Instituto Nacional de Cancerología-ESE
Colombia
Por el control del cáncer

Colombia Compra Eficiente

Public Procurement for Innovation

Call for ideas for the Magistral Production of Biotherapeutics

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I. What Is Public Procurement for Innovation?

Public Procurement for innovation is a tool that allows public institutions to acquire new and better solutions to face the challenges presented by the implementation of public policies.

Public Procurement for Innovation sets the proper conditions for suppliers of goods and services to innovate towards solving specific problems that contribute to satisfy the needs of public institutions. From this perspective, the innovation processes promoted by such public institutions consist on the creation or development of new solutions that involve an improvement to fulfill their specific needs.

This tool aims to: (i) improve public services by integrating innovative goods and services; (ii) promote business innovation, mainly for small and medium-sized enterprises, by ensuring a potential buyer (the public institution); and (iii) boost the internationalization and marketing of the innovation.

In this case, public institutions share the risks and benefits of the development of the innovative solution with the innovator, which can later sell it if successful.

There are two types of public procurement process:

A. Commercial Public Procurement: process of acquisition of goods or services that already exist or that will be soon launched to the market, but that require a technological adaptation in order to fulfill the need of the public institution.
B. Pre-commercial Public Procurement: process of acquisition of research and development services that allow the exploration of ideas and alternatives, and the design of solutions or prototypes. The degree of innovation is greater in the pre-commercial public procurement than in the commercial public procurement, but it does require previous R&D.

The procured R&D is mainly technical and does not cover commercial R&D aimed at launching the good or service to the market. In both cases, public institutions and providers share both the risks during the phase of co-development that are naturally attached to any R&D endeavor, and the benefits that may result in better conditions of procurement of the innovative solution for the buyer and other public institutions, or in royalties of the intellectual property (IP) of the developed solution.

II. What is Instituto Nacional De Cancerología (INC)?

The Instituto Nacional de Cancerología –INC- is a high complexity Colombian university hospital that advises the Ministry of Health and Social Protection regarding oncological serviced for the design, formulation and evaluation of public policies, plans programs and research projects, teaching, epidemiologic vigilance, prevention and neoplasic related illnesses treatment. Currentlly, the INC has developed a strategy to reduce cancer treatment expenditure, through the magistral -or low volume- production of radiopharmaceuticals (drugs used for diagnosis or therapy of various types of cancer), produced for specific patients, with an individualized dose. The INC is an entity of reference regarding the production, control and use of radiopharmaceuticals as well as it is the national training center for medicine and nuclear pharmacy.

III. What is Colombia Compra eficiente?

During the late 2011, the Government of Colombia went through a deep institutional restructuration. Recommendations from both the World Bank and the Inter-American Development Bank, after an assessment of the Colombian procurement system according to the OECD standards, emphasized on the importance of creating an institution that could provide guidelines and manage the processes regarding public procurement.

Hence, Colombia Compra Eficiente was created as an autonomous agency seconded by Government's Planning Department. In economic terms, Colombia Compra Eficiente is the directing body of the public procurement system, meant to articulate the different stakeholders in the system, including procuring officials and private suppliers. Its main duties are:

▪ Proposing public policies and regulations to increase value for money on the procurement acquisitions.

▪ Designing and implement framework agreements.

▪ Developing and managing the e-procurement platform SECOP.

IV. Need statement

The INC radiopharmacy, which has been operating for more than 10 years, prepares magistral radiopharmaceuticals. Some of these employ peptides and monoclonal antibodies labeled with radioisotopes to treat and diagnose oncologic diseases through gammagraphic techniques and positron emission tomography -PET-. These preparations are flexible and the results of this experience has shown to be favorable because patients are treated faster and timely, with a rigorous medical monitoring of the clinical results, including an adequate management of the adverse events related to the therapy. These peptides and monoclonal antibodies used to elaborate magistral radiopharmaceuticals, are bought by the INC and the price of these preparations are set according to these costs, which guarantees operational sustainability and an important cost reduction for the institution and the health system, as well as it may constitute a relevant source of income.

The main need of the INC, as a university center of investigation and scientific activities, is the development of a magistral production unit of biotechnological products –BTs- , that guarantees quality, effectiveness and regulatory requirements. This would impact the treatment of patients, strengthen the INC pharmaceutical service (minimizing the costs), impulse the development of other services (such as the radiopharmacy, nuclear medicine and PET) and promote the creation of knowledge, investigation and development on the country. This, considering the fact that the radiopharmacy counts already with the capacity and experience to receive the transference of technology required for their production.

V. Challenge

The objective of the challenge is to propose a technological solution that allows the magistral production of BTs, at a lower price than that of the market. This proposals will be received on the email address cpi@colombiacompra.gov.co , taking into account the terms and conditions described on the following section.

VI. Conditions of the challenge

Through this call for ideas we expect the interested to propose a flexible model of development and production of BTs. This means that the model could include the process starting from the development of the cell line of the low-scale fermentation process, to the downstream process of purification, dosage and dispensation, or could also be proposed as a modular (phases) process.

Any model suggested must include, not only the strategy of technology transference to the INC and the quality control of the process and the final product, but also the mechanisms to solve the inherent challenges to the production, prescription, use, vigilance, and acceptation of the biotherapeutic products.

The proposed solution does not require safety and effectiveness clinical data development and compilation, because this element will be further designed and produced by the INC medical and pharmaceutical staff. Nevertheless, the communication between the INC and the interested should be considered, for the adequate design of the clinic-epidemiologic studies.

The proposals must meet each of the standards and regulations, at national, international and transnational level.

The innovators should write a maximum 10 pages document, describing the model that meets the challenges of the call, including the infrastructure, technological and human requirements; the technology transference scheme, the schedule in which a trial or prototype would be delivered, and a preliminary expenditure calculation. Additionally, innovators must establish possible or available schemes regarding financial viability of the proposal, either through the private sector or international organizations, including multilateral bank, which may be added to the public national funding.

By the time proposals are presented, the INC, the Universidad Nacional de Colombia and Colombia Compra Eficiente will start a technical, individualized and confidential dialogue between the technical team of the INC and the technical team appointed by the innovators. Colombia Compra Eficiente will follow the process related with the public procurement of innovation, including the legal affairs.

The proposals must be sent to an institutional email during the first 2 months after the call is published. All the information about the process will be available on the INC website and on the *public procurement for innovation* section of the Colombia Compra Eficiente website.

The technical dialogue will take place during the month after the proposals reception is closed, via meetings with the innovators, which may be personal or virtual, whichever is better suited to their place of residence.

With the results obtained from the dialogue period, the INC and Colombia Compra Eficiente will establish the final tender documentation of the call, in order to select the innovative proposal that responds best to the needs and requirements of the challenge.

It is fundamental to clarify that the ideas presented on the call will be only used as inputs on the construction of the General Conditions documentation. Additionally, those who participate on the challenge for innovative ideas will not have any preferential treatment on the subsequent stages of the Public Procurement for Innovation process. Finally, it is important to inform that those who do not participate on the call, are allowed to participate on the process selection stage[1].

VII. Minimum technical requirements

1. Suitable physical infrastructure for the magistral production of injectable sterile BTs, including air and temperature standards.

2. Fulfillment of local Good Compounding Practices, as well as the policies for the production of injectable sterile BTs

3. Access to the standardized and certified cell line/expression system.

4. A system for the controlled storage of the cell line/expression system.

5. A disposable bio-reactor with a size up to 50 liters.

6. A purifying system capable of concentrating biomass and separating and purifying the desired API's.

7. A system for a safe final disposal of impurities and biologic material.

8. Develop a standardized quality control process in order to ensure that the products remain free from all kind of impurities, aggregates, protein cleavages, degradations, crosslinking, undesirable post-translational modifications or altered three-dimensional structure. This quality control process must also grant the power, biological activity and short-term stability of the final Magistral preparation[2].

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1 Guidelines to understand the Public Procurement for Innovation process. *Colombia Compra Eficiente.* Available on:https://www.colombiacompra.gov.co/sites/cce_public/files/20170427_guia_para_entender_la_compra_publica_innovadora.pdf

2 The following is a list of the usual release tests and parameters evaluated for reference products in the biotechnological manufacture that can be used as a guide: Molecular weight, higher order structure, heterogeneity, functional properties, impurity profile, degradation profile for stability, primary, secondary, tertiary and quaternary protein structure, peptide map, conformational analyses, carbohydrate characterization, host cells proteins, conformational analysis and bioassays (cell line or *in vivo*.

9. Define the specifications of the magistral preparations, the quality control techniques and the instrumental requirements in order to achieve the technology transference.

10. In order to avoid problems with the lack of instrumental equipment, it is possible to choose if the analyses are done by the innovator or outsourced, although there will be a minimum instrumental requirement to be accomplished according to the local capabilities[3].

11. Have an individualized packaging system, according to each prescription made by a doctor and to the needs of each patient.

12. Disposition and willingness to work and cooperate with hospital and local authorities regarding compliance with the regulations for the production of the magistral preparations.

13. Make a pharmacovigilance process.

14. Disposition and willingness to work and cooperate with doctors regarding the formulation, dosage and prescription monitoring.

15. A team of specialized human resource (pharmacist, doctor, experts in biotechnology).

16. Willingness to teach and transfer knowledge.

VIII. Motivation for the interested

This call is an important opportunity to establish a collaborative relationship between government, private sector and academia, which allows putting into practice an innovative R&D project, which will actually impact the public health, especially regarding accessibility. Consequently, the interested get an opportunity to become recognized internationally as a reference point in terms of public procurement and personalized medicine, which could imply the publication of academic products such as papers or scientific articles on recognized journals. In this same sense, material such as videos and publications may be created and uploaded on the websites of the participating entities. All of the previous could mean that a greater number of offerers could be interested on the process and would allow the innovators to engage in commercial arrangements with other possible buyers. Additionally, it is possible to obtain funding from different institutions, such as the INC and other private and public entities, making the development process viable for the researchers. This project may benefit, not only those who are directly involved, but would also optimize processes to improve health access through a viable and innovative process.

3 A possible solution to the instrumental requirements may be the emergence of completely automated platforms (e.g., Synthetic Genomics' BioXp benchtop instrument). If not, the usual techniques are HPLC with multiple detectors, Gas Chromatography, high-resolution mass spectrometry, capillary electrophoresis and circular dichroism.