Public Consultation No. 54/2023 DECEIIS/SECTICS/MS - Productive Development Partnerships Program - PDP

Body: Ministry of Health

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

Status: Active

Publication in Official Gazette: 08/12/2023

Opening: 11/12/2023

Closure: 09/01/2024

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

Contact: deceiis@saude.gov.br

***

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, of the Federal Constitution, and in accordance with Law No. 8,080, of September 19, 1990; Law No. 14,133, of April 1, 2021; Decree No. 11,714, of September 26, 2023; Decree No. 11,715, of September 26, 2023; GM/MS Ordinance No. 1,354, of September 27, 2023, RESOLVES:

Art. 1 Annex XCV of Consolidation Ordinance No. 5/GM/MS, of September 28, 2017, comes into force with the following changes:

CHAPTER I
GENERAL PROVISIONS

Art. 1 This Ordinance establishes the Program for Productive Development Partnership - PDP, which aims to guide the national investment effort in innovation and production, public

and private, through technological transfers of strategic products to reduce vulnerability of the SUS and expansion of access to healthcare.

Art. 2 For the purposes of this Ordinance, the following criteria are adopted:

I - agreement between partners: that establishes joint execution mechanisms, consultations, exchanges of information, documents and actions with a view to implementing the PDP project, in compliance with the criteria, guidelines and guidelines of this Ordinance, without intervention from the Ministry of Health.

II - Technical Assessment Committee - CTA: collegiate body established within the scope of the Health Economic-Industrial Complex - Ceis, which has among its activities, analyzing and evaluating the PDP, in its different phases.

III - Deliberative Committee - CD: collegiate body established within the scope of Ceis, of a deliberative nature, whose technical advice is provided by the CTA.

IV - Regulatory Technical Committee - CTR: guidance body in relation to regulatory-sanitary aspects relating to technologies and products of interest to the SUS.

V - critical technological component - CTC: input, product or process of the production chain, whose production is relevant to the country's technological domain.

VI - 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.

VII - critical technological device - DTC: technological device, associated with the pharmaceutical form, required for the administration of the medication.

VIII - private entity - EP transferring the technology: legal entity under private law, national or international that develops and/or holds the technology and is responsible for transferring technology for local production.

IX - private entity that owns/develops the active pharmaceutical ingredient - IFA or the DTC associated with the pharmaceutical form: legal entity governed by private law, national or international, that holds the technology or is responsible for the national development and local production of the IFA, or the DTC associated with the pharmaceutical form, when applicable;

X - Public Institution - IP: body or entity of the public, direct or indirect administration, of one of the three spheres of the government, which acts in research, development or local production.

XI - Scientific, Technological and Innovation Institution - ICT: body or entity of the direct or indirect public administration or legal entity governed by non -profit legally constituted under Brazilian law, with headquarters and forum in the country, which includes its institutional mission or in its social or statutory objective, basic or applied research of a scientific or technological nature or the development of new products, services or processes;

XII - active pharmaceutical ingredient - IFA: any substance, of chemical or biological origin, introduced into the formulation of a pharmaceutical form that, when administered to a patient, acts as an active ingredient.

XIII - internalization of technology: proof of incorporation and absorption of technology, in a way that makes IP/ICT holders of the skills and abilities that ensure the manufacture of the product(s) contemplated in the Executive Project in the national territory and make them capable of technological portability to meet the demands of the SUS;

XIV - Product Development Partnerships - PDP: partnerships that involve cooperation through an agreement between public institution(s) and/or ICT(s) and private entity(ies) for the transfer and absorption of technology, training production and technological development in the country, aiming at the local production of strategic technologies and products to meet the demands of the SUS;

XV - production platform: installed and enabled production line intended for the manufacturing process of products and inputs, constituting a common structure for various products.

XVI - technological platform: set of specialized technological and productive skills for the development and manufacture of related products and services, the result of accumulated experience and knowledge.

XVII - technological portability: technical and managerial capacity to transfer a given technology between public institution(s), ICT and private entities or between public institutions/ICT.

XVIII - productive and technological solutions for the SUS: platforms, routes, products or technological services necessary for the execution of public policies, actions, measures, mechanisms, initiatives and national programs for the promotion, prevention, diagnosis, treatment and rehabilitation of health, and which cover the strategic products for the SUS referred to in art. 75 of Law No. 14,133, of April 1, 2021;

XIX - Executive Project - PE: document presented by IP, and when applicable, ICT containing a PDP project proposal, in accordance with the Guidelines and Requirements for the Preparation of a PDP Project Proposal established in this Ordinance.

XX - Term of Commitment - TC: contract or similar instrument signed between the Ministry of Health, IP/ICT and private entity(ies) that aims to establish the PDP and that contains, at least, clauses of obligations of the parties involved , conditions for purchasing the product covered by the PDP, guarantee of local production, intellectual property rights and sanctions; and

XXI - verticalization: set of stages, units and production systems that determine the degree of internalization of the production chain of the product subject to PDP in the country.

Art. 3 The objectives of Product Development Partnerships are:

I - expand access to strategic technologies, products and services to reduce SUS vulnerabilities.

II - use the State's purchasing power in order to promote local production to overcome production and technological challenges and expand access to health.

III - strengthen public-private partnerships in production and innovation activities to meet the demands of the SUS.

IV - reduce productive and technological dependencies to meet the health needs of the Brazilian population in the short, medium and long term, following the constitutional principles of universal and equal access to health actions and services.

V - induce scientific, technological and productive development within the scope of Ceis, stimulating the public and private production network in the country and its strategic actions for the SUS.

VI - develop and consolidate technological and production platforms in Ceis to promote the development, innovation and manufacturing of strategic technologies, products and services for the SUS in the national territory.

VII - promote the development and manufacturing of strategic technologies, products and services for the SUS in the national territory.

VIII - contribute to preparedness for emergencies and global health situations; and

IX - contribute to the ecological and digital transition of Ceis.

CHAPTER II

PRODUCTS AND SERVICES ELIGIBLE FOR PDP

Art. 4 Products listed in the Matrix of productive and technological challenges in the Brazilian Public Healthcare - SUS, determined by act of the Minister of State for Health, are eligible for PDP and that meet the following requirements:

I - health registration in the country or prospect of registration within 24 (twenty-four) months for PDP objects subject to Health Surveillance.

II - absence of patent restriction that impacts the proposed arrangement or loss of restriction within 24 (twenty-four) months.

III - centralized acquisition or acquisition capable of centralization, or acquisition through programs, measures, initiatives, and specific actions with the purpose of rationalizing access to strategic products and services for the SUS, within the scope of Ceis; and

IV - high dependence on imports.

Single paragraph. For the purposes of art. 75 of Law No. 14,133, of April 1, 2021, the products from the Matrix of productive and technological challenges in the Brazilian Public Healthcare - SUS are considered strategic for the SUS.

CHAPTER III
OF SUBJECTS PARTICIPATING IN THE PDP

Art. 5 The subjects participating in the PDP may be:

I - Public Institution - IP, individually or jointly with other public institutions or ICT.

II - Scientific, Technological and Innovation Institution - ICT; and

III - Private Entity - EP, developer, holder or transferor of technology, individually or jointly with other private entities.

§ 1 In the case of Medical Devices and Information and Connectivity Technologies, there is no obligation for IP participation in the proposed arrangement.

§ 2 The public IP/ICT must carry out a public process to select private entities, respecting the principles of art. 37 of the Federal Constitution of 1988, in particular, those of advertising, legality and morality, as well as the provisions of Law No. 8,666, of 1993, Law No. 14,133, of 2021 and Law No. 13,303, of 2016.

CHAPTER IV
PROCESS

Art. 6 The process for establishing a PDP covers the following phases:

I - Phase I - PDP project proposal: submission phase by IP/ICT and analysis of the proposal by the Ministry of Health, CTA and CD and, in case of approval, celebration of the Term of Commitment - TC between the Ministry of Health, IP/ICT and EP.

II - Phase II - PDP project: phase in which the technology transfer process between partners begins through planning and carrying out training, development and absorption of scientific and technological knowledge involved in the partnership. It begins after the publication of the extract of the Term of Commitment in the Official Gazette of the Union (DOU), by the Ministry of Health.

III - Phase III - PDP: phase in which there is technology transfer covering the process of internalization of technology and production of the product subject to PDP by IP/ICT, according to a previously established schedule. At this stage, the acquisition of the product by the MS begins, following the publication by the Ministry of Health of the instrument formalizing the first acquisition; and

IV - Phase IV - Technology Internalization: verification phase of the completion of the transfer and full absorption of the technology subject to the PDP, as provided for in the Executive Project. It begins immediately after the end of Phase III. At this stage, the manufacturing of the product subject to the PDP must be proven in the industrial park with national IFA and the productive and technological domain by IP/ICT, according to the approved production arrangement.

Section I
The PDP Project Proposal - Phase I

Art. 7 The PDP project proposal must be prepared considering the health challenges and the productive and technological solutions for the SUS, observing the eligibility criteria for the PDP.

Single paragraph. The PDP project proposal must be presented in accordance with the established model, available on the MS electronic portal.

Art. 8 The period for submitting proposals will be announced by the Ministry of Health.

§ 1 PDP project proposals received after the established deadline will not be analyzed.

§ 2 After the deadline for receiving proposals, rectification of proposals or the presentation of additional information will not be permitted, except in cases where there is a request for adjustment by the evaluation and deliberation bodies, in accordance with § 5 of art. 19.

Subsection I
Guidelines and Requirements for Preparing a PDP Project Proposal

Art. 9 The PDP project proposal must be presented considering:

I - object, according to the Matrix of productive and technological challenges in the Brazilian Public Healthcare - SUS.

II - partners involved.

III - productive and technological arrangement.

IV - identification of the stages of the production process, with the forecast of which will be internalized and executed by IP/ICT.

V - intellectual property, including information on the possible existence of a technology licensing agreement.

VI - registration and certification of products covered by the PDP subject to Health Surveillance.

VII - schedule (Phase II and Phase III).

VIII - production process.

IX - technical-operational training planning.

X - internalization of technology by IP/ICT.

XI - estimated sales price.

XII - economic-financial capacity to offer the product and to internalize the technology.

XIII - investments, including the need to build a manufacturing plant; AND

XIV - risk analysis.

§ 1 The schedule for Phase II and Phase III must be proposed according to technological complexity, respecting the limits of two years and ten years, respectively.

§ 2 In cases of need to build a manufacturing plant to make the PDP viable, Phase II may be extended, justifiably, as long as it is presented in the Executive Project proposal and approved by the collegiate bodies.

§ 3 For Medical Device PDPs, the Phase III deadline will be a maximum of five years and may be extended for another five years in cases where there is provision in the Executive Project for incremental innovations focused on therapeutic gain.

§ 4 For Medical Device PDPs, the proposing ICT may associate with a private manufacturing unit in the country for the purpose of production on a sufficient scale to meet demand, with ICT being considered the legal manufacturer, in accordance with current health legislation.

§ 5 The proposed prices must be compatible with those practiced by the SUS and, when necessary, with the prices of international markets in the countries covered by the Medicines Market Regulation Chamber - CMED, considering the principles of economy and advantage.

§ 6 If, at the time of forming the partnership, the price presented in the proposal is higher than those practiced by the SUS or the prices on international markets in countries covered by the Medicines Market Regulation Chamber, prior to establishing the partnerships, a

justification must be provided with economic evidence that supports the value in terms of technological input;

§ 7 Prices must decrease throughout Phase III, according to technological complexity.

§ 8 An estimate of the price and supply capacity of the product with imported and national IFA must be presented.

§ 9º A technical-economic feasibility study and indication of viable production capacity for the product subject to the PDP must be presented, considering the estimated demand for the national and regional market, when applicable.

§ 10. The legal representatives of the PDP partners must sign a joint declaration of agreement with all the terms of the project proposal presented, which must be included in the list of documents that make up said proposal.
Art. 10. The Guide for preparing and submitting a PDP project proposal will be published on the Ministry of Health's website.

Subsection II
Technological Skills

Art. 11. The project proposal must include full access to knowledge and detailed production technology of the product subject to PDP by IP/ICT, including, among others, analytical methods, processes, input specifications, critical equipment and all the technical support necessary for the absorption and internalization of the technology.

Art. 12. Technology transfer must include the effective internalization of skills that ensure technological mastery of the product subject to the PDP during Phase III.

§ 1 It is mandatory to present the degree of verticalization of the IFA/CTC that is being proposed, accompanied by a technical-economic feasibility study and indication of viable production capacity for each intermediary and for the IFA/CTC.

§ 2 For biotechnological products, it is mandatory to provide for the transfer of the Master Cell Bank - BCM, or equivalent, in sufficient quantity to ensure the transfer of technological knowledge required for production from the Working Cell Bank - BCT, or equivalent, aiming at national production autonomy by IP/ICT, informing the quantity and forecast of autonomy, in number of batches.

§ 3 For Information and Connectivity Technologies, the proposed project must cover the domain of the technological core.

Subsection III
PDP Project Proposal Assessment Instances

Art. 13. The analysis and evaluation of Product Development Partnerships - PDP will be carried out by the Technical Evaluation Committee - CTA and the Deliberative Committee - CD, established within the scope of the Health Economic-Industrial Complex - Ceis.

Subsection IV
PDP Project Proposal Analysis Criteria

Art. 14. The following criteria must be considered when evaluating the merit of the PDP project proposal:

I - adequacy of the schedule to the complexity of the technology involved and regulatory and health requirements.

II - prediction of technology internalization, considering:

a) internalization of technology with national production; AND

b) national production of the IFA/CTC or DTC associated with the pharmaceutical form.

III - degree of verticalization of production stages of the IFA/CTC or DTC associated with the pharmaceutical form for the national manufacturing park.

IV - productive capacity of the proposing institution and partner companies.

V - rationality of planned investments, indicating the source, schedule compatible with the evolution of activities and the need for resources.

VI - projection of savings generated for the SUS in product acquisitions.

VII - governance, professionalization, integrity and environmental sustainability program; and

VIII - availability of human resources to make the project viable.

Art. 15. The following criteria must be used to classify PDP project proposals:

I - deadline for internalization of technology and production by IP/ICT, according to the approved production arrangement, to supply the product to the MS.

II - history of successful PDP completion, with the incorporation of products into the IP/ICT portfolio.

III - availability of technological and production platforms and compatibility of the nature of the project with the activities carried out by the proposing public institution.

IV - investments applied by the private entity to execute the PDP that contribute to regional or national development.

V - price proposal, representation of the decreasing scale of values and the viability of the project.

VI - presentation of a technological solution associated with technology transfer, with synergy for future technologies.

VII - developed national IFA/CTC.

VIII - participation in the Prevention, Diagnosis and Treatment of Neglected Populations and Diseases Program - PPDN or Vaccine, Serum and Blood Products Program - PPVACSH and; and

IX - product whose technological development was carried out, entirely or partially, in the country, with public resources.
Art. 16. The criteria referred to in arts. 14 and 15 must be considered by the CTA, as set out in its internal regulations.

Subsection IV
The PDP Project Proposal Administrative Process Instruction

Art. 17. SECTICS/MS will be responsible for instructing the administrative process of the PDP project proposal.

Art. 18. PDP project proposals submitted through the Electronic System or other means made available by the Ministry of Health will be registered in the Electronic Information System - SEI by SECTICS/MS.

§ 1 The information contained in PDP project proposals 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. 19. PDP project proposals submitted in disagreement with the provisions of Chapter II of this ordinance, with the submission deadline or with the model established by the Ministry of Health do not require analysis.

Single paragraph. SECTICS/MS must formalize to the proponent the non-compliance of the proposal with the procedure established by this Ordinance.

Art. 20. The Guide for submitting a PDP project proposal will be published on the Ministry of Health's electronic portal.

Subsection V
PDP Project Proposal Approval Process

Art. 21. IP/ICT must be summoned by SECTICS/MS for oral presentation of the PDP project proposal before the CTA and, when applicable, before the CD.

§ 1 SECTICS/MS must define a presentation schedule, safeguarding the confidentiality of proposals.

§ 2 The EP(s) may participate, on a complementary basis, in the oral presentation meeting of the PDP project proposal.

§ 3 The EP(s) will not have the right to an oral presentation, being restricted to providing clarifications, when requested by the CTA or the 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 Executive Project.

§ 5º the CTA, during the oral presentation of PDP project proposals, may request additional clarifications from the IP/ICT regarding the proposal presented, which must be included in the minutes or analysis report.

Art. 22. The CTA must carry out a merit analysis, classify each PDP project proposal and issue a recommendation opinion for approval or disapproval, the administrative process of which will be submitted to the CD.

Art. 23. After receiving the process referred to in art. 20, the CD must make a decision regarding the approval or disapproval of the proposals, as set out in its internal regulations.

Art. 24. In the case of feasibility of more than one PDP project proposal for the same product, the demand from the Ministry of Health must be divided according to criteria established by the CTA.

Art. 25. The preliminary result of the evaluation of PDP project proposals must be published on the Ministry of Health's electronic portal.

Art. 26. The preliminary result of the evaluation of PDP project proposals must be officially communicated by SECTICS/MS to IP/ICT, within 15 (fifteen) days after the disclosure established in art. 23.
Art. 27. The IP/ICT is entitled to file an administrative appeal in view of the preliminary result of the evaluation of the PDP project proposal, based on reasons of legality and merit, in the sole and final instance, addressed to the Minister of State for Health, under the terms of Law No. 9,784/1999.

Art. 28. The administrative appeal must be addressed to the Minister's Office (GM/MS), which must then be sent to the Legal Consultancy (CONJUR/MS) for knowledge and admissibility judgment.

Art. 29. The admitted administrative appeal must be forwarded to SECTICS/MS for an analysis of the merits and subsequent forwarding to the collegiate bodies.

§ 1 To evaluate the appeal, a new CTA must be established, created specifically for this purpose.

§ 2 In the case of an administrative appeal, the proposals may be reclassified, and the Ministry of Health's demand redivided according to the same criteria set out in the CTA's internal regulations.
Art. 30. The appeal and the opinions drawn up must be forwarded to the Minister of State for Health for a final decision.

Art. 31. The Ministry of Health must publish the final result of the evaluation of PDP project proposals through an Ordinance published in the DOU and published on the Ministry's website.
Art. 32. Approved PDP project proposals must be formalized by signing the Term of Commitment signed by the legal representatives of the PDP partners and the Ministry of Health.

Single paragraph. PDP project proposals for the same product must have different Term of Commitment and must be monitored individually.

Art. 33. The extract from the Term of Commitment relating to the approved PDP project proposal must be published by the Ministry of Health in the DOU and maintained on its website in an easily accessible location dedicated to information about PDP.
Art. 34. The list of PDP project proposals that are not approved must be published on the Ministry of Health's website, with the respective motivation.

Art. 35. The approval of PDP project proposals does not bind the Ministry of Health to the obligation to finance investment demands that may be identified by IP/ICT, including funding expenses for project execution.
Art. 36. The internal regulations of the CTA and the CD must define, on a complementary basis, the rites, deadlines, documentation and methodology to be used to consider the analysis criteria and competencies in the evaluation and decision process relating to the PDP.

Section II
The PDP Project - Phase II

Art. 37. Phase II begins with the publication of the extract of the Term of Commitment in the DOU, by the Ministry of Health.

Art. 38. The PDP will be automatically suspended after the end of the deadline approved for Phase II, for reassessment of the feasibility of continuing the project by the CTA and the CD.

Art. 39. The PDP partners must sign an agreement that establishes joint execution mechanisms, consultations, exchanges of information, documents and actions with a view to implementing the PDP project, in compliance with the criteria, guidelines and guidelines of this Ordinance, without intervention from the Ministry of Health.

§ 1 The copy of the official publication of the extract of the agreement signed between the partners must be sent to the Ministry of Health within 180 (one hundred and eighty) calendar days after the publication of the extract of the Commitment Term in the DOU.

§ 2 The established agreement must provide for sanctions in case of non-compliance by the parties.

Art. 40. The provision of information and documents regarding the execution of the PDP project for the Ministry of Health must be carried out by IP/ICT.

§ 1 During Phase II, the Public Institution or ICT must send, on an ordinary basis, a biannual monitoring report to the Ministry of Health.

§ 2 Monitoring reports must be sent, without fail, by the last business day of June and December and will follow the model available on the Ministry of Health's website.

Section III
PDP - Phase III

Art. 41. Phase III begins with the publication of the instrument relating to the first acquisition of the product subject to PDP by the Ministry of Health, upon prior demonstration by the IP/ICT of compliance with the activities presented in the schedule.

Single paragraph. Year I (one) of the PDP must begin with the publication of the specific instrument referring to the first acquisition of the product subject to the PDP by IP/ICT from the Ministry of Health.

Art. 42. The following are requirements for the start of Phase III:

I - product incorporated into the SUS.

II - centralized acquisition.

III - health registration of the product subject to the PDP for the product subject to the PDP subject to Health Surveillance.

IV - CBPF in force at the manufacturing site of the product covered by the PDP subject to Health Surveillance; AND

V - publication of the extract from the technology transfer contract between all PDP partners.

Single paragraph. Item I is not mandatory for Medical Devices and Information and Connectivity Technologies.

Art. 43. For the first acquisition, ownership of the health registration of the product covered by the PDP subject to Health Surveillance may belong to IP/ICT or EP, as long as it is in a proven process of development, transfer and absorption of technology, under the terms of items XXXII and XXXIV, of art. 24 of Law No. 8,666, of June 21, 1993, and items XII and XVI of art. 75 of Law No. 14,133/2021.

§ 1 If the product subject to the PDP has a health registration in the name of EP, IP/ICT must have all the technical information and a copy of the entire content of the dossier of said registration approved by ANVISA, as well as the documentation required for its eventual update.

§ 2º IP/ICT must submit a request for registration to ANVISA, in its name, of the product subject to the PDP, in accordance with current health legislation, within a period of up to 60 (sixty) days of the first acquisition of the product subject to the PDP.

§ 3º IP/ICT must forward to the Ministry of Health a copy of the protocol of the aforementioned documentation presented with ANVISA within 30 (thirty) days, counting from the end of the period referred to in § 2º.

Art. 44. The technology transfer contract for the product subject to the PDP must be established between all PDP partners, without intervention from the MS.

§ 1 The presentation of the extract from the official publication of the technology transfer contract to the Ministry of Health by IP/ICT is a mandatory requirement for the start of Phase III.

§ 2 The established contract must provide for the full transfer of technology as provided for in the approved executive project and its possible changes, including all technological competencies provided for in articles 11 and 12 of this ordinance, responsibility of the parties and sanctions in case of non-compliance, especially regarding the failure to comply with the scheduled schedule.

§ 3 The contract must be compatible with the Term of Commitment and the PDP governing standard.

Art. 45. The acquisition of the product subject to PDP by the Ministry of Health must only occur if all the steps described in Sections I and II of Chapter IV of this Ordinance have been completed.

Single paragraph. The product subject to the PDP must meet the presentations, specifications, forms and quantities required by the Ministry of Health, respecting health regulations.

Art. 46. For PDPs referring to the same product, the acquisition must be carried out respecting the percentages established for each PDP, as decided by the Delivery Committee.

§ 1 In cases where a PDP first meets the requirements for Phase III, it will be responsible for supplying the total demand of the Ministry of Health until the other PDPs meet the requirements for Phase III and the division of responsibilities approved for the phase begins. each project, subject to supply capacity and advantage.

§ 2 In cases of an increase in the percentage foreseen for the acquisition period, the initially foreseen value must be renegotiated, considering the gain in scale.
Art. 47. After the first acquisition of the product subject to PDP subject to Health Surveillance, within the scope of the PDP, the Ministry of Health must carry out new acquisitions only upon proof, through the monitoring mechanisms provided for in this Ordinance, that IP/ICT has the health registration of the aforementioned product with ANVISA and compliance with the activities set out in the schedule, demonstrating the transfer and absorption of technology, industrial and technological training of IP and private entities, when applicable.
Art. 48. In the case of products with PDP in Phase III, which meet the requirements established in this Ordinance, the Ministry of Health must carry out acquisitions within the scope of current partnerships and under supply conditions.

§ 1 The Ministry of Health will not purchase products subject to PDP suspended or terminated by the procedure established in this Ordinance.

§ 2 If there is a current contractual instrument, the obligations assumed must be fulfilled by the parties, respecting the established delivery schedule.
Art. 49. The acquisition of the product covered by the PDP will be carried out by the responsible Secretariats of the Ministry of Health, and will be carried out after analyzing the following items:

I - service capacity:

a) verification of IP/ICT's ability to supply the product covered by the PDP in the presentations, pharmaceutical forms and technical specifications requested by the Ministry of Health; and

b) verification of the technical and operational conditions of IP/ICT to deliver the product covered by the PDP in the quantities, terms and conditions recommended by the requesting areas of the MS.

II - demand from the Ministry of Health at the time of acquisition of the product covered by the PDP; and

III - prices, economy and advantage.

a) before the start of Phase III, the proposed price may be adjusted in cases where there is a change in the price of the product subject to the PDP in the national and international markets of the countries covered by the Medicines Market Regulation Chamber - CMED; and

b) the annual adjustment may consider the variation in average prices in the national and international markets of the countries covered by the Medicines Market Regulation Chamber - CMED, and the variation in prices measured by the IPA of the pharmaceutical sector.

Single paragraph. SECTICS/MS is responsible for establishing mechanisms for monitoring the prices of products subject to PDP on the market, in order to contribute to the assessment of prices of products subject to PDP.

Art. 50. The administrative process for acquiring the product subject to the PDP must comply with current legislation, as well as contain all the information necessary to prove the regularity of the PDP regarding the development, transfer and absorption of technology.

Art. 51. The Secretariats of the Ministry of Health, responsible for the acquisition of products covered by the PDP, must consult the technical area of SECTICS/MS, responsible for monitoring the PDP regarding the stage and evolution of the PDP technology transfer, in beginning of each acquisition process.

Art. 52. The technical area of SECTICS/MS, responsible for monitoring the PDP, must forward the following documents to the Secretariats of the Ministry of Health responsible for acquisitions:

I - electronic address for accessing the health registration of the product covered by the PDP.

II - electronic address for accessing the CBPF of the manufacturing site contained in the health register and/or its publication in the DOU.

III - electronic address to access the extract from the Technology Transfer Agreement, published in the DOU, or equivalent official instrument, in the case of a state or district institution; and

IV - technical note prepared by the SECTICS/MS technical area responsible for monitoring the PDP containing, at least, the following criteria:

a) PDP partners.

b) object of the PDP, specifying the product, presentations, pharmaceutical form and technical specifications.

c) objective of the PDP.

d) deadline foreseen by IP/ICT for the internalization of the technology (duration of Phase III).

e) current stage of technology transfer; and

f) estimated sales price and supply capacity, as set out in the Executive Project.

Single paragraph. The Secretariats of the Ministry of Health responsible for the acquisition of products, objects of the PDP, may request from SECTICS/MS, if within their possession or competence, other information and documents that are necessary for the proper instruction of the acquisition procedure.

Art. 53. During Phase III, IP/ICT must send, on an ordinary basis, a quarterly monitoring report to the Ministry of Health.

Single paragraph. Monitoring reports must be sent, without fail, by the last business day of April, August and December and will follow the model available on the Ministry of Health's website.

Art. 54. Public production of the product covered by the PDP subject to Health Surveillance with IFA or national DTC for supply to the Ministry of Health must occur during Phase III.

§ 1 The development of the national IFA by PDP's pharmaceutical partner must be completed by Year II (two) of Phase III, aiming to supply the nationalized product from Year III (three) of Phase III.

§ 2 The post-registration changes to include IP/ICT, when applicable, as a manufacturing location must occur at least 12 (twelve) months before the completion of Phase III.

§ 3 The manufacturing of the product subject to the PDP by IP/ICT must occur at least 12 (twelve) months before the completion of Phase III.

Subsection II
Internalization of Technological Skills

Art. 55. The EP must guarantee IP/ICT, during Phase III, full access to knowledge and detailed production technology of the product subject to the PDP, including, among others, analytical methods, processes, input specifications , critical equipment and all the technical support necessary for the absorption and internalization of the technology, according to the approved Executive Project.

§ 1 The nationalization of the IFA/CTC is mandatory according to the degree of verticalization presented in the approved Executive Project.

§ 2 For biotechnological products, it is mandatory to transfer the Master Cell Bank - BCM, or equivalent, in sufficient quantity to ensure the transfer of technological knowledge required for production to the Working Cell Bank - BCT, or equivalent, and autonomy of national production by IP/ICT, according to the approved Executive Project.

§ 3 Mastery of the technological core that allows the portability of information technology and connectivity must be guaranteed.

Art. 56. Technology transfer must include the effective internalization of skills that ensure technological mastery and national production of the product covered by the PDP.

Single paragraph. Failure to comply with the provisions of the **caput** of this article subjects PDP partners to the sanctions provided for in Chapter VIII of this ordinance.

Section IV
Verification of Technology Internalization - Phase IV

Art. 57. Phase IV, in which the Ministry of Health must verify the internalization of the technology by IP/ICT, begins immediately after the end of Phase III.

Single paragraph. Phase IV referred to in the **caput** has a maximum duration of 24 (twenty-four) months.

Art. 58. Within 90 (ninety) days after the completion of Phase III, IP/ICT must forward to the Ministry of Health the Technology Transfer and Internalization Report of the product subject to the PDP containing documents that prove the internalization of the technology and the production of the product subject to the PDP, in addition to information on the production of the national IFA or DTC by the partner(s), when foreseen.

§ 1 IP/ICT must prove that it holds the registration and is the manufacturer of the product subject to the PDP, in accordance with current health legislation.

§ 2 The report must be accompanied by a Joint Declaration of Completion of Technology Transfer and Internalization signed by all PDP partners.

§ 3 The report must follow the model available on the Ministry of Health's website.

Art. 59. To verify the internalization of the technology **in loco**, the SECTICS/MS technical area, responsible for monitoring, must carry out a technical visit to the IP/ICT, and, when necessary, to the national EP(s), and prepare the Technology Transfer and Internalization Verification Report.

Art. 60. Upon receipt of the Technology Transfer and Internalization Report referred to in art. 58 and issuance of the Technology Transfer and Internalization Verification Report referred to in art. 59, the SECTICS/MS technical area responsible for monitoring the partnership must prepare a Technical Note and forward the documents for analysis and manifestation by the evaluation and deliberation bodies (CTA and CD).

§ 1 Where appropriate, the CD may recommend the application of sanctions to the Ministry of Health.

§ 2 The CD may recommend, when necessary, the period of operation of the public institution or ICT assisted by the private entity in order to promote the competitiveness of public production and active pharmaceutical inputs after technology transfer.

Art. 61. After evaluation of the CTA and deliberation of the CD, resulting in proof of the internalization of the technology, SECTICS/MS must publish in the DOU, Ordinance for the Internalization of the Technology of the product subject to the PDP, this being the closing milestone of the PDP.

Single paragraph. After publication of the PDP closing milestone, the partnership is considered concluded, including for monitoring purposes.

Art. 62. At the end of Phase IV, the IP/ICT must ensure the internalization of technology, including technological skills, and the national manufacturing of the product subject to PDP, in accordance with an approved production arrangement, and suitable for technological portability to meet the demands of the SUS.

Art. 63. The public institution or ICT that successfully completes the PDP may propose a new PDP for a product on the same technological platform, in a complementary or substitutive way to the product object of the incorporated PDP, in order to ensure the supply of strategic products for the SUS and rationalize investments made in production and technological platforms.

§ 1 The proposed product must meet the eligibility criteria for the PDP.

§ 2 Approval of the partnership must be evaluated by the CTA and resolved by the CD, under the terms defined in this ordinance.

Art. 64. After the start of Phase IV, the acquisition of products subject to a completed PDP must occur in accordance with current legislation, considering public production capacity and the manufacture of medicines with national API.

CHAPTER V
INSTITUTIONAL RESPONSIBILITIES

Art. 65. The Ministry of Health is responsible for:

I - prepare, publish and update the Matrix of productive and technological challenges in the Brazilian Public Healthcare – SUS.

II - encourage IP/ICT to present PDP project proposals aligned with CEIS technological platforms.

III - encourage EPs to participate in initiatives that favor investment, technological development, innovation and the generation of jobs and income in Brazil.

IV - receive and analyze PDP project proposals (Phase I).

V - participate and provide technical and administrative support for carrying out CTA and CD activities.

VI - celebrate and formalize the TC of each approved PDP project proposal.

VII - publish the TC extract of each approved PDP project proposal.

VIII - carry out technical visits to the manufacturing units of PDP partners.

IX - request information and documents from ANVISA, necessary for monitoring the PDP, in order to support technical visits, CTA and CD meetings.

X - organize and coordinate, annually, meetings of the Technical Monitoring Team - ETM.

XI - monitor and evaluate partnerships, from the PDP project (Phase II) to the internalization of the technology (Phase IV).

XII - prepare the Technology Transfer and Internalization Verification Report and the Technical Note and forward them to the evaluation and deliberation bodies.

XIII - participate in meetings of the Regulatory Technical Committee - CTR.

XIV - carry out acquisitions of products subject to current Phase III PDP, in accordance with the criteria and guidelines established in this Ordinance.

XV - publish, on the Ministry of Health's website, public information relating to PDPs, containing at least the following criteria:

a) laws, decrees, ordinances, resolutions and other normative instruments.

b) PE models, monitoring report and technology transfer and internalization report.

c) PDP project proposals under analysis, approved or disapproved.

d) list of PDPS and their respective stages; and

e) acquisitions of products subject to PDP with an address for access to publicizing the act.

XVI - apply sanctions.

Art. 66. ANVISA is responsible for:

I - coordinate the CTR.

II - carry out the analyzes required within the scope of PDP projects and during the PDP execution stages in relation to registration and post-registration changes, according to the deadlines in current legislation.

III - prioritize, in accordance with current health standards, the required analyzes of products subject to PDP.

IV - support SECTICS/MS, providing technical regulatory-sanitary information in the monitoring and evaluation activities of the technical development of PDP projects to meet the sanitary quality and internalization requirements of production in the country; and

V - participate in the CTA.

Art. 67. The IP/ICT proposing and executing the PDP is responsible for:

I - prepare and submit the PDP project proposal, according to the EP model, in compliance with the criteria, requirements, guidelines and guidelines of this Ordinance.

II - present, orally, the PDP project proposal to the CTA and, when applicable, to the CD, after a formal invitation from the Ministry of Health.

III - demonstrate the production capacity, equipment and human resources necessary to execute the PDP project at IP/ICT, making the relevant adjustments to execute the technology transfer.

IV - carry out the risk analysis and technical-economic feasibility study of the project.

V - sign the Term of Commitment together with the Ministry of Health and EP.

VI - conclude agreements, contracts or other legal instruments with partners of the PDP project, following the criteria and guidelines of this Ordinance and the premises forming part of the Term of Commitment signed, without prejudice to the addition of other conditions necessary to meet the public interest, in compliance with current legislation.

VII - petition the registration dossier and post-registration changes of the product subject to PDP with ANVISA, in accordance with current legislation and established schedule.

VIII - request prioritization of analysis from ANVISA, in accordance with current legislation.

IX - forward to the Ministry of Health a copy of the petition protocol requesting registration of the product subject to PDP.

X - guarantee with the private entity the internalization of technological competences and, when applicable, the internalization of the national production of the DTC associated with the pharmaceutical form.

XI - actively participate in the development of the product subject to the PDP with EP, monitoring the entire technological and health regulatory cycle.

XII - carry out training for your team, coordinated with private entities, in order to absorb the knowledge necessary to carry out the technology transfer of the product subject to the PDP.

XIII - gather documentary evidence of absorption of the technological knowledge involved in the partnership.

XIV - participate in technical visits to national and international partner EP(s), together with the Ministry of Health.

XV - comply with the PDP schedule.

XVI - send to SECTICS/MS monitoring reports on the current PDP, demonstrating the activities carried out, in progress and planned.

XVII - present the status of the current PDP and, when requested, supporting documentation during the technical visit to IP/ICT.

XVIII - participate in meetings of the CTR and ETM of the Ministry of Health.

XIX - enter into a specific instrument with the Ministry of Health to supply products within the scope of the PDP, respecting current legislation and the terms of this Ordinance.

XX - guarantee the supply and delivery of products according to the quantity and schedule previously agreed with the Ministry of Health.

XXI - at the end of the technology transfer, have completed the planned activities and carried out all stages of manufacturing the product subject to the PDP, as provided for in the PE.

XXII - prepare and send to the Ministry of Health the PDP Technology Transfer and Internalization Report in Phase IV.

XXIII - sign the Joint Declaration of Agreement to the Terms of the Executive Project Proposal; AND

XXIV - present, during Phase IV, the Joint Declaration of Completion of Technology Transfer and Internalization signed by the PDP partners.

§ 1º the choice and contractual relations with EP are the sole responsibility of the IP/ICT celebrating the PDP, including in relation to its qualification and the assessment of the regularity of its legal situation and suitability.

§ 2 IP/ICT must present additional information regarding the confidentiality of the proposal at the time of submission, if necessary.

Art. 68. EP is responsible for:

I - participate in the preparation of the PDP project proposal, in compliance with the criteria, requirements, guidelines and guidelines of this Ordinance.

II - demonstrate the production capacity, equipment and human resources necessary to execute the PDP project, making the relevant adjustments to execute the technology transfer.

III - sign the Term of Commitment together with the Ministry of Health and IP/ICT.

IV - conclude agreements, contracts or other legal instruments with partners of the PDP project, following the criteria and guidelines of this Ordinance and the premises forming part of the Term of Commitment signed, without prejudice to the addition of other conditions necessary to meet the public interest, in compliance with current legislation.

V - guarantee, within its sphere of responsibility, the internalization of the national production of the IFA, and when applicable, the internalization of the national production of the DTC associated with the pharmaceutical form or the CTC, as provided for in the EP.

VI - guarantee the transfer of technology and effective compliance with the technical-regulatory schedule under its responsibility.

VII - share the development of the product subject to the PDP with IP.

VIII - carry out training, in order to transfer the necessary knowledge for the effective development and execution of the technology transfer of the product subject to the PDP to IP/ICT.

IX - receive technical visits from teams from the Ministry of Health and public partners (IP/ICT).

X - petition the registration dossier and post -registration changes of the product object of PDP with ANVISA, according to current legislation and established schedule.

XI - comply with the PDP schedule, agreeing with all PDP partners the possibility of any necessary alteration, under penalty of imposition of the administrative sanctions provided for in the contract and current legislation, without prejudice to the liability for the damages caused by its non -compliance.

XII - periodically inform IP/ICT, according to the defined schedule, of the activities carried out, in progress and planned, including intellectual property data, assisting IP/ICT in preparing monitoring reports and substantiated justifications in case of changes to the schedule and sending documents to IP/ICT on the progress of the project and the activities inherent to its implementation, which include technology transfer, guarantee of supply and national production of technological skills and, when applicable, DTC associated with pharmaceutical form;

XIII - guarantee the supply and delivery of the product subject to the PDP in accordance with the quantity and schedule agreed by IP/ICT to meet the demands of the Ministry of Health.

XIV - actively participate with IP/ICT and the Ministry of Health in the preparation and dissemination of information regarding products subject to PDP distributed on the SUS network.

XV - sign the Joint Declaration of Agreement to the Terms of the PDP Project Proposal; AND

XVI - issue, together with IP/ICT, the Joint Declaration of Completion of Technology Transfer and Internalization signed by the PDP partners.

CHAPTER VI
MONITORING AND EVALUATION

Art. 69. Each PDP must be continuously monitored from the PDP project (Phase II) to the internalization of the technology (Phase IV), for the purpose of verifying advances in the process of production, development, transfer and absorption of technology.

Art. 70. Monitoring and evaluation of PDPs must comply with the following criteria:

I - compliance with the PDP schedule; AND

II - compliance with the obligations and responsibilities defined in the Executive Project for the establishment of the PDP.

Art. 71. Technical monitoring of training, technological and productive activities, through technology transfer and execution of the approved schedule, must be carried out by the SECTICS/MS technical area.

Single paragraph. SECTICS/MS may establish agreements with well-known public institutions in order to technically subsidize the monitoring of PDPs.

Art. 72. The specific instruments and methodologies for technical monitoring of the PDP must comprise the following dimensions:

I - monitoring of registration, post-registration activities, certification of good manufacturing practices, the technical process of technology transfer and absorption and the development of the capabilities of the public institution or ICT to the new technological level, aiming to comply with the schedule execution of the PDP.

II - analysis of monitoring reports by the IP/ICT to the Ministry of Health.

III - information of a technical-regulatory nature provided and discussed within the scope of the CTR.

IV - information regarding the development, transfer and absorption of technology presented and discussed within the scope of the ETM; AND

V - information regarding technical visits carried out by the Ministry of Health at public and private manufacturing units.

§ 1 ETM meetings must be held annually, coordinated by SECTICS/MS with the presence of representatives of PDP partners, representatives of the technical area of SECTICS/MS that is responsible for monitoring PDP and representatives of the final area of the Ministry of Health.

§ 2 Technical visits to national IP/ICT and EP must occur at least once each year, during the duration of Phases II and III.

§ 3 Technical visits to international EPs must occur primarily in Phase III, with at least one technical visit during Phase III.

Art.73. SECTICS/MS must issue notification to IP/ICT when the monitoring and evaluation mechanisms identify that the partnership is in disagreement with the requirements, criteria, guidelines and guidelines established in this Ordinance.

Art. 74. PDP partners are subject to notification in the event of:

I - not carrying out the actions foreseen in the approved project.

II - not making the proposed or required adjustments for the development, transfer and absorption of technology and national public production of the product subject to the PDP, as provided for in the approved project.

III - not actively participate in the development, transfer and absorption of technology and national public production of the product covered by the PDP and, when applicable, in the internalization of national production of the IFA, CTC or DTC associated with the pharmaceutical form.

IV - not carry out training for your team, jointly coordinated, in order to absorb the knowledge necessary for the development and effective transfer and absorption of technology of the product subject to the PDP.

V - not send to the Ministry of Health, specifically to SECTICS/MS, monitoring reports that demonstrate the activities carried out, in progress and planned and, in case of delay in the schedule, present reasoned justifications.

VI - not complying with current legislation and the terms of this Ordinance, as well as the legal instruments signed with the Ministry of Health for the supply of products within the scope of the PDP.

VII - make changes to the project, in disagreement with the guidelines established in Chapter VI.

VIII - repeatedly delay the delivery of the product covered by the PDP; and

IX - terminate the PDP, after the Ministry of Health has purchased the product covered by the PDP.

Art. 75. The CTA and the CD, at any time, may recommend to SECTICS/MS the issuance of notification and the application of sanctions for PDPs that are in disagreement with this Ordinance.

Art. 76. The IP/ICT, after receiving the notification referred to in art. 73, you will have a period of up to 10 (ten) days to present a formal statement to SECTICS/MS, with a view to resolving the reason for the notification.

§ 1 The manifestation of the IP/ICT must be analyzed by the technical area of SECTICS/MS, within 30 (thirty) days.

§ 2 PDPs whose justifications and adjustments are not accepted by the technical area of SECTICS/MS responsible for monitoring the PDP will be forwarded to SECTICS/MS with a recommendation for suspension.

Art. 77. SECTICS/MS must officially communicate the suspension to the IP/ICT and will grant a period of 10 (ten) calendar days, counting from the date of receipt, for a formal statement.

§ 1º SECTICS/MS must communicate to the Secretariats of the Ministry of Health responsible for executing the instruments for acquiring products subject to the PDP and to the Executive Secretariat (SE/MS) about the suspension of the PDP.

§ 2 The IP/ICT manifestation must be analyzed by the SECTICS/MS technical area responsible for monitoring the PDP through a Technical Note, which will be forwarded together with all documentation to the CTA.
Art. 78. Exceptionally, the PDP may be suspended by SECTICS/MS, without notification.

Art. 79. The suspension of PDP does not interrupt the counting of time and monitoring and evaluation activities and must occur as established in Chapter VI of this Ordinance.

Art. 80. The CTA must evaluate and recommend the restructuring or termination of the suspended partnership and will forward a technical opinion and the respective motivation for deliberation by the CD.

Art. 81. Partnerships in which there is a possibility of reversing the facts that led to the suspension may be restructured, in order to meet the requirements, criteria, guidelines and guidelines established in this Ordinance.

Art. 82. For PDPs whose restructuring proposal is approved, the period in which the PDP remains suspended may be increased to the end of Phase III, upon deliberation by the CD.

Single paragraph. SECTICS/MS must communicate to the Secretariats of the Ministry of Health, responsible for executing the instruments for purchasing the products covered by the PDP, and to the SE/MS about the removal of the suspension condition of the PDP.

Art. 83. Partnerships that are proven to be terminated must be terminated:

I - damage to the Public Administration or its use in disagreement with the objectives set out in this Ordinance.

II - impossibility of reversing the facts and problems identified during monitoring.

III - lack of interest in continuity on the part of IP, upon reasoned justification.

IV - in cases where the obsolescence of the Medical Device is proven.

V - other hypotheses of public interest.

§ 1º SECTICS/MS must communicate to the Secretariats of the Ministry of Health, responsible for executing the specific instruments for acquiring the products covered by the partnerships, to SE/MS and to ANVISA, about the extinction of the PDP.

§ 2 The extract of the extinction decision will be published in the DOU, by specific act of the Minister of State for Health.

Art. 84. The CD may recommend sanctions for partnerships that are in disagreement with this Ordinance, in accordance with the provisions of Chapter VIII.

CHAPTER VII
CHANGES

Art. 85. IP/ICT may present a proposal to change the PDP in Phase II and III to SECTICS/MS.

Art. 86. The proposed change must be sent to SECTICS/MS with a reasoned justification, for subsequent evaluation by the CTA and the CD regarding the change:

I - of private entities involved in the partnership, in common agreement, observing the provisions of Chapter III.

II - IP/ICT, as long as there is more than one IP/ICT partner in the PDP as established in the Commitment Term.

III - the technology of the product subject to the PDP.

IV - IFA or DTC/CTC production technology.

V - the degree of verticalization of the IFA or DTC/CTC.

VI - supply capacity.

VII - the sales price of the product subject to the PDP.

VIII - presentation, drug concentration and/or pharmaceutical form.

IX - schedule.

X - object, in a complementary or substitute manner, in cases where PDP partners introduce the product related to the PDP object with incremental innovation or replacement, and there is incorporation into the SUS, when appropriate; and

XI - the percentage of PDP demand.

§ 1 The change in the percentage of demand must include an analysis of the impact on other established PDPs, when applicable, as well as demonstrating the economic advantage of the proposal.

§ 2 In cases of an increase in the percentage foreseen for the acquisition period, the initially foreseen value must be renegotiated, considering the gain in scale.

§ 3 Changes involving regulatory and health aspects must be analyzed within the scope of the CTR, to support the evaluation of the CTA and the CD.

Art. 87. Changes to the PDP schedule in Phase II that impact the period of validity of Phase II may be analyzed by ETM.

Single paragraph. If necessary, changes to the Phase II schedule may be forwarded for evaluation by the CTA and deliberation by the CD.

Art. 88. Schedule changes that impact the deadline for Phase III of the PDP must be analyzed by the CTA and deliberation by the CD, and cannot exceed, in time, 25% of the initially approved period.

§ 1 In cases of change of object, the deadline proposed for Phase III may be restarted.

§ 2 In the PDP for Medical Devices, the Phase III term may be extended due to changes due to incremental innovation with a focus on therapeutic gain, limited to 10 (ten) years.

§ 3 In exceptional cases, the deadlines established in Article 9, § 1 of this ordinance may be extended according to the CTA's analysis and the CD's deliberation, aiming at the complete internalization of the technology.

Art. 89. The result of the change request must be officially forwarded by SECTICS/MS to the requesting IP/ICT(s).

CHAPTER VIII
SANCTIONS AND THEIR APPLICABILITY

Art. 90. The IP/ICT and the EP will be subject to administrative and judicial measures, in addition to sanctions provided for by law and in signed contracts.

§ 1 Failure to follow this Ordinance and the signed legal instrument, without prejudice to any sanctions that may be applied, will require the violating party to provide clarifications to the other parties.

§ 2 The IP/ICT and the EP will be responsible in relation to any applicable sanctions, with the parties being responsible for non-compliance with the obligations assumed, according to the EP.

§ 3º the provisions of the caput are subject to situations of unforeseeable circumstances, force majeure or other hypotheses duly substantiated by current legislation.

Art. 91. For total or partial non-execution of the Term of Commitment, the Ministry of Health may, subject to prior defense, apply the following sanctions:

I - warning.

II - fine; AND

III - temporary suspension of participation in new PDPs.

§ 1 The sanction provided for in item II of the **caput** of this article, calculated in the form of the acquisition contract, cannot be less than 0.5% (five tenths of a percent) nor more than 30% (thirty percent) of the value of the contract celebrated, in accordance with § 3 of art. 156, of Law No. 14,133, of April 1, 2021.

§ 2 The sanctions provided for in items I and III of the **caput** may be applied, separately or cumulatively, with those in item II.

Art. 92. It is up to the Ministry of Health to apply sanctions.

Single paragraph. Considering the CD's competencies, the committee may recommend sanctions for partnerships that do not comply with this Ordinance.

Art. 93. The adoption of the measures provided for in Chapter VIII does not exclude the application of other sanctions and penalties provided for in current legislation.

Art. 94. Sanctions may be appealed, in accordance with Law No. 9,784, of January 29, 1999.

CHAPTER IX
FINAL PROVISIONS

Art. 95 This Ordinance applies to PDPs in force in Phases II and III.

§ 1 The partnerships referred to in the **caput** must be adjusted, in accordance with the rules set out in this Ordinance, within 12 (twelve) months of its publication.

§ 2 The flowchart of the PDP establishment process must be made available on the Ministry of Health's website.

Art. 96 Other agreements and partnerships for technological development and technology transfer established by public institutions aiming at local production, which aim to supply products for the SUS, must be adapted, as applicable, to the PDP model, within a period of 12 (twelve) months of publication of this Ordinance.

Single paragraph. During the adaptation period provided for in the **caput**, acquisitions may be made, as long as there is a joint technical opinion from SECTICS/MS and the final area regarding the relevance of the product and advances in the technology transfer process. "(NR)0

Art. 2 The following are revoked:

I - (xxxxx)

II - (xxxxx)

Art. 3 This Ordinance comes into force on the date of its publication.