

**PRLIMINARY MARKET CONSULTATION. BASIC CLAUSE.
SERVICE OF REGISTRATION AND PROMOTION OF THE ADHERENCE TO
MEDICATIONS IN ELDERLY PATIENTS (SAMPA) FOR THE OUTPATIENT
PHARMACEUTICAL CARE UNIT (UAF-PEX) OF THE MIGUEL SERVET
UNIVERSITY HOSPITAL OF ZARAGOZA**

ANNOUNCEMENT

CLAUSE

The Preliminary Market Consultation is announced for the search of innovative solutions in innovation projects related to the Service of Registration and Promotion of the Adherence to Medications in Elderly Patients (SAMPA).

Information about it can be found on the:

<http://sectorzaragozados.salud.aragon.es/pags/cpi>

DESCRIPTIVE REPORT OF THE NEEDS TO BE SATISFIED AND SCOPE OF THE CONSULTATION CLAUSE

The present preliminary consultation to the market, based on the provision of Article 40 of the Public Procurement Directive 2014/24 / EU, is intended to solicit market information on possible solutions to the need to improve the pharmacotherapeutic process of patients to which drugs are dispensed from the outpatient pharmaceutical care unit (UAF-PEX) of the Miguel Servet University Hospital of Zaragoza (HUMS) through the use of new technologies.

The overall objective is to acquire a comprehensive service to improve safety in the use of medicines and ensure the adherence of chronic elderly patients (> 60 years). The beneficiaries will be: onco-hematologic patients, HIV, pulmonary arterial hypertension and chronic renal failure.

The general needs are defined in the descriptive report, published on the tender's website: <http://sectorzaragozados.salud.aragon.es/pags/cpi>

SPECIFIC OBJECTIVES OF THE CONSULTATION CLAUSE

The specific scope of the market consultation can be delimited around three specific objectives described in relation to the lines of action detailed below:

SPECIFIC OBJECTIVE 1.- SAFETY: The dispensing error rate will be <1%.

It aims to achieve a minimum error rate, close to zero, in the process of prescription-validation-dispensing of drugs to the outpatient.

Areas of activity:

1.1- Electronic prescription

Electronic prescription platform (integrated with health systems in use in the HUMS) and which includes at least:

- Incorporation of patient data: identification, sex, age.
- Incorporation of prescribing clinician data: Identify clinical staff and department.
- Identify prescribed drug, including administration type, dose and dosage schedule.
- Incorporation of allergies and intolerances of the patient.
- Incorporation of anthropometric characteristics and clinical patient's data of interest.
- Identify duration of treatment and validity of the prescription.
- Identify pathology or reason for indication.
- Pharmaceutical validation against prescription on the same platform.
- Prescription schedule.
- Two-way clinician-pharmaceutic information exchange system.
- Incorporation of specific protocols by drug.
- Incorporation non-pharmacological prescription.

Functional Specifications

- The service must be functionally integrated with existing or existing tools in the market for health management, such as:
 - Patient management (BDU).
 - Management of professionals (SIRHGA).
 - Medication database (Farmatools).
 - Outpatient Dispensing Module (Farmatools).
 - Electronic patient record (EPR).
 - Consistency of information among all support systems.
- Must incorporate aids to prescription (protocols, maximum dose, allergies, dosage in special situations: IR and IH ...).
- It must allow the exchange of clinician-pharmaceutic information integrated in the prescription and that allows an easy visualization to professionals accessing the tool.
- Must generate prescription schedules to facilitate the measurement of adherence.

1.2- Improvement of the efficiency and safety in the drug's logistics

Automated stock management and drug storage UAF-PEX:

- Automated storage to ensure:
 - Drug quality: adequate storage conditions and preservation of the correct packaging.
 - Control of consumption and real-time inventory information.
 - Automatic entry of the drug in the warehouse identifying: medication, presentation, storage conditions, batch and expiry date.
 - Eliminate location errors.
 - Optimize the storage space.
 - Management of expirations.
 - Alert of medications under minimum stock and idle.
- Virtual stock management of medicines.
- Automated management of the withdrawal of drug batches due to a health alert.

Functional Specifications

- The system must be located in the current outpatient dispensing area of HUMS, providing structural solutions that allow for its optimum performance.
- The system must respect the safety and health regulations on noise conditions, thermal dissipation, vibrations, electrical safety, etc.

- Have adequate storage capacity for the needs of HUMS. Not less than 14,000 containers with a 60-40% room temperature to controlled atmosphere ratio.
- Manage two different automated storage areas:
 - storage of drugs at room temperature.
 - storage of drugs in a controlled atmosphere.
- Guarantee the continuity of the service, maintaining the system despite partial breakdowns.
- Handle the load and the dispensing simultaneously.
- Make optimum use of storage spaces.
- Allow for manual and automatic entry with identification of drug codes (bar codes), registering medicines, batches, expiration and any information necessary for their management.
- Have automatic warehouse cleaning ability.
- Have alarms, controls and temperature register, allowing for monitoring.
- Integrate with the center's own temperature control systems. As with the management and information systems of the center, just as in the prescription module.
- Allow manual access to the drug in emergency situations.
- Reduce deviations between real stock and computerized stock to <0.1%.
- Decrease the stock breakage index (<0.4%).
- Reduce the time of auxiliary technical personnel in the daily management of the warehouse (<40 minutes).
- Ensure the integrity of the medication, without exceeding the number of damaged containers 0.001%.
- A training plan for professionals must be carried out.
- Commitment to operate at full capacity within 4 months from the award date.

SPECIFIC OBJECTIVE 2.- TRACEABILITY: 75% of the medicines dispensed from the UAF-PEX will present complete traceability including registration of medication, lot and expiration per patient.

It aims to achieve a reliable and agile system so that it can react quickly and adequately, given any risk detected in the quality and safety of drugs.

Area of activity:

2.1. - Automated Dispensing

The automated management of the dispensing of medicines should include at least:

- Safe dispensing through an automated system.
- Complete traceability of medicines dispensed to the patient including expiration and batch.
- Scheduled dispensation via scheduling a pharmaceutical consultation.
- Dispensation through a point of self-dispensation with pharmaceutical aid, outside the opening hours of the Pharmacy Service.
- Possibility of incorporating, if the legislation allows, the delivery of medication at home with pharmaceutical aid virtually or via phone.

Functional Specifications

- Provide mechanisms that allow the dispensing of the drug at dispensing points (minimum 6 and with the potential to expand).
- Have a system of identification and registration of the person who collects the medicine (providing digital certificate for each user).
- Provide a direct, unattended, dispensing mechanism.
 - The device must allow the validation of the unique dispensing receiver (with digital certificate).
 - The device must allow the allocation of the prescription that corresponds to each user linked to the dispensing receiver.
 - The device must have an aid system by image and/or sound to facilitate the procedure in the remote dispensing.
- Limit dispensing by authorized profiles.
- Dispense a minimum of 200 containers/hour at the dispensing points, with a waiting time from the dispensing request to the reception of the medicine <30 seconds.
- Allow patient citation and anticipation of patients' medication needs in advance of appointment/reception.
- Ensure traceability of all medicines dispensed to the patient.
- Achieve a dispensing error rate of <1%.
- Optimize pharmacist' time to increase pharmaceutical care, by eliminating the need for a manual dispensation. Drugs that require manual dispensation will be <15%.

SPECIFIC OBJECTIVE 3.- ADHERENCE: The project will lead to an improvement in the management of adherence, with identification of the problem in 100% of patients monitored.

It aims to achieve a comprehensive service that includes a program to inform and train the patient on their pathology and treatment and a double monitoring system of adherence. This system should include the assessment of the agreement between prescribing and dispensing to detect the primary noncompliance, and the assessment of adherence in real time through the personal registration by the patient of self-administered medication.

Areas of activity:

3.1. Assessment of adherence through agreement between prescription and dispensing

- Evaluation of the adhesion to detect non-adherence (non-collection of the drug).
- Adherence assessment to detect mismatch between prescription and delivered amounts of medication.
- Non-adherence alert systems (adjusted to the prescription's characteristics).
- Classification of the patient's non-adherence risk in tiers.

Functional Specifications

- The system must incorporate:
 - Tool for calculating adhesion and persistence through prescribed amounts and dispensed quantities.
 - Alerts of non-adherence configurable according to the prescription.
 - Incorporation of adherence measurement questionnaires through simple patient consultations.
 - Transmitting alerts to the clinician regarding non-adherence.

- Inclusion of graphs that allow a visual and quick evaluation of the persistence of the prescribed treatment over time.
- Classification of the patient's non-adherence risk in tiers.
- Record of specific actions or instructions to be performed in a high-risk patient and narrow drug-therapeutic follow-up.

3.2. Availability of an outpatient repository

The repository will include:

- Public area:
 - Generalized information on healthy living habits, use of medications and measures to promote adherence, and information from the outpatient area.
 - Answers to frequently asked questions.
 - Information about patient associations.
- Private area with access through a personal user:
 - Information by pathology.
 - Individual information per patient through a personal user: patient's pathology and treatment: drugs, calendar, rules of administration, adverse effects, what to do if a dose is missed, etc.
 - Area of general and/or personal warnings.
 - Area of consultations.
 - Contact with the Center and/or professionals.
 - Training between peers.
 - Management of appointments.
 - Possibility of visualization and correction or updating of adhesion.

Functional Specifications

- The repository must comply with all the requirements of the LOPD for the use of individual patient data.
- The visible contents will be configured according to the patient.
- The repository will allow the configuration of contents visible to all patients, a group of patients (e.g. affected by the same pathology) or a specific patient.
- The appointment management system will be integrated with the citation system in use.
- The peer training area will require supervision for issuance.
- A configurable message system will be connected to the adhesion measuring application.

3.3. Availability of a distributed platform

This platform will allow:

- Evaluation of real-time adherence through the registration of drug administrations by the patient.
- Availability of a distributed platform to record the drug administration in real-time, and to have tools to support adherence to both pharmacological and non-pharmacological aspects.
 - General information about medicines and healthy habits.
 - Information related to the Outpatient Pharmacy Care Consultation (time, location, telephone contact, email...).
 - Specific information by pathology and/or patient:

- Information on a pathology.
- Information about the treatment: performance, posology (dosage), adverse effects, interactions.
- Support for the correct intake of the medication favoring adherence and thus the achievement of health goals. This section will allow setting reminders for medication intake, as well as recording the intake and SMAQ adherence questionnaires.
- Data related to medical appointments and analytical controls.
- Agenda, including events scheduled for each day.

Functional Specifications

- Evaluation of real-time adherence through the registration of administrations by the patient.
- The visible contents will be configurable depending on the user and their pathology.
- The platform will allow the configuration of visible contents to a group of patients (e.g. affected by the same pathology) or a specific patient.
- LOPD compliance will be ensured.
- Will be connected to the citation system in use to notify the patient.
- Connects to the adhesion measurement application.
- You will have a configurable message system.
- Must have an evolving maintenance to adapt to the needs that arise.

TEMPORARY FORECAST FOR PUBLIC BID CLAUSE

The provisional forecast to be able to carry out the bidding and fulfill the functional need is 7 months long and is considered to have an estimated value of 800.000€. Proposals that exceed the estimated value will be accepted.

FEASIBILITY OF EUROPEAN PUBLIC FUNDING CLAUSE

The need described can be supported by public funding of the STOP & GO Project.

DEFINITION OF INNOVATION CLAUSE

"Innovation" means the introduction of a new or significantly improved product, service or process, including, but not limited to, production, building or construction processes, a new marketing method or new business practices, workplace organization or external relations, inter alia with the aim of helping to solve societal challenges or to support the Europe 2020 strategy for smart, sustainable and inclusive growth "(Clause 1.2 of the 2014 Directive / 24 / EU).

MULTIDISCIPLINARY TECHNICAL EQUIPMENT CLAUSE

They are part of the multidisciplinary technical team (CITAR members of the technical team: roles, not people)

- Head Pharmacy Service
- Head Information Systems Service
- Deputy Director of Engineering
- Pharmacy Supervisor
- Head of UAF-PEX
- Member of Information Systems SALUD

Its function in this procedure prior to the contract is to advise the contracting authority to prepare the questionnaires and information that will be used to support the preliminary consultation to the market, and to resolve the doubts and questions that arise during the same.

In addition, the technical team will participate in the preparation of the report containing the results of the consultation.

APPLICATION OF THE PRINCIPLES OF TRANSPARENCY, EQUALITY OF TREATMENT AND NON-DISCRIMINATION CLAUSE

Participation in the consultation, contacts with participants or exchanges of information shall in no case lead to infringements of the Community principles of transparency, equal treatment and non-discrimination in public procurement, and shall not have the effect of restricting or limiting Competition, or grant advantages or exclusive rights.

PROCEDURE OF CONSULTATION CLAUSE. ELECTRONIC FORM

1. All those interested in participating in the consultation will complete the request form to participate in the consultation, available in Annex 1 and on the website <http://sectorzaragozados.salud.aragon.es/pags/cpi>.

For the any doubts and questions, the interested parties will complete the corresponding form, available in Annex 2 and in the website <http://sectorzaragozados.salud.aragon.es/pags/cpi>. The doubts and questions asked will be answered and published by the contracting authority on the website <http://sectorzaragozados.salud.aragon.es/pags/cpi>.

For the presentation of solutions the interested parties will fill in the corresponding electronic form, available in Annex 3 and in the web site <http://sectorzaragozados.salud.aragon.es/pags/cpi>.

All forms must include the necessary identification data as well as any information deemed appropriate.

2. The call is open and is addressed to individuals or legal entities who intend to collaborate with (the proposing body is the Manager of HUMS) by providing information on the state of science or the market as to whether there are certain developed or developing solutions related to the subject of this consultation and, where appropriate, submitting proposals specifying both the definition and scope of tasks, such as its implementation and degree of technological innovation.

The submission of several proposals by the same individual or legal entity will be allowed.

PROCEDURE OF CONSULTATION CLAUSE. DEVELOPMENT

1. This preliminary consultation to the market has a term of one month from its publication
2. The electronic portal will include the various issues and additional information <http://sectorzaragozados.salud.aragon.es/pags/cpi>
3. The use of the content of the proposals will be limited exclusively to their use in the definition of the specifications of any contracting procedure that follows the preliminary consultation to the market.
4. The Final Report with the results of the Consultation will be published on the website <http://sectorzaragozados.salud.aragon.es/pags/cpi>

LANGUAGE OF THE CONSULTATION CLAUSE

The official language of this preliminary market consultation is English.

In order to facilitate the participation of Spanish bidders, the consultation's documents will also be provided in Spanish.

Tenderers may submit their proposals or information in English.

The communication with the bidders during the consultation procedure to answer the questions they raise will be done in Spanish and in English.

CONTENT TO BE FACILITATED BY PARTICIPANTS CLAUSE

The participants in the consultation should facilitate the level of development in which the proposed solution is, the estimated execution time and the economic impact assessment.

CONFIDENTIALITY CLAUSE

Participants will include in the information to facilitate their express consent so that the contracting authority can disseminate their participation and the issues and/or solutions raised in the consultation process.

However, the contracting authority may not disclose any technical or commercial information that may have been provided by the participants, which they have designated and reasoned as confidential.

It is the participants who must identify the documentation or the technical or commercial information that they consider to be confidential, and it is not permissible for them to make a generic declaration or declare that all documents or all information is confidential. Participants may designate some of the documents submitted as confidential.

This circumstance should be clearly reflected (in any form or in the margin) in the document itself designated as such.

PROTECTION OF COMMERCIAL SECRETS CLAUSE

The protection of all information considered commercial secret is guaranteed.

It is considered a trade secret in accordance with Clause 2 of Directive 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed information and business information (trade secrets) against its unlawful acquisition, use and disclosure of information unknown to the general, relevant, public; which has commercial value; and that it has been the subject of measures to keep it secret, that although it does not refer to industrial secrets, there is nothing to prevent them from understanding that they are excluded, so that it may be understood that business secrets include commercial and industrial secrets.

CONSENT FOR DISSEMINATION OF INFORMATION CLAUSE

In order to ensure the transparency of the process, the availability of the best possible information and the effective exchange of experiences and opinions, the participants give their consent for the contracting authority to include in an accessible and up-to-date form the information communicated in the framework of the consultation.

Specifically the participants in the consultation give their consent to use the information provided throughout the procedure on the final day where they will be informed of the results of the consultation.

PROTECTION OF PERSONAL DATA CLAUSE

In accordance with the rules of Protection of Personal Data, the contracting authority will store the contact details of the participants in the preliminary consultation on the market in a file that will be their property. This data will be kept for the sole purpose of facilitating contact during the preliminary market consultation procedure.

INFORMATION OF PATENTS AND OTHER INDUSTRIAL OR INTELLECTUAL PROPERTY RIGHTS CLAUSE

Solutions and technical specifications communicated in the context of the preliminary market investigation may refer to a particular make, type, manufacture or provenance or specific procedure, or refer to a patent or other intellectual or industrial property rights.

CONSULTATION PROCEDURE CLAUSE. CLOSING. FINAL REPORT

"Once the deadline for submitting proposals has been reached, the contracting authority will compile the proposals submitted, as well as the other information gathered during the consultation. If it is deemed necessary, it may request those who submit proposals to clarify some points of their proposals. In addition, it reserves the right to convene individual participants individually to make a more detailed presentation or to expand information on their proposal.

The contracting body, with the assistance and participation of the multidisciplinary technical team, will prepare a final report that will be part of the file, which will include all the information collected with the consultation. In particular, the report shall include all actions taken; The contributions received from the participants in the consultation; Where appropriate, the studies carried out and their authors; The entities consulted, the questions that have been asked and the responses they have given ".

SUBSEQUENT PUBLIC PROCUREMENT PROCEDURE CLAUSE

Following the preliminary consultation, the contracting authority will publicize the results, respecting the principle of confidentiality.

If it deems it appropriate, it may initiate the corresponding procurement procedures as established in the public procurement regulations, defining the functional specifications of the systems, services, products or works to be developed based on the solution ideas collected as a result of the consultation.

In any case, these procedures will be open to all possible proposals that meet the established conditions, whether or not they were linked to the preliminary market consultation. Preliminary consultations may not entail the generation of incentives or advantages for the companies participating in it when awarding contracts, nor can it be recognized as an award criterion or as a favorable value to the same prior participation in the process of the award. Preliminary consultation to the market.

Attachments

ANNEX 1. Application form for participation in the preliminary market consultation.

ANNEX 2. Form for the presentation of questions and questions.

ANNEX 3. Proposal Form for Innovative Solutions for the Service of Registration and Promotion of Drug Adherence in Elderly Patients (SAMPA).