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New rules for public private partnerships under the Brazilian Health Industrial Complex (CEIS)

The new strategy for the Health Industrial Complex (CEIS) issued by the Brazilian Ministry of Health ("MoH") applies to medicines, vaccines, diagnostic reagents, advanced therapies, medical devices (including software), technology and digital health, and health treatments and services.

> Decree No. 11.715/2023 (institutes the new CEIS policy) and Decree No. 11.714/2023 provides for the Deliberative Committee (CD) and the Technical Evaluation Commission (CTA) within the scope of the CEIS.

The new CEIS policy has the following objectives:

I.

To reduce the Brazilian public health system's (SUS) vulnerability and expand access to healthcare through developing and receiving technologies.

II.

Strengthening local production of goods and services deemed strategic for the SUS (a weakness highlighted by the pandemic).

III.

Articulating public policy instruments, such as the use of government purchasing power, financing, regulation, and scientific and technological infrastructure.

IV.

Boosting research & development, innovation, and the production of technologies and services.

V.

Promoting digital and ecological transition.

VI.

Expand and modernize the local infrastructure of Brazilian players.

VII.

Support initiatives related to global health, especially in Latin America and Africa.

Matrix of Health Productive and Technological Challenges

Differently from the list of strategic products issued in the past, the MoH has decided to identify key challenges and the technological platforms or products that are considered strategically important for the SUS. Applicable molecules or technical characteristics are no longer predefined, which gives more flexibility for entities to present their proposals of partnership and projects to the MoH.

These challenges are mapped out in a Matrix of Health Productive and Technological Challenges, divided as follows:

Block I – Health Emergencies Preparation.

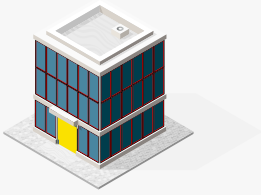
It includes vaccines covered by the National Immunization Program (PNI) and others, molecular diagnostic tests, blood products, bioproducts, and modernization of technological services in hemotherapy, immunoprotective serums, antimicrobial API, herbal medicines, and medical devices, including software, artificial intelligence algorithms and applications, internet of things (IoT) and digital systems for healthcare assistance (e.g. telehealth, telemonitoring, telediagnosis, among others) and management.

Block II – Critical Diseases for the SUS.

It includes neglected diseases (tuberculosis, Chagas disease, leprosy, schistosomiasis, leishmaniasis, malaria); HIV/AIDS and viral hepatitis; skin, breast, prostate, colorectal, lung, trachea, and bronchial, cervical, thyroid, lymphoma, leukemia and pediatric cancers; cardiovascular diseases, diabetes, and rare diseases, among others.

Key Players

Health Services



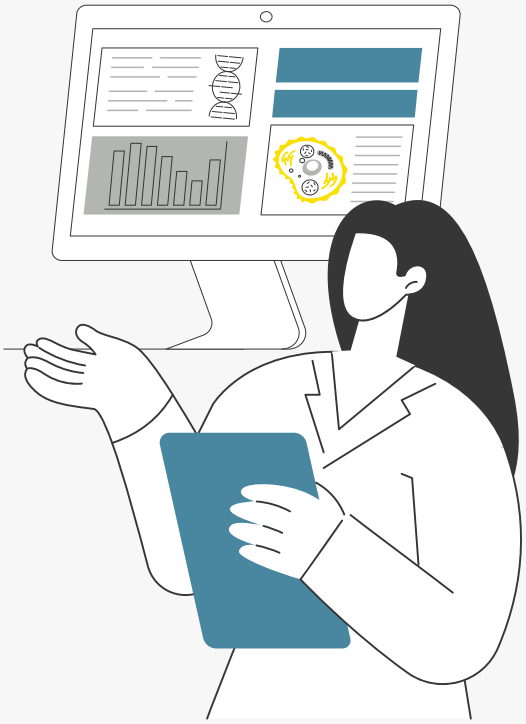
Public and private laboratories or manufacturers

Science and Technology Institutions (ICTs)

Industry and Technology

CEIS Programs

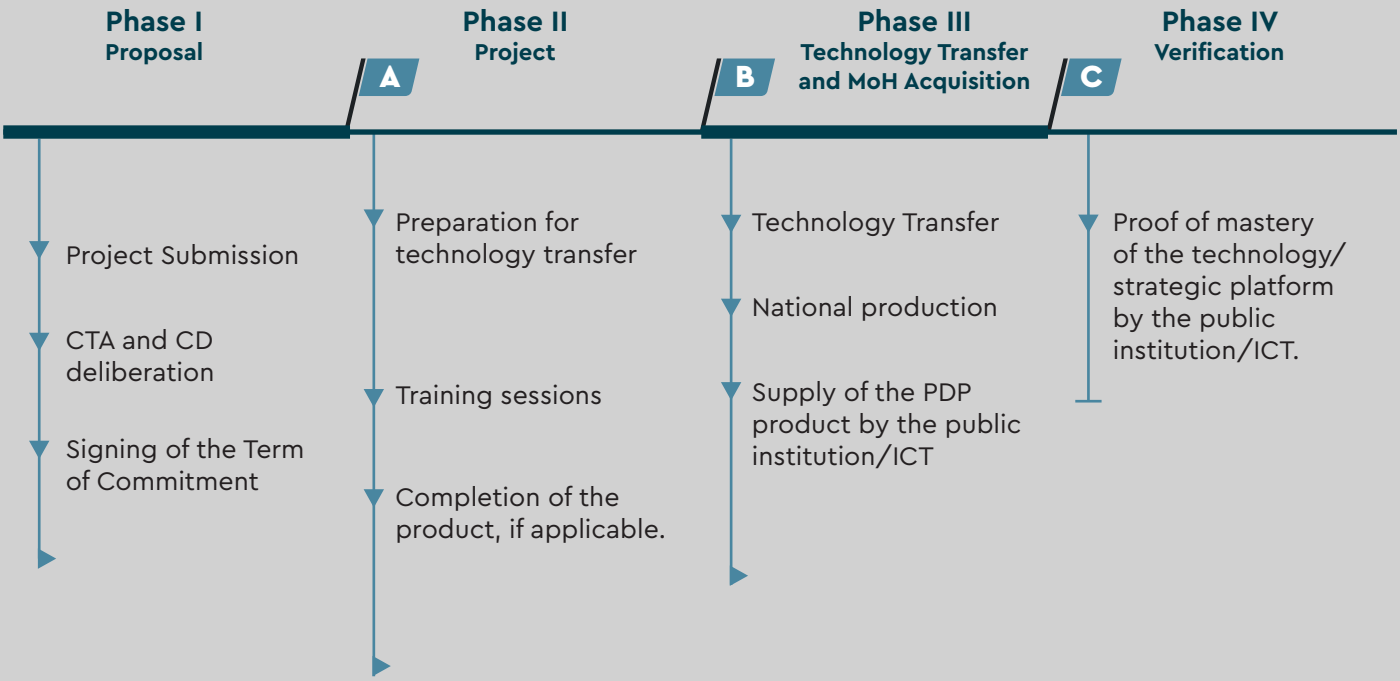
I. Productive Development Partnerships Program (PDPs) – MoH Ordinance No. 4.772/2024



Productive and technological solutions for the SUS listed in the Matrix of Productive and Technological Health Challenges and that meet the following eligibility criteria:

- Marketing authorization or prospect of submission within 36 months – counted from the date of the proposal's submission.
- Absence of patent restrictions that could impact the proposed arrangement or expected loss of the restriction within 36 months from the date of the proposal's submission.
- Centralized acquisition or likely to be centralized or acquired through specific public health programs, measures, initiatives, and actions coordinated by the MoH.
- High dependence on product importation or expected discontinuation of the product.

PDP Phases



MARCOS TEMPORAIS

- A: Term of Commitment publication.
- B: Acquisition of product or service by the MoH.
- C: Publication of the Term of Reference for the technology internalization.

II. Local Innovation Development Program – PDIL (new)

Cooperation to develop solutions that are part of the Matrix of Productive and Technological Health Challenges and promote local production and technological innovation. The projects must also promote training actions for an ICT, public laboratory, private non-profit organization, startups, and/or public companies, as well as contribute to the digital and ecological transformation and sustainability of the CEIS.

This modality requires the introduction of a novelty or improvement that results in new products, services, or processes or that adds new functionalities or characteristics to an existing product, service, or process capable of presenting improvements and effective gains in quality or performance for local production.

The PDIL can be implemented through agreements, terms of decentralized execution (TED), technological orders (no definition or criteria specified), Public Contracts for Innovative Solutions (CPSI), technological compensation agreements, and other instruments.

Assessment criteria for PDIL proposals by the MoH include:

- ☑ Adequacy of the timetable for executing the project stages and detailed resource plan.
- ☑ Proposing entities' technological and productive capacity to execute the project, considering current capabilities and planned investments by the partners.
- ☑ Availability of qualified human resources for the project execution, considering existing capacities and planned investments.
- ☑ Innovative character, clinical benefit, or benefit to the public health system.
- ☑ Relevance of the counterparts offered within the partnership to the SUS.
- ☑ Forecast of other sources of funding to make the project feasible.
- ☑ Technical and economic rationale of the implementation plan.

III. Expansion and Modernization of the CEIS' Infrastructure – PDCEIS (MoH Ordinance No. 2.262/23):

Its purpose is to articulate investments for the expansion of productive and technological capacities within the framework of the national strategy for CEIS development.

The program will be carried out in partnership with public and private non-profit institutions, through the transfer of federal funds for the development of projects, considering the legislation relating to each type of partnership. This modality allows incentives and funding via Federal Growth Acceleration Program (PAC).

IV. Preparation for Vaccines, Serums and Blood Products' Program – PPVACSH (MoH Ordinance No. 2.260/23)

It aims to expand access to vaccines, immunoprotective serums, blood products, and bioproducts produced by recombinant technology and other technological routes, as well as the production capacity of public laboratories.

V. Production and Technology Development for Neglected Populations and Diseases' Program – PPDN (MoH Ordinance No. 2.259/23)

It aims to expand access to the prevention, diagnosis, and treatment of neglected populations and diseases, as well as the local production of APIs, medicines, medical devices, components and other health-related products.

The PDCEIS, PPVACSH and PPDN provide that the MoH may sign agreements and partnerships with national or international bodies and entities, whether public or private, for technical cooperation or financial support.

OVERVIEW OF PUBLIC PROCUREMENT

As a general rule, public procurement must be made through bidding processes, which aim to select the most advantageous proposal for the Public Administration, based on rules that guarantee a level playing field for all participants.

The bidding procedures and modalities (e.g. competition, tender, competitive dialog, public sale and auction) apply to public contracts signed between a private and a public entity.

There are circumstances, however, in which the Public Administration is exempt or waived from bidding and can conduct a public procurement directly with a private company – for example, whenever there is a transfer of technology to a public laboratory related to a product deemed as strategic to the SUS.

This can include medicines, APIs, medical devices (including software), or other components, depending on the additional criteria/regulations of the MoH and the capabilities of the entities.

COMPETITIVE DIALOG

Promotes dialog between the public entities and potential bidders previously selected, based on objective criteria, to develop one or more alternatives capable of meeting public needs. Bidders can submit a final proposal after the dialog phase has ended.

Modalities & Counterparts

PRODUCTIVE DEVELOPMENT PARTNERSHIPS (PDP): Established between public institutions, ICTs, and/or private entities for the development, transfer, and absorption of technology, as well as local production and training with products considered strategic.

Counterparts: Technology transfer | Product Acquisition | Research and development

TECHNOLOGICAL ORDERS (ETECS): Contracting with ICTs and/or private for-profit or non-profit entities for research, development, and innovation activities involving certain technological risk, solving a specific technical problem, or obtaining an innovative health-related product, service, or process.

Counterparts: Technology transfer | Product Acquisition | Research and development

TECHNOLOGICAL COMPENSATION AGREEMENTS: Arrangements to promote local technological development and capacity building of SUS' strategic products and services.

Counterparts: Technology transfer | Product Acquisition | Research and development | Patient monitoring | Clinical trials

RISK SHARING AGREEMENT: A contract in which the risk related to the use of the medicine (or other product) is shared between the payer and the supplier. Both decide on flexible price conditions based on certain clinical or financial outcomes (e.g. patient quality of life, number of hospitalizations, short/long-term effects).

Counterparts: Product Acquisition | Patient monitoring

PUBLIC CONTRACT FOR INNOVATIVE SOLUTIONS (CPSI): Provided for in the Legal Framework for Startups. The aim is to contract innovative solutions, with or without technological risk, to overcome a technological challenge identified by the Public Administration. At the end of the CPSI, the Public Administration may enter into a supply agreement with the same entity without the need for a new tender.

Counterparts: Research and development | Patient monitoring | Clinical trials

HEALTH STRATEGIC ALLIANCES: Cooperation involving public and private entities, ICTs, non-profit private entities, and startups for Research and Development (R&D) activities aimed at generating productive and technological solutions for the SUS, as well as the transfer and dissemination of health technologies.

Counterparts: Technology transfer | Product Acquisition |Research and development | Patient monitoring | Clinical trials

FACTORS TO CONSIDER

FUNDING

Possibility of centralized purchasing and criteria for public fund transfer (federal, state or municipal).

CHARACTERISTICS OF THE DISEASE

Existence of reference centers for the relevant disease and the possibility of monitoring patient outcomes.

RELEVANCE TO THE SUS

Likelihood of having the product or service be considered as strategic, as well as stage of development and technological risk embedded.

TECHNOLOGY

Ownership and availability of the intellectual property of the technology and/or product.

Count on **Machado Meyer**

Our expertise in Life Sciences and Healthcare uniquely positions us to assist your company in evaluating the critical legal aspects applicable to innovative projects, as well as to define the pros and cons of each type of partnership with public laboratories and ICTs. This includes, but is not limited to, regulatory, contractual, tax, intellectual property, compliance, and litigation issues.

GET IN TOUCH

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