

Norway-Oslo: Vaccines
OJ S 235/2016 06/12/2016
Contract notice
Supplies

Directive 2004/18/EC

Section I: Contracting authority

I.1. Name and addresses

Official name: Nasjonalt Folkehelseinstitutt (FHI) [The Norwegian Institute of Public Health]
National registration number: 983744516
Postal address: Lovisenberggata 8
Town: Oslo
Postal code: 0456
Country: Norway
For the attention of: Ole Andreas Fuglesang
E-mail: ole.andreas.fuglesang@fhi.no
Telephone: +47 21077000

Internet address(es):

General address of the contracting authority: <http://www.fhi.no>
Address of the buyer profile: <https://kgv.doffin.no/ctm/Supplier/CompanyInformation/Index/1063>
Electronic access to information: <https://kgv.doffin.no/ctm/Supplier/Documents/Folder/149976>

Additional information can be obtained from:

the abovementioned address

Specifications and additional documents (including documents for competitive dialogue and a dynamic purchasing system) can be obtained from:

the abovementioned address

Tenders or requests to participate must be submitted: the abovementioned address

I.2. Type of the contracting authority

National or federal agency/office

I.3. Main activity

Health

I.4. Contract award on behalf of other contracting authorities

The contracting authority is purchasing on behalf of other contracting authorities: no

Section II: Object of the contract

II.1. Description

II.1.1. Title attributed to the contract by the contracting authority

HPV-vaccinations for boys and girls in the child vaccination programme.

II.1.2. Type of contract and place of performance or delivery

Supplies

Purchase

Main site or place of performance: Oslo.

NUTS code NO0 Norge

II.1.3. Information about a framework agreement or a dynamic purchasing system

The procurement involves the establishment of a framework agreement

II.1.4. Information about framework agreement

Framework agreement with a single operator

Duration of the framework agreement

Duration in years: 4

Estimated total value of purchases for the entire duration of the framework agreement

Estimated value excluding VAT:

Range: between 25 000 000 and 180 000 000 NOK

Frequency and value of the contracts to be awarded: Particular for 2017: Delivery of 50 000 doses by 30.6.2017 and a total of 75 000 doses by 31.8.2017, including the 50 000 doses that shall be delivered by 30.6.2017.

The contracting authority will make active call-offs when needed for 2018 and beyond, with 6 months written notice before the delivery date. See the contract draft.

II.1.5. Short description of the contract or purchase(s)

The aim of the procurement is to enter into a framework agreement for the delivery of HPV vaccinations, i.e. vaccinations against the human papillomavirus, for boys and girls in the Norwegian child vaccination programme. The start-up for the vaccinating girls is anticipated to be August 2017. The target group is girls and boys aged 12-13 years. A decision has not yet been made as to whether boys will be offered the vaccination. The start-up date is also unknown. The decision on whether boys shall be offered the vaccination will be taken by the Ministry of Health and Care Services and it will require the Norwegian Parliament's approval.

II.1.6. CPV code(s)

33651600 Vaccines

II.1.7. Information about the Government Procurement Agreement (GPA)

The procurement is covered by the Government Procurement Agreement: yes

II.1.8. Lots

This contract is divided into lots: no

II.1.9. Information about variants

Variants will be accepted: no

II.2. Scope of the procurement

II.2.1. Total quantity or scope

There is uncertainty surrounding the number of doses as it is dependent on how many of the year in question choose to be vaccinated (vaccine coverage) and other uncertainties described below.

The vaccine coverage for the HPV vaccination in girls is somewhat lower than for other vaccinations in the child vaccination programme, but it has been relatively stable/slowly increasing. The vaccine coverage that could be achieved for boys is uncertain.

Norway currently has a 3 dose regime for vaccination against HPV, but the Norwegian Institute of Public Health is reviewing available documentation on a possible transition to only 2 doses. The work can result in the Norwegian vaccination programme being altered. The conclusion was not ready at the time this notice was published.

This notice has a span for the number of doses per annum from 50 000 — 150 000 doses, due to the uncertainty as to whether boys will be included in the programme, the degree of vaccination coverage (particularly for boys) and whether there will be a transition from a 3

dose regime to a 2 dose regime.

The contracting authority has estimated the annual need for doses can be indicated from which of the following scenarios occur in the contract period:

- Vaccination of only girls, 2 doses to each girl gives a need of 50 000 doses per annum.
- Vaccination of only girls, 3 doses to each girl gives a need of approx. 75 000 doses per annum.
- Vaccination of girls and boys, 2 doses to each child gives a need of approx. 100 000 doses per annum.
- Vaccination of girls and boys, 3 doses to each child gives a need of approx. 150 000 doses per annum.

The Contracting Authority is obliged to purchase a minimum volume of 50 000 doses per annum in accordance with the contract. Call-offs in addition to the minimum volume will depend on vaccine coverage, a decision on whether boys shall be included in addition to girls and a decision on the 3 or 2 dose regime.

The contracting authority is not bound by the value estimate. The calculation is based on an estimated price per dose. As a result of this, and other described uncertainties, the estimate of the procurement's value is very uncertain.

See the tender documentation for further information.

Estimated value excluding VAT:

Range: between 25 000 000 and 180 000 000 NOK

II.2.2. Information about options

Options: yes

Description of options: In order to take care of a possible circumstance in which a higher vaccine coverage than expected is achieved, and in which both boys and girls receive 3 doses each, the contract has an option for the procurement of an extra 30 000 doses per annum. (Supply agreement point 3.7).

II.2.3. Information about renewals

This contract is subject to renewal: no

II.3. Duration of the contract or time limit for completion

Start 1.3.2017. Completion 1.3.2021

Section III: Legal, economic, financial and technical information

III.1. Conditions related to the contract

III.1.1. Deposits and guarantees required

III.1.2. Main financing conditions and payment arrangements and/or reference to the relevant provisions governing them

III.1.3. Legal form to be taken by the group of economic operators to whom the contract is to be awarded

III.1.4. Contract performance conditions

The performance of the contract is subject to particular conditions: yes

Description of particular conditions: Annex 2 'Supply Agreement' includes all the valid contract terms.

A selection of the special contract terms are given below:

- In 2017 the tenderer will be obliged to deliver a minimum of 50 000 doses by 30.6.2017 and

a total of 75 000 doses, including the 50 000 doses described above by 31.8.2017 (Supply Agreement point 3.6).

— Resale. The Norwegian Institute of Public Health can, after a written agreement with the tenderer, resell delivered but non-distributed vaccine doses (Supply Agreement point 15, 15.1)

— Social and ethical responsibility The Norwegian Institute of Public Health requires ethical and socially responsible production. (Supply Agreement, point 10, 10.1 — 10.4).

— Tenderers shall be a member of the Legemiddelsansvarsforeningen.

III.2. Conditions for participation

III.2.1. Suitability to pursue the professional activity, including requirements relating to enrolment on professional or trade registers

List and brief description of conditions: The tenderer must have the affairs in order with respect to the payment of tax, employer contribution and value added tax (VAT).

Documentation: Tax and VAT certificate. Foreign tenderers: See the tender documentation (Annex 1).

Tenderers shall be a legally established company.

Documentation: Company Registration Certificate. Foreign tenderers: Confirmation that the tenderer is registered in a trade register or company register in accordance with the law in the country where the tenderer is established.

III.2.2. Economic and financial ability

List and brief description of conditions: The tenderer shall have sufficient financial strength to comply with the contractual obligations.

Documentation: The tenderer's last two approved annual accounts including notes with the Board's and auditor's reports. The Contracting Authority reserves the right to carry out a credit assessment. Financial strength will be evaluated in relation to turnover, operating profit margin, solidity and liquidity.

III.2.3. Technical and professional ability

List and brief description of conditions:

Tenderers shall have good implementation ability.

Documentation: A list of the most relevant deliveries in the last three years, including information on the volume, dates and the name of the recipient.

Tenderers shall have sufficient delivery capacity for HPV vaccines throughout the entire contract period.

Documentation: Tenderers shall submit confirmation that the tenderer (and any sub-suppliers, c.f. the tender documentation's point on commitment statements), have the capacity to deliver:

1. Up to 180 000 doses of HPV vaccines per annum throughout the contract period.
2. 50 000 doses of HPV vaccine by 30.6.2017
3. A total of 75 000* doses of the HPV vaccine by 31.8.2017

*including the 50 000 doses described in point 2 above.

Tenderers shall have the necessary licences. The offered vaccine must be produced by a manufacturer holding authorisation from the relevant authorities in the EU/EEA to manufacture drugs. If the tenderer does not manufacture the vaccine itself, the tenderer must have the necessary authorisation from the relevant authorities in the EU/EEA to trade in pharmaceuticals. If the vaccine is imported, the import licence that covers the offered vaccine must be presented.

Documentation: A copy of the manufacturing licence in the manufacturing country, or a copy of the sales licence from the relevant authority.

A copy of the wholesaler or manufacturer licence in Norway.

Tenderers shall be a member of the Legemiddelsansvarsforeningen.
Documentation: Valid proof of membership or confirmation that confirms membership.

III.2.4. Information about reserved contracts

III.3. Conditions specific to services contracts

III.3.1. Information about a particular profession

Execution of the service is reserved to a particular profession: no

III.3.2. Information about staff responsible for the performance of the contract

Obligation to indicate the names and professional qualifications of the staff assigned to performing the contract: no

Section IV: Procedure

IV.1. Type of procedure

IV.1.1. Type of procedure

Open

IV.1.2. Information about the limits on the number of candidates to be invited

IV.1.3. Information about reduction of the number of solutions or tenders during negotiation or dialogue

IV.2. Award criteria

IV.2.1. Award criteria

The most economically advantageous tender in terms of Criteria below

1. Price. Weighting 30
2. Quality, including effect and safety. Weighting 70

IV.2.2. Information about electronic auction

An electronic auction will be used: no

IV.3. Administrative information

IV.3.1. File reference number attributed by the contracting authority

16/13364

IV.3.2. Previous publication concerning this procedure

no

IV.3.3. Conditions for obtaining specifications and additional documents or descriptive document

Payable documents: no

IV.3.4. Time limit for receipt of tenders or requests to participate

23.1.2017 - 13:00

IV.3.5. Estimated date of dispatch of invitations to tender or to participate to selected candidates

IV.3.6. Languages in which tenders or requests to participate may be submitted

Danish. English. Swedish.

Other: Norwegian.

IV.3.7. Minimum time frame during which the tenderer must maintain the tender

Duration in days: 090 (from the date stated for receipt of tender)

IV.3.8. Conditions for opening of tenders

Date: 23.1.2017 - 13:30

Place: Official name: Folkehelseinstituttet

National registration number: 983 744 516

Persons authorised to be present at the opening of tenders: no

Section VI: Complementary information

VI.1. Information about recurrence

This is a recurrent procurement: no

VI.2. Information about European Union funds

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

VI.3. Additional information

VI.4. Procedures for review

VI.4.1. Review body

Official name: The appeals board for public procurements, KOFA

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

VI.4.2. Review procedure

VI.4.3. Service from which information about the review procedure may be obtained

VI.5. Date of dispatch of this notice

5.12.2016