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Market Dialogue for the Acquisition of a Pharmacovigilance System - May to June 2020

Final Report

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Introduction

In May and June 2020, the Danish Medicines Agency conducted a market dialogue with interested parties i.e. providers of IT pharmacovigilance (PV) systems that already exist on the European Market. The purpose of which has been to contribute to the qualification of the upcoming tender on the acquisition of a PV system to replace our involvement in the British PV system. The contribution has consisted of assessing whether the market is mature enough to supply pre-built systems that can be configured to our needs and only need a minimum of customization.

The purpose of the market dialogue must be seen in a larger context with the rest of the pharmacovigilance modernization project. It is not only the answers provided here that determines how the Danish Medicines Agency will specify the requirements for the forthcoming tender. Emphasis will also be placed on what the other national competent agencies in Europe has chosen to do, the development in EMA and the Danish Medicines Agency's IT environment and strategy.

The purpose of this report is to account for the process surrounding the market dialogue itself and ensure that none of the participating suppliers subsequently possess information that can place them better in a tender than others with consequent risk of being disqualified. In addition, the report briefly informs about the overall course.

Finally, it must be emphasized that the market dialogue is not the tender process itself, which is why the Danish Medicines Agency will neither disqualify nor pre-qualify any solutions on the basis of the answers obtained here. The market dialogue and all the Danish Medicines Agency other studies are solely intended to ensure and qualify input to the tender. Solutions offered, that do not meet the Danish Medicines Agency's specifications for a PV system, will of course fare worse than solutions that meet these. The final specifications, as in all other tenders, will be stated in the tender material, when available.

The Danish Medicines Agency thanks all the participating parties for their contributions, which have secured the Danish Medicines Agency a much more complete understanding of the market.

Background

At present we collaborate with MHRA and occupy a part of their PV system, Sentinel, which is due to retire. Given the unclear situation about Brexit, DKMA has seen it fit to investigate the various ways in which we could acquire a replacement system in order to be fully compliant with the E2B(R3) deadline of 30th of June 2022.

An initial analysis from 2016 concluded there were two ways to move forward if the Danish Medicines Agency should choose to discontinue the arrangement with MHRA and were to acquire a pharmacovigilance system. The first option was to build a PV system on a standard platform and the second was to buy a PV system, that was already in the market. Given the recent development about Brexit the Danish Medicines Agency set about to further investigate both possibilities.

To gain an understanding of the implications of developing a custom-built PV system, the Danish Medicines Agency had a review of the recently acquired standard platform conducted. The review clearly states that such a solution is technically possible.

To investigate the possibility to acquire a PV system, that was already in use in the European market, the Danish Medicines Agency launched a number of initiatives. Prior to market dialogue a survey was conducted about the IT systems supporting pharmacovigilance within the National Competent Agencies of European Medicines Regulatory network.

The questions in the survey were as follows:

- What PV system are you currently using for ICSR management?
- Is your PV system custom built or based on “commercial off the shelf” (COTS) technology?
- If your PV system is based on COTS, which PV system are you using and who is your vendor?
- What year did you go live with your current PV system?
- How does ICSRs from patients, healthcare professionals and other stakeholders enter your PV system (e-forms, paper forms, web-service etc.)?
- What level of business automation does your PV system deliver with regards to ICSR management?
- What other IT systems is your PV system integrated with, e.g. data entry, signal detection, data analysis?
- Overall, how satisfied are you with your current PV system?

Out of 31 NCA’s 18 responded and the basics were: seven NCA’s indicated, that they use custom built software to support human PV processes and nine NCA’s respond that they relied on various COTS software. This was a vital hint that mature solutions were available on the European market.

Analogous to that the Danish Medicines Agency interviewed several agencies around the world to gain an understanding of both implementation of the various PV systems both commercially off the shelf and custom-built and the experience afterwards.

The Market Dialogue

Purpose and Limitations

To conclude the investigations about the possibility to acquire a commercially available PV system the Danish Medicines Agency conducted a market dialogue. The purpose was to assess whether a set of assumptions were valid enough to be used as the basis for a future tender. The market dialogue was announced via TED and was open to all interested vendors.

Process and participants

The process itself was straightforward: The market dialogue was a written procedure and was opened on the 13th of May and concluded on the 5th of June. The list of interested parties consisted of ABcube, Everis, IQVIA, Netcompany, NNIT, PharmApp, and SAS Institutes.

The assumptions posed by the Danish medicines Agency

The assumptions were construed to cover a range of topics in order to shed light on whether the Danish Medicines Agency was on solid ground to pursue a commercially available PV system or not. The topics included the future system, vendor-customer relationship, the tender itself and the makeup of the ensuing project.

The following paragraphs are direct excerpts from the document. The answers from the various interested parties are *not* included in the text:

The Safety Database is already available in the market

DKMA envisions that the PV 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).

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 the 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 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?

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?

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.

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.

The data model in the commercially 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.

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.

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.

Project Organization

Project organization and collaboration model are standard but tuned to high throughput.

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.

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.

Conclusion

All in all, the assumptions were confirmed as a basis for a tender i.e. there are mature commercially available PV system on the European market that by all accounts can meet the required specifications by both national and European regulation and the needs of the Danish Medicines Agency. The replies highlighted numerous points of interest and several proposals to make a tender more robust and so acquire both the best suited product and a productive customer-vendor-relationship.

The way forward

The market dialogue has only addressed the specific assumptions related to a tender concerning a PV system, that is already commercially available and not the possibility to acquire a customer specific system based on a CRM-platform. Equally, it was never the purpose of the market dialogue to decide the final make up of a future tender. In connection with this market dialogue a similar approach was adopted to investigate the market for signal detection and handling system. The Danish Medicines Agency must clarify the ramifications of a crucial question before deciding on the way forward: Should there be a single tender containing both a pharmacovigilance system and a signal detection and handling system or should there be two separate tender each containing its separate system?

Regardless of the answer the Danish Medicines Agency plans on announcing a tender no later than the 1st of February 2021. Should the decision be to conduct two separate tenders the second will be announced no later than 1st of May 2021.

The Danish Medicines Agency wish to thank every organization and person who has contributed to the market dialogue.