SYKEHUSINNKJØP

National Standard Agreement

for the delivery and use of the pharmaceutical drug

XXXX PRIOR TO MARKETING AUTHOROZATION AND UNTIL DECISION TO INTRODUCE TO THE SPECIALIST HEALTH SERVICE IN NORWAY

Case number: YYYY/NN

HELSE NORD HELSE MIDT-NORGE HELSE SØR-ØST HELSE VEST

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1 The Framework Agreement: Parties, Purpose and Background

This National Standard Agreement constitutes a Framework Agreement (the «Framework Agreement») for the delivery and use of the pharmaceutical drug «name of the drug» prior to marketing authorization and until decision on introduction to the Specialist Health Service of «name of the drug» (the «pharmaceutical drug»)

The Framework Agreement is concluded by

- South-Eastern Health Authority (Helse Sør-Øst RHF)
- Western Norway Health Authority (Helse Vest RHF)
- The Central Norway Health Authority (Helse Midt-Norge RHF)
- Northern Norway Health Authority (Helse Nord RHF)

hereafter jointly referred to as the «Contracting Authorities»

and

- The Supplier´s name and corporate form

hereafter referred to as the «Supplier».

The Contracting Authoritites and the Supplier are hereafter jointly referred to as the «Parties».

The Purpose of the Framework Agreement is to regulate the overall duties relating to delivery and receipt of the pharmaceutical drug to hospitals (Hospital Trusts and Hospital Pharmacy Enterprises – hereafter jointly referred to as the «Customer») that follow from binding agreements entered into after the commencement of the Framework Agreement. The Contracting Authorities, the Supplier and the Customer are hereafter jointly referred to as the «Parties to the Framework Agreement».

The Framework Agreement is based on the «Guidelines for use of new pharmaceutical drugs prior to marketing authorization» («Retningslinjer for bruk av nye legemidler før markedsføringstillatelse»). The document is available here.

The «Guidelines for use of new pharmaceutical drugs prior to marketing authorization» was subject to decision in The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway on February 2 2018 in case number 13-2018.

The Terms in the Framework Agreement can not be revised in following binding agreements between the Supplier and the Customer, excempt the Contracting Authorities´ written consent.

The Customers that have the option for delivery of the pharmaceutical drug under the Framework Agreement are listed in Appendix 2.

The criteria for medical treatment are listed in Appendix 3.

The criteria for medical treatment defines under which criteria patients may be included and any potential criteria to stop an ongoing medical treatment.

The Supplier is responsible for entering into a Treatment Agreement with the Customer treating the Patient. The Treatment Agreement shall contain details in regards to the treatment (ordering procedures, contact information and so forth). The Treatment Agreement is filed by both the Supplier and The Customer. The Supplier is responsible for providing Sykehusinnkjøp HF, divisjon legemidler (hereafter referred to as «LIS») with a copy of the finalized Treatment Agreement.

LIS will advise the Contracting Authorities on matters regarding the Framework Agreement and manage the Framework Agreement on behalf of the Contracting Authorities. The Framework Agreement(s) will be signed electronically in www.pharmaweb.no.

2 The Subject of the Framework Agreement

The Framework Agreement applies to all use of the pharmaceutical drug cf. Appendix 1 and Appendix 3. The Framework agreement applies to all patients meeting the medical criterias in Appendix 3. The number of patients can not be limited by the Supplier to a predefined number. Any new patients may not be included under the terms of the Framework Agreement after the pharmaceutical drug is granted its first marketing authorization, regardless of which indication the marketing authorization applies to.

Remove reduntant alternatives:
Compassionate Use Program (CUP)
Compassionate Use Named Patient (Godkjenningsfritak)

The Responsible Clinician must apply for approval from the Supplier, and adhere to regulatory requirements (approval exemption from the Norwegian Medicines Agency) before starting treatment for any given Patient. The Responsible Clinician and the Health Trust have the sole responisiblity for the medical treatmets of Patients and for all use of the pharmaceutical drug.

3 Documents in the Framework Agreement

The Framework Agreement comprimises the following documents: This Framework Agreement with Appendixes 1-6 and any other written documentation. Should there be a conflict between any provisions in the documents, the order of priority shall be:

- The Framework Agreement with all Appendixes generated in PharmaWeb
- Other written documentation (The finalized Treatment Agreement)

Meetings between the Customer and its employees and the Supplier shall be conducted in accordance with the guidelines of the Customer and the cooperation agreement between the RHFs (the Contracting Authorities) and the Association for the Pharmaceutical Industry in Norway (Legemiddelindustrien – in Norwegian referred to as «LMI») / Melanor - Bransjeforeningen for medtek og lab (in Norwegian referred to as «Melanor»). The cooperation agreements between the RHFs and LMI and the RHFs and Melanor constitutes appendixes to the guidelines for the day-to-day cooperation. 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 cooperation agreements is available here.

4 Commencement and Duration of the Framework Agreement

4.1 *Commencement and Duration*

The Supplier shall from the start of a medical treatment deliver the pharmaceutical drug free of charge until The National System for Managed Introduction of New Health Technologies within the Specialist Health Service in Norway decides to introduce the pharmaceutical drug and the pharmaceutical drug is available to purchase for a negotiated price. This Framework Agreement will then be superseded by a new Framework Agreement between the Contracting Authorities and the Supplier that regulates the negioated terms for further use of the pharmaceutical drug.

If the pharmaceutical drug is decided not to be introduced to the Spesialist Health Service in Norway, the Supplier is obligated to deliver the pharmaceutical drug free of charge to those patients that have started treatment, until treatment is stopped for medical reasons.

4.2 *Termination / Breach*

The Parties to this Framework Agreement are entitled to terminate parts or all of this Framework Agreement with immidiate effect if medical information emerges indicating that the pharmaceutical drug can not be used as intended.

5 Costs of using the pharmaceutical drug

5.1 Prices

The price for the pharmaceutical drug shall be zero (0) for as long as there are patients being treated or until the pharmaceutical drug is decided introduced, cf. 4.1.

All expenses for the pharmaceutical drug and delivery cost (either to Hospital Pharmacy Enterprise or to Wholesaler and Hospital Pharmacy Enterprise) shall be paid by the Supplier, including transportation expenses, production etc. and any regulatory fees, including statutory import value added tax.

All prices are to be index linked January 1st every year according to the wage and price index (Statistics Norway – in Norwegian «Statistisk sentralbyrå»).

5.2 Terms of Payment

The Hospital Pharmacy Enterprise will invoice the Supplier for its own services (and the Wholesaler´s services) on a monthly basis.

Payment terms for an invoice from the Hospital Pharmacy Enterprise is 30 days.

6 Ordering and Distribution

Remove reduntant alternatives:

The Supplier will import the pharmaceutical drug and distribution (import) is directly to the Hospital Pharmacy Enterprise: Ordering of the pharmaceutical drug will be done by the Hospital Pharmacy Enterprise.

Distribution is to be carried out by an Wholesaler: The Supplier must have a valid Norwegian Wholesaler- and Quality-Agreement with the current Wholesaler(s). Ordering of the pharmaceutical drug will be done by the Wholesaler(s).

The Hospital Pharmacy Enterprise will import the pharmaceutical drug: Ordering and formalities regarding to this is specified in Appendix 4.

7 Delivery

7.1 *Terms of Delivery*

The Supplier shall deliver the pharmaceutical drug that is produced, transported and stored in accordance with current GMP / GDP (Good Manufacturing Practice / Good Distribution Practice)
The pharmaceutical drug shall be delivered to the Hospital Pharmacy Enterprise in accordance with Incoterms DDP.

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

Remove reduntant alternatives:

Delivery to a Wholesaler shall be carried out in accordance with agreement between the Supplier and the Wholesaler, and as a minimum in accordance with the terms of this Framework Agreement, see Appendix 5.

Delivery to a Hospital Pharmacy Enterprise shall be carried out in accordance with the terms of this Framework Agreement, see Appendix 4.

7.2 *Place of Delivery*

Remove reduntant alternatives:

Import is to be carried out by the Supplier and the pharmaceutical drug is delivered directly to the Hospital Pharmacy Enterprise. See Appendix 4.

Import is to be carried out by the Wholesaler to the Hospital Pharmacy Enterprise. See Appendix 5.

Import is to be carried out by the Hospital Pharmacy Enterprise. See Appendix 4.

7.3 *Lead time*

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.

7.4 *Deviations*

7.4.1 Deviations in Delivery

The Supplier shall as soon as possible notify the Hospital Pharmacy Enterprise if a delivery can not be made in accordance with an agreed delivery time. If the delay lasts beyond the first three days after the agreed delivery time, the Hospital Pharmacy Enterprise may claim compensation from the Supplier for an economic loss that arises for the Hospital Pharmacy Enterprise itself or the Customer due to the delay.

7.4.2 Deviations in Quality

The Customer have the right to demand redelivery (replacement of the pharmaceutical drug) if the delivered pharmaceutical drug has deviations in quality.

7.5 Redelivery due to damage that occurs after delivery

The Customer have the right to demand redelivery (replacement of the pharmaceutical drug) if the pharmaceutical drug is damaged after initial delivery.

In case of redelivery (replacement of the pharmaceutical drug) which is due to circumstances arising after handover to the Customer, the Supplier´s necessary costs relating to transportation shall be paid by the Hospital Pharmacy Enterprise.

In case of redelivery (replacement of the pharmaceutical drug) which is due to lack of necessary information / training from the Supplier, the Supplier shall redeliver (replace the pharmaceutical drug) free of charge for the Customer.

The supplier shall in all cases pay any obligatory import value added tax.

7.6 *Return of pharmaceutical drug / Destruction*

Remove reduntant alternatives

Return to the Hospital Pharmacy Enterprise and destruction will be carried out in accordance with the Hospital Pharmacy Enterprise´s internal procedures, unless otherwise is agreep upon and specified in Appendix 4.

Return to the Wholesaler and destruction will be carried out in accordance with the Wholesaler´s internal procedures and terms, unless otherwise is agreep upon and specified in Appendix 5.

8 Requirements applicable to the Customer

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 information / training related to the pharmaceutical drug, cf. 9.5.

The Customer shall notify the Supplier as soon as there are new patients it is appropriate to treat and keep the Supplier updated on current treatments and any possible discontination of treatments.

Section 8 must be viewed in light of the type of pharmaceutical drug and the Treatment Agreement.

9 Requirements applicable to the Supplier and the pharmaceutical drug

9.1 *Requirements for routines for product recall*

The Suppliers hall 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.

9.2 *Requirements for ethical trade*

It is required that products covered by this Framework Agreement are produced in a lawful and ethical sound manner, see Appendix 6 – «Ethical requirements for the Supplier». If the Supplier uses subcontractors to fulfill the Framework Agreement, the Supplier is obliged to pass on the requirements for etichal trade to the subcontractor and contribute to the subcontractors compliance with the requirements.

9.3 *Requirements for membership of the Drug Liability Association*

The Supplier shall have and maintain product liability insurance through the Norwegian insurance scheme for pharmaceuticals («the Drug Insurance»). The Supplier shall carry such insurance through membership of the Drug Liability Association (in Norwegian «Legemiddelansvarsforeningen»). Documentation proving such membership shall be provided prior to the commencement of the Framework Agreement.

9.4 *Requirements for membership in a return scheme*

Norwegian suppliers will no later than the commencement of the Framework Agreement produce documentation proving that the Supplier is a member of a return scheme for the return of waste / excess packaging or that the Supplier complies with the requirements through its own return scheme where the waste / excess packaging is handled in an environmentally friendly way («Grønt Punkt Norge AS» or similar arrangement). Foreign Suppliers not able to obtain a membership in Grønt Punkt Norge AS or similar arrangement, is obligated to enter into an agreement with the applicable Wholesaler ensuring that the Wholesaler pays the packaging fee to the return scheme on behalf of the Supplier.

9.5 *Requirements for training*

The Supplier shall give the necassary information / training related to the pharmaceutical drug before the Customer use, produce or in other ways make use of the pharmaceutical drug, cf. 8.1.

The necassary information / training shall include a summary of those clinical and pre-clinical data relating to the pharmaceutical drug that is of relevance (according to «Investigator´s Brochure» and «Pharmacy Manual»), for example any safety measures that must be taken in connection with the storage, handling, manufacture and use of the pharmaceutical drug.

If the Supplier fail to give the necassary information / training relating to the pharmaceutical drug, in accordance with the information avilable at the time of the conclusion of the Framework Agreement, the Supplier may be held liable for any damage or financial loss incurred by the Customer.

Meeting activities shall be conducted in accordance with the guidelines of the Customer and in accordance with the cooperation agreements as mentioned in section 3.

10 General provisions

10.1 *Revision*

The Customer is entitled to audit the Supplier´s systems, routines and activities that relate to the delivery of the pharmaceutical drug. In the case of an audit, the Supplier shall provide reasonable assistance free of charge.

10.2 *Follow-up meetings*

LIS may call for a status meeting where LIS, the Customer and the Supplier participate.

Both the Customer and the Supplier are obliged to keep available necessary personnel for these meetings.

10.3 *The principle of loyalty*

The Parties to the Framework Agreement shall have due regard to the other party´s interests in relation to the pharmaceutical drug during the duration of the Framework Agreement. The Parties to the Framework Agreement shall during the duration of the Framework Agreement refrain from activitites that may harm the other party´s reputation. The Parties to the Framework Agreement undertakes to refrain from mentioning the terms or content in such a way that it may harm the other party´s reputation or relation to third parties. The Parties to the Framework Agreement shall not externally consider or comment on the views or dissatisfaction of patients or others who adress the Parties of the Framework Agreement, but state that such inquieries shall be directed to the party´s contact person for the Framework Agreement.

10.4 *Publicity*

Neither the Contracting Authorities, the Customer or the Supplier shall use the other party´s name, logo or the like in any form of marketing, advertising or statement without the other party´s consent.

10.5 *Assignment*

If during the duration of the Framework Agreement a restructuring of the Customer or other entities that are wholly or partly owned by the Contracting Authorities occurs, or a restructuring of the Supplier, the party´s legal successor may use the Framework Agreement. The same applies if during the duration of the Framework Agreement an antity / enterprise owned by the Customer and / or the Supplier is established.

If the Supplier sells or in any other way transfers the rights to the pharmaceutical drug to a third party, LIS shall be notified.

Apart from these exceptions, neither the Contracting Authorities, the Customer or the Supplier may transfer its rights or obligations under the Framework Agreement to a third party, without the other contracting party´s written consent.

11 Changes to the Framework Agreements / Renegotiations

If during the Framework Agreement the Hospital Pharmacy Enterprise experiences any significant change in the scope of resource allocation in relation to the Framework Agreement, the Hospital

Pharmacy Enterprise is entitled to revise Appendix 4 Section 5 after prior negotiations with the Supplier and after a written notice of three months.

Other changes to the Framework Agreement shall be made in writing and will only be valid if it signed by both the Contracting Authorities and the Supplier.

12 Disputes

12.1 *Applicable law*

The Framework Agreement shall be subject to Norwegian law and the Norwegian courts of law.

12.2 *Amicable Settlement*

If a dispute regarding the Framework Agreement arises, the parties to the dispute shall try to come to an amicable solution by negotiations or mediation.

12.3 *Court proceedings*

If negotiation or mediation does not resolve the dispute, the dispute shall be brought before the ordinary Norwegian courts of law. If a dispute is to be tried in court, this does not in itself release the Parties to the Framework Agreement from their rights and obligations under the Framework Agreement.

12.4 *Venue*

Venue shall be the Contracting Authorities / The Customer`s venue, unless the parties to a dispute agree upon another venue.

13 Signatures

The Framework Agreement is only processed electronically in www.pharmaweb.no. Both the Contracting Authorities and the Supplier is responsible for filing a copy signed by both parties.

14 List of Appendices

Appendix 1: Pharmaceutical drug
Appendix 2: The Customers with an option for delivery of the pharmaceutical drug
Appendix 3: The Criteria for medical treatment
Appendix 4: Template Agreement between the Supplier and the Hospital Pharmacy Enterprise
Appendix 5: Cooperation Agreement between the Supplier and the Wholesaler [Redunant if the Supplier or the Hospital Pharmacy Enterprise is to import the pharmaceutical drug]

Appendix 6: Ethical requirements for the Supplier

Appendix 6:

Ethical requirements to the Supplier

Ethical requirements – contract terms

The Supplier shall respect basic human- and labour rights and the environment, both in their own business and the supply chain. The Supplier shall respect basic human- and labour rights and the environment, both in their own business and the supply chain.

The Supplier undertakes to deliver pharmaceuticals to the Norwegian RHF´s underlying health trusts (the Customer), which are produced under conditions which complies with the provisions set out below. The provisions are based on key UN conventions, ILO conventions and national labour legislation at the place of production.

The provisions describe minimum standards. Where international conventions and national laws and regulations address the same issues, the highest standard applies. The Suppliers will ensure compliance with the provisions in the supply chain when using sub suppliers to fulfill the Framework Agreement.

Rights of the employees - The fundamental conventions of the International Labour Organization (ILO)

The Supplier will ensure compliance with the fundamental conventions of ILO in their own business and with the sub suppliers contributing to the fulfilment of the Framework Agreement. This implies:

Prohibition against child labour (UN Convention on the Rights of the Child art. 32, ILO Conventions no. 138 and 182)

- Every child has the right to be protected against economic exploitation in work, and against carrying out work which may undermine their educational and developmental opportunities.
- The minimum age for workers shall not be less than 15 and comply with
    - the national minimum age for employment, or;
    - the age of completion of compulsory education,

whichever of these is higher. If local minimum is set at 14 years in accordance with developing country exceptions under ILO Convention 138, this lower age may apply.

- There shall be no recruitment of child labour defined as any work performed by a child younger than the age(s) specified above.
- No person under the age of 18 shall be engaged in labour that is hazardous to their health, safety or morals, including night work.
- In cases of child labour, the Supplier shall work towards a speedily outphasing. The Supplier shall at the same time undertake to ensure that children are being provided for and able to pursue an education until the child is no longer of school age.

Prohibition against forced and compulsory labour (ILO Conventions no. 29 and 105)

- There shall be no forced labour, bonded or involuntarily prison labour.
- Workers shall not be required to lodge deposits or identity papers with their employer and shall be free to terminate the contract of employment with a reasonable period of notice.

Prohibition against discrimination (ILO Conventions no. 100 and 111)

- There shall be no discrimination in the working life due to ethnicity, religion, age, disabilities, gender, marital status, sexual orientation, membership in a trade union or political affiliation.

Freedom of association and the protection of the right to collective bargaining (ILO Conventions no. 87 and 98)

- Workers, without exeption, shall have the right to join or form trade unions of their own choosing and to bargain collectively. The employer shall not interfere with or obstruct the formation of unions or collective bargaining.
- The Supplier shall contribute so that the workers are able to meet the management to discuss wages and general conditions if these rights are limited or under development. The workers shall not suffer negative consequences as a result.

Statutes and regulations in national law

The Supplier will ensure compliance with labour law and labour legislation, both in their own business and with the sub suppliers contributing to the fulfilment of the Framework Agreement. This implies compliance with laws and regulations regarding 1) wage and working-time provisions; 2)

health, environment and security; 3) regular employment conditions; 4) inhumane and harsh treatment; and 5) relevant statutory social insurances.

Follow-up

The Supplier will ensure compliance with the rights set out in the paragraphs above, both in their own business and with the sub suppliers who contribute to the fulfilment of the Framework Agreement. This will upon request be proved or documented in one of the following ways:

- Self-assesments and/ or
- Follow-up meetings and/ or
- An audit by an independent third party[1] and/ or
- Third party certification, for example SA8000 or the like.

Breaches

Breaches of the provisions will be regarded as breaches of the Framework Agreement. The Supplier is, in the event of such a contractual breach, obliged to remedy the highlighted breaches within a deadline set by Sykehusinnkjøp HF, divisjon legemidler, as long as the deadline is not unreasonably short.

The rectifications shall be documented in writing and in the manner decided by Sykehusinnkjøp HF, divisjon legemidler. Failure to remedy the breach / breaches may be regarded as a serious breach giving Sykehusinnkjøp HF, divisjon legemidler the right to terminate the Framework Agreement on behalf of the Contracting Authorities / Customers to the Framework Agreement.

1 The Contracting Authority, or a party authorised by the Contracting Authority, shall have the right to conduct announced, semi-announced or unannounced audits of one or several parties in the supply chain during the contract period. The Supplier shall, in the event of an audit, be obliged to provide the names of and contact information for sub-suppliers. Contact information shall be treated confidentially.