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| **National Standard Agreement**  For the delivery and use of the medicine XXXX prior to marketing authorization and until decision to introduce to the Specialist Health Service  |



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# General information

This National Standard Agreement constitutes a Framework Agreement (the ‘Framework Agreement’). The Framework Agreement is based on ‘Guidelines for use of new medicines prior to marketing authorization’ (‘Retningslinjer for bruk av nye legemidler før markedsføringstillatelse’) and amendement May 12th 2021 (‘Tillegg til *Retningslinjer for bruk av nye legemidler før markedsføringstillatelse)*. Vilkår for legemidler med kort forventet behandlingsvarighet’). These documents are available on nyemetoder.no.

The initial guidelines were subject to decision in The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway (‘Beslutningsforum for nye metoder’) February 2nd in 2018 in case number 13-2018. The revision of terms for agreements on ‘compassionate use’ for medicines for short-term use was subject to decision
June 21st in 2021 in case number 072-2021. ‘Short-term’ is generally understood to mean an expected average duration of treatment of up to 6 months.

# Parties to the Framework Agreement

Customers (the ‘Customer’) to this Framework Agreement are listed in Appendix 2 (Administrative purposes). Customers enter into an agreement with the supplier (the “Supplier named on the cover page ("Supplier").

The Norwegian Hospital Procurement Trust, Pharmaceutical division (Sykehusinnkjøp HF, divisjon legemidler) is the Customer’s advisor and contract manager (‘Contract Manager’) who can be contacted regarding this agreement as stated on the cover page. Customer also means a representative of the Customer, or someone for whom the Customer responds, such as the Contract Manager or the person(s) who act as contract wholesaler at any given time.

The Framework Agreement is signed electronically in Mercell. Each party is responsible for archiving a copy signed by both parties.

The Norwegian Hospital Procurement Trust (Sykehusinnkjøp HF, divisjon legemidler) is advisor to the Customer and manage the Framework Agreement on the Customer´s behalf (‘Contract Manager’).

# The Subject of the Framework Agreement

This agreement (“Agreement”) is a Framework Agreement between the Customer and Supplier, and gives the Customer the right to order medicines in accordance with the front page of the Agreement as described in Appendix 1 (‘Contract Medicines’). The Contract Medicines are indicated by an article number and ATC code. Each article number shall be regarded as an independent agreement, so that each provision in the Agreement applies to each individual Contract Medicine.

Each Customer is legally and financially responsible for call-offs (orders) made in accordance with the Agreement.

The Framework Agreement applies for all usage of the Contract Medicine(s) Contract Medicines) as specified in Appendix 3 (Criteria for Medical Treatment). The Framework Agreement applies to all patients that meet the criteria for treatment. The Supplier is not at liberty to limit the amounts of patients. New patients may, as a main rule, not be included under the Framework Agreement from the time the medicine is granted its first marketing authorization (‘MA’) in Norway, regardless of which indication the MA applies to.

The Framework Agreement applies to Medicine(s) in:
Compassionate Use Program (CUP)
Compassionate Use Named Patient (CUNP)

Criteria for start-up and termination of treatment with the medicine is listed in Appendix 3.

# Contract documents and Rules of interpretation

The following documents are part of the Framework Agreement. In case of conflict between any provisions set out in the documents, the order of priority shall be:

The Agreement consists of the following documents:

* The Agreement (this document)
* Appendix 1 Contract Medicine(s)
* Appendix 2 Administrative provisions
* Appendix 3 Criteria for Medical Treatment
* Appendix 4 Agreement between Supplier and Hospital Pharmacy
* Appendix 5 Contractual requirements for ethical trade
* Appendix 6 Change protocol (not enclosed)

The documents included in the Agreement complement each other. If the contract documents contain provisions that conflict with each other, the most recent documents shall take precedence over the older documents. If this does not resolve the conflict, special provisions prevail over general ones, and provisions drawn up separately for the Agreement prevail over standardised provisions.

To the extent that an issue is not covered by the contract documents listed above, the following documents shall apply:

* Other written documentation (Treatment agreements)

For matters not covered by the Agreement, the Act of 13 May 1988 #27 concerning the sale of goods (the Sale of Goods Act) shall apply.

The collaboration agreements between the Regional Health Authorities (‘RHF’) and the Association of the Pharmaceutical Industry in Norway (‘LMI’), as well as the collaboration agreement between the regional health authorities and Melanor are included as part of the Framework Agreement. A breach of any of the mentioned collaboration agreements will be reported to LMI and / or Melanor and may provide grounds for termination of the Framework Agreement. An example of such a cooperation agreement is available [her](http://www.helse-sorost-vinnvinn.no/pdf-bibliotek/)e.

# Duration of the Framework Agreement

## Duration

The Supplier undertakes to deliver the medicine from the commencement of a medical treatment in accordance with the Framework Agreement until The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway (‘Beslutningsforum’) decides whether to introduce the medicine, and the medicine is available to purchase for a negotiated price, or until all Treatment Agreements are concluded for medical reasons. If Beslutningsforum decides to introduce the medicine, this Framework Agreement will be superseded by a new framework agreement that regulates the negotiated terms for further use of the medicine, including guidelines given by Beslutningsforum.

If Beslutningsforum decides not to introduce the medicine, the Supplier is still obligated to deliver the medicine free of charge (non-commercial packages) and then commercial packages in accordance with the terms of the Framework Agreement until patient treatment that have started is concluded for medical reasons, cf. Appendix 3.

## Inclusion of Patients

New patients may be included in Compassionate Use Program (CUP) /
Compassionate Use Named Patient (CUNP) until the medicine is granted MA.

New patients may be included in Compassionate Use Program (CUP) / Compassionate Use Named Patient (CUNP) [x] months from the Framework Agreement entries into force. The Parties may agree to extend the inclusion period beyond this.

Patients may be included until commercial packages are available for purchase in Norway. Such inclusion after marketing authorization, but before available commercial packages, must be done in agreement with the supplier. “Commercial package available for purchase” means that the package, which has Norwegian marketing authorization and a maximum price, is available for ordering at the pharmaceutical wholesaler(s). Available for purchase is independent of government funding.

Regardless of the first paragraph, the Supplier has the right to close inclusion of new patients with effect from two (2) months after written notice has been sent (from the date notice is sent). The duration of the inclusion period, even upon notice to close inclusion, cannot be less than three (3) months.

## Termination

The Customer has the right to terminate all or part of the Framework Agreement with effect from three (3) months after written notice has been sent (calculated from det date notice is sent). This does not prevent The Parties from agreeing on a shorter notice period.

The Customer has the right to terminate all or part of the Framework Agreement with immediate effect if there is repeated or prolonged delivery failure of the medicine. Prolonged delivery failure shall mean four (4) weeks of delivery failure.

The Parties to this Framework Agreement are entitled to terminate all or part of the Framework Agreement with immediate effect if medical information emerges indicating that the medicine cannot be used as intended.

Both Parties have the right to terminate the agreement if the medicine is not granted marketing authorization in EU. The Supplier has the right to terminate the agreement for new patients if the medicine is granted marketing authorization in EU, but the Supplier chooses not to market the medicine in Norway. The agreement cannot be terminated for patients already included and receiving treatment.

After switching to commercial packages, the Supplier may, after giving the Customer written notice and reasonable time to rectify the situation, terminate a Treatment Agreement with immediate effect if the Customer uses the medicine to treat patients that are not enlisted in a Treatment Agreement.

Any termination of the Framework Agreement must be in writing and substantiated.

## Effects of Expiration or Termination

The terms of the Framework Agreement shall apply to all call off contracts to the Customer that is confirmed by the Supplier within the duration of the Framework Agreement, even if delivery takes place after expiry of the Framework Agreement.

# Prices and Price Regulation

## Prices

### Non-commercial packages

The Customer´s price for the medicine shall be zero (NOK 0) for as long as the Patient is treated with non-commercial packages or until the medicine is decided introduced and the medicine is available to purchase for a negotiated price, cf. 4.1 (1). Non-commercial packages, without cost for the Customer, shall be delivered for a minimum of six (6) months after the medicine is granted MA. This does not prevent The Parties from agreeing on a longer period of delivery of non-commercial packages.

All expenses for the medicine and delivery cost to Hospital Pharmacy Enterprise, including transportation expenses and any government-determined fees and statutory import value added tax, shall be paid by the Supplier.

### Commercial packages

 Price per package (RHF GIP) is up to 10 % of the maximum price set by the Norwegian Medicines Agency, limited upwards to a yearly treatment cost per patient of NOK 100 000 (RHF GIP) Price per package is calculated based on the medicine’s SPC for one year of treatment for a patient weighing 75 kg including wastage if applicable.

This price will enter into force from the time commercial packages are available for delivery to the Customer´s Wholesaler, but at the earliest six (6) months after the medicine is granted MA. The price will apply for as long as patients are in treatment or until the medicine is decided introduced, cf. 4.1 (1).

Upon decision to introduce the medicine, the price shall be in accordance with negotiated terms from the time the medicine can be delivered to these terms.

## Price Regulation

All prices that the Hospital Pharmacy Enterprise are to invoice will be index linked January 1st every year according to the wage and price index (Statistics Norway), cf. Appendix 4.

## Invoicing

The Hospital Pharmacy Enterprise will invoice the Supplier for its services on monthly basis, cf. Appendix 4.

Payment terms for invoices from the Hospital Pharmacy Enterprise is Net 30 days.

# Ordering, Distribution and Delivery

## Ordering and Distribution

### Non-commercial packages

Placement of orders (call offs) will be done by Hospital Pharmacy Enterprise, cf. Appendix 4.

The Supplier is responsible for import and distribution of the medicinemedicine directly to the Hospital Pharmacy Enterprise.

The Hospital Pharmacy Enterprise is responsible for import of the medicine. Additional requirements and information are set out in Appendix 4.

### Commercial packages

Placement of orders (call offs) will be done by the Customer´s Wholesaler(s).

The Customer´s Wholesaler is responsible for distribution of commercial packages to the Customer.

#### The Supplier´s relation to the Customer´s Wholesaler(s)

The Supplier must have a valid Wholesaler- and Quality-Agreement with the Customer´s current Wholesaler(s) that is of relevance to this Framework Agreement (‘Wholesaler(s)’).

Placement of orders (call offs), invoicing and payment will be carried out by the Wholesaler(s).

Payment terms for invoices to the Wholesaler(s) is minimum 30 days End of Month.

The Supplier shall sell the pharmaceutical drug to the Wholesaler(s) to LIS GIP, cf. 5.1.2. The exception to this is if the trade of the medicine mainly takes place outside health trust financing. In that case the Wholesaler(s) shall buy the medicine in accordance with its own purchasing price and the Supplier shall refund the difference between LIS GIP and the Wholesaler(s) purchasing price to the Wholesaler(s). If the medicine is bought to LIS GIP but later sold to another buyer than the Customer, the Wholesaler(s) shall refund the difference between LIS GIP and the Wholesaler(s) purchasing price to the Supplier.

## Terms of Delivery

The Supplier shall deliver the medicine that is produced, transported and stored in compliance with current GMP / GDP (Good Manufacturing Practice / Good Distribution Practice).

Ownership and responsibility for the medicine is transferred from the Supplier to the Customer upon delivery.

### Non-commercial packages

The medicine shall be delivered to the Hospital Pharmacy Enterprise in accordance with Incoterms DDP (2020).

Delivery to the Hospital Pharmacy Enterprise shall be in accordance with the terms of the Framework Agreement, cf. Appendix 4.

### Commercial packages

The medicine shall be delivered to the Wholesaler(s) in accordance with Incoterms DDP (2020).

Delivery to the Wholesaler(s) (commercial packages) shall otherwise take place in accordance with the agreements between the Supplier and the Wholesaler(s), and at a minimum in accordance with the terms of the Framework Agreement.

## Place of Delivery

### Non-commercial packages

Import shall be conducted by the Supplier and the Medicine is to be delivered directly to the Hospital Pharmacy Enterprise, cf. Appendix 4.

Import shall be conducted by the Hospital Pharmacy Enterprise, cf. Appendix 4.

### Commercial packages

The medicine shall be delivered to the Wholesaler(s), at current time Alliance Healthcare Norge AS, Langhus.

## Lead time

### Non-commercial packages

The medicine shall be delivered not later than 14 days after the Customer has made an order, unless otherwise is agreed upon and specified in the Treatment Agreement and Appendix 4.

### Commercial packages

The Suppliers hall adhere to a lead time (the time from a received order until delivery is completed) of maximum five (5) days, unless otherwise is agreed upon.

## Delivery deviations

### Non-commercial packages

The Supplier shall notify the Hospital Pharmacy Enterprise as soon as possible if a delivery cannot take place in accordance with the agreed delivery time.

### Commercial packages

In the event of delayed or non-delivery, the Suppliers hall immediately notify the Hospital Pharmacy Enterprise, the Norwegian Medicines Agency, and the Contract Manager. 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 Appendix 2.

In the event of a delay, following an agreed transition to commercial packages, the Contract Manager may demand daily fines and compensation from the Supplier, cf. Section 10.

If a delay results in the product not being able to be used within the agreed period of use, the Customer / Wholesaler(s) may cancel the order (call off). This also applies to a notified delay in the first paragraph.

# Customer obligations

The Customer shall provide reasonable and necessary participation so that the Supplier is able to fulfil its obligations under the Agreement.

The Customer (the responsible clinician) must apply for approval from the Supplier and adhere to regulatory requirements (receive approval exemption from the Norwegian Medicines Agency) before starting treatment for any given patient. The Customer (the responsible clinician) have the sole responsibility for the medical treatment of patients and for all use of the medicine.

The Customer shall not use, produce or in other ways make use of the medicine before the Supplier has given the Customer the necessary training / information related to the medicine, cf. 8.11.

The Customer shall keep the Supplier informed of any side effects during use, as well as inform the Supplier as soon as possible about discontinuation of treatments. This must be viewed in context of the type of medicine and the Treatment Agreement.

The Customer shall use the medicine solely to treat patients that are included in a Treatment Agreement.

The Contracting Authorities undertakes to follow up a Customer in breach of a Treatment Agreement. This will be done by the Contract Manager.

# Supplier obligations

## Treatment Agreement

The Supplier is responsible for entering into a Treatment Agreement with the Hospital department treating the patient. The Treatment Agreement shall contain details with regards to the treatment (ordering procedures, contact information and so forth). The Treatment Agreement shall be archived by both the Supplier and the Customer. The Supplier is responsible for providing a copy to the Contract Manager.

## Notice of switch to commercial packages

The Supplier undertakes to notify the Contract Manager of a switch to commercial packages no later than six (6) weeks before transitioning to delivery of commercial packages.

## Routine in case of Product Recall

The Supplier undertakes to have routines for medicine recall in the case that the medicine / a batch of the medicine is not suitable for intended use.

## Ethical Trade

The Supplier shall respect fundamental requirements relating to human rights and labour rights.

The products delivered to the Customer shall be manufactured under conditions compatible with the requirements specified in Appendix 5 Contractual Requirements for Ethical Trade. The requirements are built on the UN Guiding Principles on Business and Human Rights using due diligence as a method.

The requirements specify minimum standards. Where conventions and national laws and regulations deal with the same topic, the highest standard shall always apply. If the Supplier use subcontractors(s) to fulfil the Framework Agreement, the Supplier is obligated to continue and contribute to compliance with the requirements of its subcontractors..

## Processing of personal data

The Supplier functions as the Data Controller for the personal data processed in connection with the delivery, and is responsible for ensuring that measures have been implemented to ensure satisfactory information security with regard to confidentiality, integrity, availability and robustness when processing health and personal data.

The measures shall be documented and the Customer may at any time request documentation showing that adequate and relevant measures have been implemented. In case of doubt as to whether the Supplier has a satisfactory level of information security, the Customer may demand a halt to the processing of personal data and demand that personal data previously processed be deleted if the situation is not corrected.

Failure to take action will be deemed a significant breach of the Agreement. The Supplier is obligated, at own expense, to ensure that the necessary measures are taken so that the processing of health and personal data can be resumed.

## Participation in Verification Scheme (Falsified Medicines Directive)

### Commercial packages

The Supplier undertakes to pay a fee to Nomvec AS (The Norwegian Medicines Verification Company) for operation of the medicines verification system in the duration of the Framework Agreement. The Supplier shall provide documentation to the Contract Manager upon request.

## Membership of the Drug Liability Association

The Supplier undertakes to have and maintain product liability insurance through the Norwegian insurance scheme for pharmaceuticals, cf. Lov om produktansvar av 23. desember 1988 nr. 104 kapittel 3. The Supplier shall provide documentation to the Contract Manager upon request.

## Membership of Return Scheme

The Supplier undertakes to have and maintain a membership of a return scheme for final processing of packaging.

If the Supplier is a company filed in Norway, the Supplier undertakes to have and maintain membership of a return scheme or to comply with the requirements through its own return scheme where the excess packaging is handled in an environmentally friendly way (‘Grønt Punkt Norge AS’ or similar arrangement). Norske leverandører plikter i avtaleperioden å være medlem i en returordning eller oppfylle forpliktelsen gjennom egen ordning for sluttbehandling hvor emballasjen blir tatt hånd om på en miljømessig forsvarlig måte (‘Grønt Punkt Norge AS’ eller tilsvarende ordning).

If the Supplier is a company filed abroad and not able to obtain membership of ‘Grønt Punkt Norge AS’ or a similar arrangement, the Supplier undertakes to enter into an agreement with the applicable Wholesaler(s) ensuring that the Wholesaler(s) will pay the packaging fee to the return scheme on behalf of the Supplier.

The Supplier shall provide documentation to the Contract Manager upon request.

## Requirements for the Contract Medicine(s)

### Regulatory requirements

The Supplier undertakes that the medicine meets the requirements of applicable laws and regulations.

#### Commercial packages

The Supplier undertakes that the commercial package shall have a valid item number in Farmalogg.

### Shelf life

#### Commercial packages

The Supplier undertakes to deliver the medicine which at the time of delivery have a shelf life equal to, or longer, than 12 months.

The shelf life requirement in the first paragraph does not apply if the medicine for regulatory reasons have a shorter shelf life.

If the Supplier receives an order for the medicine and the Supplier only has the medicine with a remaining shelf life of less than 12 months, the Supplier undertakes to notify the Wholesaler(s) and await acceptance of the shelf life before confirming the order and delivery is carried out.

## Provide information in case of changes

The Supplier undertakes to notify the Contract Manager if the Supplier makes, or is about to make, organizational changes such as changes to organization number, name, portfolio, or similar changes.

The same applies if the Supplier wishes to make changes as set out in Section 13 or changes that in other ways may be of importance to the contents of the Framework Agreement.

## Return of medicine / Destruction

### Non-commercial packages

Any return to the Hospital Pharmacy Enterprise and destruction will be carried out in accordance with the Hospital Pharmacy Enterprise´s internal routines, unless otherwise is agreed upon in Appendix 4.

### Commercial packages

The Supplier undertakes to accept returns and credit the value of returned medicine from the Wholesaler(s) in the following cases:

* If the medicine is deregistered by the Norwegian Medicines Agency.
* If the medicine is withdrawn from sale by order of the Norwegian Medicines Agency.
* If the medicine has quality defects. Exceptions from this apply if damages or quality defects occur in the distribution chain from the Wholesaler(s).
* If the medicine is outdated, presumed that the Wholesaler(s) follows the ‘first expired, first out”-principle. The same applies for return of the medicine that has been delivered with a remaining shelf life of less than 12 months, independent of the cause for shorter shelf life.
* At the end of the duration of the Framework Agreement, the Wholesaler(s) have the right to adjust stock by returning the medicine that is unsold, given that the Supplier no longer has an agreement to deliver the medicine or that the Supplier has entered into a new agreement where significantly smaller volume of the medicine is expected.

Any return is to be made within four (4) months after the end of the duration of the Framework Agreement.

Handling and transport costs with regards to returns shall be covered by the Supplier.

The Wholesaler(s) with license issued by the Norwegian Medicines Agency are obliged by regulations (forskrift om grossistvirksomhet med legemidler av 21. desember 1993 nr. 1219 § 9) to adhere to the EU Commission´s guidelines on good distribution practice (GDP). Any return of the medicine from the Wholesaler(s) to the Supplier presumes compliance to GDP 6.3 throughout the supply chain.

As an alternative to returning the medicine to the Supplier, the Wholesaler(s) may carry out destruction of the medicine. The Wholesaler(s) must obtain written consent from the Supplier prior to destruction. Furthermore, the following conditions must be met:

* The medicine that are to be destructed shall be stated in the monthly return message, and the Supplier credit the Wholesaler(s) for the value (the actual purchase price) at the current price of the time of return.
* To cover costs for return and destruction, the Wholesaler(s) invoices the Supplier a minimum fee of NOK 3500 or 1 % of invoiced actual purchase price, in accordance with the Framework Agreement Chapter 2, for the returned / destructed medicine.
* The Wholesaler(s) must destruct the medicine within four (4) months after the end of the duration of the Framework Agreement.

## Training

The Supplier undertakes to give the Customer the necessary training / information regarding the medicine before the Customer takes the medicine in use.

The necessary training / information shall contain a summary of the relevant clinical and preclinical data concerning the medicine (in accordance with the ‘investigator´s brochure’ and ‘pharmacy manual’), e.g. safety measures to be taken in connection with storage, handling, manufacturing and use of the medicine. If the Supplier fails to give the Customer the necessary training / information in accordance with the information basis available at the time of entering into the Framework Agreement, the Supplier may be held accountable for damage or financial loss that occurs to the Customer.

Meeting activities shall be conducted in accordance with the guidelines of the Customer and the cooperation agreements as set out in Section 3.

# Joint obligations

### Cooperation

The Parties shall cooperate loyally on the implementation of the Agreement.

The Parties shall, without undue delay, notify each other of circumstances they understand or should have understood may have an impact on the execution of the Agreement.

9.1.2 Communication and meetings

Communication regarding the Agreement shall be conducted in accordance with the contact details provided on the cover page of the Agreement. Enquiries must be answered without undue delay.

The Contract Manager will, where deemed appropriate, conduct at least one annual status and evaluation meeting with the Supplier. In addition, either Party may, with at least 5 (five) business days' notice, convene a meeting with the other Party to discuss the manner in which the Agreement is implemented, including progress and status.

# Breach of Contract

## Commercial packages

If the medicine fails to fulfil the requirements set out in the Framework Agreement, this shall be considered a breach.

If a Party to the Framework Agreement fails to fulfil its obligations under the Framework Agreement, this shall be considered a breach. This does not apply if the situation is due to the other Party´s circumstances or Force Majeure.

In the event the Wholesaler(s) or the Contract Manager addresses the Supplier regarding a breach, the Supplier undertakes to follow up the inquiry no later than the following business day.

# Sanctions for Breach of Contract

## Daily fines due to delays

### Commercial packages

In the event of a breach as set out in Section 9, the Contract Manager can demand the Supplier to pay a daily fine for each day the breach persists.

In case of delayed delivery: The daily fine shall be 1 % of the price for the call-off that due to the delivery cannot be used as presumed. The daily fine shall not be less than NOK 250.

Daily fines can run for a maximum of four (4) weeks.

Daily fines are to be charged by the Contract Manager.

## Compensation

### Non-commercial packages

If a delay in delivery persists more than three days following an agreed delivery date, cf. 6.4.1, the Hospital Pharmacy Enterprise can claim compensation for any direct loss incurred by itself or the Customer, unless the Supplier proves that the delay is not due to the Supplier or circumstances for which the Supplier is liable. Daily fines are deducted in the event of compensation for the same breach.

Compensation may not be claimed for indirect losses, including, but not limited to, lost profits of any kind, lost saving and claims from third parties.

A claim for compensation does not apply if delivery deviations are due to regulatory, patent-related / patent technical reasons, an order by the Norwegian Medicines Agency that prevent / stops delivery, or Force Majeure.

A claim for compensation shall be in writing.

### Commercial packages

The Customer can claim compensation for any direct loss, including loss as result of pre-treatment of a patient and preparations in hospital and pharmacy, if there is a breach as set out in Section 9, unless the Supplier proves that the delay is not due to the Supplier or circumstances for which the Supplier is liable. Daily fines are deducted in the event of compensation for the same breach.

Compensation may not be claimed for indirect losses, including, but not limited to, lost profits of any kind, lost saving and claims from third parties.

A claim for compensation does not apply if delivery deviations are due to regulatory, patent-related / patent technical reasons, an order by the Norwegian Medicines Agency that prevent / stops delivery, or Force Majeure.

A claim for compensation shall be made in writing.

## Re-delivery

### Quality deviations

The Customer has the right to demand re-delivery if a delivery of the medicine has quality deviations of significance for patient treatment.

### Damage occurred after delivery

#### Non-commercial packages

In the event of a re-delivery due to lack of necessary training / information from the Supplier, the Suppliers hall re-deliver the medicine free of charge for the Customer.

The Supplier undertakes to do its utmost to ensure re-delivery if damage occurs to the medicine after delivery. In the event of a re-delivery due to circumstances for which the Customer is liable, the Supplier´s documented additional costs, including necessary costs related to transport, shall be compensated by the Customer.

## Termination for Breach of Contract

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

The Customer may terminate all or part of the Framework Agreement with immediate effect if delivery of the medicine is significantly delayed or if there are repeated delays in individual deliveries.

### Termination after transition to commercial packages

After transition to commercial packages the Supplier may, after giving the Customer written notice and reasonable time to rectify the matter, terminate the Framework Agreement with immediate effect if the Customer repeatedly has used the medicine to treat patients that are not enlisted in a Treatment Agreement.

# Force Majeure

If the fulfilment of the Parties' obligations under the Agreement is rendered impossible by an extraordinary situation beyond the control of the either Party – such as war, riot, natural disaster, public injunctions and prohibitions, epidemic/pandemic, strike or lockout – and which could not reasonably have been taken into account at the conclusion of the Agreement (Force Majeure), the other Party shall be notified of this as soon as possible. The affected party's obligations are suspended for the duration of the Force Majeure situation. The corresponding obligations of the other party shall be suspended for the same period. If progress is hindered by a subcontractor, the same applies if the subcontractor is hindered by such circumstances beyond its control as mentioned in the first sentence.

In force majeure situations, the other party may only terminate the Agreement with the consent of the affected party, or if the situation lasts or is assumed to last longer than 60 (sixty) calendar days from the time the obstacle occurs, and then only with 15 (fifteen) calendar days notice.

In connection with force majeure situations, 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 disclosed as soon as possible.

In the case of Force Majeure, each party shall cover its costs as a result of the force majeure situation.

Each Party covers its own costs related to the termination of the contractual relationship. The Customer shall pay the agreed price for the part of the delivery that was contractually delivered before the Agreement was terminated, and will be refunded any advance paid for undelivered parts of the delivery. The Parties may not bring any other claims against each other as a result of termination of the Agreement pursuant to this provision.

# General Provisions

## Duty of Confidentiality

The Parties shall maintain confidentiality of, and prevent others from gaining access to or knowledge of, all confidential information and material of which they become aware of in connection with the Agreement and its execution. This includes, but is not limited to, information about:

1. Operational, commercial or business matters that may be of competitive importance to keep secret,
2. Any personal information.

The duty of confidentiality applies to the Parties' employees and others acting on behalf of the Parties in the execution of the Agreement. If necessary, a non-disclosure agreement must be signed. In such cases, it must be stated which information is covered by the duty of confidentiality and how it is to be safeguarded. The Parties shall maintain the duty of confidentiality even after the termination of the contractual relationship. Employees or others who resign from their service with one of the parties shall be required to maintain confidentiality even after resignation.

This provision does not prevent the information from being used to the extent necessary for the execution of the Agreement.

Both Parties can use general knowledge (know-how) that is not confidential and that they have acquired in connection with the Agreement.

The confidentiality provisions in the Act of 10 February 1967 concerning procedures in administrative matters (the Public Administration Act) also apply to the Parties and others for whom they may be responsible.

## Reputational Loyalty

The Customer and the Supplier shall safeguard each other's interests regarding the subject matter of the Agreement during the contract period. During the contract period, the parties shall not engage in activities that could harm the other Party's reputation. Nor shall the Parties discuss the terms or content of the Agreement in such a way that would or may damage the other Party's reputation or relationships with third parties. The Parties shall, upon request from third parties, inform that such enquiries shall be directed to the contact person for the Agreement.

## Audits

The Customer via 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 shall provide reasonable assistance – free of charge.

The Supplier has the right to conduct government-mandated audits of the Customer´s systems, routines and activities associated with the Framework 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 revisions, the Supplier and Customer may agree on compensation.

## Data processor

To the extent that the delivery involves the Supplier processing health and personal data on behalf of the Customer, the Supplier acts as a Data Processor. The Customer acts as the Data Controller. The Customer shall carry out an independent risk analysis before a data processing agreement can be entered into.

Processing of health and personal data cannot take place until a data processing agreement has been entered into between the Supplier and the Customer.

The Supplier is responsible for costs in connection with the risk assessment and data protection assessment resulting from changes in the Supplier's infrastructure that are not attributable to the Customer.

## Conveyance of the Agreement

The Customer may transfer its rights and obligations under the Agreement to other public entities, e.g. through restructuring of the health trusts, changes in ownership of the health trusts, changes in the regional structure and the like. The enterprise that receives the rights and obligations is entitled to corresponding terms, provided that the rights and obligations of the Agreement are transferred together.

The Supplier may only assign its rights and obligations under the Agreement with the written consent of the Customer. This also applies if the Supplier is merged with another company, split into several companies or if the transfer takes place to a subsidiary or other company in the same group. Consent shall not be unreasonably withheld. Any transfer constitutes an amendment and must be stated in Appendix 5 Change Protocol.

# Changes to the Framework Agreement

Any change to the Framework Agreement must be made in writing and will only be valid if signed by both Parties. No significant changes shall be done in the Agreement. Changes in or additions to the Framework Agreement may in any case not conflict with forskrift om offentlige anskaffelser av 12. august 2016 nr. 974 § 28-2. Any changes to the Framework Agreement made shall be included in Appendix 6.

When commercial packages are available and a maximum price has been set by the Norwegian Medicines Agency, an addition to the Framework Agreement shall be made. The addition shall contain item number(s) and price(s) for the medicine and be signed by both Parties. The Contract Manager shall then notify the Wholesaler(s) of price(s) and expected volume of the medicine.

In the event of any significant changes in the use of resources, the Hospital Pharmacy Enterprise shall have the opportunity to revise Appendix 4 – Section 5 after prior negotiations with the Supplier and 3 months written notice.

If the Supplier wants to start using or change subcontractor to fulfil obligations under the Framework Agreement, written consent from the Contract Manager is required.

# Disputes, Choice of Law and Venue

The Framework Agreement is governed by Norwegian law.

Disputes between the Parties regarding the Agreement should be resolved through negotiations.

If a dispute relating to the Agreement is not resolved by negotiations, the Parties may attempt to resolve the dispute by mediation. The Parties may choose to apply the Norwegian Bar Association's rules for mediation by a lawyer, or modified as the Parties wish. It is assumed that the Parties agree on a mediator with the expertise the Parties believe is best suited to the dispute. The detailed procedures for arbitration and mediation are determined by the mediator, in consultation with the Parties.

If the Parties do not come to an agreement, the dispute shall be settled by ordinary court proceedings. The place of venue for the Agreement is the Customer's jurisdiction, unless the Parties agree on another legal venue.

**List of Appendices**

Appendix 1: Contract Medicine(s)
Appendix 2: Administrative provisions
Appendix 3: Criteria for medical treatment
Appendix 4: Agreement between the Supplier and the Hospital Pharmacy Enterprise
Appendix 5: Contractual requirements for ethical trade
Appendix 6: Change protocol (not enclosed)