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National Standard Agreement

For the delivery and use of the pharmaceutical drug XXXX prior to marketing authorization and until decision to introduce to the Specialist Health Service

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0 General information

This National Standard Agreement constitutes a Framework Agreement (the 'Framework Agreement'). The Framework Agreement is based on 'Guidelines for use of new pharmaceutical drugs 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 pharmaceutical drugs 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.

1 Parties to the Framework Agreement

The Contracting Authorities and the Supplier are hereafter jointly referred to as the 'Parties'. The Parties to the Framework Agreement are listed on the front page.

The Framework Agreement is signed electronically in the portal www.pharmaweb.no. The Parties are individually responsible for keeping an edition signed by all Parties.

Customers (the 'Customer') that have the right and option to accede the Framework Agreement and call of contracts are listed in Appendix 2.

The Customer is responsible legally and economically for call offs made in accordance with the Framework Agreement.

If there is a restructuring of the Hospital Trusts in the duration of the Framework Agreement, cf. Lov om helseforetak m.m. av 15. juni 2001 nr. 93 § 50, the Customer´s legal successor may use the Framework Agreement. The same applies if a trust or company owned by the Customer is established in the duration of the Framework Agreement.

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').

2 The Subject of the Framework Agreement

The Framework Agreement gives the Customer the right to call off contracts that fall under the Framework Agreement and gives the Supplier the right and obligation to perform in accordance with the terms of the Framework Agreement. The Framework Agreement does not entail an obligation for the Customer to purchase a specific amount from the Supplier.

The Framework Agreement applies for all usage of the pharmaceutical drug(s) listed in Appendix 1 ('the pharmaceutical drug') as specified in Appendix 3. 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 not be included under the Framework Agreement from the time the pharmaceutical drug is granted its first marketing authorization ('MA') in Norway, regardless of which indication the MA applies to.

The Framework Agreement applies pharmaceutical drug in (remove redundant alternative / text):
Compassionate Use Program (CUP)
Compassionate Use Named Patient (CUNP)

Criteria for start-up and closure of treatment with the pharmaceutical drug is listed in Appendix 3.

The pharmaceutical drug(s) / item(s) covered by the Framework Agreement is listed in Appendix 1.

3 Documents in the Framework Agreement

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:

- This Framework Agreement with Appendices
- Other written documentation (Treatment Agreement)

Matters not covered by the Framework Agreement are governed by Lov om Kjøp av 13. mai 1988 nr. 27.

The cooperation agreements that exist between the Regional Health Authorities ('RHF') and the Association of the Pharmaceutical Industry in Norway ('LMI') and the RHF and Melanor constitutes appendixes to the Framework Agreement. A breach of any of the mentioned cooperation 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 here.

4 Duration of the Framework Agreement

4.1 Term

The Supplier undertakes to deliver the pharmaceutical drug 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 pharmaceutical drug and the pharmaceutical drug is available to purchase for a negotiated price or until all Treatment Agreements are concluded for medical reasons. If Beslutningsforum decides to introduce the pharmaceutical drug, this Framework Agreement will be superseded by a new framework agreement that regulates the negotiated terms for further use of the pharmaceutical drug, including guidelines given by Beslutningsforum.

If Beslutningsforum decides not to introduce the pharmaceutical drug, the Supplier is still obligated to deliver the pharmaceutical drug 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.

4.2 Inclusion of Patients

(Remove redundant alternative / text, include necessary text)
New patients may be included in Compassionate Use Program (CUP) /
Compassionate Use Named Patient (CUNP) until the pharmaceutical drug is granted MA.

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

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.

4.3 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 pharmaceutical drug. 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 pharmaceutical drug cannot be used as intended.

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 pharmaceutical drug to treat patients that are not enlisted in a Treatment Agreement.

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

4.4 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.

5 Prices and Price Regulation

5.1 Prices

5.1.1 Non-commercial packages

The Customer´s price for the pharmaceutical drug shall be zero (NOK 0) for as long as the Patient is treated with non-commercial packages or until the pharmaceutical drug is decided introduced and the pharmaceutical drug 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 pharmaceutical drug 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 pharmaceutical drug 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.

5.1.2 Commercial packages

The Customer´s price for the pharmaceutical drug is 10 % of the maximum price set by the Norwegian Medicines Agency, limited upwards to NOK 100 000 (both amounts in 'LIS GIP'; the Wholesaler(s) purchasing price as per the Customer´s agreement with the Supplier) per year per patient.

This price will entry 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 pharmaceutical drug is granted MA. The price will apply for as long as patients are in treatment or until the pharmaceutical drug is decided introduced, cf. 4.1 (1).

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

5.2 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.

5.3 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.

6 Ordering, Distribution and Delivery

6.1 Ordering and Distribution

6.1.1 Non-commercial packages

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

(Remove redundant alternative / text) The Supplier is responsible for import and distribution of the pharmaceutical drug directly to the Hospital Pharmacy Enterprise.

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

6.1.2 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.

6.1.2.1 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 pharmaceutical drug mainly takes place outside health trust

financing. In that case the Wholesaler(s) shall buy the pharmaceutical drug 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 pharmaceutical drug 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.

6.2 Terms of Delivery

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

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

6.2.1 Non-commercial packages

The pharmaceutical drug 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.

6.2.2 Commercial packages

The pharmaceutical drug 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.

6.3 Place of Delivery

6.3.1 Non-commercial packages

(Remove redundant alternative / text) Import shall be conducted by the Supplier and the pharmaceutical drug 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.

6.3.2 Commercial packages

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

6.4 Lead time

6.4.1 Non-commercial packages

The pharmaceutical drug 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.

6.4.2 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.

6.5 Delivery deviations

6.5.1 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.

6.5.2 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.

7 Requirements applicable to the Customer

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 pharmaceutical drug.

The Customer shall not use, produce or in other ways make use of the pharmaceutical drug before the Supplier has given the Customer the necessary training / information related to the pharmaceutical drug, 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 pharmaceutical drug and the Treatment Agreement.

The Customer shall use the pharmaceutical drug 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.

8 Requirements applicable to the Supplier

8.1 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.

8.2 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.

8.3 Routine in case of Product Recall

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

8.4 Ethical Trade

The Supplier undertakes that the pharmaceutical drug is produced in a lawful and ethical sound manner, cf. Appendix 6. If the Supplier use subcontractors(s) to fulfil the Framework Agreement, the Supplier is obligated to pass on the requirements for ethical trade to the subcontractor(s) and contribute to the subcontractor(s) compliance with the requirements.

8.5 Participation in Verification Scheme (Falsified Medicines Directive)

8.5.1 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.

8.6 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.

8.7 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.

8.8 The pharmaceutical drug

8.8.1 Regulatory requirements

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

8.8.1.1 Commercial packages

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

8.8.2 Shelf life

8.8.2.1 Commercial packages

The Supplier undertakes to deliver the pharmaceutical drug 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 pharmaceutical drug for regulatory reasons have a shorter shelf life.

If the Supplier receives an order for the pharmaceutical drug and the Supplier only has the pharmaceutical drug 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.

8.9 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.

8.10 Return of pharmaceutical drug / Destruction

8.10.1 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.

8.10.2 Commercial packages

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

- If the pharmaceutical drug is deregistered by the Norwegian Medicines Agency.
- If the pharmaceutical drug is withdrawn from sale by order of the Norwegian Medicines Agency.
- If the pharmaceutical drug has quality defects. Exceptions from this apply if damages or quality defects occur in the distribution chain from the Wholesaler(s).
- If the pharmaceutical drug is outdated, presumed that the Wholesaler(s) follows the 'first expired, first out"-principle. The same applies for return of the pharmaceutical drug 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 pharmaceutical drug that is unsold, given that the Supplier no longer has an agreement to deliver the pharmaceutical drug or that the Supplier has entered into a new agreement where significantly smaller volume of the pharmaceutical drug 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 pharmaceutical drug from the Wholesaler(s) to the Supplier presumes compliance to GDP 6.3 throughout the supply chain.

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

- The pharmaceutical drug 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 pharmaceutical drug.
- The Wholesaler(s) must destruct the pharmaceutical drug within four (4) months after the end of the duration of the Framework Agreement.

8.11 Training

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

The necessary training / information shall contain a summary of the relevant clinical and preclinical data concerning the pharmaceutical drug (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 pharmaceutical drug. 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.

9 Breach of Contract

9.1 Commercial packages

If the pharmaceutical drug 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.

10 Sanctions for Breach of Contract

10.1 Daily fines due to delays

10.1.1 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.

10.2 Compensation

10.2.1 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.

10.2.2 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.

10.3 Re-delivery

10.3.1 Quality deviations

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

10.3.2 Damage occurred after delivery

10.3.2.1 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 pharmaceutical drug free of charge for the Customer.

The Supplier undertakes to do its utmost to ensure re-delivery if damage occurs to the pharmaceutical drug 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.

10.4 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 pharmaceutical drug is significantly delayed or if there are repeated delays in individual deliveries.

10.4.1 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 pharmaceutical drug to treat patients that are not enlisted in a Treatment Agreement.

11 Force Majeure

Should an extraordinary situation arise which is beyond the control of the Parties, which makes it impossible to fulfil obligations under this agreement, and which could not reasonably have been considered at the conclusion of the Framework Agreement, the other Party shall be notified as soon as possible. The obligations of the affected Party are suspended for as long as the extraordinary situation lasts. The other Party's consideration is suspended for the same period.

In a Force Majeure situation, the other Party may only terminate the Framework Agreement with the affected Party's consent, or if the situation lasts or is assumed to last longer than 90 (ninety) calendar days, calculated from the time the situation arises. Each of the Parties 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 Framework Agreement is 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 result of termination of the Framework Agreement pursuant to this provision.

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.

At the time of entering into the Framework Agreement, a pandemic related to the covid-19 virus had broken out. According to the Framework Agreement's regulation for Force Majeure, this is a factor that the Supplier could reasonably have considered and thus not something that can be invoked as force majeure. In order not to exclude the possibility of invoking Force Majeure related to the covid-19 virus, the Framework Agreement's regulation for Force Majeure is amended for Force Majeure which has a primary causal connection to covid-19, so that the first paragraph of the provision reads:

Should there be an impediment to fulfilment

1. due to conditions with a primary causal connection to covid-19,
2. which is beyond the control of the Parties,
3. which makes it impossible to fulfil obligations under the Framework Agreement and
4. which is due to resolutions that had not been made, including import bans or stoppages in business or transport, or other circumstances that had not occurred at the time of entering into the Framework Agreement, including illness or quarantine for employees which had not already occurred,

the other Party shall be notified of this as soon as possible. The obligations of the affected Party are suspended for as long as the situation lasts. The other Party´s consideration is suspended for the same period.

12 General Provisions

12.1 The Principle of Loyalty

The Parties shall safeguard each other's interests regarding the subject matter of the Framework Agreement in the duration of the Framework Agreement. In the duration of the Framework Agreement, the Parties shall not engage in activities that weaken the other Party's reputation. The Parties shall also not discuss the terms or content of the Framework Agreement in such a way that this may damage the other Party's reputation or relationship with third parties. The Parties shall upon inquiry from a third party, state that such inquiries shall be directed to the contact person for the Framework Agreement.

12.2 Revision

The Contract Manager has the right to conduct necessary revisions of the Supplier´s systems, routines and activities connected to the Framework Agreement. In the event of a revision, the Supplier undertakes to provide reasonable assistance free of charge.

The Supplier has the right to conduct government-mandated revisions of the Customer´s systems, routines and activities connected to the Framework Agreement. A revision 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 a revision. In the case of labour intensive revisions, the Parties may agree on compensation.

12.3 Follow-up Meetings

The Contract Manager may convene a status meeting for the Framework Agreement in which the Contract Manager, the Customer and the Supplier participate.

12.4 Assignment

The Supplier may only transfer its rights and obligations under the Framework Agreement with the written consent of the Contract Manager. This also applies if the Supplier is merged with another company, divided into several companies or if the transfer takes place to a subsidiary or other company in the same group. The Contract Manager cannot deny to consent without objective reason.

13 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. 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 pharmaceutical drug and be signed by both Parties. The Contract Manager shall then notify the Wholesaler(s) of price(s) and expected volume of the pharmaceutical drug.

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.

14 Disputes

14.1 Applicable Law

The Framework Agreement is governed by Norwegian law.

14.2 Amicable Settlement

In the event of a dispute regarding the Framework Agreement, the Parties shall try to come to an amicable settlement by negotiations or mediation.

14.3 Court Proceedings

In the event that negotiations or mediation does not resolve a dispute, the dispute shall be brought before the ordinary Norwegian courts of law. If a dispute is to be decided in court, this does not entail that the Parties are released from fulfilling their obligations under the Framework Agreement.

14.4 Venue

Venue shall be the venue of the Contracting Authorities / the Customer unless the Parties agree upon another venue.

List of Appendices

Appendix 1: Pharmaceutical drug
Appendix 2: Administrative provisions
Appendix 3: Criteria for medical treatment
Appendix 4: Cooperation Agreement between the Supplier and the Hospital Pharmacy Enterprise
Appendix 5: Ethical requirements to the Supplier
Appendix 6: Changes to or additions to the Framework Agreement (not attached)