

**Public Consultation No. 53/2023 DECEIIS/SECTICS - Development and Local Innovation Partnerships - PDIL.**

**Body:** Ministry of Health

**Sector:** MS - Department of the Health and Innovation Economic-Industrial Complex for the SUS

**Status:** Active

**Publication in the DOU:** 12/08/2023

**Opening:** 12/11/2023

**Closing date:** 01/09/2024

**Contributions received:** 16

**Responsible for the consultation:** MS - Department of the Health and Innovation Economic-Industrial Complex for the SUS – DECEIIS/SECTICS

**Contact:** deceiis@saude.gov.br

Establishes the Development and Local Innovation Partnerships - PDIL.

**THE MINISTER OF STATE FOR HEALTH** , in the use of the powers conferred on her by items I and II of the sole paragraph of art. 87, as well as articles 23, 24, 200, 213, 218, 219 and 219-As of the Federal Constitution of 1988, and in accordance with Law No. 8,080, of September 19, 1990; Law No. 10,973, of December 2, 2004; Decree No. 9,283, of February 7, 2018; Decree No. 11,715, of September 26, 2023, and Annex CVII of the GM/MS Consolidation Ordinance No. 5, of September 28, 2017, **RESOLVES:**

Art. 1 The Development and Local Innovation Program - PDIL is hereby established, with the purpose of promoting the local development of innovative solutions aimed at health challenges in order to reduce productive and technological vulnerability, promoting the sustainability of the Unified Health System - SUS - and expanding access to healthcare

Single paragraph. The productive and technological solutions for the SUS included in the Matrix of productive and technological challenges in the Brazilian Public Healthcare - SUS will be eligible, in accordance with the guidelines for the implementation of the National Strategy for the Development of the Health Economic-Industrial Complex.

Art. 2 For the purposes of the PDIL, the following are considered

I - strategic alliances in health: agreements established involving companies, Scientific, Technological and Innovation Institutions - ICTs, public institutions and private non-profit entities with the purpose of undertaking mutually beneficial projects, based on the union of tangible and intangible resources, focused on research and development activities that aim to generate innovative products, processes and services, in addition to the transfer and dissemination of health technologies;

II - health challenges for the SUS: health problems, diseases and illnesses prioritized due to technological and productive vulnerabilities or economic impact that affect access to health or the sustainability of the SUS;

III - level of technological maturity: metric with nine levels that allows ordering and comparing the development of technologies according to the stage of development, with a view to supporting decisions to promote resources for innovation and those related to technology transition; And

IV - health technologies: pharmaceuticals, biopharmaceuticals, medicines, immunobiologicals, medical devices, communication and connectivity technologies applied to health, among others, as applicable.

Art. 3 The objectives of the PDIL are:

I - induce technological, productive development and local innovation to expand access to health and reduce the technological vulnerability of the SUS;

II - promote training actions for ICTs, public producers, **startups** and companies regarding the process of development, registration, production and incorporation of technologies in the SUS; And

III - contribute to the digital and ecological transition of the Health Economic-Industrial Complex - CEIS.

Art. 4 PDIL implementation strategies are:

I - act in conjunction with the institutions that are part of the Executive Group of the Health Economic-Industrial Complex - Geceis - and the Forum for Articulation with Society - FAS;

II - stimulate the improvement of the regulatory environment as an inducer of technological, productive development and local innovation for the CEIS;

III - leverage, through the State's purchasing power, technological and productive development and local innovation;

IV - direct funding to projects and actions that aim to induce the development of productive and technological solutions for the SUS; And

V - promote the establishment of strategic alliances for the development of innovative health solutions, within the scope of the CEIS.

Art. 5 Participation in the PDIL will be through direct support for projects of interest to the Ministry of Health, selected from among those presented in a continuous flow to the

Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex, or through a public call.

Art. 6 The PDIL will be executed through the formalization of the following instruments:

I - technological orders focusing on development, innovation and production of solutions to overcome technological and production challenges;

II - public contracts for innovative solutions;

III - technological compensation agreement;

IV - competitive dialogues;

V - agreements, terms of decentralized execution - TED, technical cooperation agreements, aimed at supporting projects for the development of new technologies and innovation linked to technological and productive challenges;

VI - economic subsidy, according to specific rules of the bodies that are part of the Executive Group of the Health Economic-Industrial Complex; or

VII - other similar legal instruments that focus on development, innovation and production of solutions to overcome technological and productive challenges

Single paragraph. The following will be published on the Ministry of Health website:

I - specific guidelines for each of the instruments referred to in the caput of this article; And

II - the extract of each of the projects financed by PDIL.

Art. 7 Pre-projects will be submitted within the scope of PDIL by ICTs, public institutions, private non-profit entities or strategic alliances between these and private companies, and will present a clear and cohesive work plan containing, at least:

I - identification of the proponent;

II - the object of the project according to the Matrix of productive and technological challenges in the Brazilian Public Healthcare - SUS;

III - the project objectives;

IV - justifications;

V - identification of potential partners;

VI - the definition of delivery stages, with express reference to the level of technological maturity;

VII - indication of evidence of compliance with the technological development stages to be presented at the conclusion of each stage;

VIII - the execution schedule suitable for completing the stages;

IX - the resource application plan linked to the fulfillment of the stages;

X - the counterparts for the SUS, including the daily life of intellectual property, the perception of economic rights, the transfer of technology, the gratuity of services or products, among others;

XI - evaluation indicators;

XII - other funding sources than that listed in art. 23 of this Ordinance;

XIII - the risk matrix; and

XIV - governance, professionalization and integrity program of the proposing institution, in compliance with the provisions of art. 4th of GM/MS Ordinance No. 1,354, of September 27, 2023.

Art. 8 The PDIL pre-project will be submitted through an electronic system or other means made available by the Ministry of Health.

§ 1 The information contained in the PDIL pre-projects is covered by industrial and commercial secrecy, in accordance with art. 22 of Law No. 12,527, of November 18, 2011.

§ 2 Any additional information regarding the confidentiality of the proposal must be informed by the proponent at the time of submission.

Art. 9 Approval of projects under the PDIL will be subject to evaluation regarding compliance with the following criteria:

I - obedience to the requirements of art. 7th of this Ordinance;

II - criticality of the technological challenge;

III - social, economic and environmental impact of health technology;

IV - the institution's competence and experience in developing a technological solution linked to the specific theme of the proposal

V - nature, experience and productive capacity of the institution or partner institutions in developing a technological solution linked to the specific theme of the proposal;

VI - level of technological maturity; And

VII - linkage to the objectives of the Vaccine, Serum and Blood Products Program - PPVACSH and prevention, diagnosis and treatment of neglected populations and diseases Program - PPDN.

Single paragraph. Projects within the scope of the PDIL will be evaluated and prioritized according to the degree of adherence to the criteria set out in items I, II, IV, V and VI of the **caput** and weighted in light of items III and VII.

Art. 10. The Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex, through the Department of the Health Economic-Industrial Complex and Innovation for the SUS, will be responsible for managing the PDIL within the scope of the Ministry of Health, and must, among other duties:

I - arrange the receipt and selection of proposals;

II - carry out the prior assessment of proposals to support technological, productive and local innovation development projects submitted to the PDIL, in accordance with art. 7th of this Ordinance;

III - evaluate the suitability of the proposal in light of the available legal instruments;

IV - carry out technical-economic analysis to carry out transfers;

V - monitor and supervise the execution of the project through the deliveries, results and indicators listed in the work plan;

VI - propose adjustments to achieve the objectives set; It

VII - instruct the administrative process of the PDIL project in accordance with items II to VI of the **caput** and forward it for analysis and evaluation by the Technical Assessment Committee - CTA and the Deliberative Committee - CD, in accordance with art. 11 of this Ordinance.

§ 1 The Department of the Economic-Industrial Complex of Health and Innovation for the SUS may invite the following to participate in the evaluation of projects:

I - professionals with renowned knowledge in the field;

II - specialists from other public administration bodies and entities

III - representatives from other departments of the Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex; or

IV - representatives from other departments of the Ministry of Health.

§ 2 In order to give greater effectiveness to the PDIL, the Department of the Economic-Industrial Complex of Health and Innovation for the SUS may promote the training of ICT teams, public laboratories and **startups** regarding the process of development, production, registration and incorporation of technologies in the SUS.

Art 11. After prior assessment by the Department of the Health Economic-Industrial Complex and Innovation for the SUS, the Technical Assessment Committee - CTA and the Deliberative Committee - CD, established within the scope of the Health Economic-Industrial Complex, will carry out the analysis and evaluation of projects.

Art. 12. ICTs, public or private non-profit institutions must be summoned by the Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex for oral presentation of the PDIL project proposal to the CTA and, when applicable, before the Deliberative Committee.

§ 1 The Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex must define a presentation schedule, safeguarding the confidentiality of proposals.

§ 2 The partner institution, public or private, of the proposing institutions referred to in the caput, may participate, on a complementary basis, in the oral presentation meeting of the PDIL project.

§ 3 The partner institution referred to in § 2 will not have the right to an oral presentation, being restricted to providing clarifications when requested by the CTA or CD.

§ 4 In the case of the oral presentation referred to in the **caput**, the information provided must not differ from that presented in the PDIL project.

§ 5º The CTA, during the oral presentation of the PDIL projects, may request additional clarifications from public or private non-profit institutions regarding the proposal presented, which must be included in the minutes or analysis report.

Art. 13. The CTA must carry out a merit analysis, classify each project and issue a technical recommendation opinion for approval or disapproval, the administrative process of which will be submitted to the CD.

Art. 14. After receiving the process, the CD must make a decision regarding the approval or disapproval of the proposals, as set out in its internal regulations.

Art. 15. The result of the evaluation must be published on the Ministry of Health's website and officially communicated by the Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex to the proposing institutions within fifteen days after the CD's decision.

Art. 16. A period of ten days is established for requesting review from the CD, without suspensive effect, counting from the receipt of formal communication of the decision from the Ministry of Health.

Art. 17. Proposing institutions are entitled to file an administrative appeal in the face of the review of the project referred to in art. 16, based on reasons of legality and merit, in accordance with Law No. 9,784/1999.

Art. 18. To evaluate the appeal, a Technical Appeal Evaluation Committee must be established, created specifically for this purpose, in accordance with Decree No. 10,001, of September 3, 2019.

Art. 19. The appeal and the opinions provided must be forwarded for a final decision to the Secretary of Science, Technology and Innovation and the Health Economic-Industrial Complex.

Art. 20. The administrative appeal must be decided within a maximum period of fifteen days, extendable for an equal period.

Art. 21. The Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex must disclose the final result of the evaluation of PDIL projects through a decree published in the Official Gazette of the Union and published on the Ministry of Health's website.

Art. 22. For monitoring and evaluation purposes, the PDIL will observe, where applicable, the following phases:

I - development of technology, according to the stages foreseen in the project;

II - registration with the competent authorities;

III - production of technological productive solutions for the SUS; And

IV - incorporation into the SUS.

Single paragraph. Projects supported under the PDIL will be monitored through situational reports and technical visits, comprising the development phases established by the Program and their results

Art. 23. The Ministry of Health must expressly express its interest in the ownership or co-ownership of intellectual property generated from projects financed by the Ministry considering the objectives of the PDIL, after consulting the Department of the Health Economic-Industrial Complex and Innovation for the SUS.

Art. 24. The financial resources for financing projects approved for order or direct support from the Ministry of Health will come from the account of the work program "5020 - Scientific, Technological and Productive Development in Health, set out in the programmatic functions of the Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex.

Art. 25. The Ministry of Health will preferentially contract, in accordance with current legislation, projects that, after completing the stages of art.22 of this Ordinance, are approved within the scope of the PDIL, registered with the competent authorities and incorporated into the SUS.

Single paragraph. The preference mentioned in the **caput**:

I - it will be up to ten years, for projects that, according to the analysis and evaluation of CTA and CD, are considered to be of greater technological complexity; or

II - it will be up to five years, for projects that, according to the analysis and evaluation of CTA and CD, are considered to be of less technological complexity.

Art. 26. The rules and penalties provided for in the rules governing the instruments signed within the scope of the PDIL or in the signed contract must be observed.

Art. 27. The Secretariat of Science, Technology and Innovation and the Health Economic-Industrial Complex will make available, on the website, manuals containing guidelines for submitting projects within the scope of the PDIL.

Art. 28. The strategic alliances in force for the technological, productive development and local innovation of innovative solutions that aim to supply products to the SUS must be adapted, as applicable, to the PDIL model, within twelve months of the entry into force of this Ordinance .

Art. 29. This Ordinance comes into force on 2023.

NÍSIA TRINDADE LIMA