

**Norway-Oslo: Provider services**  
**OJ S 249/2022 27/12/2022**  
**Contract notice**  
**Services**

**Legal Basis:**  
Directive 2014/24/EU

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**Section I: Contracting authority**

**I.1. Name and addresses**

Official name: Statens Legemiddelverk  
National registration number: 974761122  
Postal address: Grensesvingen 26  
Town: OSLO  
NUTS code: NO Norge  
Postal code: 0663  
Country: Norway  
Contact person: Gunnar Carelius  
E-mail: [gunnar.carelius@legemiddelverket.no](mailto:gunnar.carelius@legemiddelverket.no)  
Telephone: +47 22877900  
**Internet address(es):**  
Main address: <https://permalink.mercell.com/193162086.aspx>  
Address of the buyer profile: <http://www.legemiddelverket.no/>

**I.3. Communication**

The procurement documents are available for unrestricted and full direct access, free of charge, at: <https://permalink.mercell.com/193162086.aspx>  
Additional information can be obtained from the abovementioned address  
Tenders or requests to participate must be submitted electronically via: <https://permalink.mercell.com/193162086.aspx>

**I.4. Type of the contracting authority**

National or federal agency/office

**I.5. Main activity**

Health

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**Section II: Object**

**II.1. Scope of the procurement**

**II.1.1. Title**

Solution for eSubmission Management.  
Reference number: 22/29667

**II.1.2. Main CPV code**

72410000 Provider services

**II.1.3. Type of contract**

Services

#### **II.1.4. Short description**

Procurement of a SaaS solution to handle dossiers connected to applications for marketing licences for medicines - eSubmissions.

#### **II.1.5. Estimated total value**

Value excluding VAT: 6 000 000,00 NOK

#### **II.1.6. Information about lots**

This contract is divided into lots: no

### **II.2. Description**

#### **II.2.2. Additional CPV code(s)**

48100000 Industry specific software package, 72220000 Systems and technical consultancy services

#### **II.2.3. Place of performance**

NUTS code: NO081 Oslo

#### **II.2.4. Description of the procurement**

The overall aim of the procurement is to solve the Norwegian Medicines Agency's (NOMA) need for eSubmission management. The procurement is connected to the ongoing process of modernising NOMA's case management systems. The modernisation has uncovered a need to reduce manual work connected to handling the reception, making available, and journaling of dossiers that are submitted for applications for marketing licences (MT) for case management. The existing systems are difficult to continue without a large part of the manual work be transferred from the archive function to executive employees. By introducing a system that both handles loading, validating, and making dossiers available, and which can be integrated with the next generation case management system in NOMA, this problem will be solved:

- To automatise the process of receiving, validating, and making dossiers available that are received from CESP, Common Repository, and in the future DADI / PL
- Lay the basis for being able to automatise corrections and updates to cases in NOMA's new case management system, DELE
- To facilitate NOMA's executive employees having a suitable and user friendly tool for insight in and processing of all relevant dossiers
- To facilitate the use of eCTD version 4.0

#### **II.2.5. Award criteria**

Price is not the only award criterion and all criteria are stated only in the procurement documents

#### **II.2.6. Estimated value**

Value excluding VAT: 6 000 000,00 NOK

#### **II.2.7. Duration of the contract, framework agreement or dynamic purchasing system**

Duration in months: 36

This contract is subject to renewal: yes

Description of renewals:

The provisions in SSA-L are renewed annually for one year at a time after three years.

#### **II.2.10. Information about variants**

Variants will be accepted: no

## **II.2.11. Information about options**

Options: no

## **II.2.13. Information about European Union funds**

The procurement is related to a project and/or programme financed by European Union funds:  
no

## **II.2.14. Additional information**

### **Section III: Legal, economic, financial and technical information**

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#### **III.1. Conditions for participation**

##### **III.1.1. Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers**

List and brief description of conditions:

Documented by a company registration certificate or equivalent documentation that shows that the tenderer is registered in a register of business enterprises, a trade register, a professional register or a register of commerce in their home country.

##### **III.1.2. Economic and financial standing**

List and brief description of selection criteria:

The economic and financial standing must be documented by the following information:

- a. The last approved annual accounts with the annual report and the auditor's report.
- b. Solidity assessment from a company with a licence to run a credit information company. The evaluation must not be older than 3 months from the deadline for receipt of tenders. It must be based on the last approved accounting figures and should report on the credit worthiness and degree of bankruptcy risk (bankruptcy prediction).
- c. Parent company guarantee (if relevant).

##### **III.1.3. Technical and professional ability**

List and brief description of selection criteria:

K3 - Tenderers must have good competence and capacity for the delivery and further development of eSubmission management system.

K3 - Documentation requirement:

- a. Description of the tenderer's organisation that is relevant for this delivery.
- b. Description of the total competence and capacity that the tenderer has available.

K4 - Tenderers must have relevant experience from equivalent medicine authorities to NOMA.

K4 - Documentation requirement:

Up to three customer references in the last three years.

The references must include, amongst other things,

Automatic downloading from CESP and Common Repository, technical validation, and making available in the offered system

Integration between the offered system and the customer's case management system

Migration of existing eSubmission documents to the offered system

Complete Annex K4 - Customer References

K5 - Tenderers must have established a satisfactory management system for information security (ISMS).

K5 - Documentation requirement:

A copy of an information security certificate (ISO27001/equivalent), issued by an accredited certification bodyies, if relevant.

A description of the tenderer's ISMS, as well as how it is implemented and managed internally.  
The requirement must be fulfilled by both the tenderer and any collaborating companies.

K6 - Tenderers must have a sufficient quality management system established.

K6 - Documentation requirement:

A copy of a quality management certificate (ISO 9001/equivalent), issued by an accredited certification body, if relevant.

A description of the tenderer's quality management system as well as how it is implemented and managed internally.

The requirement must be fulfilled by both the tenderer and any collaborating companies.

## **Section IV: Procedure**

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### **IV.1. Description**

#### **IV.1.1. Type of procedure**

Open procedure

#### **IV.1.3. Information about a framework agreement or a dynamic purchasing system**

#### **IV.1.8. Information about the Government Procurement Agreement (GPA)**

The procurement is covered by the Government Procurement Agreement: yes

### **IV.2. Administrative information**

#### **IV.2.2. Time limit for receipt of tenders or requests to participate**

Date: 27/01/2023 Local time: 12:00

#### **IV.2.3. Estimated date of dispatch of invitations to tender or to participate to selected candidates**

#### **IV.2.4. Languages in which tenders or requests to participate may be submitted**

English, Norwegian

#### **IV.2.6. Minimum time frame during which the tenderer must maintain the tender**

Tender must be valid until: 28/04/2023

#### **IV.2.7. Conditions for opening of tenders**

Date: 27/01/2023 Local time: 12:00

Place:

Oslo

## **Section VI: Complementary information**

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### **VI.1. Information about recurrence**

This is a recurrent procurement: no

### **VI.2. Information about electronic workflows**

Electronic invoicing will be accepted

Electronic payment will be used

### **VI.3. Additional information**

### **VI.4. Procedures for review**

#### **VI.4.1.**

**Review body**

Official name: Oslo tingrett

Postal address: Postboks 2106 Vika

Town: Oslo

Postal code: 0125

Country: Norway

E-mail: [oslo.tingrett@domstol.no](mailto:oslo.tingrett@domstol.no)

**VI.5. Date of dispatch of this notice**

22/12/2022