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**Norway-Vadsø: Pharmaceutical products
2020/S 234-578905**

Voluntary ex ante transparency notice

Supplies

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority/entity

I.1) Name and addresses

Official name: Sykehusinnkjøp HF
National registration number: 916879067
Postal address: Postboks 40
Town: Vadsø
NUTS code: NO NORGE
Postal code: 9811
Country: Norway
Contact person: Ninja Elise Seippel
E-mail: ninja.elise.seippel@sykehusinnkjop.no
Telephone: +47 98405239

Internet address(es):

Main address: <https://permalink.mercell.com/143902910.aspx>
Address of the buyer profile: <http://www.sykehusinnkjop.no/>

I.4) Type of the contracting authority

Body governed by public law

I.5) Main activity

Health

Section II: Object

II.1) Scope of the procurement

II.1.1) Title:

Esketamine Injeksjons for Reserves
Reference number: 2020/1871

II.1.2) Main CPV code

33600000 Pharmaceutical products

II.1.3) Type of contract

Supplies

II.1.4) Short description:

The government has decided that establish two levels of medicine reserves in Norway. A decision has been made in project B180 (National Reserves of Medicines), owned by Helse Vest RHF [the Western Norway Regional Health Authority] and managed by Sjukehusapoteka Vest HF, that a national reserve must be

established for several selected medicines. This means that reserves must be developed as soon as possible. The time aspect is central to reserve considerations and in light of the ongoing SARA-CoV-2 pandemic. The Voluntary ex ante transparency notice applies to injections of Esketamine, ATC code: N01AX14

II.1.6) **Information about lots**

This contract is divided into lots: no

II.1.7) **Total value of the procurement (excluding VAT)**

Value excluding VAT: 300 000.00 NOK

II.2) **Description**

II.2.3) **Place of performance**

NUTS code: NO01 Oslo og Akershus

II.2.4) **Description of the procurement:**

Sykehusinnkjøp HF, medicines division (Sykehusinnkjøp), is procuring and obtaining tenders for health company financed medicines. Sykehusinnkjøp has been given a mandate to procure the medicine. Sykehusinnkjøp has previously announced and held an open tender contest for parenteral pharmaceutical special preparations ('LIS 2001c Parenteral Pharmaceutical Special Preparations' the tender). The contest included the mentioned medicine, as the tender documentation annex 3 - 'Active Ingredients List' requested tenders for the active ingredient (the medicine or reasonable alternatives).

Sykehusinnkjøp therefore believes that there are grounds to make the procurement without a contest. The basis for the grounds are in accordance with the public procurement regulations, Section 13-4 a), c.f., Section 13-3. Tenders were not received in the above-mentioned contest for the active ingredient in question (medicine or reasonable alternatives), and this part of the contest must therefore be marked as unsuccessful.

Sykehusinnkjøp has now examined which relevant medicines fulfil the regulatory requirements in Norway. If a medicine has a marketing licence in Norway, you cannot just procure an alternative medicine with a marketing licence in another country in the EU/EEA area. This is in the law on medicines, etc., Sections 8 and 10, sml. regulations on medicines chapter 2. This is further connected to Sykehusinnkjøp as a medicine intermediary having a right to its operations, c.f., the regulations on wholesaler operations with medicines, Section 33. According to www.legemiddelsok.no there are no other companies that the Supplier that have a marketing licence for the medicine in Norway.

Sykehusinnkjøp has assessed that no other possible tenderers of the medicine will be able to fulfil the regulatory requirements in Norway (marketing licence in Norway), and be able to deliver so that the contract is fulfilled by the contracting authority's required date, and that there are no reasonable alternatives to the medicine.

It is, therefore, objectively impossible to hold an ordinary contest or a contest in accordance with the public procurement regulations, Section 13-3. The scope of the contract is not larger than necessary.

Based on this, Sykehusinnkjøp intends to enter into a contract between Helse Vest RHF and the Supplier for the procurement of the medicine.

Sykehusinnkjøp requests that those who have objections to this voluntary ex-ante transparency notice submit feedback before the waiting period, which is set to 10 days calculated from the day after the publication of the voluntary ex-ante transparency notice. If no objections are received, a contract will be signed after the waiting period has expired.

II.2.5) **Award criteria**

Price

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 IV: Procedure

IV.1) **Description**

IV.1.1) **Type of procedure**

Award of a contract without prior publication of a call for competition in the Official Journal of the European Union in the cases listed below

- The procurement falls outside the scope of application of the directive

Explanation:

Sykehusinnkjøp HF, medicines division (Sykehusinnkjøp), is procuring and obtaining tenders for health company financed medicines. Sykehusinnkjøp has been given a mandate to procure the medicine.

Sykehusinnkjøp has previously announced and held an open tender contest for parenteral pharmaceutical special preparations ('LIS 2001c Parenteral Pharmaceutical Special Preparations' the tender). The tender includes the named medicine, as the tender documentation Appendix 3 - 'Active Ingredients List' tenders were requested for the active substance (the medicinal product or reasonable alternatives).

Sykehusinnkjøp therefore believes that there are grounds to make the procurement without a contest. The basis for the grounds are in accordance with the public procurement regulations, Section 13-4 a), c.f., Section 13-3. Tenders were not received in the above-mentioned contest for the active ingredient in question (medicine or reasonable alternatives), and this part of the contest must therefore be marked as unsuccessful.

Sykehusinnkjøp has now examined which relevant medicines fulfil the regulatory requirements in Norway. If a medicine has a marketing licence in Norway, you cannot just procure an alternative medicine with a marketing licence in another country in the EU/EEA area. This is in the law on medicines, etc., Sections 8 and 10, sml. regulations on medicines chapter 2. This is further connected to Sykehusinnkjøp as a medicine intermediary having a right to its operations, c.f., the regulations on wholesaler operations with medicines, Section 33.

According to www.legemiddelsok.no there are no other companies that the Supplier that have a marketing licence for the medicine in Norway. Sykehusinnkjøp has assessed that no other possible tenderers of the medicine will be able to fulfil the regulatory requirements in Norway (marketing licence in Norway), and be able to deliver so that the contract is fulfilled by the contracting authority's required date, and that there are no reasonable alternatives to the medicine.

It is, therefore, objectively impossible to hold an ordinary contest or a contest in accordance with the public procurement regulations, Section 13-3. The scope of the contract is not larger than necessary.

Based on this, Sykehusinnkjøp intends to enter into a contract between Helse Vest RHF and the Supplier for the procurement of the medicine.

Sykehusinnkjøp requests that those who have objections to this voluntary ex-ante transparency notice submit feedback before the waiting period, which is set to 10 days calculated from the day after the publication of the voluntary ex-ante transparency notice. If no objections are received, a contract will be signed after the waiting period has expired.

IV.1.3) **Information about framework agreement**

The procurement involves the establishment of a framework agreement

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

The procurement is covered by the Government Procurement Agreement: yes

IV.2) **Administrative information**

Section V: Award of contract/concession

Contract No: 1

V.2) **Award of contract/concession**

V.2.1) **Date of contract award decision:**

24/11/2020

V.2.2) **Information about tenders**

The contract has been awarded to a group of economic operators: no

V.2.3) **Name and address of the contractor/concessionaire**

Official name: Pfizer AS

National registration number: 915213596

Town: Oslo

NUTS code: NO01 Oslo og Akershus

Country: Norway

The contractor/concessionaire will be an SME: no

V.2.4) **Information on value of the contract/lot/concession (excluding VAT)**

Initial estimated total value of the contract/lot/concession: 300 000.00 NOK

Total value of the contract/lot/concession: 300 000.00 NOK

V.2.5) **Information about subcontracting**

Section VI: Complementary information

VI.3) **Additional information:**

VI.4) **Procedures for review**

VI.4.1) **Review body**

Official name: Øst-Finnmark tingrett

Postal address: Postboks 54

Town: Vadsø

Postal code: 9811

Country: Norway

Internet address: <https://www.domstol.no/Enkelt-domstol/ost-finnmark-tingrett/>

VI.4.2) **Body responsible for mediation procedures**

Official name: Klagenemda for offentlige anskaffelser

Postal address: Postboks 439 Sentrum

Town: Bergen

Postal code: 5805

Country: Norway

E-mail: postmottak@kofa.no

Internet address: <http://www.kofa.no>

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

26/11/2020