Brazil's National Development Strategy for the Economic-Industrial Health Complex

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On June 18, 2024, the Executive Group of the Brazilian Economic-Industrial Health Complex (GECEIS) presented a new regulatory framework for Productive Development Partnerships (PDPs) and the Local Development and Innovation Partnership Program (PDIL). These partnerships are designed to boost medication supplies and improve technological and production-related vulnerabilities within Brazil's Universal Health System (SUS).

The publication of the PDP and PDIL programs represents a vital part of the Brazilian government's National Development Strategy for the Economic-Industrial Health Complex (CEIS), launched on September 26, 2023.

The following pages of this e-book outline the key aspects of this strategy.

What is the National Development Strategy for the CEIS?

The National Development Strategy for the CEIS is based on the Technological and Production Challenges in Health Matrix[1] (Matrix) – which replaces the list of strategic products incorporated into the SUS[2] – as well as criteria and guidelines for meeting the SUS' priority demands and operational CEIS development programs.

The Matrix is divided into two blocks, which encompass the following health-related challenges:

Technological and Production Challenges in Health Matrix

BLOCK I

Preparing the SUS for Sanitary Emergencies

- Preparing for emergency responses and protection against immuno-preventable diseases;
- Modernizing production technology for immuno-protective serums;
- Overcoming vulnerabilities regarding blood derivatives, bioproducts and the modernization of technological services in blood therapy;
- Technological and economic vulnerabilities in accessing health services;
- Technological alternatives for sustainable development and green chemistry;
- Technologies for the SUS.

BLOCK II

Critical Conditions and Diseases in the SUS

- Neglected diseases and groups;
- High incidence cancers;
- Cardiovascular diseases;
- Diabetes;
- Diseases associated with Brazil's aging demographic;
- Rare diseases;
- Other non-communicable chronic diseases.

1 GM/MS Ordinance No. 2,261/2023

2 GM/MS Ordinance No. 704/2017, revoked by GM/MS Ordinance No. 2,261/2023

The regulatory and public consultations published within the scope of the CEIS are structured as follows:

The **Matrix** establishes priority demands from the SUS that will guide the development of the CEIS – including the PDP, PDIL, Production and Technological Development Program for Neglected Populations and Diseases (PPDN); Vaccine, Serum and Blood Product Development Program (PPVACSH) and the CEIS Infrastructure Expansion and Modernization Program (PDCEIS).

The **PPDN** and the **PPVACSH** establish guidelines for two of the National Development Strategy's priority themes: treatments for neglected population groups and diseases, and expanding local public producers' capacity and access to vaccines, immuno-protective serums, blood derivatives, and bioproducts.

The **PDIL**, the **PDPs** and the **PDCEIS** make the Matrix operational via instruments such as public contracts and collaboration agreements (*convênios*). Projects submitted under these programs that meet the PPDN and PPVACSH's objectives will have an additional criterion in their selection and classification, as per the regulation of each respective program.

Matrix

Establishes **priority demands** for the SUS that will guide the National Development Strategy for the CEIS.

PPDN **PPVACSH**

Establish **criteria and guidelines** for CEIS priorities.

PDP **PDCEIS** **PDIL**

Programs that make the Matrix, PPDN and PPVACSH's demands **operational** via instruments such as public contracts and agreements.

Regulatory background

The texts proposed via the public consultations led to the following regulations being issued: GM/MS Ordinance No. 4,472/2024 (PDP) and GM/MS Ordinance No. 4,473/2024 (PDIL).

CEIS Infrastructure Expansion and Modernization Program (PDCEIS)

GM/MS Ordinance No. 2,262/2023

This program seeks to implement and modernize the development, production, and innovation infrastructure of non-profit public and private institutions within the CEIS' scope.

- **Participation:** The PDCEIS will be made operational via public calls or via project proposals directly supported by the Ministry of Health's Department of Science, Technology, Innovation and the Health Economic-Industrial Complex (SECTICS), depending on the priorities the Ministry of Health establishes via the Matrix.[3]
- **Selection criteria:** Among other aspects, projects will be selected if they demonstrate a link to the priorities of government programs and strategic or urgent programs within the health sector.[4]
- **Contracting:** The type of project and the institutions involved will determine what type of contract will be signed.[5] Possibilities include decentralized execution terms, collaboration agreements, or transfer contracts, as well as other agreements between the Ministry of Health and public or private non-profit institutions.

3 Article 5, Paragraph 1 of GM/MS Ordinance No. 2,262/2023
4 Article 6, Item V of GM/MS Ordinance No. 2,262/2023
5 Article 5, Paragraph 5 of GM/MS Ordinance No. 2,262/2023

Production and Technological Development Program for Neglected Populations and Diseases (PPDN)

GM/MS Ordinance No. 2,259/2023

The PPDN is one of the programs that establishes guidelines for setting priorities for the SUS. This program's priority demand concerns the eradication of neglected diseases and improving neglected populations' access to disease prevention, diagnosis and treatment.[6]

Operation: Projects submitted under the operational programs that meet the PPDN's objectives will have an additional criterion in their selection and classification, as per the regulation of each respective program.

Vaccine, Serum and Blood Product Development Program (PPVACSH)

GM/MS ORDINANCE NO. 2,260/2023

Just like the PPDN, the PPVACSH also establishes guidelines for the SUS' priority agenda. This program prioritizes expanding access to vaccines, immuno-protective serums, blood products, and bioproducts produced by recombinant technology and other forms, as well as boosting public producers' capacity to produce these products.[7]

Operation: Projects submitted under the operational programs that meet the PPVACSH's objectives will have an additional criterion in their selection and classification, as per the regulation of each respective program.

6 Article 1 of GM/MS Ordinance No. 2,259/2023

7 Article 1 of GM/MS Ordinance No. 2,260/2023

Productive Development Partnerships (PDPs)

GM/MS Ordinance No. 4,472/2024

Eligibility

Production and technology-related solutions listed in the Matrix are eligible for PDPs, provided the Ministry of Health approves them and they meet the following requirements:[8]

- PDP solutions subject to sanitary surveillance must have sanitary registration in Brazil or the prospect of such registration being submitted within 36 months of the project proposal's submission;
- No existing patent restriction that impacts the proposed arrangement or loss of restriction within 36 months of the date of the project proposal's submission;
- Product acquisition is centralized or capable of being so, or the product is acquired via programs, measures, initiatives and specific actions coordinated by Brazil's Ministry of Health within the scope of CEIS; and
- The product is highly dependent on imports or its production is expected to be discontinued in Brazil.

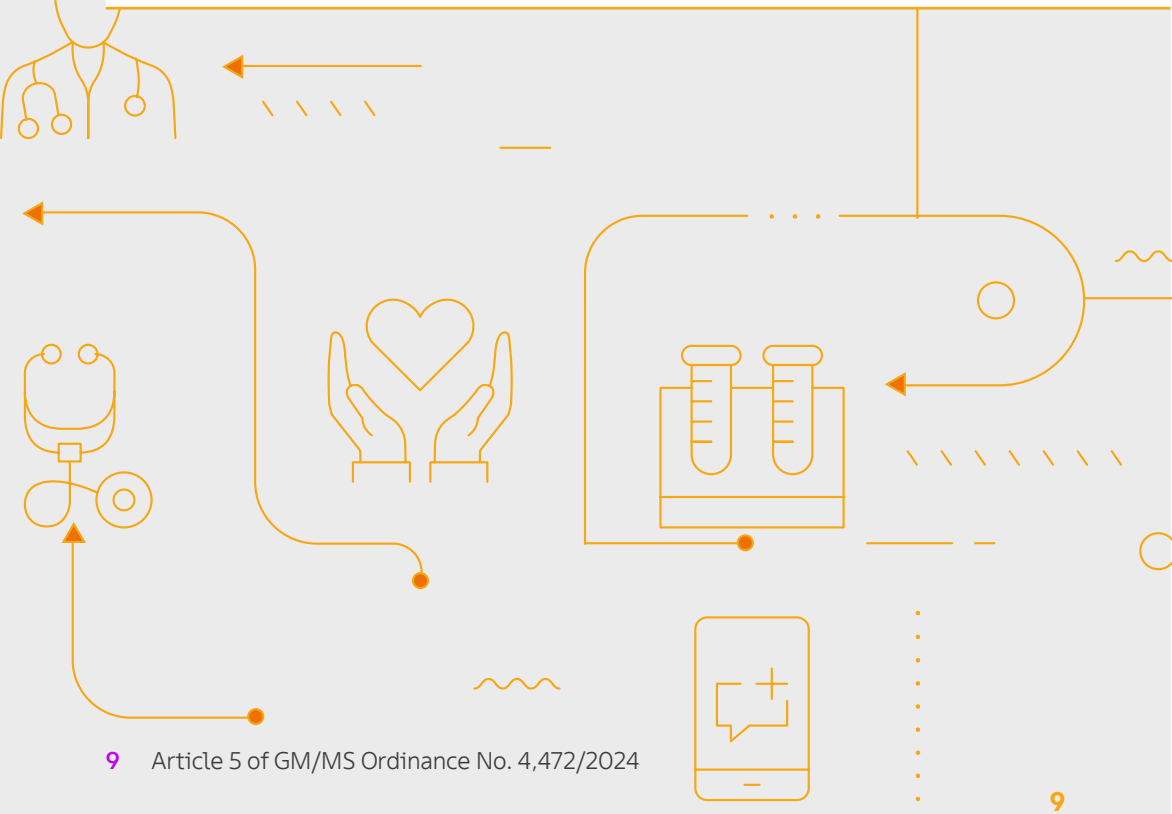
8 Article 4 of GM/MS Ordinance No. 4,472/2024

Participation

PDP participants may be a:[9]

- Public Institution (PI) or Scientific, Technological and Innovation Institution (STII) proposing the project, individually or jointly with other public institutions or STIIs; and
- Private entity (PE) developer, holder, transferor, or recipient of technology, individually or jointly with other private entities.

Please note! International organizations, support foundations or other non-profit organizations can play a complimentary role in the project, as long as their production-related responsibilities are clearly defined.



9 Article 5 of GM/MS Ordinance No. 4,472/2024

Operation[10]

PHASE I →	PHASE II →	PHASE III →	PHASE IV
PDP Project Proposal	**PDP Project**	**PDP**	**Verifying the technology's incorporation into the SUS**
Proposal submission phase by the IP/ICT, which is analyzed by the Ministry of Health, Technical Evaluation Committee (CTA) and Deliberative Committee (CD) before the result is published.	Preparation phase for carrying out the technology transfer between the stakeholders – including training and the completion of the product development stage to absorb the scientific and technological details created by the partnership.	Phase involving the technology transfer, which includes the process of internalizing the technology, production and supply of the PDP product by the IP/ICT in line with a previously established schedule.	Phase verifying the completion of the transfer and absorption of the PDP product, as provided for in the Executive Project.
Begins after the project proposal submission period is completed. Ends with the publication of either the result (in case of rejection) or the summary of the term of commitment (in case of approval).	Begins with the summary of the term of commitment being published in Brazil's Official Federal Gazette (DOU) by the Ministry of Health. Ends when the instrument for formalizing the first acquisition of the product is published.	Begins with the instrument formalizing the first acquisition of the product being published. Ends after the period approved by the collegiate bodies to incorporate the technology has elapsed.	Begins immediately after the conclusion of Phase III. Ends with the summary of the deliberation term for incorporating the technology being published.

Prior to Phase III, the CTA and the CD will conduct a further review of the PDP, considering (among other things) price updates and demand for the product.

10 Article 6 of GM/MS Ordinance No. 4,472/2024

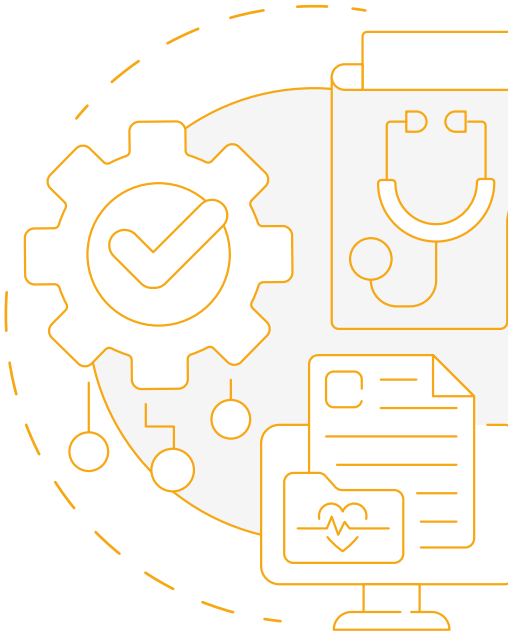
Proposal Submission

Information on the following aspects should be submitted:[11]

- The product, in accordance with production and technology solutions for the SUS;
- Involved partners, their qualifications in relation to carrying out the proposal and the way in which they were selected;
- Intellectual property, exclusivity contracts or commercial agreements, including information about the possible existence of agreements or other restrictions for licensing or access to technology;
- Economic and financial capability to offer the product and internalize the technology;
- A price estimate;
- Local production of supply chain inputs, in addition to the active IFA/ CTC/DT product.[12]

In addition, information on the following topics is also required:

- Governance, professionalization, and integrity programs;
- Environmental sustainability Initiatives and actions; and
- Anti-racism, gender equality and diversity promotion policies.



11 Article 8 of GM/MS Ordinance No. 4,472/2024

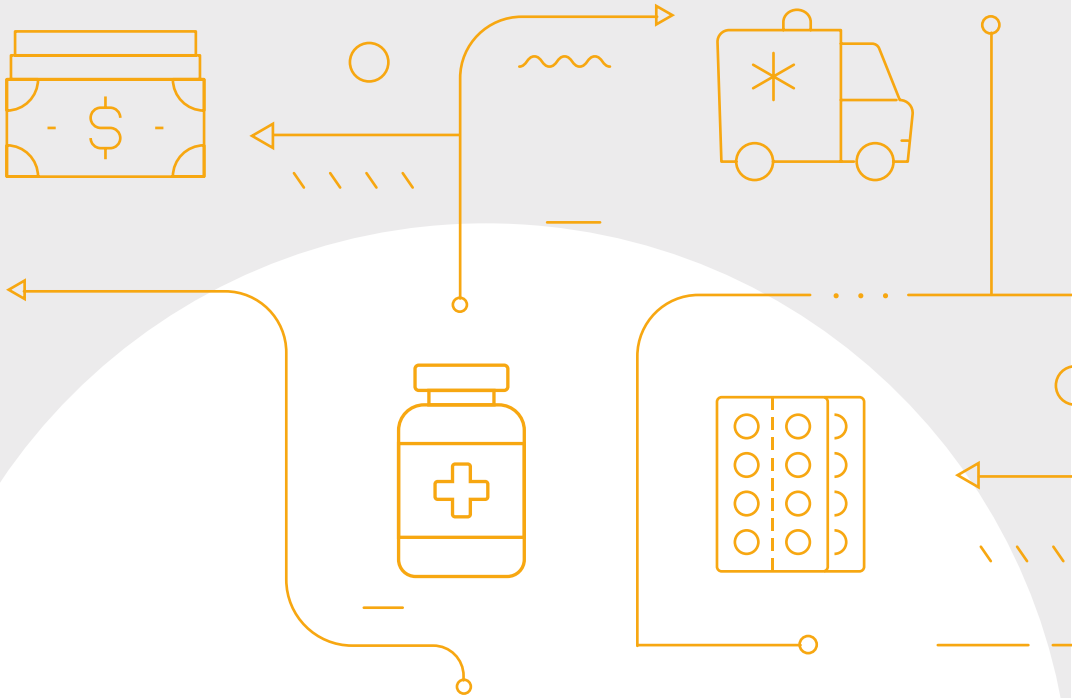
12 Active Pharmaceutical Ingredient (API), Critical Technological Component (CTC) or Technological Device (TD).

Price

The proponent must justify their proposed price considering the value of the product and the technology.

Furthermore, proposed prices must be compatible with those in other contracts within the scope of the SUS prior to the partnership beginning, and in a price survey carried out in line with the relevant federal legislation. When applicable, the prices must also be compatible with those on international markets in countries covered by the Medicines Market Regulation Chamber (CMED), considering the principles of economy and advantage.[13]

The prices should decrease during Phase III, in line with the technological complexity involved.



13 Article 8, Paragraph 4 of GM/MS Ordinance No. 4,472/2024

Evaluation Criteria

The analysis and evaluation of correctly submitted PDP project proposals will be carried out by the Technical Evaluation Committee (CTA) and the Deliberative Committee (CD) established within the scope of the CEIS. Among other aspects, the committees will consider the following:

MERIT[14]

- Whether the implementation schedule is sufficient for the complexity of the technology involved, and the regulatory and sanitary requirements;
- The potential for internalizing the technology;
- Production capacity of the proposing institution and partner companies;
- Projected savings for the SUS in acquiring the product subject to the PDP; and
- Potential for contribution to other markets – especially in relation to global health – after meeting the demand of the SUS.

CLASSIFICATION[15]

- A shorter timeframe for the internalization of technology and production by the IP/ICT, according to the proposed productive arrangement;
- History of product internalization subject to PDP in the IP/ICT portfolio;
- Investments the private entity makes to carry out the PDP that contribute to regional or national development;
- Lowest overall price proposal, considering the initial price, where it is represented in relation to the decreasing scale of values, and the project's feasibility;
- Presentation of technological solutions associated with the technology transfer that may synergize with future technologies;
- Shortest time for production with the local API, CTC or DT; and
- Participation in the PPDN or PPVACSH.

14 Article 16 of GM/MS Ordinance No. 4,472/2024

15 Article 17 of GM/MS Ordinance No. 4,472/2024

Results

The Ministry of Health must release the final evaluation of the PDP project proposals via an Ordinance published in the DOU and on the Ministry's website.[16]

Monitoring

Each PDP must be continuously monitored from the PDP project (Phase II) to the internalization of the technology (Phase IV) to verify progress in the production, development, transfer and technology absorption processes.[17]

Changes

The IP/ICT – in agreement with the other PDP partners – may present a proposal to SECTICS to change the PDP in Phases II and III.[18]

Partnership Termination

PDPs that either cause or encounter the following situations must be terminated:[19]

- Damage to Brazil's public administration or use contrary to the objectives set out in the regulation;
- Irreversible events and problems identified during monitoring;
- The IP/ICT's lack of interest in continuing the PDP, based on a substantiated justification;
- The solution's technological obsolescence or the discontinuation of its use by the SUS, as well as other situations in the public's interest.

Penalties

In addition to penalties provided for by law and in signed contracts, PDP partners may be subject to administrative and judicial measures that ensure contradictory and broad defense in accordance with the responsibilities defined in the Executive Project and Term of Commitment.[20]

16 Article 26 of GM/MS Ordinance No. 4,472/2024
17 Article 59 of GM/MS Ordinance No. 4,472/2024
18 Article 72 of GM/MS Ordinance No. 4,472/2024
19 Article 71 of GM/MS Ordinance No. 4,472/2024
20 Article 76 of GM/MS Ordinance No. 4,472/2024

Local Development and Innovation Partnership Program (PDIL)

GM/MS Ordinance No. 4,473/2024

The PDIL is one of the new programs proposed by the Ministry of Health within the scope of the National Development Strategy for the CEIS. The program seeks to promote the local development of innovative solutions to health challenges, the sustainability and resilience of the SUS, and the expansion of access to health in order to reduce production and technology-related vulnerabilities within the SUS.

The PDIL may be implemented by promoting local innovation projects. The rollout of such projects will be subject to funding from the Ministry of Health's budget.

The main aspects of the PDIL are outlined below.

Eligibility

Production and technology-related solutions for the SUS meeting objectives defined in the regulation and included in the Matrix approved by the Health Minister are eligible for the PDIL.[21]

Participation

Project proposals can be submitted by a public institution, ICT, or private non-profit entity. The proponent may establish strategic health alliances in cooperation with other public institutions, ICTs or private non-profit entities, public or private companies, and startups.[22]

21 Article 1, sole paragraph of GM/MS Ordinance No. 4,473/2024

22 Article 7 of GM/MS Ordinance No. 4,473/2024

Contracting

The PDIL may be implemented via local innovation projects collaboration agreements, decentralized execution terms, technological orders, public contracts for innovative solutions, technological compensation agreements, and other related instruments. SECTICS – through the Department of the Economic-Industrial Complex of Health and Innovation for the SUS – will define the appropriate legal instrument for the proposal.[23]

Project Submission

The period for submitting proposals will be published by the Ministry of Health on its official website at least 30 calendar days prior to the deadline.[24]

Project Proposal

The proponent must include the following elements in the project proposal:[25]

- The proponent's identity;
- The identity of partners in the strategic health alliance (if applicable);
- The subject of the project, describing the technology or product to be developed or being developed in line with the solutions of the Matrix;
- The project's objectives, targets, and indicators for assessment;
- Project justification, including choice of technology and clinical benefit for the health system;
- Proof of technological maturity level;
- The schedule for the rollout of the project, indicating how each stage of technological development will be met and a detailed plan for allocating resources;

23 Article 5 of GM/MS Ordinance No. 4,473/2024

24 Article 6, Paragraph 2 of GM/MS Ordinance No. 4,473/2024

25 Article 8 of GM/MS Ordinance No. 4,473/2024

- The countermeasures for the SUS, which may include (but are not limited to) co-ownership of intellectual property for the Ministry of Health or the public institution, the perception of economic rights, transfers of technology and knowledge, or free services or products.

Only projects with countermeasures that guarantee the technology will be available to the SUS will be accepted (if successfully developed).[26]

Furthermore, the following information should be submitted:

- The proponent's governance, professionalization, and integrity programs;
- Social, economic, territorial, and technological impacts of the relevant health technology;
- Environmental sustainability initiatives and actions;
- Anti-racism, gender equality, and diversity promotion policies; and
- A risk management plan.

Analysis Procedures

SECTICS will be responsible for overseeing the PDIL project's administrative process and sending it for analysis and evaluation by the Technical Assessment Committee (CTA) and the Deliberative Committee (CD).[27]

The evaluation of the project proposals must be published on the Ministry of Health's website within 30 days of the CD's deliberations.[28]

26 Article 8, sole paragraph of GM/MS Ordinance No. 4,473/2024

27 Article 9, Item VI of GM/MS Ordinance No. 4,473/2024

28 Article 16 of GM/MS Ordinance No. 4,473/2024

Evaluation Criteria for Proposals

The criteria for evaluating the merits of PDIL project proposals include:

MERIT[29]	CLASSIFICATION[30]
Ensuring the schedule for the project's stages is adequate and providing a detailed plan for allocating resources;	The partners' competence and experience in introducing technologies or products into the market, including ongoing investments;
Technological and production capacity of the proponent and its partners to carry out the proposal, considering existing capabilities and planned investments by the partners;	The partners' experience in incorporating products into the SUS (when applicable), including ongoing investments in health technology management;
The proposal's innovative nature, clinical benefit or benefit to the health system;	Higher levels of technological maturity;
The relevance of countermeasures to the SUS;	Project proposals that have already been supported by the Ministry of Health or other public bodies at previous stages of technological development;
Other possible sources of funds to make the project viable; and	Project proposals that contribute to improved technological capacity and innovation in order to serve the PPVACSH or the PPDN;
The technical and economic feasibility of the detailed application plan.	The competence and experience of the proponent and its partners in developing production and technology-related solutions associated with the specific theme of the proposed projects; and
	Social, economic, territorial, technological, and environmental impacts of health technology and potential actions that can enhance positive impacts or mitigate negative impacts.

29 Article 13 of GM/MS Ordinance No. 4,473/2024

30 Article 14 of GM/MS Ordinance No. 4,473/2024

Registration and Incorporation

The relevant competent bodies may prioritize the registration and analysis stages for incorporating products resulting from the PDIL into the SUS.[31]

Post-Project Supply

The Ministry of Health may contract supplies of the technologies or products stemming from the PDIL[32] for up to ten years (counted from the date the solution is finalized).

Penalties

In the event public funds are found to have been misappropriated (as a result of intent, fraud or gross negligence), the proponent will be responsible for reimbursing such funds. This reimbursement does not prejudice the suspension of future transfers, refunding the Brazilian Treasury for investments made by the Ministry of Health, suspension from participating in new PDIL proposal submission rounds, being impeded from bidding and contracting within the scope of Brazil's federal administration, and other potential legal penalties.[33]

31 Article 25 of GM/MS Ordinance No. 4,473/2024.

32 Article 5, Paragraph 3 of GM/MS Ordinance No. 4,473/2024.

33 Article 26 of GM/MS Ordinance No. 4,473/2024.

Adapting Pre-Existing Partnerships

The new regulations provide for rules applicable to partnerships that are already underway on the date they are published.

- **PDPs:** Ordinance No. 4,472/2024 establishes it will govern partnerships already underway on the date of its publication, respecting the agreements signed and the obligations between the parties.

  The ordinance goes further by establishing that any technological development and technology transfer agreements and partnerships that IPs or ICTs establish by December 31, 2022, involving local production for the SUS, must be adapted to the PDP model, as provided for by the procedure in the new regulation. This rule also applies to cases where there is a product acquisition agreement in effect on the date of the ordinance's publication that the Ministry of Health signed.

  As of June 21, 2024, technological development and technology transfer agreements and partnerships in the situations above must be reported to SECTICS within 60 days. The application to adapt the agreement to the PDP model must be submitted to the same department within 180 days.

- **PDIL:** GM/MS Ordinance No. 4,473/2024 establishes that existing strategic health alliances for the local development of innovative solutions seeking to supply products to the SUS can be adapted to the PDIL model by June 21, 2025 (i.e., twelve months after the ordinance took effect).

PDPs and the PDIL: A Comparison

	PDP	PDIL
Objective	Technological transfers of strategic products to reduce vulnerabilities within the SUS and expand access to health.	The development of local production and innovation to solve challenges in health and the sustainability and resilience of the SUS. *The SUS countermeasures may include (but are not limited to) co-ownership of intellectual property for the Ministry of Health or the public institution; the perception of economic rights; transfers of technology and knowledge; or free services or products.
Eligibility	Production and technology-related solutions for the SUS that meet the objectives defined in the regulations and are included in the Matrix are eligible for PDPs – provided the other requirements estab-lished in Article 4 of GM/MS Ordinance No. 4,472/2024 are met.	Production and technology-related solutions for the SUS that meet the objectives defined in the regulations and are included in the Matrix are eligible for the PDIL.
Participants	A public institution or scientific, technological and innovation institution proposing the project, individually or jointly with other public institutions or ICT; and A private developer, holder, transferor or receiver of the technology, individually or jointly with other private entities.	A public institution, a scientific, technological and innovation institution or a private non-profit entity may submit a proposal. It may establish strategic health alliances in cooperation with other public institutions, ICTs or private non-profit entities, public or private companies and startups.

	PDP	PDIL
Operation	SECTICS will be responsible for overseeing the PDP project's administrative process, as well as sending it for analysis and assessment by the Technical Evaluation Committee (CTA) and the Deliberative Committee (CD).	SECTICS will be responsible for overseeing the PDIL project's administrative process, as well as sending it for analysis and assessment by the Technical Evaluation Committee (CTA) and the Deliberative Committee (CD).
Submission	The Ministry of Health will announce the period for submitting proposals on its official website at least 30 calendar days prior to the final submission deadline.	The Ministry of Health will announce the period for submitting proposals on its official website at least 30 calendar days prior to the final submission deadline.
Post-Partnership	After the start of Phase IV, acquisitions of products subject to PDPs may be evaluated according to public policies for local production with the aim of reducing vulnerabilities within the SUS in accordance with current legislation.	The Ministry of Health may contract supplies of technologies or products resulting from the PDIL for up to ten years after the solution is finalized. It must consider issues such as the level of demand from the SUS and the principles of economy and advantage.

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