Ministerie van Volksgezondheid,
Welzijn en Sport

MINISTRY OF HEALTH, WELFARE AND SPORT

Horizon Scanning System

Report Open Market Consultation

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1. Introduction

This document is the report of the open market consultation (OMC) initiated by the Dutch Ministry of Health, Welfare and Sports (and supported by the other partners in the BeNeLuxA initiative), between October 18th and November 27th 2018. It was performed in the form of a meeting and an online questionnaire. The meeting took place on the 12th of November 2018, in The Hague, the Netherlands and attracted participants from the Netherlands, the UK and the US.

The OMC aimed to inform market operators regarding the upcoming joint procurement of the Horizon Scanning System (HSS) and to understand the operators' capabilities to satisfy the procurers' needs and to obtain operators' input on the viability of the procurement plans and conditions, as described in the OMC document.[1]

The HSS procurement is planned by several public procurers from various countries. These public procurers intend to procure jointly as part of the Horizon Scanning Initiative (IHSI). The definitive composition of the procurers consortium (participating countries in the IHSI) is expected to be decided at the end of 2018/beginning of 2019, when financial and organisational commitment are expected to be finalised. The HSS procurement is expected to take place in 2019 under Belgian law.

This report outlines the steps undertaken in the context of this OMC, a summary of the questions asked and answers given during the physical meeting on the 12th of November 2018, an overview of the answers to the EU Survey and an analysis of the outcomes of the market consultation.

The following attachments form part of this document and can be downloaded:

- Presentation 12 November 2018 The Hague
- EU Survey list of questions

2. Summary meeting of November 12th 2018

On the 12th of November 2018, a meeting was organised at the premises of the Dutch Ministry of Health, Welfare and Sports in the Hague, the Netherlands.

During the meeting , several questions were asked by the participating market parties. These are presented below, together with the accompanying answers.

Nr.	Question	Answer
1	Does the parameter 'therapeutical value' for the definition of the high impact reports refer to 'relative therapeutical value'?	The parameters for the estimation of the high impact are given as examples. In the tender documentation we will not prescribe a specific methodology for the estimation of high impact, but we allow the market players to propose their own scoring mechanism.
2	How should the health care costs be estimated?	The bidders in the future HSS procurement should estimate the costs based on open, publicly available data. The HSS database should not be filled out by the producers of pharmaceuticals or medical technologies.

[1] For more information, see: http://www.beneluxa.org/news2

	When should the HSS/library be available?	We plan to request the phased creation of the HSS. In the first phase, the database for pharmaceuticals should be built. Depending on experience we expect this to be up and running as soon aspossible, but within 2 years from the signing of the awarded contract. In a second phase, which will be completed later, the HSS database should be extended to include medical technologies. The awarded contract, covering also maintenance will be signed for a longer period, to be decided before the publication of the tender.
3	How are you going to approach the Horizon Scanning of medical technologies, as your knowledge is mainly on the pharmaceuticals?	We ask the market players to propose a methodology for scanning and identifying the high impact medical technologies 2,5 years before market entry. Our ambition is to have a qualitative database that will complement the European Commission's EUDAMED.
4	Are you expecting to find the IT and medical expertise in one supplier?	No, consortia and subcontracting will be accepted.
5	You mentioned that the HSS should only contain open/public data. How should we deal with confidential information submitted by industry?	We will explicitly request in the tender documentation that only open/publicly available data should be included. No confidential data from industry should be collected.
6	If we do not collect data from industry, we will be limited in our estimation of future costs. How do you suggest to address this?	We believe that it is in the interest of industry to provide non-confidential information regarding future costs. Moreover, there are other sources such as stock exchanges and investors reports that may be used to estimate costs. We will accept such estimates, as long as clearly referenced.
7	We foresee difficulties in the level of interpretation of data and how to differentiate between factual information and judgments.	In the tender documentation, we will clarify which fields should be factual and which may/should be based on assumptions. We will also explain which sources may not be used (e.g. asking the doctors what price they expect for a specific pharmaceutical). We will accept estimation in the form of ranges. Lastly, we want to stress again the importance of including clear reference of sources that underline the assumptions.
8	Should the HSS guarantee an audit trail (e.g. based on blockchain technology)?	It is beneficial to have an accurate trail of changes in the database. We will consider including this feature in the tender documentation.

9	Do we consider patient volumes when we estimate costs?	No, you only need to come up with a price range. Individual countries will subsequently (outside the scope of the HSS) apply the price range to their own national data.
10	Shall we design agnostic groupings of data?	Yes, each country will interpret the data based on their national situation. For example, a hospital will refine their estimations based on their own number of patients.
11	Are you only targeting medical technologies in grade 2b/3?	Yes, we are only interested in grade 2b/3 and first-in-class medical technologies (e.g. not plasters). Due to the fast pace of innovation in medical technologies, we estimate that HS of medical technologies will have to deal with very large amounts of information. In order to limit the complexity, we refer initially only to grade 2b/3 medical technologies. However, we will allow for flexibility to extend the scope of the HSS on medical technologies in a later stage of the contract. This approach will be embedded in the tender documentation.
12	Can you confirm that high impact assessments are part of the HSS?	Yes, we are looking for high impact assessments that are as factual and methodologically sound as possible. The aim is to prevent duplication of data collection and create a common knowledge source.
13	Can the estimations made by the supplier in the HSS be challenged in court by the industry?	We are not aware of such instances.
14	Do other countries believe that horizon scanning is a mandatory task ?	Participation in the upcoming HSS is optional for countries. We have at this moment around 15 countries that are potentially interested in jointly procuring such a system. Although a voluntary collaboration countries are aware of the benefits in jointly setting-up the HSS.

3. Summary replies EU Survey

Two parties provided responses to the published EU Survey. The respondents indicated to have the capability to submit a compliant proposal to the HSS procurement, either individually or by forming a consortium.

Regarding the budget, the respondents indicated a range of several million euro per year, depending mainly on the time horizon for the pre- and post-market scanning, scope of the pharmaceuticals and medical devices. Other elements that impact the budget are the number of topics identified for

scanning, the prioritisation of disease/conditions for scanning and the sophistication of the desired IT infrastructure.

The respondents indicated that they have past experience with defining methodologies for identifying, classifying and estimating the impact (clinical effectiveness and cost) of pharmaceuticals and medical devices. The respondents also indicated that they have expertise in collecting information directly from manufacturers during product evaluations and/or health technology assessments of drugs and medical devices, while being able to prevent any conflict of interests. As well, the respondents indicated that they have the capabilities to form and maintain external and internal pools of medical experts.

The respondents did not identify any (technical) barriers to partially restricting access to the HSS database or offering different degrees of access per end-user to the restricted area. They did suggest technological functionalities that would add value, such as artificial intelligence, predictive modelling, semantic engines and blockchain integration. They also indicated that they are capable of delivering modern user interfaces that are compatible with modern browsers and mobile devices, are backed by distributed and highly scalable open-source search technology.

The respondents did not identify any inadvertencies in the requirements as described in the Market Consultation document. However, they cautioned about under-estimating and under-sizing the scope of the infrastructure and capabilities needed to deliver a suitable solution.

They also indicated that they do not own any relevant IPR or and are not aware of any relevant standards in addition to those mentioned in the Market Consultation document or of any blocking IPR.

4. Conclusions

The input received from the participants in the market consultation confirmed that a HSS fully complying with the currently defined requirements is not readily available on the commercial market. However, the respondents confirmed their capability of submitting a suitable proposal. Only few market operators have the combined IT and medical capabilities to submit an offer, while other parties are willing to form consortia in order to satisfy the procurement need. The market also confirmed that they do not own relevant patents related to the IT technology and are not aware of any blocking IPR that would create impediments for submitting an offer.