

TENDER PROCEDURE RULES

Procedure with negotiations after prior announcement

pursuant to the Norwegian Public Procurement Act and Norwegian Public Procurement Regulations, part I and part III

Tender for delivery of Advanced Unit Dose Dispensing and Packaging Solution

for delivery to

Sykehusapotekene i Midt-Norge HF
Sykehusapotekene HF

Case archive no.: 2022/512

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1 General information regarding the tender procedure

1.1 Contracting Authority

Sykehusinnkjøp HF was founded on 17 December 2015 and has the strategic and operational responsibility for procurements in the specialist health services. The enterprise has four owners, Helse Sør-Øst RHF, Helse Nord RHF, Helse Midt-Norge RHF and Helse Vest RHF, each of which owns 25 percent.

The enterprise shall only offer services to its owners, their wholly owned organisations, non-profit organisations with service-level agreements with the regional health authorities and organisations subject to or wholly-owned by the Norwegian Ministry of Health and Care Services that contribute to delivering specialist health services.

In this tender procedure, Sykehusinnkjøp HF Division Vest, acts on behalf of the following enterprises:

- Sykehusapotekene i Midt-Norge HF
- Sykehusapotekene HF

1.2 Communication

All communication in the process shall occur via the Merccell portal, www.merccell.no. Other communication with individuals participating in the decision-making process is not permitted, and replies should not be expected to enquiries made otherwise. This is to ensure that all communication is logged. For questions that concern all tenderers, the Contracting Authority will answer in anonymised form by providing the answer as supplementary information.

1.3 Purpose and scope of the procurement

The purpose of this tender is to purchase an advanced unit dose production solution, including hardware, software, maintenance and support of the software, consumables and spare parts to Sykehusapotekene i Midt Norge HF and Sykehusapotekene HF (Optional). This advanced solution should be able to produce unit doses from various medication forms, have sufficient capacity, and have a high degree of automation throughout the solution. The tender also includes services such as training, documentation, maintenance, development of the software/hardware, and more as needed.

Sykehusapotekene i Midt-Norge HF has decided to establish a centralized production plant for unit doses, located at the Hospital Pharmacy in Trondheim. The unit doses produced in Trondheim will be distributed to the other hospital pharmacies in HMN, stored at these pharmacies and then dispensed for use at their local hospitals. The unit doses will be delivered to local ward stocks at the hospitals, but some patient specific deliveries may be part of a future solution. The offered solution must be suitable to fulfill the needs of Sykehusapotekene i Midt-Norge's total planned workflow, including unit dose production at the centralized production plant, and storage and further handling of the unit doses, both at the centralized production plant and at the regional hospital pharmacies.

According to the planned design, the production plant in Trondheim will include:

- fast-dispensing unit dose production systems (UDPS) that produce unit doses from bulks of oral solids (these are part of a different tender).
- advanced unit dose production systems (UDPS) for producing unit doses from other medication forms.

The total production volume needed of unit doses is expected to be approximately 8 million unit doses in 2025. Approximately 2,4 millions of these unit doses will be produced from the advanced UDPS subject of this tender. The offered solution must be able to work in connection with all the other elements needed for the total production plant, in accordance with the workflow and ICT structure described in Part II – K Appendix 3.

The offered solution shall be operated by Pharmacy staff with sufficient training from the Contractor.

1.4 Partial tenders

This tender procedure is divided into 2 partial tenders.

- Contract 1 - Sykehusapotekene i Midt-Norge HF (Region Central)
- Contract 2 (Optional) - Sykehusapotekene HF (Region South-East)

The Tenderers may submit tenders for one or more of the partial tenders.

1.5 Number of suppliers

The Contracting Authority will enter into agreements with 1 Contractor for each partial tender.

1.6 Agreement period

Not applicable.

1.7 Option of extension

Not applicable.

1.8 Other options

The Contracting Authority shall have the option of expanding the agreement with the following products/services:

- Maintenance agreements (SSA-V) for the offered solutions.
- Other options listed in Appendix 7a - Price sheet

1.9 Structure of the tender specification

The tender specification comprises all documents, except the announcement and the European Single Procurement Document, which the Contracting Authority designs or refers to in order to describe or determine the elements in the procurement or tender procedure, including documents that describe what will be procured, the contract terms and how the Contracting Authority will implement the tender procedure, and any supplementary documents and additional information.

The attachment are included as part of the actual tender specification. The appendices will be included in the final agreement document.

The tender specification consists of this document and the following attachments:

Document:	Name	Description / instructions
Part I	Tender procedure rules	Presents the rules for implementation of the tender procedure.
Part I Attachment 1	Letter of application	To be completed and attached to the request.
Part I Attachment 2	Letter of tender	To be completed and attached to the tender.
Part I Attachment 3	Information regarding applicant / tenderer	To be completed and attached to the request.
Part I Attachment 4	Response sheet references	To be completed and attached to the request.
Part I Attachment 5	Declaration of Commitment	To be completed and attached to the request (if applicable).

Part II	SSA-K Purchase Agreement	To be completed upon awarding of contract.
Part II - K Appendix 1	Customer requirement specification	Tenderers' information
Part II - K Appendix 1a ICT requirements	Customer requirement specification - ICT	To be completed and attached to the tender
Part II - K Appendix 2	Contractor description of the deliverables	To be completed and attached to the tender
Part II - K Appendix 3	Customer technical platform	Tenderers' information
Part II - K Appendix 4	Delivery date and other deadlines	Tenderers' information
Part II - K Appendix 5	Approval test	Tenderers' information
Part II - K Appendix 6	Administrative provisions	To be completed upon awarding of contract.
Part II - K Appendix 7	Total price and pricing provisions	To be completed and attached to the tender
Part II - K Appendix 7a	Price sheet	To be completed and attached to the tender
Part II - K Appendix 8	Changes to the general contractual wording	Tenderers' information
Part II - K Appendix 9	Changes to the conclusion of Agreement	Tenderers' information
Part II - K Appendix 10	Licence terms and conditions for standard and free software	To be completed upon awarding of contract.
Part III	SSA-V Maintenance Agreement	To be completed upon awarding of contract.
Part III - V Appendix 1	Customer requirement specification	Tenderers' information
Part III - V Appendix 2	Contractor description of the deliverables	To be completed and attached to the tender
Part III - V Appendix 3	Software and or equipment to be maintained	To be completed upon awarding of contract.
Part III - V Appendix 5	SL with standardised price reduction	Tenderers' information
Part III - V Appendix 6	Administrative provisions	To be completed upon awarding of contract.
Part III - V Appendix 7	Total price and pricing provisions	To be completed and attached to the tender
Part III - V Appendix 8	Changes to the general contractual wording	Tenderers' information
Part III - V Appendix 9	Changes to the conclusion Agreement	Tenderers' information
Part III - V Appendix 10	Third party's terms and conditions	To be completed and attached to the tender

1.10 Bidding inspection / bidding conference

No bidding inspection / bidding conference will be held.

1.11 Amendments to the tender documents and additional information

If the tenderer finds that the tender specification does not offer sufficient guidance or there are suspected errors in the tender documents, additional information shall be requested via the Mercell system.

We encourage tenderers who experience that the Contracting Authority may have set unreasonable minimum requirements to address this matter with the Contracting Authority during the offer period, within the time limit for submitting additional questions. This is a better solution than risking that the Contracting Authority will be obligated to reject the offer.

The Contracting Authority will reply to the questions in a general and anonymised manner. Answers to questions, other additional information or amendments to the tender documents will be communicated via the Mercell portal to all tenderers who have expressed their interest. It is the tenderer's responsibility to keep abreast of any changes.

The Contracting Authority will also be able to make amendments to the tender documents during the process on its own initiative, pursuant to the Norwegian Public Procurement Regulations Section 14-2 (1).

1.12 Tentative schedule

The Contracting Authority has proposed the following time frames for the process:

Activity	Time
Prequalification phase	
Date sent for announcement	30.05.2022
Time limit for submitting questions regarding the tender specification	24.06.2022
Time limit for submitting requests to participate in the tender procedure	04.07.2022
Processing of requests to participate in the tender procedure. Notification of any rejections and any reduction of the number of tenderers	Week 27 (tentative)
Tendering phase	
Invitation to tender	Week 27 (tentative)
Time limit for submitting questions regarding the tender specification	19.08.2022
Time limit for submitting tenders	29.08.2022
Evaluation / negotiations	September/Oktober/ November (tentative)
Selection of supplier and announcement to tenderers	Q4 2022 (tentative)
Formation of contract	Q4 2022 (tentative)

2 Rules for implementation of the tender procedure

2.1 Procurement procedure

The procurement is implemented as a restricted competitive bidding procedure pursuant to the Norwegian Act on Public Procurement of 17 June 2016 (Public Procurement Act) and the Norwegian Regulations on Public Procurement (Public Procurement Regulations) of 12 August 2016 no. 974.

In a restricted competitive bidding procedure, all interested suppliers may submit a request to participate in the tender procedure. Only qualified suppliers will have the opportunity to submit a tender.

Negotiations may apply to all aspects of the tender. Negotiations will take place in several phases, preferably in written form, but also in verbal form. The Contracting Authority reserves the right to reduce the number of tenders after each phase, based on the award criteria. The Contracting Authority will end the negotiations by setting a mutual time limit for receiving the final tenders from the remaining suppliers. Negotiations regarding the final tenders will not be permitted.

2.2 Tax certificate

The selected supplier shall upon request submit certificates for tax and VAT. This is only applicable if the selected supplier is Norwegian.

2.3 Public disclosure

Tender and procurement protocol are exempt from public disclosure until the announcement of contract awarding, cf. the Norwegian Freedom of Information Act of 19/05/2006 no. 16 Section 23.

Tenderers shall submit a version of the tender in which content that is considered trade secrets or personal data is redacted. If no redacted version is submitted, the Contracting Authority will assume that the tenderer does not have any information that is exempt from public disclosure.

In case of a request to access information, the Contracting Authority shall, irrespective of the aforementioned, assess whether the information is of such a nature that the Contracting Authority is obligated to exempt it from public disclosure.

3 Processing of requests to participate in the tender procedure

3.1 General requirements for the request

The tenderer is responsible for answering / providing details regarding all questions, requirements and matters of clarification in the qualification specification.

Should the request from the Applicant contain conflicting provisions, the documents will apply in the following order: Letter of application, submitted documentation, other.

3.2 General requirements for the design of the request

The request shall be submitted with a file name according to the following structure:

Nr	Document
1.	Application letter
2.	Information regarding tenderer
3.	Documentation of qualification requirements - Registration
4.	Documentation of qualification requirements - Economic and financial capacity
5.	Documentation of qualification requirements - Technical and professional qualifications

6.	Documentation of qualification requirements - Quality management standards
7.	Declaration of Commitment (if applicable)
8.	Other documents

3.3 Submission of the request

All requests shall be submitted electronically via the Mercell portal, www.mercell.no, within the deadline for submitting requests to participate in the tender procedure. Late tender submissions will be rejected. (The system does not permit the electronic submission of tenders via Mercell after the time limit has expired.) See also section 6.1 below, for guidelines for user registration in Mercell, etc.

4 The European Single Procurement Document (ESPD)

4.1 General information regarding the European Single Procurement Document

As preliminary documentation of the fulfilment of qualification requirements, and that there are no reasons for rejection, the supplier must complete an ESPD form integrated in Mercell. The supplier(s) who are awarded a contract must prior to awarding of contract document that they satisfy the qualification requirements in accordance with the stated documentation requirements.

In accordance with the Norwegian Public Procurement Regulations, Section 17-1 (3), the Contracting Authority can, at any time in the competition, ask the tenderer for all or parts of the documentation if this is necessary to ensure that the competition is being conducted correctly.

4.2 National rejection grounds

In accordance with the ESPD part III, Rejection grounds, Section D, "Other rejection grounds that are laid down in national legislation in the Contracting Authority's member state", it is specified that all rejection grounds in the Norwegian Public Procurement Regulations, Section 24-2, including the purely national rejection reasons, apply to this tender procedure:

- Section 24-2 (2). This provision states that a Contracting Authority can reject a supplier when they are aware that the supplier has been convicted in a final and enforceable judgement or has accepted a fine for the stated punishable offences.
- Section 24-2 (3) (i). The rejection ground in the ESPD form only applies to serious errors in professional performance, whilst the Norwegian rejection ground also includes other serious errors that may call into question the supplier's professional integrity.

5 Qualification requirements

The purpose of setting requirements for the tenderer's qualifications is to ensure that the tenderer is capable of fulfilling the agreement throughout the period of agreement. In order to have a request evaluated, the supplier must fill out the electronic self-declaration form in Mercell as preliminary documentation of the fulfilment of all qualification requirements.

The tenderer may receive support from other businesses to fulfil the financial qualification requirements in section 5.2 and/or the requirement of technical and professional qualifications/ Quality management standards in section 5.3 and 5.4 by checking this off in chapter III, section C of the ESPD form. The tenderer shall in this case submit separate self-declarations for each of the supporting businesses. The procurement document shall

contain information requested in the ESPD form, sections A and B, part II and part III, as well as information in part IV and V to the extent this is relevant to it, or to the specific requirements for which the supplier needs support from other companies. In addition, the tenderer must document that they have the necessary resources by submitting a declaration of commitment from these businesses, see Attachment 5 – Declaration of Commitment.

5.1 Registration

In the event the tenderer consists of several suppliers or a main supplier and sub-contractor, all the companies must individually fulfil the requirements of this section and submit all requested documentation.

Qualification requirements	Documentation requirements
The Contractor must be a legally established business.	<ul style="list-style-type: none"> Norwegian Contractors must provide an updated certificate of registration. Non-Norwegian Contractors must provide certificate(s) of registration obtained the country of establishment, translated into English if applicable, and confirmed by notary.

5.2 Economic and financial capacity

Qualification requirements	Documentation requirements
The Contractor must have sufficient economic and financial solidity to be able to fulfill the contractual obligations.	<p>The Contracting Authority will evaluate the Contractors' fulfillment of the qualification requirement in one of the following ways:</p> <ul style="list-style-type: none"> The Contractor shall present the annual financial reports for the last two financial years together with the auditor's annual report. Credit rating report from a reputable credit rating agency For newly founded companies, the Contractor shall provide accounts and audit reports covering the time for which the company has been in operation. The Contractor may submit a parent company guarantee or a guarantee from the Contractor's owners at least covering an amount equivalent to the Purchase Price.

5.3 Technical and professional qualifications

Qualification requirements	Documentation requirements
The Contractor shall have sufficient capability and capacity to fulfill the contractual obligations.	The Contracting Authority will consider the Contractor's experience with delivering the goods and services, based on the following information submitted by the Contractor:

	<ul style="list-style-type: none"> • A brief description of the company, the company's organization and business areas. • A list of the most important and most relevant deliveries in the last three years, including information about value and time of delivery, as well as the name of the public or private recipient. The list must reflect the type of equipment offered in this tender. • If the Contractor rely on other legal entities' capacity, the Contractor shall document that the necessary resources will be available, by submitting a declaration of commitment from the relevant subcontractor. The declaration must indicate that the subcontractor has necessary resources available throughout the course of the contract period, see Attachment 5 – Declaration of Commitment.
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5.4 Quality management standards

Qualification requirements	Documentation requirements
The supplier must have a certified quality system.	<ul style="list-style-type: none"> • Documentation that the Contractor is ISO 9001 Quality Management System certified. • The client also accepts certificates issued by bodies in other EEA states. The client will accept other documentation for a similar quality system if the supplier does not have the opportunity to obtain such certificates within the deadline, and this is not due to the supplier himself. This presupposes that the supplier documents that these measures correspond to the requested quality standards.

The Contracting Authority will inform the applicants of the results of their qualification submissions.

6 Requirements for the tender

6.1 Submission of the tender

All tenders shall be submitted electronically via the Mercell portal, www.mercell.no, within the deadline for receipt of tenders. The system does not permit the submission of bids via Mercell after the expiry of the time limit for receipt of bids. If the tenderer submits a bid for several partial deliveries, each partial delivery must be signed electronically.

If the tenderer is not a Mercell user or has questions regarding functionalities in the tool, please contact Mercell Support at tel.: +47 21 01 88 60 or by email to: support@mercell.com

We recommend submitting the bid well in advance of the expiry of the time limit. Submitted bids may be amended until the expiry of the time limit for receipt of bids. The most recently submitted tender is considered the final bid.

6.2 General requirements for the tender

The tenderer is responsible for answering / providing details regarding all questions, requirements and matters of clarification in the tender specification.

Costs incurred by the tenderer in connection with preparation, submission and follow-up of the tender will not be reimbursed.

6.3 Language

The tender, including completed attachments must be completed in English.

6.4 Requirements for tender structure

The tender shall be submitted with a file name according to the following structure:

Nr	Document
1.	Letter of tender
2.	K Appendix 2 Contractors description of the deliverables K Appendix 1a ICT requirements
3.	K Appendix 7a Price sheet
4.	K Appendix 10 Licence terms and conditions for standard and free software
5.	V Appendix 2 Contractor description of the deliverables
6.	V Appendix 7 Total price and pricing provisions
7.	V Appendix 10 Third party's terms and conditions
8.	Other documents
9.	Redacted version of the tender

File *K Appendix 7a Price sheet* shall be delivered in Excel format. Other files, incl. the redacted tender, shall be delivered in PDF format.

6.5 Tender opening

The tender opening will not be public.

6.6 Public disclosure

Tender and procurement protocol are exempt from public disclosure until the announcement of contract awarding, cf. the Norwegian Freedom of Information Act of 19/05/2006 no. 16 Section 23.

Tenderers shall submit a version of the tender in which content that is considered trade secrets or personal data is redacted. If no redacted version is submitted, the Contracting Authority will assume that the tenderer does not have any information that is exempt from public disclosure.

In case of a request to access information, the Contracting Authority shall, irrespective of the aforementioned, assess whether the information is of such a nature that the Contracting Authority is obligated to exempt it from public disclosure.

6.7 Contracting Authority's reservations

The Contracting Authority reserves the right to cancel the procurement if the result of the procurement involves a significant increase in cost in relation to the amount allocated in the budget for the procurement.

6.8 Tenderer's reservations and deviations

If the tenderer makes reservations regarding parts of the tender specification, this shall be stated clearly in Attachment 1 – Letter of Tender. The same applies to deviations. Any reservations or deviations shall be precise and unambiguous so that the Contracting Authority may assess these without contacting the tenderer.

Reservations regarding the tender specification, including contract terms and Requirements specification will be priced (as additions in the tender sum) in connection with the Contracting Authority's evaluation. If the reservations or deviations cannot be priced or are material, this may result in a rejection of the tender.

When assessing whether one or more deviations are material, the extent of the deviations, the importance of the issue from which there are deviations, and the extent to which a deviation may delay the tender procedure / result in competitive advantages will be assessed, among other things. If the tender contains deviations which, *per se*, are not material, these deviations may, however, be considered cumulatively material, based on a concrete assessment.

6.9 Deadline for tender acceptance

The deadline for tender acceptance is set as 6 months from the tender deadline.

6.10 Alternative bids

Alternative bids will not be accepted.

6.11 Parallel bids

The Contracting Authority does accept parallel bids. Parallel bids refers to bids that entirely satisfy the performance or functional requirements specified in K Appendix 1 and V Appendix 1. An example of this is when a tenderer submits a tender for several different products that cover the same need. This may involve different models, manufacturers or the like. Separate requirements specifications and price sheets for parallel tenders must then be completed when submitting the Tender.

6.12 Tenderer's obligations in case of errors or deficiencies in the tender specification

If the tenderer discovers errors, deficiencies or other omissions or matters that are unclear in the tender specification, the tenderer shall promptly notify the Contracting Authority thereof.

7 Award criteria

Awarding will occur on the basis of which tender has the best ratio of cost and quality, based on the following criteria:

Award criterion	Weight	Details
Total cost	25 %	The total cost covers, among other things, procurement costs, operating costs, price of parts, accessories, consumables, training expenses and services costs.

Award criterion	Weight	Details
		We refer to K Appendix 7/V Appendix 7 - Total price and pricing provisions and K Appendix 7a - Price sheet for further information.
Quality - Technical solution - General	7,5 %	<p>We refer to K Appendix 1 and V Appendix 1 for a detailed overview of requirements included in the award criterias.</p> <p>All evaluation requirements will have a reference to the individual award criterion in a separate column of the documents.</p>
Quality - Instalation, test and validation	5 %	
Quality - Technical solution - Functionality	12,5 %	
Quality - Technical solution - Regional pharmacies	2,5 %	
Quality - Technical solution - Patient safety	10 %	
Quality - Technical solution - Ease of use	10 %	
Quality - Technical solution - Deliverables	7,5 %	
Quality - Automation	5 %	
Quality - ICT - General	2,5 %	
Quality - ICT - Functional	5 %	
Quality - ICT - Integration	2,5 %	
Contractor services	5 %	
Total	100 %	