

Denmark-Copenhagen: Industry specific software development services

OJ S 45/2022 04/03/2022

Contract award notice

Services

Legal Basis:

Directive 2014/24/EU

Section I: Contracting authority

I.1. Name and addresses

Official name: Lægemiddelstyrelsen
National registration number: 37052485
Postal address: Axel Heides Gade 1
Town: Copenhagen S
NUTS code: DK01 Hovedstaden
Postal code: DK-2300
Country: Denmark
Contact person: Troels Mogensen
E-mail: trm@dkma.dk
Telephone: +45 44889344
Internet address(es):
Main address: <http://www.lmst.dk>

I.1. Name and addresses

Official name: Swedish Medical Products Agency
Town: Uppsala
NUTS code: SE121 Uppsala län
Country: Sweden
Contact person: Stefan Palm
E-mail: stefan.palm@lakemedelsverket.se
Internet address(es):
Main address: <https://www.lakemedelsverket.se/en>

I.2. Information about joint procurement

The contract involves joint procurement
In the case of joint procurement involving different countries, state applicable national procurement law:
Swedish law

I.4. Type of the contracting authority

Ministry or any other national or federal authority, including their regional or local subdivisions

I.5. Main activity

Health

Section II: Object

II.1. Scope of the procurement

II.1.1. Title

Productization of Pharmacovigilans (PV)
Reference number: 2022021688

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 (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. For this contract and on the execution of the procured bid, the DKMA will act as coordinator and provide leadership in completion of the work procured. The SMPA and the DKMA intends to productize and customize existing IT support for the management of adverse reactions and signals for human medicine and veterinary medicine. This contract has previously been published by the SMPA where it unfortunately did not attract any bidders and therefore we have now awarded it by means of a negotiated procedure.

II.1.6. Information about lots

This contract is divided into lots: no

II.1.7. Total value of the procurement

Value excluding VAT: 21 000 000,00 DKK

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

II.2.3. Place of performance

NUTS code: DK011 Byen København

II.2.4. Description of the procurement

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.

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 the basic procurement without options 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

II.2.11. Information about options

Options: yes

Description of options:

Further productization and adaptation of the Background system, beyond the DKMA MVP referenced in II.2.4.

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

- No tenders or no suitable tenders/requests to participate in response to open procedure

Explanation:

DKMA and SMPA have previously twice published the same contract without receiving any bids. The contract includes developing a new pharmacovigilance solution for the DKMA, which will be compatible with the new EU pharmacovigilance regulations nomenclature to be introduced in June 2022, in accordance with regulation EU/520/2012.

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.2.1. Previous publication concerning this procedure

Notice number in the OJ S: [2021/S 227-597618](#)

IV.2.8. Information about termination of dynamic purchasing system

IV.2.9. Information about termination of call for competition in the form of a prior information notice

The contracting authority will not award any further contracts based on the above prior information notice

Section V: Award of contract

A contract/lot is awarded: yes

V.2. Award of contract

V.2.1. Date of conclusion of the contract

04/02/2022

V.2.2. Information about tenders

Number of tenders received: 3

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

V.2.3. Name and address of the contractor

Official name: Isife ApS

National registration number: 38819259

Town: Søborg

NUTS code: DK012 Københavns omegn

Postal code: 2860

Country: Denmark

The contractor is an SME: yes

V.2.4. Information on value of the contract/lot

Initial estimated total value of the contract/lot: 21 000 000,00 DKK

Total value of the contract/lot: 21 000 000,00 DKK

V.2.5. Information about subcontracting**Section VI: Complementary information**

VI.3. Additional information

The value of the contract stated in V.2.4 is the maximum figure based on the previously tendered contract, including options.

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

28/02/2022