

APPENDIX 7. NATIONAL REQUIREMENTS IN NORWAY

Case number:



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0. GENERAL INFORMATION ABOUT THIS APPENDIX

The provisions of the Appendix (any given sections) are not separately consecutively numbered but are numbered according to the clause of the Framework Agreement to which they relate.

1. THE FRAMEWORK AGREEMENT

- 1.1.a The Norwegian Hospital Procurement Trust (hereafter referred to with the Norwegian name “Sykehusinnkjøp HF”) was established 17 December 2015. Sykehusinnkjøp HF is owned by the four Regional Health Authorities (in the following referred to by the Norwegian abbreviation “RHF” / “RHF’s”) with 25 percent each: Helse Sør-Øst RHF, Helse Midt-Norge RHF, Helse Vest RHF og Helse Nord RHF. Sykehusinnkjøp HF has the strategical and operational responsibility for procurements in the specialist health services in Norway. Legemiddelinnkjøpssamarbeidet (“LIS”) was transferred to Sykehusinnkjøp HF 1 November 2016 and named division pharmaceuticals (hereafter referred to as “Sykehusinnkjøp HF, divisjon legemidler”).
- 1.1.b Sykehusinnkjøp HF, divisjon legemidler is the Norwegian Contracting Authority on behalf of the four Regional Health Authorities and their underlying Health Trusts / Customers as specified in section 1.2.c.
- 1.1.c Sykehusinnkjøp HF, divisjon legemidler is registered as a broker of medicinal products in Norway.
- 1.2.a The Customers specified in section 1.2.c have the right, but not the obligation, to purchase pharmaceuticals from the Supplier on an ongoing basis.
- 1.2.b Each Customer is legally and financially responsible for orders placed under the Framework Agreement. Sykehusinnkjøp HF, divisjon legemidler will advise the Customers on matters regarding the Framework Agreement and manage the Framework Agreement on behalf of the Customers.
- 1.2.c Information regarding the four RHF’s and the underlying Health Trusts in Norway as well as other noncommercial hospitals (all named by their Norwegian names) who shall have the prospect of entering into the Framework agreement:



Regional Health Authorities (RHF)

Helse Sør-Øst RHF

Helse Vest RHF

Helse Midt-Norge RHF

Helse Nord RHF

Health Trusts / Customers

Akershus universitetssykehus HF

Diakonhjemmet Sykehus

Lovisenberg diakonale sykehus

Oslo Universitetssykehus HF

Sykehuset Østfold HF

Sykehuset Innlandet HF

Sykehuset i Vestfold HF

Sykehuset Telemark HF

Sørlandet Sykehus HF

Vestre Viken HF

Sunnaas sykehus HF

Helse Stavanger HF

Helse Fonna HF

Helse Bergen HF

Helse Førde HF

Helse Møre og Romsdal HF

St. Olavs hospital HF

Helse Nord-Trøndelag HF

Helgelandssykehuset HF

Nordlandssykehuset HF

Universitetssykehuset i Nord-Norge HF

Finnmarkssykehuset HF



- 1.3.a The Customer, or its representative, will place orders with a Wholesaler (hereinafter referred to as “the Wholesaler”) appointed by the RHF. The Wholesaler will be responsible for the ordering of pharmaceuticals from the Supplier and for the invoicing and payment, see section 8 and 11. The Supplier will deliver pharmaceuticals to the Wholesaler, see section 9.
- 1.3.b At the commencement of the Framework Agreement the following applies:
- Pharmaceuticals being used in the Customers hospital facilities or delivered to patients from the hospital pharmacy enterprises serving the public, are covered by an agreement with Alliance Health Care Norge AS. Alliance Health Care Norge AS is the Wholesaler for delivery to the Customers.
 - Pharmaceuticals being delivered to patients in privately owned pharmacies and financed by the RHF (in Norwegian “H-reseptlegemidler”), are covered by an agreement with Norsk Medisinaldepot AS.
- 1.3.c The RHF may enter into wholesale agreements with other Wholesalers during the agreement period of the Framework Agreement. Sykehusinnkjøp HF, divisjon legemidler will inform the Supplier of any change regarding Wholesaler agreements in order for the Supplier to enter into agreements with another Wholesaler.
- 1.3.d The Supplier shall have a valid wholesale- and quality agreement with the Wholesaler before the commencement of the agreement period. The agreement shall reflect and ensure compliance with the terms and conditions of the Framework Agreement including the appendices.
- 1.7.a Sykehusinnkjøp HF, divisjon legemidler has drawn up Guidelines for the day-to-day cooperation in connection with delivery of medicines to the Wholesaler in Norway. The guidelines will be available at Sykehusinnkjøp HF’s homepage. The Supplier is required to be familiar with the guidelines as they include a description of the procedures regarding delivery to the Norwegian market. In case of conflict between the guidelines and the Framework Agreement / Appendix 7, the Framework Agreement / Appendix 7 will prevail.



4. REQUIREMENTS APPLICABLE TO THE SUPPLIER AND THE PHARMACEUTICALS

- 4.3.a Pharmaceuticals are required to have a valid item number on the item number update from Farmalogg two months prior to the commencement of the Framework Agreement, see clause 4.3 of the Framework Agreement.

The Supplier is, in case of a delay, obligated to inform Sykehusinnkjøp HF, divisjon legemidler as soon as possible. The information shall contain the reason for the delay. Delays will be regarded as backorders, see clause 12.1.1 of the Framework Agreement.

In order to ensure that the item number is included in the item number update from Farmalogg [e.g. 1 December 2019], an item number has to be assigned from Farmalogg at least 14 days in advance [e.g. 15 November 2019] at the latest. Please note that it takes Farmalogg 1-5 days to assign an item number.

Suppliers without a valid item number have to apply for an item number from Farmalogg. For more information see: <https://www.farmalogg.no/en/Info-about-article-numbers/>

The Supplier shall send Sykehusinnkjøp HF, divisjon legemidler the receipt from Farmalogg showing that the Supplier has applied for and is assigned an item number. The information shall be sent to annkir@sykehusinnkjop.no.

- 4.5.a The Supplier shall have and maintain product liability insurance through the Norwegian insurance scheme for pharmaceuticals (“the Drug Insurance”), in accordance with The Norwegian Product Liability Act of 23 December 1988, Chapter 3. 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.
- 4.7.a Return of pharmaceuticals in accordance with the Framework Agreement clause 4.7 shall be regulated by current Wholesaler agreement(s) between the Customer and the Wholesaler(s) (return from the Customer / Hospital pharmacy enterprise to the Wholesaler(s), if need be, before return to the Supplier), and between the Wholesaler and the Supplier in a manner as they agree upon, see section 1.3.d and the Framework Agreement clause 12.8.2.



5. INFORMATION ON THE PHARMACEUTICALS AND COOPERATION

5.3.a 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 RHF's and the Association for the Pharmaceutical Industry in Norway (Legemiddelindustrien – in Norwegian referred to as “LMI”). The cooperation agreement between the RHF's and LMI constitutes an appendix to the guidelines for the day-to-day cooperation, see clause 1.7.a of this appendix.

7. CORPORATE SOCIAL RESPONSIBILITY

7.3.a 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 complies with the duty through its own return scheme where the waste / excess packaging is handled in an environmentally friendly way (Grønt Punkt Norge or similar). Foreign Suppliers not able to obtain a membership in Grønt Punkt Norge AS, 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.

7.3.b 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 and underlying health authorities, 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:

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

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.

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
 - o the national minimum age for employment, or;
 - o 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 exception, 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-assessments and/ or
- Follow-up meetings and/ or
- An audit by an independent third party¹ and/ or

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



- Third party certification, for example SA8000 or the like.

Breaches

Breaches of the provisions in sections 7.3.a and 7.3.b 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 for Sykehusinnkjøp HF, divisjon legemidler and on behalf of the RHF's / Customers listed in section 1.2.c.

8. ORDERING

- 8.1.a The individual Hospital Pharmacy enterprise or the pharmacy providing the hospital with pharmaceuticals will place continuous orders with the Wholesaler.
- 8.1.b The Wholesaler will be responsible for placing orders with the Supplier. Orders will be placed continuously.
- 8.1.c Further requirements regarding the order of pharmaceuticals will be regulated in an agreement between the Wholesaler and the Supplier, see section 1.3.d.
- 8.1.d The item number from Farmalogg shall appear on the confirmation of order.

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.



9. DELIVERY

- 9.1.a The Supplier delivers the order no later than 5 working days after the Supplier's receipt of the order. "Working days" means Mondays through Fridays, except for Norwegian public holidays. Since the date of some Norwegian public holidays may change from year to year, contact between the Supplier and the Wholesaler, to make sure ordered pharmaceuticals is delivered, is required.
- 9.1.b The Supplier will deliver DDP (Delivery Duty Paid according to the latest available version of Incoterms) to the Wholesaler, see section 1.3.
- 9.1.c The Supplier will deliver pharmaceuticals to the Wholesaler in accordance with the Supplier's agreement with the Wholesaler and the Framework Agreement including appendices, see section 1.3.d.
- 9.4.a Regarding requirement 9.4 to 9.8 in the Framework Agreement:
The requirements stated in the Framework Agreement applies unless the Supplier and the Wholesaler agrees differently.

10. PRICES

- 10.1.a The pharmaceuticals is sold to the Wholesaler to the prices in NOK listed in Appendix 1, see the Framework Agreement clause 10.
- 10.1.b The pharmaceuticals are sold to the Customer to the Pharmacies Retail Price (in the following referred to as "PRP"). The PRP will, in addition to the price in NOK listed in appendix 1, include the Wholesalers' margin (regulated in an agreement between the four Regional Health Authorities in Norway and the Wholesaler), the pharmacy mark up (regulated by the Norwegian government), a packaging fee (regulated by the Norwegian government) and value added tax (VAT).



11. TERMS OF PAYMENT

11.1.a The Wholesaler will be responsible for invoicing and payment. At the commencement of the Framework Agreement the following applies:

Invoices will be sent per e-mail to the Wholesaler(s). See section 14.

11.1.b The item number from Farmalogg shall appear on the invoice.

11.1.c The payment conditions for the Wholesaler will not be less than the rest of the month free after delivery plus 30 days.

11.1.d The terms of payment will be further specified in the agreement between the Supplier and the Wholesaler prior to the commencement of the Framework Agreement., see section 1.3. The Supplier and the Wholesaler have to agree upon a model for the settlement of accounts, see section 11.1.e.

11.1.e The Supplier and the Wholesaler shall settle the accounts for the pharmaceuticals delivered under the Framework Agreement according to one of the following models for the settlement of accounts:

- A) The Wholesaler purchase the pharmaceuticals to the price in NOK listed in appendix 1. However, if a pharmaceutical is bought to the price in NOK listed in appendix 1 and is sold to another buyer than one of the Customers (see section 1.2.c), the Wholesaler shall pay the Wholesaler's ordinary purchase price for the pharmaceutical to the Supplier. This indicates a system with two prices for pharmaceuticals delivered to the Wholesaler.
- B) The Wholesaler purchase the pharmaceuticals to the Wholesaler's ordinary purchase price. If the pharmaceutical is sold to one of the Customers (see section 1.2.c), the Supplier will refund to the Wholesaler - or be refunded by the Wholesaler - (whichever is applicable, depending on the prices) the difference between the price in NOK listed in appendix 1 and the Wholesaler's ordinary purchase price.

11.1.f Due to technicalities with the accounts, the Supplier has to commit to sell the pharmaceuticals to the price in NOK listed in appendix 1 to the Customers in the agreement with the Wholesaler, see section 1.3.d.



12. BREACH BY THE SUPPLIER

12.7.1.a The Supplier shall immediately inform Sykehusinnkjøp HF, divisjon legemidler, the Wholesaler and the Function for shortage of pharmaceuticals and pharmaceuticals emergency preparedness ("Mangelscenteret" – mangelscenteret@ous-hf.no) in the situations stated in the Framework Agreement clause 12.

12.8.2 Instead of returning the pharmaceuticals to the Supplier, the Customer concerned may upon the prior written consent of the Supplier destruct the pharmaceuticals. Pharmaceuticals being destructed shall be listed on the monthly return notice, and the Supplier shall credit the value (price stated in Appendix 1) at the time of return. In order to cover the cost incurred due to destruction, the Supplier shall pay a fee of 1 % of the previous invoiced price for the pharmaceuticals.

14. CONTACT PERSONS

14.2.a The day-to-day contact person of **Sykehusinnkjøp HF, divisjon legemidler**

Name: Monica Stensgård

Phone no: +47 47 25 62 92

E-mail adress: monica.stensgaard@sykehusinnkjop.no

14.2.b The contract manager of **Sykehusinnkjøp HF, divisjon legemidler**

Name: Bente Hayes (Director of Sykehusinnkjøp HF, divisjon legemidler)

Phone no: +47 90 17 95 21

E-mail adress: bente.hayes@sykehusinnkjop.no

14.2.c *Wholesaler – Alliance Health Care Norge AS*

Name: Mimmi Skandsen (Head of Rx)

Phone no: +47 91 87 86 67



E-mail adress: m.skandsen@boots.no

14.2.d *Wholesaler – Norsk Medisinaldepot AS*

Name: Hans-Arvid Karlsen (Head of buying)

Phone no: +47 97 08 86 21

E-mail adress: hans-arvid.karlsen@nmd.no