Market consultation: Preparation software system for cytostatics

Amsterdam UMC: location AMC and location VUMC

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1 Inleiding

The market exploration regarding a preparation software system for cytostatics We intend to issue a request for quotation. The purpose of this market consultation is:

- Exploring the market;
- To explore the capabilities of the applications
- To establish the scope
- To identify potential risks.

1.1 Contracting authority

This market consultation is organized by Amsterdam UMC, hereafter collectively referred to as: UMC.

Since January 1, 2024, VUmc and AMC have merged into a single entity called Stichting Amsterdam UMC. Amsterdam UMC will strive to harmonize both locations in the coming years.

Mission: “Together, as UMC, we work toward a society in which diseases are prevented and patients are cured. We conduct scientific research to continuously improve our treatments. And we train the best doctors and nurses for the future. Together, we provide the very best care”.

UMC wants to make a substantial contribution to the quality of healthcare and thus to people's well-being. As university medical centers, we focus on a leading position in education and training, scientific research and patient care. Location VUMC will focus primarily on planned elective care and Location AMC on acute care and women & children.

The UMC is in a state of flux. Due in part to major renovations, there are shifts and relocations of nursing departments that call on the flexibility and effort of the organization and Suppliers. Various projects are also underway to support care. In addition, work is underway to harmonize care and (facility) services of both UMC locations.

For more information, https://www.amsterdamumc.nl

1.2 Relevant divisions and departments.

The client is the hospital pharmacy of the Amsterdam UMC.
In the Amsterdam UMC, people work with full dedication and commitment on high-quality care, research and education.Ensuring the best possible working conditions for employees and the quality

and safety of our preparations within the hospital pharmacy are therefore extremely important. To ensure these things, we use different types of software and hardware within the pharmacy. These must also be able to work together with our hospital information system: EPIC. In this, the hospital pharmacy is supported by ICT Amsterdam UMC and EvA Amsterdam UMC.

1.3 Assignment Description

Current situation

Policy and legislation:

- GMP-z en GAMP.

General:

When a patient is admitted to Amsterdam UMC and needs medications, these are supplied from the hospital pharmacy. Some of these drugs are purchased ready to use (e.g. tablets, capsules, etc.). A medication may also need to be processed before it can be given to the patient. The medication must then be made ready for administration (VTGM). For the most part, this is done in the preparation rooms of the hospital pharmacy. There are different types of VTGM: VTGM individual, VTGM in-series, VTGM in stock and VTGM of cytostatics. Cytostatics are often dosed by weight or body surface area, which is why dosing can vary greatly from patient to patient. Cytostatics should work well, and thus should not be dosed too low. In addition, cytostatics can also cause many side effects, so it is also important not to overdose. A cytostatic enters in a vial, from this vial the correct dosage is raised and added to, for example, an infusion bag. This infusion bag can then be administered to the patient on the nursing ward. It is important that the patient is administered the right product in the right dosage. In addition, it is also important that the preparation staff in the pharmacy and the nurses on the ward are exposed as little as possible to the cytostatics (as these are hazardoussubstances). The hospital pharmacy bears responsibility for this. To reduce the risk of human error, supportive preparation software and chemo robots are used.

Current process in hospital pharmacy:

- Cytostatics are prescribed by medical specialists and then verified by pharmacists (verifying the correctness of the prescription) in EPIC. After cytostatics are verified, preparations are shot through an automatic interface to the current software or cytostatics robot, or paper protocols are printed out.
- In the preparation room: drugs and preparation supplies are collected by pharmacy assistants for preparations that go through current software or paper protocols.

In the cleanroom:

- With the current software, the preparations can be carried out gravimetrically (with scales as a second check for dosage of cytostatics) or volumetrically (the volume of raised cytostatic is checked by a second pharmacy technician as a check for dosage). The identity of the vials of cytostatic is checked by barcode scanning and if this is not possible it is checked by the circulation.
- In the case of the cytostatic robot, the preparation is transferred to robot 1 or robot 2. The robots are loaded by employees, who load syringes, infusion bags, infusion lines and drug vials, among other things. The robots determine from the weight of the vial, among other things, whether the correct dosage has been pulled up by the robotic arm. Vials are identified using recognition software.

- In the case of a paper protocol, all checks are confirmed by the second pharmacy technician with their initials. Thus, this applies to vial identification, dosage control and in process controls such as whether everything has been dissolved.

At release: the pharmacist checks that all preparations have been done correctly. This involves looking at appearance, packaging, labeling and 'in process' controls.

The cytostatics VTGM process is the responsibility of the hospital pharmacist production. Software interface and EPIC issues surrounding the cytostatics process are the responsibility of the hospital pharmacist ICT.

Current systems:

- CMS (manual preparation of chemotherapy with software support). This system is going to be discontinued, so we need to look for a replacement for it.
- Apotecamanager with Apotecachemo (cytostatics robots).
- Paper protocols in case cytostatics cannot be prepared via CMS or Apoteca.

Current landscape:

- Current software interface:
  o EPIC -> CMS. No automatic interface back. Via an export, every night the used stock and 1x per week the claim lines are read into EPIC.
  o EPIC -> Apotecamanager. Apotecamanager -> EPIC.

- Current application landscape/infrastructure: CMS is an application running on Microsoft Edge and Apotecamanager is an application running on Oracle. Both options have been issued by ICT as secured for the future. The new software must be able to interoperate with existing software within Amsterdam UMC.

Desired situation.
We are looking for a system that can fill the gap left by CMS when it ceases to be available January 1, 2026. Our goal is to be able to perform manual preparation of chemotherapy with software support where the user sees Dutch text on the screen. Depending on the situation, it will then also be possible to expand to VTGM of non-cytostatics. What this software support looks like may vary. What is important to us is that the solution complies with legislation (GMP-Z and GAMP). With this we want to ensure that we have a system that ensures accurate preparations (medication safety). In addition, the system must be safe to work with for our employees.

The quality of the product is guaranteed, among other things, by in-process controls that are recorded and can be viewed afterwards by the releasing pharmacist. In addition, the software must fit the situation in the pharmacy. It is also important to us that a software interface (including logistical) is possible from and to EPIC. After a successful implementation of the new system at the cytostatics department of the Amsterdam UMC has been completed, it is our goal to continue this

project and to support as large a part as possible of the preparations within the hospital pharmacy with this new system. This expansion will then include VTGM-in-series, individual VTGM (non-cytostatics), TPV customization and stock preparations.

However, it is not possible to say with certainty what the developments will be within hospital pharmacy after the implementation of the new system in the cytostatics department. Because health care is in a state of flux, these future changes cannot yet be determined with certainty.

1.3.1 DELIVERABLE

Amsterdam UMC is looking for one supplier for a system that can perform manual preparation of chemotherapy with software support. After a successful implementation of the new system at the cytostatics department of Amsterdam UMC has been completed, it is our goal to continue this project and support as large a portion of the preparations within the hospital pharmacy as possible with this new system.

DOELSTELLINGEN

The objective of this tender is to select a system that can realize maximum efficiency in the processes, and is as user-friendly as possible, and supports the employees in their work as much as possible.

1.3.2 SCOPE

Responsibilities invested as follows: see Appendix 1 Scope

1.3.3 PRECONDITIONS

Archive:

- Retention requirement: 15 years
- Current Archive:
  o Electronic archive: 15 years
  o Internal archive for paper workflow: E0-109 and E0-112; Drawers in VTGM preparation room for the duration of 1 year, then external (firm Deudekom).
- Data for data migration: not applicable, no data need be migrated (CMS database must remain available, however, for retrieval of preparations, to be coordinated with ICT)

1.4 STAKEHOLDERS AND TARGET GROUPS

Several target groups apply within the hospital

- Hospital pharmacy: pharmacy assistants/pharmacy staff and pharmacists.

1.5 Scope

Cytostatics: 39 pharmacists + 25 pharmacy assistants, 15,000 preparations per year
Later (other VTGM workplaces): 39 pharmacists + 50 pharmacy assistants/pharmacy workers

1.6 PROCEEDINGS

Participating market participants are expected to be willing to share their specific knowledge on this topic with the UMC. The effort will consist of reading this document and studying and answering the attached questionnaire. You may then be invited to explain your consultation paper in person.
For this Market Consultation, the procedure is as follows:

- The market parties are given the opportunity to ask questions about this Market Consultation (see Appendix 3)
- Based on the UMC's answers to the questions, the market parties will formulate their answers to the questions (see Appendix 2);
- The UMC may require further information from (one of) the market parties if certain answers are not clear;
- If the UMC sees reason to do so, after the deadline for submitting the market consultation document has passed, it may invite some parties to obtain further information. Which parties these will be is entirely at the discretion of the UMC;
- The results of this market consultation shall be appended anonymously to the tender documents for the European tendering procedure or incorporated into the Schedule of Requirements (PoR) so that all tenderers in the European tendering procedure can take note of the results of the market consultation.
- In a second round of questions, UMC may/will offer the requirements package for review. This round of questions will be entirely in writing.

1.7 PRINCIPLES OF PROCEDURE

With respect to the market consultation, it should be kept in mind that the market consultation in itself is not part of the upcoming tender procedure. It is an aid for the UMC to be able to draw up the Statement of Requirements in an appropriate manner, taking into account the most up-to-date knowledge from the market.

De marktconsultatie dient daarom in het navolgende juridische kader te worden geplaatst:

- Therefore, the market consultation should be placed in the following legal framework:
- The market consultation is published on the TenderNed platform;
- The results of the market consultation will be collected, anonymized and provided or processed with the tender documents;
- The market consultation will in principle take place in writing;
- The market consultation is entirely without obligation for both the UMC and the participating market parties: the consultee cannot derive any rights from participation in this consultation;
- It may be decided at a later date to follow up the consultation, in which case participation is of course again entirely voluntary;
- The UMC will treat the information provided confidentially. If confidential information is involved, please mention this in the answer to the question;

- Correspondence and information provided will not be returned afterwards and may form part of the tender procedure. Participating parties grant permission to process the information provided in the PvE.
- The UMC can and may use the information obtained from the market consultation in whole or in part when drawing up tender documents and/or drawing up the contract;
- The information provided during the market consultation may differ significantly from the information provided at a later stage for the purpose of the tender procedure;
- No compensation is provided for participation in the market consultation;
- All communication regarding this consultation will take place via the TenderNed platform;
- The language used during this consultation is Dutch/ English.

This market consultation has been carefully compiled. Should you nevertheless encounter any contradictions and/or imperfections, please inform the UMC by using the question & answer module.

1.8 Submission

1.8.1 DIGITAL OFFERING

This Market Consultation will take place entirely digitally and online via TenderNed.
It is only permitted to submit your response for this Market Consultation digitally via TenderNed. This means, among other things, that:

- Entrepreneur registers on TenderNed;
- Entrepreneur reviews and completes the questionnaires;
- The submission of questions by Entrepreneur is submitted via the form for asking questions;
- The Memorandum of Information by UMC is also published.

If you have any questions or uncertainties about the operation of TenderNed, you can contact the Service Desk

1.8.2 ASKING QUESTIONS

You can submit anonymous questions regarding this Market Consultation in writing using Appendix 3. The questions asked and the answers (Notes of Information) will be made available to all registered suppliers.

The schedule for questions and answers (Notes of Information) can be found in the Schedule on TenderNed.

2 Schedule

Below you can find the planning of the market consultation process:

Proces	**Date and time**
Publication Market Consultation	thu 26th of march 2025
Deadline for asking questions	Tue 8th of april 2025 12:00 uur
Intended date for answering questions	mon 14 april 2025
Submit questionnaire (written)	fri 18th of april 2025, 12:00 uur

* Please indicate via "Messages" in TenderNed on which days you are available, who you are coming with (max. 3 people) and what time you prefer.