

Sweden-Uppsala: Industry specific software development services

OJ S 227/2021 23/11/2021

Contract notice

Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: Läkemedelsverket

National registration number: 202100-4078

Postal address: Box 26

Town: Uppsala

NUTS code: SE121 Uppsala län

Postal code: 75103

Country: Sweden

Contact person: Stefan Palm

E-mail: stefan.palm@lakemedelsverket.se**Internet address(es):**Main address: <http://www.lakemedelsverket.se>**I.3. Communication**The procurement documents are available for unrestricted and full direct access, free of charge, at: <https://tendsign.com/doc.aspx?Uniqueld=af0qozbxy&GoTo=Docs>

Additional information can be obtained from the abovementioned address

Tenders or requests to participate must be submitted electronically via: <https://tendsign.com/doc.aspx?Uniqueld=af0qozbxy&GoTo=Tender>**I.4. Type of the contracting authority**

National or federal agency/office

I.5. Main activity

Health

Section II: Object

II.1. Scope of the procurement**II.1.1. Title**

Productization of Pharmacovigilans (PV)

Reference number: 2.3.1-2021-075721

II.1.2. Main CPV code

72212100 Industry specific software development services

II.1.3. Type of contract

Services

II.1.4. Short description

The Swedish Medical Products Agency intends to productize and customize existing IT support for the management of adverse reactions and signals for human medicine and veterinary medicine.

The Swedish Medical Products Agency (SMPA), together with the Danish Medicines Agency (DKMA) have established a horizontal collaboration regarding development, use and maintenance of a joint Pharmacovigilance Solution in order to fulfil their respective obligations under EU regulation as National Competent Agencies with respect to performance of pharmacovigilance activities. In the work on tenders and on the execution of the procured bid, the Swedish Medical Products Agency (SMPA) will act as coordinator and provide leadership in completion of the work procured.

II.1.5. Estimated total value

II.1.6. Information about lots

This contract is divided into lots: no

II.2. Description

II.2.2. Additional CPV code(s)

48180000 Medical software package, 48814000 Medical information systems, 48900000 Miscellaneous software package and computer systems, 72212180 Medical software development services, 72260000 Software-related services, 72500000 Computer-related services

II.2.3. Place of performance

NUTS code: SE121 Uppsala län

Main site or place of performance: Uppsala

II.2.4. Description of the procurement

The Swedish Medical Products Agency intends to productize and customize existing IT support for the management of adverse reactions and signals for human medicine and veterinary medicine.

Invitation

The Swedish Medical Products Agency (SMPA), together with the Danish Medicines Agency (DKMA) have established a horizontal collaboration regarding development, use and maintenance of a joint Pharmacovigilance Solution in order to fulfil their respective obligations under EU regulation as National Competent Agencies with respect to performance of pharmacovigilance activities. As part of the collaboration SMPA shall provide the Background System serving as the basis the of joint development.

SMPA, acting in its own name and on behalf of DKMA, invites interested suppliers to submit a bid for the procurement of IT consultancy services for the purpose of enabling the Background system to act as a joint platform for the collective and individual needs of several National Competent Agencies (Productization). In the work on tenders and on the execution of the procured bid, the Swedish Medical Products Agency (SMPA) will act as coordinator and provide leadership in completion of the work procured.

The procurement will apply only to the productization and adaptation of the Background system for collective use by the members of the Consortium (at present SMPA and DKMA). DKMA will need an interim solution (DKMA MVP) to go live 30th June 2022. This means that this procurement does not include work or services related to development or maintenance of the SMPA pharmacovigilance system used as the Background system, which are covered by the procurement awarded by SMPA in 2019 (see contract notice 2019/S071-167957).

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

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

Start: 03/01/2022 End: 02/01/2024

This contract is subject to renewal: no

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 IV: Procedure

IV.1. Description

IV.1.1. Type of procedure

Open procedure Accelerated procedure Justification:

Prior information notice [2021/S 197-512930](#) sent October 6, 2021.

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: 06/12/2021 Local time: 23:59

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

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

Tender must be valid until: 06/06/2022

IV.2.7. Conditions for opening of tenders

Date: 07/12/2021 Local time: 13:00

Section VI: Complementary information

VI.1.

Information about recurrence

This is a recurrent procurement: no

VI.3. Additional information

MerCell notice: <https://opic.com/id/afoqozbxy>

VI.4. Procedures for review**VI.4.1. Review body**

Official name: Förvaltningsrätten i Uppsala

Town: Uppsala

Country: Sweden

VI.5. Date of dispatch of this notice

18/11/2021