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Unión Europea

GOBIERNO DE ESPAÑA MINISTERIO DE ECONOMÍA Y EMPRESA

JUNTA DE ANDALUCIA

Servicio Andaluz de Salud
CONSEJERÍA DE SALUD

1/2018_CPI PRELIMINARY INQUIRY OF THE ANDALUSIAN HEALTH SERVICE WITHIN THE FRAMEWORK OF THE "PRECISION DIAGNOSIS AND TREATMENT OF INFECTIONS DISORDERS AND CANCER" INITIATIVE FOR THE SEARCH OF INNOVATIVE SOLUTIONS WITHIN THE ANDALUSIAN PUBLIC HEALTH SERVICE.

Precedents

On the 4th of December of 2017, the Ministry of Economy, Industry and Competitiveness, MEIC, and the Andalusian Health Service, herein after referred to as AHS, signed an agreement (with reference CPI-2017-11-SAS-4) in order to contribute in the improvement of public services, through promotion of business innovation, by means of selection of actuations and projects related to "PRECISION DIAGNOSIS AND TREATMENT OF INFECTIONS DISORDERS AND CANCER" (initials in Spanish are ASURANT) and LIQUID BIOPSY.

The agreement is set in the Promotion Program of Innovation by Demand (FID HEALTH)[1], financed with ERDF (European Regional Development Fund), which manages the MEIC in collaboration with the Ministry of Health, Social Services and Equality, (Spanish initials are MSSSI) and Autonomic Regions and which pursues improvement of public health services through promotion of business innovation in development of solutions for needs that are not covered by the public health service based on demand.

The PRECISION DIAGNOSIS AND TREATMENT IN INFECTIONS DISORDERS AND CANCER initiative, is set in the emerging framework of Precision Medicine (PM), which are dealt with in more depth in **Annex I** and **Annex II**.
The initiative started up now, forms part of the Innovative Public Purchase Strategy of

[1] http://www.idi.mineco.gob.es/portal/site/MICINN/menuitem.8ce192e94ba842bea3bc811001432ea0/?vgnextoid=fa85b7ffe276cd510VgnVCM1000001d04140aRCRD
[2] http://ris3andalucia.es

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the Andalusian Public Health System, (SSPA initials in Spanish), which is developed by the General Secretariat of R+D+i of the Autonomic Community and Andalusian Health Service within the context of R+i strategy in Health, the Andalusian 2014-2020/RIS3 [2] Innovative Strategy and the Strategy for impulse and Consolidation of the Public Innovation Purchases, (CPI in Spanish initials) of the Administration of the Andalusian Regional Government whose formulation was passed by the Government on the 4th of September of 2018 (Andalusia Government Bulletin no. 175, 10th of September 2018).

The Innovative Public Buying Strategy (ECPI initials in Spanish) is one of the promotion actions of health innovation of the Andalusian Public Health Services and pursues improvement and sustainability by means of development of innovative solutions based on needs identified by the system and through collaboration with the industrial sector supported by new procedures in public buying.

The Health Council of the Regional Government of Andalusia, in accordance with what is foreseen in the Decree of the President no. 12/2015 dated 17th of June, of the Vice-Presidency and about re-structuring of Councils and in the Decree no. 208/2015 dated 14th of July, whereby the organic structure is established of the Health Council and the Andalusian Health Service, is the Administrative organ of the Regional Government of Andalusia which is responsible for the rules of health policies and superior management of the organisms directly responsible for provision and management of the health services of the Autonomous Community, under the name of Andalusian Public Health Services (Spanish initials SSPA). This System is defined in Section 43 of the 2/1998 Act dated 15th of June, of the Andalusian Health, in Title VII of the Andalusian Health Ordinance, as the set of resources, organizational means and actuations of the public health administrations of the Autonomic Community or those associated to it, oriented towards satisfying the right to health protection through promotion, prevention of disorders and health care.

The Andalusian Health Service (Spanish initials SAS) has as its mission, rendering health care to Andalusian citizens, offering quality public health services, insuring accessibility, equity and user satisfaction, seeking efficiency and optimal use of resources.

The Andalusian Health Service is an administrative agency of those set forth in Section 65 of the 9/2007 Act of the 22nd of October, and with respect to contracting, it is ruled by Decree 39/2011 of the 22nd of February, whereby is set the administrative organization for management of contracting of the Administration of the Regional Government of Andalusia and its instrumental bodies and is regulated in the regime of uniformed goods and services.

With respect to the above, the recently passed 9/2017 Act of Public Sector Contracts, which transposes legal ordinance of Spain of the European Parliament Directives and those of the Council 2014/23/UE and 2014/24/UE, of the 26th of February 2014, establishes explicitly in section 115, that contracting organs may carry out market

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studies and address consultations to financial operators that are active in it with the aim of correctly preparing bidding and informing the financial operators about its plans and the requirements it will be demanding in order to concur to the procedure.

This procedure applies to all types of contracts, specially to Public Innovation Purchases, (CPI in Spanish initials).

The core fundaments of these initiatives are the existence of a need of the health system that is not yet addressed or insufficiently addressed, susceptible to be dealt with by market agents (**Annexes I and II**).

Thus, the definition of this need that is not yet addressed which justifies and articulates the definition of the challenge that the Andalusian Health Service formulates to the market agents for development of solutions by means of a formal public bidding process.

The MEIC-AHS ("the operation" in terminology of the Ministry, "the initiative" in terms of the SSPA) is structured in two areas "ASURANT" (Annex I) and "LIQUID BIOPSY" (Annex II). Each area answers a not yet covered need identified by the AHS, and obeys to specific goals that in sum pursue the search and development of one or several solutions that comply with functional requirements or specifications, defined by the users-buyers of these. These functional requirements are the same and/or should be aligned with what the AHS could apply to include it in its buying catalogue or technology evaluation procedure (AETSA, Andalusian Agency for Health Technology Assessment) for inclusion in the portfolio of services offered by the AHS.

First. Notice

With a prior nature to purchase bidding, the AHS consider of interest obtaining information about the financial operators, the social agents and the knowledge agents, and knowing the state of the art and identifying and specifying the characteristics of the possible solutions that best adapt to service requirements and user needs. This information may be incorporated, if deemed so, to planning and elaboration of the technical specifications of the procedure for later hiring.

Consequently, this Preliminary Consultation of the Market is convened about the two needs not covered and identified in "ASURANT" (further information in Annex I) and "LIQUID BIOPSY" (more information in Annex II).

Both areas of development form part of the R+i strategies associated to the Integral Program for prevention and control of infections associated to health care and appropriate use of anti-microbian elements (PIRASOA)[2] and to the Integral Oncology Plan of Andalusia (PIOA)[3].

[3] http://pirasoa.iavante.es/
[4] http://www.csalud.junta-andalucia.es/salud/channels/temas/temas es/P 2 ANDALUCIA EN SALUD PLANES Y ESTRATEGIAS/plan

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As of these areas, a series of challenges arise for which collecting necessary information is attempted for preparing an eventual public bidding innovation hiring in the setting of the initiative "Precision Diagnosis and Treatment in Infectious Diseases and Cancer".

Second. Object

This notice has as its goal promotion of participation of physical or legal persons for presentation of proposals of innovative solutions in the two needs that are not yet covered of ASURANT and LIQUID BIOPSY.

Specifically, it is attempted that the AHS, as of results of this Preliminary Market Enquiry, have sufficient knowledge of the most novel and optimal solutions for launching a public innovation buying procedure.

The procedure mentioned will request proposals with the technological development level that enables transfer of it to clinical practice and whose idealness may be evaluated by the AHS and the SSPA for later eventual implementation in care processes and procedures.

Third. Participants

The notice is open and is addressed to all those persons physical or legal who may have the intention of presenting proposals for not yet covered needs, both in definition and scope, as well as in development and demonstration of clinical usefulness.

Presentation of several proposals will be admitted by a single physical or legal person, both individually or jointly with others.

In the case of a proposal being presented jointly by a group of persons or entities, identification must be done of the one representing the group, for interlocution with the AHS.

Fourth. Participation conditions

Presentation of the proposals will comply with the following basic rules:

1. Those participating must formulate their proposals filling out the request form (**Annex III**) which can be seen in the profile of the contractor of the Regional Government of Andalusia, in the section "Preliminary Consultations" (https://www.juntadeandalucia.es/temas/contratacion-publica/perfiles-licitaciones.html). The request form may be accompanied by complementary

oncologia/plan oncologia?perfil=org&desplegar=/temas es/P 2 ANDALUCIA EN SALUD PLANES Y ESTRATEGIAS/&idioma=es&tema=/temas es/P 2 ANDALUCIA EN SALUD PLANES Y ESTRATEGIAS/plan oncologia/&contenido=/channels/temas/temas es/P 2 ANDALUCIA EN SALUD PLANES Y ESTRATEGIAS/plan oncologia/plan oncologia

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documentation deemed suitable, where the proposal may be developed in greater detail.

2. The request form must contain minimal content indicated in Annex III to be reviewed and accepted. The information of this request may be published at any time, except the information declared to be confidential in nature. The annexes may be considered totally confidential or partially confidential. The AHS may publish confidential information and documentation with authorization from the entity making the proposal.

3. Presentation of proposals will be done by sending the documentation to the electronic mail of compra.innovacion.sc.sspa@juntadeandalucia.es In the subject line of the email, the expression PROPUESTA CPM 1/2018 must be stated with Name of the entity and acronym of the project.

4. In the case that a proposal is being presented jointly by a group of persons or entities, a single email address should be used for identification of the proposal and interlocution with the proposers.

5. For clarification of doubts that the participants may have, for preparation of the proposals, a frequently asked questions and answers will be made available that will be updated periodically in the profile of the bidder of the Andalusian Government in the section of "Preliminary Consultations". Also, the participants may state questions by sending an email to compra.innovacion.sc.sspa@juntadeandalucia.es stating in the subject line the expression CPM DOUBT 1/2018 Name of Entity followed by the text considered and which helps to identify the message.

6. Physical or legal persons participating in the notice must send their proposals, as well as the description of these in Spanish or English, according to the requirements set out in the request form, which is presented as **Annex III** of this notification.

7. The proposals may be presented as of the date of commencement indicated in this notification, and always as long as the proposal presentation period is open and this present consultation. The date of termination of this period will be published in the profile of the bidder of the Regional Government of Andalusia in

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the section of "Preliminary Consultations". In the event it may be considered necessary for presentation of proposals, a new period for presentation of proposals may be published in the same means.

8. The AHS will study the proposals presented. If considered of interest, individual notification of specific participants may be done to carry out a more detailed presentation or for expanding information about their proposal, product or service. In the event that this expansion of information was to be of interest to all the potential bidders, the information will be made public, with requirement of the consent of the proposer if the information were confidential in nature.

9. The AHS is not committed to financing or accepting proposals presented in this notification. Costs derived from participation in the notification will be underwritten by the parties interested.

Fifth. Technical backing

The AHS may seek support from other entities deemed necessary for correct execution and resolution of doubts and matters that arise during the preliminary market study.

The advisers, if any, may not participate in future biddings derived from the Preliminary Market Consultation. Also, at the end of the process the names of the advisers involved in the Consultation will be published at the end of the process in the profile of the bidder of the Regional Government of Andalusia.

Sixth. Application of the principles of transparency, equal treatment and non-discrimination- nor falsification of competency

Participation in the consultation, contacts maintained with the participants or exchanges of information may not give way to infractions of community transparency principles, those of equal treatment and non-discrimination, nor have as an effect restriction or limitation of competency or grant advantages or exclusive rights.

In order to assure transparency of the process, availability of the most information possible and efficient exchange of experiences and opinions, the participants will expressly grant consent that the AHS keep accessible and updated the necessary information, total or partial concerning proposals presented.

Participation in the preliminary market consultation will not grant right or preference of any sort with respect to participation in future biddings that may be held later in the area of the object of this consultation and as a consequence of it, does not imply any obligation for financing or accepting proposals presented.

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To this effect, the AHS will adopt suitable measures to guarantee upholding these principles mentioned, both in development of this notification or in any later hiring procedure.

Specifically, in application of the principles of transparency, equal treatment and non-discrimination, any information exchanged within the setting of this notification will be published in the profile of the bidder of the Regional Government of Andalusia.

In no case, during the process of consultations referred to in this article, the hiring organ may reveal to the participants in it, solutions proposed by the other participants, and these be only known totally by it.

As well as this, final results obtained in the preliminary market consultation and the Early Demand Map associated to this process will be published.

The AHS will adopt necessary measures to avoid any situation of conflicting interests. This situation arises when the staff at the service of the hiring organ, who also participates in development of the bidding process or could influence its result, has a direct or indirect financial, economic or personal interest that could seem to compromise his or her impartiality and independence in the context of the bidding procedure.

Those persons or entities that are aware of a possible conflict of interests must immediately notify this to the AHS.

Any situation that constitutes a conflict of interests or may lead to a conflict of interests during holding of the market consultancy must make this known immediately to the AHS.

Seventh. Functioning of the consultation

During development of the consultation information relative to the progress of the consultations may be published (progress cards that may specify the non-covered need and give way to more specific consultations within the process announced here). This information will be published in the profile of the hirer of the Regional Government of Andalusia.

At any time, the AHS may hold workshops, events or meetings to explain or communicate information to possible bidders regarding any of the phases mentioned previously and always complying with the principles of equal treatment, transparency and non-discrimination. The different notifications will be published in the profile of the hirer of the Regional Government of Andalusia.

The milestones mentioned earlier may take place regardless of holding new collective, individual, information requests in writing, by telephone, electronic means, through the profile of the hirer of the Regional Government of Andalusia or even demonstrations as previews of solutions being developed by the physical or legal participants.

At the end of the consultation, with enough advanced notice, the so called "Map of Early Demand" will be published of the future hiring/s attempted to convene to the effects of

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informing the market so it may prepare suitable offers with enough time, enabling better planning and risk reduction. This map will contain information relative to the object of the contracts, price estimates and execution time span estimate.

Eight. Term and management of the Preliminary Market Consultation

The term for presentation of proposals will start on the day after its publication in the profile of the hirer of the Regional Government of Andalusia in the section of "Preliminary Consultations".

Termination of this notice will take place 3 months as of publication, regardless of whether the AHS concludes the Consultation at any time during this period of time if it estimates that it has acquired a degree of definition of the solutions that is sufficient, always if 2 months have elapsed as of publishing and a minimum of three proposals have been received by the participants and this is published. Thus, the AHS may publish closure of the consultation after a minimum of two months since commencement, when it estimates that:

- It has sufficient information about innovative proposals for that need that is not yet covered in order to start an eventual public innovation hiring process or,
- It considers that the need has not generated enough interest in the market so as to uphold the consultation

Ninth. Language

The official language of this preliminary market consultation is Spanish. In order to ease participation of foreign bidders the documentation of the consultation will also be provided in English. Participants may present their proposals or information in Spanish or English. Communication with participants during the consultation procedure to answer questions arising from it, will be done in Spanish and English.

Tenth. Result of the Preliminary Market Consultation

The AHS will study the proposals presented and may use them according to what is set out in Section 115 of 9/2017 Act, 8th of November, of Public Sector Contracts, that are transposed to Spanish legal ordinance of the European Parliament Directives and of the Council 2014/23/EU and 2014/24/EU, dated 26th of February 2014, about public contracting, to define detailed functional or technical specifications that may be used in procedures for contracting goods or services that may later be notified fundamentally through the CPI procedure. In line with the above, the AHS will state in a final report the actuations undertaken. In the report these actions and those responsible for them will be listed, the entities consulted, questions made to them and answers to these questions. This report will be published in the profile of the hiring body of the Regional Government of Andalusia. In this report further steps that the AHS will take will also be published within the framework of the initiative, which may be, among others, publishing of the Early Demand Map.

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For the analysis of the different proposals presented, a Technical Committee may be named formed by staff of the proposing organ and/or other public instances considered of interest. This Committee may request the opinion of external experts with a voice but without a vote, in the deliberations.

Final results obtained by this Committee may be published along with the eventual bidding announcement, in the Profile of the hirer of the Regional Government of Andalusia in the section of "Preliminary Consultations" and by means of an announcement in the Public Sector Hiring Platform.

Eleventh. Publicity

Additionally, to the official publication of the documentation in the Profile of the hirer of the Regional Government of Andalusia, the AHS may publish in the specific web space, accessed by the page: http://www.sas. junta-andalucia.es/principal/documentosacc.asp?pagina=pv cpublica innovacion

Relevant information for the consultation about:

- Announcement of opening and description of the Consultation.
- Announcement of closure of the presentation of requests of the Consultation period. New needs not covered for the AHS.
- Update of non-covered needs.
- Specific aspects of the non-covered needs.
- Announcement of closure of the Consultation process.
- Results of the Consultation.
- Any other information considered opportune for participants.
- Besides, the AHS, if considered necessary, will simultaneously use any other means of suitable publicity and frequently used in its communications procedures: Public Sector Hiring Platform

(https://contrataciondelestado.es), Official Diary of the European Union, TED, Official Bulletins, Local publications, Internet, etc.

Twelfth. Protection of personal data and confidentiality

The AHS will store contact data of the participants in the procedure. This data will necessarily be included in the request from of Annex III, in which it will also be stated express consent and acceptance of the bases of this notification, including the possibility of spreading the participation in the procedure if relevant. A right to access, modification and cancellation rights will be handled with the exclusive purpose to enable contact during the process of the preliminary market consultation.

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On the other hand, in order to insure transparency of the process, availability of the most amount of information possible and efficient exchange of experiences and opinions, the participants will expressly state their will for the AHS to keep accessible and updated necessary total or partial information about the proposals presented.

Regardless of the possibility of disclosing the information contained in the proposals and the definition of the specifications of the projects, the Administration may not disclose the technical commercial information, which in due case, may have been enabled by the participants and that they would have designated as confidential.

The participants will be those who must identify the technical or commercial information that they consider having a confidential nature, and it will not be acceptable for the participants to make a general declaration or declare that all the documents or all the information is confidential in nature. This confidential nature affects, particularly, technical or commercial secrets and those confidential aspects of the solution. In this sense, the contents of the information included in the form available in Annex III in no case may be classified as confidential and this information may be published in the web. Only the adjuncts to this file may be designated as confidential in total or partially. This circumstance must be clearly stated (in any way or marginally) by the proposer in the document designated for this.

Thirteenth. Exploitation of Intellectual and Industrial Property

Possible ideas for solutions that may be presented in the setting of the preliminary market consultation may not mention a manufacturing or specific source or concrete procedure, nor refer to a brand, a patent or type, a certain origin or production.

The use of the content of the proposals is exclusively limited to possible inclusion in the definition process of the project which will be implemented in the specifications of an eventual procedure of later hiring.

Fourteenth. Hiring of projects

Once a definition is done of the technical and/or functional specifications of the systems, services or products to be developed (as of the ideas of innovative solutions gathered as a result of this notification) that will serve as a base for execution of a possible public hiring contract and with necessary concretion level, the AHS may start, if considered to do so, the necessary hiring process.

This eventual bidding procedure will be open to all the possible procedures that fulfill the procedure conditions, whether they have or have not been associated to the preliminary market consultation.

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Mrs. María de la Presentación Aguilera Crespillo, Official Sworn Translator-Interpreter appointed by the Spanish Ministry of Foreign Affairs and Cooperation, does hereby certify that the prior translation is a faithful and complete translation from Spanish into English of the original document.

María de la Presentación Aguilera Crespillo

Málaga, October 23, 2018.

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