



# LÆGEMIDDELSTYRELSEN

DANISH MEDICINES AGENCY

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LCC, CALW

## Market Dialogue about Commercially Available PV-systems on the European Market

The Danish Medicines Agency, DKMA, wishes to procure a system to aid in pharmacovigilance. At present we collaborate with MHRA<sup>1</sup> and occupy a part of their system, Sentinel, which is due to retire. Given the unclear situation about Brexit, DKMA has seen it fit to pursue a market dialogue with potential vendors about a system, that may eventually replace the functionalities we make use of in Sentinel. Be aware that a signal management system is not in scope.

### The vision

DKMA wants to procure a pharmacovigilance system (safety database) that matches the current and future needs of our agency. In connection with the acquisition, DKMA wishes to enter into long-term strategic cooperation with the solution provider. The collaboration must support DKMA's ongoing organizational and business goals as well as development in terms of pharmacovigilance and thus benefit both the customer and the supplier.

DKMA seeks a quick transition and to minimize or completely avoid the risks associated with a development project in light of the upcoming deadline for compliance with the E2B(R3) standard. DKMA thus finds that the procurement of an already commercially available solution or product to be more viable than to enter into a comprehensive development project. The notion of the desired solution is, that to a large extent it is already operational preferably used by other agencies and therefore commercially available across Europe.

### The Project

The DKMA foresees that the tender and ensuing project will take place according to this approximate timeline:

- Analysis in 2020 with focus on market dialogue and how to structure the tender
- Preparations for a tender in Q3 and Q4 in 2020
- Call for tender in Q1 2021 and closure in Q3 2021
- Implementation project ends Q2 2022

### The Market Dialogue

To test the idea DKMA wants to pose a set of assumptions to interested vendors, of which the answers collectively should shed light on the viability of acquiring an already commercially available product.

First and foremost, we want potential suppliers' feedback to relate to whether there are assumptions or parts of these that are fundamentally considered to be hindering a successful tender.

Any consultation responses will be treated confidentially to the extent permitted by the laws governing transparency in Danish public administration.

DKMA will thoroughly evaluate the responses received and consider whether the commenters give rise to a change of focus in relation to the ten assumptions.

DKMA asks participants to indicate under each assumption whether they consider the assumption plausible. If the recommendation or parts of the recommendation are not considered plausible, we would ask the participants to point out why it is not considered plausible and what solution / path the participants can recommend instead.

DKMA thanks all participants in advance for taking an active part in creating the best possible conditions for the supply.

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<sup>1</sup> The UK Medicines and Health Regulatory Agency.

The deadline for responses to the hearing is Friday, 5<sup>th</sup> of June, at 1 p.m.

## The Assumptions

All of the ten assumptions are presented in brief below and should be regarded as open question to which potential vendors can reply.

### *The System in General*

#### THE SAFETY DATABASE IS ALREADY AVAILABLE IN THE MARKET

DKMA envisions that the system to be acquired under a planned tender can accommodate a full solution and is already commercially available on the European market. Since it is already available it complies with GDPR, ISO27001, and the Pharmacovigilance Regulation (EU/520/2012). Please state if that is a viable vision.

Please enter your comments/ideas here

#### THE SAFETY DATABASE ALREADY COMPLIES TO A RANGE OF SPECIFICATIONS

##### REGULATORY/AGENCY REQUIREMENTS

The Safety System must be able to manage data standards and requirements outlined by EMA, ICH and ISO and capture data according to these. The system must be able to identify and manage duplicate data records/cases. The system must be able to manage standard templates for at least but not limited to narrative and letters. The system must support and manage anonymization or pseudonymization of data. The system must be able to manage controlled user access and workgroups with different access (ISO 27001/2).

##### DICTIONARIES

The system must be able to manage and support various dictionaries in latest version for both products and events, including continuous and regular update of dictionaries. Auto-encoding of applicable data. MedDRA, SNOMED, internal product dictionary and IDMP/SPOR.

##### DATA EXCHANGE

The system must be able to manage exchange of data in standardized formats from other systems, including capabilities for acknowledgements. Exchanged data must be savable, searchable and retrievable within the system. The system shall support inbound data, both R2 and R3 .xml reports. The system must manage inbound data from various sources and formats) other than R2 and R3 (minimum MS office document types, and pdf files).

##### WORKFLOW

The system must be able to manage and configure flow of data records throughout the system. Allocation of data records to users or workgroups. User created items/notifications related to a data record and a workflow. Field level validations and rule-based quality checks must be configurable. Spell check for free text fields. Work lists must be based on real time data.

##### AUDIT TRAIL

The system must have full traceability and be able to log all actions performed in database but not limited to data fields, workflow, data extraction, upload/attachment of data and report generation by date and user and/or system. Actions related to exchanged data must be logged. The log must be searchable and retrievable. The system must support versioning of data records.

##### DATA EXTRACTION

The system must allow for data queries and searches by structured data and free text fields. The system must be able to provide standardized and ad hoc report/listing generation in configurable output formats, which should also allow for aggregated data. A

tool for business analyses visualizing data including dashboard for key metrics must be available and based on real time data.

If one or more of the above described parts cannot be meet in the standard system, please provide the supplier's opinion on how these parts can be fulfilled.  
Please include if there are parts that, in the supplier's opinion, can be built on a standard platform?

Please enter your comments/ideas here.

### *The Vendor and the Customer-Vendor Relationship*

VENDOR MANAGEMENT CAN RELY ON ALREADY EXISTING STANDARDS IN THE MARKET

The DKMA has evolved comprehensive procedures for vendor management with varying degrees of interaction depending on the importance of the system and/or vendor. Based on your experience please specify the level of vendor management, that would in your view be adequate for the cooperation.

Please specify the conditions that would ensure adequate:

- Conditions for lowest TCO and optimal value
- Which conditions, in the supplier's opinion, will best serve DKMA in relation to maintenance, operation, support, across the entire ecosystem? Ownership and licensing conditions, and financial framework?

Please enter your comments/ideas here.

THE QUALIFICATIONS OF THE VENDOR

The vendor must have a qualified record of PV knowledge and management of safety databases. The vendor must be able to manage both implementation and maintenance of the system. This includes:

- Safe operation
- Safe implementation
- Compliance with service objectives
- Collaborate with mature Supplier with mature processes
- The supplier greatly supports implementation and configuration with the Customer
- The necessary information security is supported

Please specify, in your opinion, what terms and conditions a customer can reasonably demand in the tender to ensure compliance and seamless implementation and operation.

Please enter your comments/ideas here.

VENDOR OBLIGATIONS AND SYSTEM DOCUMENTATION

To be compliant, documentation for qualification of the system including validation reports must be available on DKMA premise.

Please specify what setup would, in your opinion, best satisfy compliance and how can the vendor support it?

### *Data/System Architecture*

THE SYSTEM MUST BE ABLE TO INTEGRATE WITH OTHER SYSTEMS SUCH AS DKMA'S MEDICINE REGISTER, WHICH IS SEPARATE FROM THE PV-SYSTEM

The medicine register and case handling system are separate entities in DKMA with the former based on Microsoft Dynamics and the latter is a proprietary system. The PV-system must be able to exchange information with both. Please specify what standards or protocols would be advantageous to DKMA to use.

Please enter your comments/ideas here.

THE DATA MODEL IN THE COMMERCIALY AVAILABLE SYSTEM IS BASED ON IDMP/SPOR AND THE SYSTEM IS CAPABLE OF EXCHANGING DATA WITH EMA

The medicine register at DKMA is based on an IDMP/SPOR data model and integrates with the EMA's SPOR services. To avoid inter system translation DKMA envisions that the data model of the PV system is also based on IDMP/SPOR and so allows seamless flow of data. Please state if, in your opinion, that is a viable notion.

Please enter your comments/ideas here.

THE DESIGN OF THE SYSTEM ALLOWS IT TO BE EITHER CLOUD OR ON-PREMISE

The DKMA has so far had its primary system operated on-premise but market trends in general and the visions from the European Commission points to a future of cloud-based systems. Please state what, in your opinion, would the best option for DKMA to pursue.

It is important that the new system does not convert IDMP/SPOR data into proprietary data or in any other way prevent the data from being readily exportable to i.e. The Danish National Archives. Likewise, licensing terms should preferably allow for expanded use without causing unreasonable extra costs. The DKMA also takes a very dim view at any perceived attempts at vendor lock-in.

Please enter your comments/ideas here.

#### *The Tender Process*

PROCUREMENT OF THE PV-SYSTEM IS CARRIED OUT IN ACCORDANCE WITH THE CLASSIC EU TENDER FORMAT

One of the recommendations is to carry out procurement of the Safety System according to the classic EU tender form.

DKMA intends to pre-qualify approx. five suppliers based on their technical and financial capabilities, including consultancy skills and references from similar projects.

Please enter your comments/ideas here.

#### *Project Organization*

PROJECT ORGANIZATION AND COLLABORATION MODEL ARE STANDARD BUT TUNED TO HIGH THROUGH-PUT.

DKMA must meet the E2B (R3) deadline of June 2022. Please describe what project organization and method of working the DKMA should employ together with the vendor to reach a successful implementation before June 2022.

Please enter your comments/ideas here.

#### *Project Activities*

PROJECT ACTIVITIES ARE KEPT TO AN ESSENTIAL MINIMUM.

DKMA foresees very strict timelines in the implementation project and an overview of a project plan is essential to meet the E2B (R3) deadline. Please describe a high-level project plan which contains the necessary activities for a successful implementation and their distribution. Please include activities such as data mapping, migration, testing, validation, go-live and hyper care.

Please enter your comments/ideas here.