

NEW STRATEGY FOR THE HEALTH INDUSTRIAL ECONOMIC COMPLEX



On **September 26, 2023**, the Ministry of Health ("MoH") announced the **new strategy for strengthening the health economic industrial complex**, applicable to medicines, APIs, vaccines, diagnostic reagents, treatments and health services ("New CEIS Policy"). The Brazilian government estimates R\$42.1 billion in investments (new Growth Acceleration Program - "PAC" for the CEIS, via public and private funding).

On September 27, 2023, the following rules were published:

- (i) which provides for the Deliberative Committee and the Technical Evaluation Commission within the scope of CEIS; and
- (ii) Decree No. 11.715/2023, Regarding the New CEIS Policy.

On September 28, 2023, the Brazilian Federal Court of Accounts ("TCU") recommended that the MoH suspend new PDPs until measures are adopted to evaluate technology transfers and objective criteria for selecting private partners (Ruling No. 2015/2023)

The New CEIS Policy has the **following objectives**:

- i. Reducing the vulnerability of the SUS and expanding universal access to health, through the development and absorption of health technologies;
- ii. Strengthen local production of goods and services (Evidenced by the pandemic);
- iii. Articulate public policy instruments, such as the use of state purchasing power, financing, regulation and scientific and technological infrastructure;
- iv. Create an institutional environment that favors investment, innovation, training and job creation;
- v. Boosting research, development, innovation and the production of technologies and services;
- vi. Promoting the digital and ecological transition within the Health Industrial Economic Complex;
- vii. Expand and modernize the CEIS infrastructure; and
- viii. Support initiatives related to global health, especially in Latin America and Africa.

There are 6 **programs that make up the New CEIS Policy**:

- i. Program for Productive Development Partnerships (PDPs) (reconstruction and market stability);
- ii. Program for the Preparation of Vaccines, Serums and Blood Products (**new**);
- iii. Program for Healthcare Modernization and Innovation (**new**);
- iv. Local Development and Innovation Program (**new**);
- v. Program to Encourage the National Production of Technology in Health Technology for Neglected Populations and Diseases (**new** – largest global investment); and
- vi. Program to Expand and Modernize the CEIS' Infrastructure (reconstruction and PAC incentive).

OVERVIEW - PUBLIC PARTNERSHIPS

- Public purchases must be made through bidding processes, which aim to select the most advantageous proposal for the Public Administration based on impartial rules that guarantee a level playing field for all participants. for all participants. The bidding procedures and modalities (e.g.: competition, tender, competitive dialog, auction and trading session) are generally applicable to all purchases and administrative contracts made between a private individual and a Brazilian public entity.
- There are circumstances, however, in which the Public Administration is exempt or waived from bidding, and can conduct public purchases directly with a private company - for example, whenever there is a transfer of technology to a public laboratory related to the strategic products of the Unified Health System (SUS), defined as such by the MoH. This may include medicines and/or APIs, depending on the additional criteria/regulations of the MoH and the capabilities of the entities, and may be applicable even during the technology transfer period.

COMPETITIVE DIALOG

A method introduced by the new bidding law that promotes dialog between the Public Administration and bidders previously selected on the basis of objective criteria, in order to develop one or more alternatives capable of meeting public needs. Bidders can submit a final proposal after the dialog has ended.

MODALITIES OF PUBLIC PARTNERSHIPS



PRODUCTIVE DEVELOPMENT PARTNERSHIPS (PDP) – Established between public institutions and private entities for the development, transfer and absorption of technology, production, productive and technological training, of products considered necessary for health promotion, prevention and recovery actions, with purchases centralized by the MoH (strategic products for the SUS).



TECHNOLOGICAL ORDERS ("ETECS") – Hiring Science and Technology Institutions ("ICT"), non-profit private law entities or companies to conduct research, development and innovation activities involving technological risk, solving a specific technical problem or obtaining an innovative product, service or process in the health-related area.



COMPENSATION MEASURES – Application of industrial, commercial or technological compensation measures, as provided for in the bidding law. The aim is to promote technological development and training - subject to the list of strategic products and services for the SUS. It will depend on a prior process that guarantees the competitiveness, transparency and isonomy of the tender.



RISK SHARING AGREEMENT – Although this is a modality of public partnership that has not yet been regulated, it is 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 a flexible price for the treatment, depending on the clinical or financial results (e.g. the patient's quality of life, short/long-term effects, etc.).



STARTUPS AND INNOVATION LEGAL FRAMEWORK (CPSI) – A modality provided for in the legal framework for startups and innovative entrepreneurship, which must be preceded by a bidding process. The objective is to contract innovative solutions, with or without technological risk, to overcome a technological challenge identified by the Public Administration. Once the CPSI has been concluded, the Public Administration may enter into a contract with the same contractor, without the need for a new bidding process to supply the product, process or solution resulting from the CPSI.

POSSIBLE COUNTERPARTS

The main modalities of public partnership may include the following (non-exhaustive) counterparts on private side:



PRODUCTIVE DEVELOPMENT PARTNERSHIPS (PDP)

Technology transfer

Product acquisition

Research and development



TECHNOLOGY ORDERS (ETECS)

Technology transfer

Product acquisition

Research and development



COMPENSATION MEASURES

Technology transfer

Product acquisition

Research and development

Patient monitoring

Clinical trial



RISK SHARING AGREEMENT

Product acquisition

Patient monitoring



STARTUPS AND INNOVATION LEGAL FRAMEWORK (CPSI)

Research and development

Patient monitoring

Clinical trial

SUS' STRATEGIC PRODUCTS



DEFINITION

Products that are (i) needed for the SUS for health promotion, prevention and recovery actions, with centralized acquisition or likely to be centralized by the MoH; and (ii) whose national production and its APIs or critical technological components are relevant to CEIS- as establish in MoH Ordinance MS 5/17 and Decree 11.464/23.



SUS' STRATEGIC LIST OF PRODUCTS DESIGNATION

Although current regulations establish that the MoH must annually update SUS' Strategic List of Products, there has been no update since 2017 (Ordinance MS 704/17). The MoH may also consult public bodies, private entities, experts and open public consultations on the subject.

The current federal administration is in favor of partnerships involving technology transfer. Progress is expected in the next 6 months.

THE CRITERIA INCLUDE (BUT ARE NOT LIMITED TO)

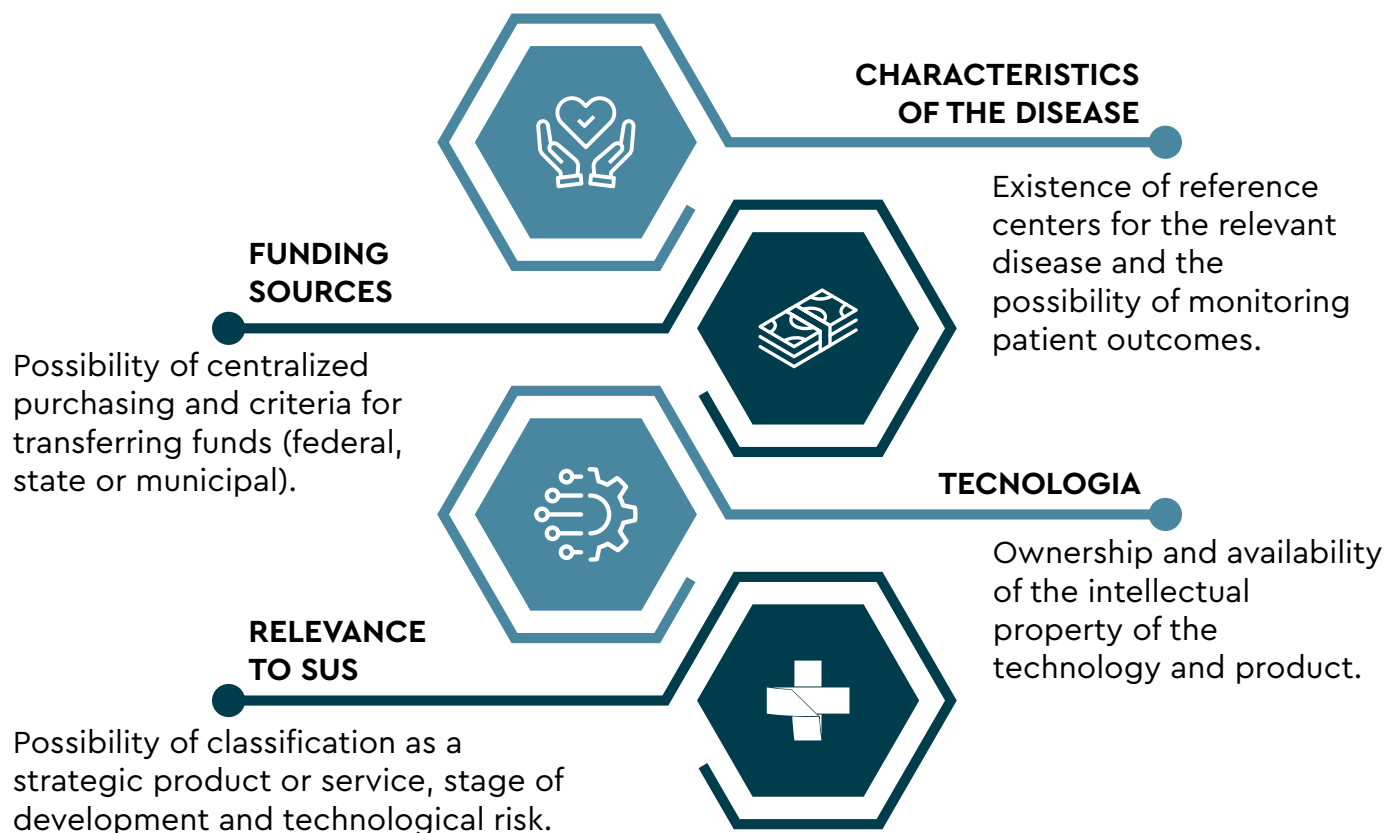
- Product's importance for the SUS, according to health promotion, prevention, and recovery policies and programs;
- Product centralized acquisition by the MoH or susceptible to centralization; and
- Products/APIs/critical technology components of national interest under the CEIS.

PLAYERS INVOLVED



- HEALTH SERVICES AND INSTITUTIONS
- PRIVATE COMPANIES
- CT&I INSTITUTIONS
- ICTS - TECHNOLOGICAL PARKS
- HEALTHTECHS, MEDTECHS AND BIOTECHS

! FACTORS TO CONSIDER



CONTACT US

RENATA ROTHBARTH

Partner

rothbarth@machadomeyer.com.br

+55 11 3150-7000

LEGAL INTELLIGENCE CENTER

Our insights on issues that impact your business

Access our content: www.machadomeyer.com/legalintelligence

MACHADO, MEYER, SENDACZ E OPICE ADVOGADOS
SÃO PAULO / RIO DE JANEIRO / BRASÍLIA / BELO HORIZONTE / NEW YORK

MACHADO
MEYER
.COM

