchase shall be equivalent to those of the Agreed Preparation, and it shall be introduced by Beslutningsforum.

6.2.6 Daily Penalty

In the event of a delay as set out in Section 6.2.1, the Customer is entitled to a daily penalty for each day the breach persists.

In case of delayed delivery: The daily penalty shall be 1% of the price for the part of the order that cannot be used as presumed due to the delay. The daily penalty shall not be less than NOK 500.

In the event of non-fulfilment of any obligations under the Agreement, the daily penalty shall amount to NOK 5000.

The daily penalty can run for a maximum of 4 weeks and amount to a maximum of 50% of the contract price of the Agreed Product.

Daily penalties can be claimed by the Customer through the Contract Manager without regard to financial loss.

6.2.7 Compensation for Delay

The Customer has the right to compensation for the loss it incurred as a result of the delay.

The Customer can claim compensation for indirect losses it incurred as a result of the delay if such delay is due to negligence on the part of the Supplier. Accrued daily penalties will not be deducted when calculating the compensation.

Indirect losses are losses described in Section 67, second paragraph of the Sale of Goods Act of 13 May 1988 no. 27.

6.2.8 Cancellation of an Order

The Customer may cancel all or part of an order with immediate effect if the delivery is significantly delayed. A delay shall always be considered significant if the Customer's purpose of the purchase is not fulfilled. There is also a significant delay if no delivery has taken place within the maximum period of the daily penalty in accordance with Section 6.2.6 (Daily Penalty).

When cancelling an order, the Customer can cancel other orders if such orders are mutually dependent. The orders are considered mutually dependent if they cannot be used for the purpose that the Parties had at the time they entered into the Agreement or at the time the orders were made.

6.2.9 Termination of the Agreement

The Customer has the right to terminate the Agreement in case of a significant delay.

If the Customer terminates the Agreement, the Supplier is not entitled to payment. However, the Supplier may demand the agreed price for the part of the order that has been delivered.

7 Breach of Contract on the Part of the Customer

7.1 What Constitutes a Breach

There is a breach on the part of the Customer if:

- Payment is not made on time, cf. Section 5.
- The Customer otherwise does not fulfil its obligations under the Agreement.

7.2 The Supplier's Rights in the Event of Breach of Contract by the Customer

7.2.1 Additional Expenses

The Supplier is entitled to compensation for the documented additional expenses it incurs as a result of a breach of contract by the Customer.

7.2.2 Cancellation

In cases where an overdue payment with the addition of interest is not made within 30 days of the due date, the Supplier may send the Customer a written notice stating that the order will be cancelled if the payment is not made within 60 days after the receipt of the notice. Cancellation shall not take place if the Customer settles the payment with the addition of interest before the deadline expires.

In case of another material breach on the part of the Customer, the Supplier may send the Customer a written notice stating that the Agreement will be terminated if the Customer does not bring the breach to an end within 45 days after the receipt of the notice. Cancellation shall not take place if the breach is brought to an end before the deadline expires.

7.2.3 Compensation

The Supplier may claim compensation for losses that can be reasonably attributed to the breach, unless it is demonstrated that the breach cannot be attributed to the Customer.

Compensation for indirect losses can only be claimed if the Customer or someone the Customer is responsible for acted with gross negligence or wilful misconduct.

Indirect losses are losses mentioned in Section 67, second paragraph of the Sale of Goods Act of 13 May 1988 no. 27.

8 Refund for Agreed Products that Cannot Be Used for Patients

The Supplier shall refund the Customer in full for the Agreed Product purchased by the Customer which, for whatever reason, cannot be used for patient treatment.

Examples of reasons that result in a refund for the Agreed Product:

- The Agreed Product cannot be used for patient treatment due to medical reasons:
  - the patient dies before treatment is given;
  - the responsible treating physician decides that the patient no longer meets the clinical requirements for treatment.
- The patient/guardian revokes their consent to treatment.

- [NOT applicable in case of a patient-unique medicine] The medicinal product expires before it can be administered to the patient. If the medicinal product is stored at the Customer's premises, the Customer is responsible for operating its warehouse in accordance with the principle of using the products with the shortest remaining shelf life first.
- Transport or handling damage, regardless of when it is detected. The Customer shall report such damage to the Supplier upon discovery, without undue delay.
- Defects in product quality, regardless of when they are detected. The Customer shall report such defects to the Supplier upon discovery, without undue delay.
- Human error on the part of the Customer which makes the Agreed Product unfit for use, provided that the Customer has made its best effort to comply with all applicable instructions and requirements regarding transportation, storage, handling, and administration of the Agreed Product.

The Customer is responsible for informing the Supplier about medicinal products that cannot be used for patients without undue delay.

In the event of repeated refund claims, which are direct consequences of the failure to use the Agreed Products due to gross negligence on the part of the Customer, the Supplier has the right to suspend further delivery until the Customer's relevant personnel have been trained by the Supplier (in accordance with Section 4.2.10) in the Agreed Product and the way it should be handled.

9 Force Majeure

If the fulfilment of the parties' obligations under the Agreement is made impossible by an extraordinary situation which is beyond the control of the parties, such as war, rebellion, natural disaster, statutory orders and prohibitions, epidemic/pandemic, strike, or lockout, and which could not reasonably have been considered at the conclusion of the Agreement (**"Force Majeure"**), the other party shall be notified as soon as possible. The obligations of the affected party are suspended for as long as the Force Majeure persists. The other party's consideration is suspended for the same period. If the progress is hindered by a subcontractor, the same applies if such subcontractor is hindered by the circumstances beyond its control as mentioned in the first sentence.

In a Force Majeure situation, the other party may only terminate the Agreement with the affected party's consent, or if the situation lasts or is expected to last longer than 60 (sixty) calendar days, calculated from the time the situation arises, and only with 15 (fifteen) calendar days' notice.

In connection with a Force Majeure situation, the parties have a mutual duty to inform each other about all matters that must be assumed to be of importance to the other party. Such information shall be provided as soon as possible.

In the event of Force Majeure, each party shall cover its own costs resulting from the Force Majeure situation.

Each party covers its own costs related to the termination of the contractual relationship. The Customer pays the agreed price for the part of the delivery that was contractually delivered before the Agreement was terminated and is refunded any advance paid for non-delivered parts of the delivery. The parties may not make other claims against each other as a result of termination of the Agreement pursuant to this provision.

10 General Provisions

10.1 Duty of Confidentiality

The Act of 10 February 1967 relating to procedure in cases concerning the public administration (the Public Administration Act), the Act of 19 May 2006 no. 16 relating to the right of access to documents held by public authorities and public undertakings (the Freedom of Information Act), and the Act of 27 March 2020 no. 15 relating to the protection of trade secrets (the Trade Secrets Act) apply to the parties and others the parties may be responsible for. Sections 10.1 and 10.2 do not prevent the disclosure of information as required by the Freedom of Information Act.

The parties shall maintain confidentiality and prevent others from gaining access to or obtaining knowledge of any confidential information and material they may acquire in connection with this Agreement and its implementation. This includes, but is not limited to information regarding:

1) Operational or business matters that may be important to keep secret for competitive reasons.
2) Anyone's personal matters.

The duty of confidentiality applies to the parties' staff and others who act on behalf of the parties in connection with implementation of the Agreement. If necessary, the parties shall sign a non-disclosure agreement. In this case, it shall be stated which information is subject to the duty of confidentiality and how it shall be handled. The parties shall retain their duty of confidentiality also after the termination of the contractual relationship. Employees or others who resign from their service with one of the parties are required to maintain the duty of confidentiality even after resignation.

This provision does not prevent the use of information to the extent necessary for the implementation of the Agreement. If this involves sharing the information with others, the party that shares the information, or on whose behalf the information is shared, shall ensure that the recipient of the information is bound by a confidentiality obligation which is at least as comprehensive as the one the party itself is bound by under this Agreement. The party shall remain responsible for potential breaches of confidentiality by others who received the information as part of implementation of the Agreement by that party.

Both parties may use general knowledge (know-how) that is not confidential and that they acquired in connection with the assignment.

10.2 Confidentiality Requirements

Each party undertakes, in accordance with applicable law, not to disclose information and knowledge that constitutes confidential information. Each party undertakes to take all necessary steps to ensure that confidential information is not made available to anyone other than the person who has the right to access such information. Each party also undertakes not to disclose information regarding negotiations between the parties to any third parties.

The provisions of this section shall not prevent:

(1) a Party from disclosing, where necessary, confidential information to directly affected stakeholders to the extent necessary for the Party to be able to fulfil its obligations or assert its rights under the Agreement, or

(2) the Supplier, provided that the appropriate confidentiality obligations are established, from disclosing such confidential information to subcontractors that they need for the Supplier to be able to fulfil its obligations under the Agreement.

However, the Supplier agrees and accepts that the Customer's obligation is limited to keeping information confidential in accordance with applicable law (particularly the Freedom of Information Act). The Supplier is aware that the Customer alone makes decisions related to confidentiality in accordance with applicable law. However, if the Customer discloses information in accordance with the preceding sentence, the Customer shall, with regard to, among other things, time periods stipulated by law, consult with the Supplier about the information disclosure.

10.3 Third Party Property Rights

The Supplier guarantees that the Supplier's services will not infringe on third party property rights, including intellectual property rights such as patents or copyrights.

The Supplier shall indemnify the Customer for any claims arising from the infringement of any third party property rights in connection with the fulfilment of the Agreement.

The parties shall notify each other of any claims regarding infringement of patents or other intellectual property rights in the manufacturing or use of the Agreed Product.

10.4 Reputation and Loyalty

The Supplier and the Customer shall safeguard each other's interests regarding the subject matter of the Agreement during the Agreement Period. The parties shall not, during the Agreement Period, conduct business activities that may have a negative impact on the other party's reputation in the eyes of a third party. During the Agreement Period, the Parties shall not disclose the terms or content of the Agreement in such a manner that can adversely affect the reputation of the other party, or its relationship with third parties. The parties shall, upon inquiry from a third party, communicate to the third party that such inquiries should be directed to the contact person for the Agreement.

10.5 Audit

The Customer, acting through the Contract Manager, has the right to conduct an audit of the Supplier's systems, routines, and activities associated with the delivery. In the event of an audit, the Supplier undertakes to provide reasonable assistance free of charge.

The Supplier has the right to conduct government-mandated audits of the Customer's systems, routines, and activities covered by the Agreement. An audit must normally be agreed at least 10 business days before it is carried out. The Supplier is obligated to simultaneously inform the Contract Manager. The Supplier may choose to use a third party when conducting an audit. In the case of labour-intensive audits, the Supplier and the Customer may agree on compensation.

10.6 Marketing

The parties agree that neither party has the right to use the other party's name, trademark, characteristics, etc. in press releases, advertisements, and the like without the written consent of the other party.

If the Supplier wants to publish information about the contractual relationship for advertising purposes or otherwise, the Supplier shall obtain a prior written approval from the Customer.

11 Disputes, Applicable Law, and Legal Venue

This Agreement is regulated by Norwegian law.

Any disputes that arise between the parties in connection with the 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 Customer's legal venue shall be used as legal venue for the Agreement unless the parties agree on another venue.