MINISTRY OF HEALTH

ORDINANCE No. 2.531, FROM NOVEMBER 12, 2014

(D.O.U OF 11/13/2014)

Redefines the guidelines and criteria for the definition of the list of strategic products for the Unified System of Health (SUS) and for the establishment of the Partnerships for Productive Development (PDP) and disciplines the respective procedures of submission, instruction, decision, transfer and absorption of technology, purchase of strategic products for the SUS by means of the PDP and the respective monitoring and evaluation.

The Minister of Health, exercising the powers conferred to him on items I and II of sole paragraph of article 87 of Brazilian Constitution, and

Considering the provisions of article 6 and 196 of the Brazilian Constitution, which established Health care as a right of everyone and duty of the State, guaranteed by means of social and economic policies that seek the reduction of diseases and other exposures and the universal and equal access to actions and services for its promotion, protection and recovery;

Considering the provisions of article 218 of the Brazilian Constitution, that established that the State shall promote and encourage scientific development, the research and technological training for the solution of Brazilian problems;

Considering the provisions of article 219 of the Brazilian Constitution, that established that the internal market integrates the national patrimony and it will be encouraged in order to enable the welfare of the population and the technological autonomy of the country;

Considering the Law No. 8.080, of November 19, 1990, that disposes about the conditions of promotion, protection and recovery of health, the organization and the functioning of the corresponding services and other providences;

Considering the Law No. 8.666, of June 21, 1993, that regulates the article 37, item XXI, of the Constitution, institutes rules for public bid and government contracts of Public Administration and other provisions;

Considering the Law No.9.784, of January 29, 1999, that regulates the administrative process in the scope of the Brazilian Federal Administration;

Considering the Law No. 10.973, of December 2nd, 2004, and respective amendments, that disposes about incentives to innovation and scientific and technological research in the productive environment and other provisions;

Considering the Law No. 12.349, of December 15, 2010, that amends the Laws No. 8.666, of June 21, 1993, No. 8.958 of December 20, 1994, and No. 10.973, of December 2, 2004; and revokes the paragraph 1st of the article 2nd of the Law No. 11.273, of February 6th, 2006;

Considering the Law No. 12.401, of April 28, 2011, that amends Law No. 8.080/1990, to dispose about the therapeutical assistance and incorporation of technology in health in the scope of the Unified System of Health (SUS), and that, in

its article 19-Q, defines that the incorporation, exclusion or amendment by SUS of its new medicines, products and procedures, as well as the constitution or alteration of clinical protocol or therapeutical guideline, are attributions of the Ministry of Health, assisted by the National Commission of Technological Incorporation in SUS;

Considering the Complementary Law No. 141, of January 13, of 2012, that regulates the paragraph 3rd of the article 198 of the Federal Constitution to dispose about the minimum values to be applied annually by the Federal Government, States, Federal District and the Cities in actions and public services of health; establishes the criteria of apportionment of resources of transferences for the health and norms of inspection, evaluation and control of the expenses with health in the 3 (three) spheres of the government;

Considering the Law No. 12.715, of September of 2012, that included the item XXXII and the paragraphs Paragraph 1st and 2nd in the article 24 of the Law No. 8.666/1993;

Considering the Decree from 12 of May of 2008, that creates, in the scope of the Ministry of Health, the Executive Group of the Industrial Complex of Health (GECIS);

Considering the Decree No. 7.508, from June 28, 2011, that regulates the Law No. 8.080/1990, to dispose about the organization of the SUS, the planning of Health, the National Relation of Essential Medication (RENAME), to which is disposed by the Ministry of Health and comprehends the selection and standardization of drugs indicated for the assistance and use against diseases or aggravate in the scope of the SUS;

Considering the Decree No. 7.540, of August 2, 2011, that establishes the “Plano Brazil Maior” (PBM) and creates its system of management;

Considering the Decree No. 7.646, of December 21, 2011, that disposes about the National Commission of Technological Incorporation in SUS and about the administrative procedure of incorporation, exclusion and alteration of technologies in health by SUS;

Considering the Decree No. 7.807, of September 17, 2012, that disposes about the definition of strategic products for the SUS, for means of the disposed in the item XXXII of the caput and Paragraph 2nd of the article 24 of the Law No. 8.666, of 1993;

Considering the Decree No. 8.269, June 25, 2014, that establishes the National Program of Platforms of Knowledge and its Administrative Committee;

Considering the Interministerial Ordinance No. 128/MPOG/MS/MCT/MDIC, of May 30, 2008, that stablishes guidelines for the public purchase of medications and drugs by the SUS;

Considering the Ordinance No. 3.031/GM/MS, of November 16, 2008, that disposes about the criteria to be considered by the Public Institutions Laboratories of production of medications in its bids for purchase of materials;

Considering the Ordinance No. 506/GM/MS, of May 21, 2012, that establishes the Program for Development of the Industrial Complex of Health (acronym PROCIS) and its Administrative Committee;

Considering the Rule of the ANVISA’s Board of Directors (acronym RDC) No. 2/Anvisa, of February 2, 2011, that

establishes about the procedures in the scope of the Brazilian Health Surveillance Agency (acronym ANVISA) for follow-up, instruction, analysis of the marketing authorization process and post-registration, in Brazil, of drugs produced under the Public-Public or Public-Private partnerships and technology transfer of interest to SUS;

Considering Rule No. 50/Anvisa of September 13, 2012, that establishes the procedures in Anvisa for the marketing authorization of products in process of development or transference of technology subject of the Partnerships of Productive Development public-public or public-private of interest of SUS;

Considering the Rule of the ANVISA's Board of Directors (acronym RDC) No. 31/Anvisa, of May 29, 2014, that regulates the simplified procedure of generic, similar, specific, dynamic, phytotherapy and biological medications' registration requirements, post-registration and registration renewal, and other providences;

Considering the RDC No. 43/Anvisa, of September 19, 2014, that regulates the untying of the registrations granted through the simplified process stablished by the RDC No. 31/2014, for medications derived from the process of Partnerships for Productive Development or transference of technology seeking the internalization of the production of medications considered strategic by the Ministry of Health and other providences;

Considering the Rule No. 001/GEPBM, of September 28, 2011, regarding the decision of the Executive Group of the Plano Brazil Maior about the creation of the Executive Committees, Council of Competition and Systemic Coordination;

Considering the Resolution No. 002/GEPBM, from 28th of September of 2011, referent to the deliberation of the Executive Group of the Larger Brazil Plan about the Internal Regiments of the Executive Committees, Council of Sectorial Competition and Systemic Coordination;

Considering that the Ministry of Health and he remaining sectors and public entities use mechanisms of transference of technologies for innovation, among them the ones established in the Law No. 10.973/2004 (Law of Innovation) and in its regulation conferred by the Decrees No. 5.563, of October 11, 2005, and No. 7.539, of August 2, 2011, with the goal to promote capacitation, reaching technological autonomy and the industrial development of the country together with the stimulation to the national production of strategic products for SUS; and

Considering that the National Plan of Health (2012 – 2015), in compliance with the Multi-annual Plan (PPA) instituted by the Law No. 12. 593, of January 18, 2012, and approved by the National Council of Health, established, as one of its 16 (sixteen) guidelines, the guideline of strengthening of the productive complex and of science, technology and innovation in health as structuring vector of the national agenda of economic, social and sustainable development, with reduction of vulnerability of access to health, states:

CHAPTER I
THE GENERAL PROVISIONS

Article 1. This Ordinance redefines the guidelines and the criteria for the definition of the list of strategic products for the Unified System of Health (SUS) and the establishment of the Partnerships of Productive Development (PDP) and establishes the respective procedures of submission, instruction, decision, transference and absorption of technology, acquisition of strategic products for the SUS in the scope of the PDP and the respective monitoring and evaluation.

Article 2. For the effects of this ordinance, the following definitions are adopted:

I - Partnerships of Productive Development (PDP): partnership that involve the cooperation by means of agreements between the public institutions and private entities for the development, transference and absorption of technology, production, productive and technological qualification of the Country in strategic products to attend to SUS's demands;

II – Strategic Products for SUS: necessary products for SUS for activities of promotion, prevention and recovery of the Health, with centralized acquisitions by the Ministry of Health or susceptible to centralization and whose national and active pharmaceutical ingredients or critical technological component's protection is relevant for the CEIS;

III – List of Strategic Products for SUS: list of strategic products for SUS that defines the annual priorities for the presentation of PDP project proposals;

IV – Economic-Industrial Complex of Health (acronym CEIS): productive system of health containing pharmaceutical industries with chemical and biotechnological base, devices for health , such as equipment and materials, and the health services;

V – Public institution: body and entity of the Public Administration, Direct or Indirect, of one of the three spheres of the Government, that act in research, development or production of drugs, serums, vaccines or health devices

VI – Private entity: legal entity of private law, non-integrant of the Direct or Indirect Public Administration, that is the holder, the developer, the licensee of the technology to be transferred or that is responsible for the manufacturing of a step of the productive chain in Brazil;

VII - Technological Core: group of technological knowledge that capacitates its holder to reproduce, develop, improve and transfer the technology of the products subjects of the PDP;

VIII – Innovation: introduction of novelty or refinement in the social or productive atmosphere that results in new products, process or services;

IX – Verticalization: group of productive steps, units and systems that determine the degree of internalization of the productive chain of the product object of the PDP in the Country; in Brazil and by the units and productive systems;

X – Active Pharmaceutical Ingredient (API): chemical or biological substance active, pharmaceutical, drug or raw material that has pharmaceutical properties with medicinal purpose of diagnostic, preventive or treatment use, employed to modify or explore physiological or pathological states, in benefit of the patient, which production is important for the domain of the technological center by the Country in the scope of the CEIS;

XI – Critical technological component: ingredient, product or process of the step of the productive chain of the industries of medical devices, such as equipment and materials, of preventive, therapeutical or diagnostic use, whose production is important for the domain of the technological center by the Country in the scope of the CEIS;

XII – Technological portability: technical and managing capacity of transference of determined technology by the private entity or that holds it to another public institution;

XIII – Basic Productive Process (acronym PPB): minimum joint of operations on the manufacturing facility that characterizes the effective industrialization of certain product;

XIV – Term of Commitment: document signed between the public institution, that is responsible for the investment, development, transference and absorption of the technology of strategic products for the SUS, and the Ministry of Health, that is responsible for the acquisition of the products subject to the PDPs; containing an attached declaration of agreement with the referred document subscribed by the private partners; and

XV – Internalization of the technology: finishing the process of development, transference and absorption of the technology subject of the PDP, by the public institution, turning it owner of every information that guarantees the technological dominium and enables technological portability for the attendance to the SUS's demands.

Article 3. The goals of the PDP are:

I - Increasing the access of the population to strategic products, combining the universal access and reduce the vulnerability of SUS;

II – Reduce the productive and technological dependences to attend the necessities of health for the Brazilian population in short, medium and long terms, following the constitutional principles of universal and equal access to the actions and the services of health;

III - Rationalize the Government's purchase power, under the selective centralization of the costs in the health sector, with view to the sustainability of the SUS and the increase of the production of strategic products in Brazil;

IV – Protect the interests of the Public Administration and the society when seeking the economy and advantage, considering prices, quality, technology and social benefits;

V – Encourage the technological development and the exchange of knowledge to the innovation in the scope of the public institutions and the private entities, contributing to the development of the CEIS and to turn them into competitive and capable;

VI - Promote the development and manufacturing in national territory of strategic products for the SUS; and

VII – Seek the technological and economical sustainability of the SUS in short, medium and long term, with the promotion of structural conditions to increase the productive capacity and the innovation in Brazil, contribute and to the reduction of the commercial deficit of the CEIS and grant access to health.

VIII – Stimulate the development of the network of public production in the Country and its strategic role for the SUS.

CHAPTER II
THE LIST OF STRATEGIC PRODUCTS FOR THE SUS

Article 4. The list of strategic products for the SUS is composed of products belonging to the following groups:

I – Group 1: Drugs;

II – Group 2: Medicines;

III – Group 3: Adjuvants;

IV – Group 4: Blood derivatives and blood components

V – Group 5: Vaccines

VI – Group 6: Serums

VII – Group 7: Biological or biotechnological products of human, animal or recombinant origin;

VIII – Group 8: health devices such as equipment and materials of use in health;

IX – Group 9: Products for diagnosis of use “in vitro”; and

X – Group 10: “software” assembled in the medical device or used in the transmission of health data, in the recovery, reconstruction and processing of signals and images or in the communication between these devices.

Sole Paragraph. There may be included in the list of strategic products for the SUS the products and goods that compose the strategic programs develop in the scope of the Ministry of Health, even if not foreseen in the groups that the ‘caput’ refers to.

Article 5. The Ministry of Health will define, annually, the list of strategic products for the SUS in conformity with the recommendations issued by the Executive Group of the Industrial Complex of Health (acronym GECIS).

Paragraph 1. The list mentioned in the ‘caput’ will be edited by an act of the Minister of Health and will observe the stated in articles 4th and 6th.

Paragraph 2. The Ministry of Health may perform specific consults to industries and entities, public and private, aside from specialists in the theme, and public consults before defining the list of strategic products for the SUS, without prejudice to the competence of the GECIS, according to Decree No. 7.807, September 17, 2012.

Article 6. The list of strategic products mentioned in the article 5 will be defined considering:

I – Necessarily the following criteria:
a) Importance of the product for the SUS, according to the policies and programs of promotion, prevention and recovery of health;
b) Centralized acquisition or susceptible centralization of the product by the Ministry of Health; and
c) Interest of national production of the product and its pharmaceutical active ingredients or critical technological components that are relevant for the CEIS; and

II – Additionally at least one of the following criteria:

a) High value of acquisition to the SUS;
b) Expressive dependence of importation of the product for the programs and activities of promotion, prevention and assistance to health in the scope of the SUS in the last three years;
c) Recent technological incorporation in the SUS; and
d) Neglected products or with potential or with risk of shortage.

Paragraph 1. Without prejudice to the revision established in the 'caput', at any time the Minister of Health can amend the list of strategic products, justifiably, after consultation to the GECIS.

Paragraph 2. The potential risk of shortage, referred to in sub item "d" of item II, will be configured when there is registry of shortage in the Country justified by the final sector of the Ministry of Health.

Paragraph 3. The strategic product for the SUS that is object of process of transference of technology in the scope of the PDP in action will be in the Ministry of Health's website and will only be contemplated in the annual definition of the list of strategic products for the SUS if the execution of a new PDP regarding the same product is possible, considering the PDP project proposals previously approved.

Article 7. The strategic products for the SUS can be subject of measures and initiatives aimed at the research, development, transference of technology, innovation and national production, with the purpose of contributing to the strengthening of the CEIS and for the extension of its access by the population.

Article 8. The list of strategic products for the SUS is available in the Ministry of Health's website www.saude.gov.br.

CHAPTER THREE
THE PARTS OF THE JOINT PDPS

Article 9. The parts of the joint PDP can be:

I – Public Institution, individually or together with other public institutions, as to enable security, technological portability, agility and dynamicity to the process of research, development and innovation; and

II – Private entity, individually or together with other private entities, with a view to enable security, technological portability, agility and dynamicity to the process of transference of technology.

CHAPTER IV
THE PROCESS

Article 10. The process for the establishment of the PDP has the following phases:

I - PDP project proposal: phase of submission and analysis of the viability of the proposal and, in case of approval, sign of the terms of commitment between the Ministry of Health and the public institution;

II - PDP Project: beginning of the phase of implementation of the approved PDP project proposal and the terms of commitment;

III – PDP: beginning of the phase of execution of the development of the product, transference and absorption of technology in effective way and signing of the contract of purchase of the strategic product between the Ministry of Health and the public institution; and

IV – Internalization of technology: conclusion phase of the development, transference and absorption of the technology object in the PDP in conditions of production of the product object of the PDP in the Country and technological portability by the public institution.

Sole Paragraph. The flowchart of the administrative process of establishment of the PDP is available at the Ministry of Health's website www.saude.org.br.

Section I
The PDP project proposal

Article 11. The PDP project proposal will be created considering the updated list of strategic products of the SUS.

Sole Paragraph. The PDP project proposal will follow the form of the executive project available at the Ministry of Health's website www.saude.gov.br.

Article 12. The PDP project proposal will be submitted by paper by the public institution to the Ministry of Health, specifically the Secretary of Science, Technology and Strategic Ingredients (acronym SCTIE/MS).

Article 13. The PDP project proposal must be formalized by the public institution before the SCTIE/MS between 1st and 30th of April.

Paragraph 1. Clarifications in relation to the elaboration of the proposal of the PDP project can occur by means of technical meetings, email or paper between the public and private entity and the Ministry of Health at any time, except during the period of analysis of the proposals and the administrative appeals.

Paragraph 2. The results of the evaluations of the proposals of will be disclosed in the meetings of the GECIS held after the term mentioned by the 'caput'.

Paragraph 3. The annual calendar of meetings defined by the GECIS will be disclosed annually together with the disclosure of the list of strategic products for the SUS and the agenda of the GECIS's meetings must be divulgated with a minimum of 7 days before the execution of the meeting.

Paragraph 4. In case of proposal of PDP projects presented in the same period related to the same strategic product for the SUS, the evaluation will be made in a joint way and the respective results disclosed simultaneously.

Paragraph 5. The opening of a new period for the presentation of PDP project proposals is possible, by means of divulgation on the Ministry of Health's website, in the exceptional case of a relevant interest of public health and in a way justified by the Minister of Health of the State.

Subsection I
The Guidelines and the Requirements for the Elaboration of the PDP projects proposals

Article 14. The development of a proposal for a PDP project must observe the following guidelines:

I – as to the parts of a PDP, it will be indicated in a detail:
a) The public institutions responsible for the absorption of technology and manufacturing of the product at the end of the phase of internalization of technology of the PDP;
b) The private entity holder or developer of the technology of the product, that will be responsible for the transference of the technology to the public institution; and
c) The public institution or private entity that will be the national developer and local manufacturer of the active pharmaceutical ingredient (IFA) or critical technological component
d) The reasons for the selection of the private entities participants of PDP by the public institutions;

II - As to the subject, it will be informed:
a) The products contained in the list of strategic products for the SUS that will be the target of the development transference and absorption of technology of the product object of the PDP;
b) The specifications of the products that will be targeted at the development, transference and absorption of technology of the product object of the PDP, according to the defined in the act of the Ministry of Health; and
c) The terms of commitment of the PDP and the schedule of its implementation, in compliance with the provisions of this Ordinance;

III - As to the intellectual property:
a) The research, development and the manufacturing of the products to be purchased in the scope of the PDP will follow integrally the current legislation; and
b) the number of the patents granted or applications in the country, related to the manufacture and transference of technology of the product object of the PDP, must be informed, indicating the respective owners and term of efficacy;

IV - As to the schedule of the executive Project:
a) The term of duration of the PDP will be proposed in accordance with the technological complexity to the internalization of the technology in the country, respecting the maximum limit of 10 (ten) years;
b) The activities prior to obtaining marketing authorization of the product in the National Health Surveillance Agency (acronym Anvisa), related to the implementation of the PDP project, will consist in the schedule, with details of the terms foreseen for the conclusion and the responsible for the execution of each item of the schedule; and
c) the schedule presented for the phases of establishment the PDP Project must be detailed containing physical and financial schedule compatible with the evolution of the activities and the necessity for resources, minimally attending to the items pointed in the model of executive project; and
d) The identification of each step of the process of establishment of the PDP and the respective activities;

V - As to the documentation for the marketing authorization and certification:
a) The registries of the product subject to the PDP by the public institution and private entity in Anvisa and the post-authorization amendments shall be included in the schedule of the PDP for development, transference and absorption of technology, with indication of the Rule of Anvisa to be followed depending on the product; and
b) The schedule of obtaining the marketing authorization or renewal of the licenses and certificates, when applicable,

including the Good Manufacturing Practice Certificate (CBPF), before Anvisa will be presented in the executive project for each participant subject public and private;

VI - As to the degree of productive integration:
a) Schedule of internalization of the technology by the public institution;
b) In case of use, in the beginning of the project, of IFA or international critical technological compound, must be appointed the fabricants and the fabrication locations;
c) Demonstration that the private entity will practice a degree productive integration in national land pertinent to the incorporation of the national production of the product subject to the PDP, being:
1. for products of chemical synthesis and mix synthesis, the Project must contemplate the national verticalization of the significant productive phases for the national pharmo-chemical productive complex and guarantee of access to the public institution to the technical knowledge, including the Master File of the Drugs (AMD); and
2. for biological products, the obligation of guarantee of transference of technology to the Master Cell Bank besides the technological knowledge required for the production of the product in the country; and
3. for medical devices, the project must contemplate the production of critical technological component, applying, when possible, the rules of origin or the PPB, respecting, when in the case, the difficulty of the production in the Country of components of non-specific use in the area of health, with highlight to the microelectronic components;

VII - As to the Process of production:
a) The project must provide the development of the CEIS and present the conditions to turn the public institution able to produce the product subject to the PDP;
b) It must be presented the flow of production accurately planned, involving, in what refers to the infrastructure:
1. The physical structure necessary, with indication if the productive plants of the partners involved have projects of investments;
2. The appropriate conditions for the execution of the project, encompassing the installations, procedures, process and organizational resources; and
3. When adaptations in the infrastructure are necessary, it will be specified by the public institution, in the executive project, the necessary resources, the budgeted values and the prevision of conclusion of the critical investments for all of the partners to enable the PDP;
c) the necessary equipment for the production process and the quality control of the product and the ingredient will be described in the executive project of the PDP, informing the nominal capacity, if the partners already have the equipment referred to or prevision of its acquisition and prevision of costs with the respective detailing of the source of resources; and
d) The human resources necessary for the execution of the process of management, development and technological absorption and guarantee of quality of the project will be related, indicating if the number, the formation and the necessary qualification;

VIII - as per the proposal for the selling price and the estimative of supply capacity:
a) The annual unitary values proposed and the annual capacity of supply of the product for the period of the project will be presented in nominal terms;
b) The prices proposed will be consistent with the ones practiced by the Unified Health System (SUS) and, when necessary, with the prices of the international market of the Countries contemplated by the Medication Market Regulation Panel (acronym CMED), considering the principles of economy and advantage;
c) the prices will be presented in a descending scale, based on real data, that will be considered according to the variation of the National Wide Consumer Price Index (acronym IPCA) or the sectorial price indexes and, when

appropriate, the tax of exchange variation, respecting CMED's regulation;
d) For the proposal of prices and estimative of capacity of supply, it will be used as source:
1. The medium prices practiced by the Public Administration and registered in the official data base, which are the Bank of Price in Health (acronym BPS) and the Integrated System of Administration of General Services (acronym SIASG);
2. The price of the last purchase of the product by the Ministry of Health, according to the extracts published in the Federal Register (acronym DOU), in case the product is of centralized acquisition;
3. The transferring value stablished in specific ordinance of the Ministry of Health or the unitary values stablished in the Chart of Procedures, Medications, Orthesis, Prothesis and Special Materials of the SUS, using, as reference, the period of 1 (one) year prior to the presentation of the proposal of the project of PDP in case of products of non-centralized acquisition;
4. The minutes of registration of prices in the Government Purchasing website and the other national systems of information of the SUS, for the remaining products of non-centralized acquisitions;
5. The medium prices in the market and registered in the national and international official data bases and used by the Public Administration, such as the Medication Market Monitoring System (SAMMED) of the CMED, the System of Support of Elaboration of Projects of Health Investments (SOMASUS), the Rotatory Fund of the Pan-American Organization of Health (OPAS) and the Global Fund of Combat of HIV, Tuberculosis and Malaria.
6. The prices defined by CMED, according to the current legislation, and
7. The medium prices in the international market of countries contemplated by CMED for the definition of entrance prices of new products when it comes to innovator products; and
e) For products with a patent expiration term to take place during the phases of the executive project, it will be presented a research with the projections of the reduction of prices consistent with the new level of the market;

IX – as for the foreign exchange balance, it will be evaluated by the public institution the impact of the importation of the finished product, pharmaceutical active ingredient, critical and intermediary technological components, presenting the foreign exchange balance and the foreign exchange annual economy estimated during the phases of the establishment of the PDP, informing the calculation method used;

X – As for the analysis of risk of the PDP project, the public institution will present in accordance with the form of the executive project available at the Ministry of Health's website www.saude,gov.br; and

XI – As for the investments necessary for the materialization of the project, these will be feasible to the capacity and financing source informed.

Paragraph 1. Regarding the participants of the PDP mentioned in the item I of the 'caput', copies of the following documents shall be presented when applicable:

I - Corporate Taxpayer Identification Number (CNPJ);

II – Address of the productive plant;

III – Inspection Certificate;

IV – Authorization of operation and/or special authorization of operation;

V – GMP or the report of sanitary inspections with the proof of the fabrication conditions;

VI – Term of approval of the construction project, amplification and/or reform of the physical structure issued by the local sanitary vigilance.

VII – Sanitary registration of the product object of the PDP granted by Anvisa in the name of the subject participants of the PDP.

Paragraph 2. If applicable, but not possible, the presentation of the documents listed on the terms of paragraph 1st together with the PDP project proposal, must be presented with the schedule for its accomplishment together with the competent entities and organs and founded justifications, according to the process of investment, development, absorption and transference of technology, in order to analyze the instances of evaluation of the proposal.

Paragraph 3. The parts of the PDP mentioned in item I of the 'caput' will sign a joint declaration, agreeing with all of the terms of the PDP project proposal, also agreeing with the information contained in the executive project, which will also contain the list of documents that compose the mentioned proposal.

Paragraph 4. The conditions of additional uses of the Master Cells Bank referring to the product object of the PDP might be defined through an agreement between the subjects participants of the PDP.

Subsection II
The instances of evaluation of the PDP project proposal

Article 15. The analysis and evaluation of the proposal of the PDP project will be made by the Technical Evaluation Commissions and the Deliberative Committee.

Article 16. The Technical Evaluation Commission will:

I - issue a report about the PDP project proposal;

II - suggest terms, criteria and specific conditions to the execution of the PDP project;

III - evaluate the degree of productive integration within Brazilian territory proposed by the national production of the product;

IV – evaluate the economy and advantage of the PDP Project

V – Verify if the terms of development and technological absorption, including the regulatory steps, are compatible with the schedule proposed; and

VI – evaluate the possibility and viability of execution of more than one PDP related to the same product, in order to stimulate the competition and reduce the vulnerability of SUS, indicating, when applicable, the feasibility of more than one project per product, due to sanitary matters, technical scale, economical or the required investments; and

VII – other competences that have been attributed in the terms of this Ordinance.

Article 17. The Technical Evaluation Commission will be composed by the following members:

I – Ministry of Health;
a) 1 (one) from the Secretary of Science, Technology and Strategic Input (acronym SCTIE/MS); and
b) 1 (one) from each Secretary whose competence is related to the subject of the PDP project proposal;

II – 1 (one) from the Ministry of Industrial Development and External Trade (acronym MDCI);

III – 1 (one) from the Ministry of Science, Technology and Innovation (acronym MCTI);

IV – 1 (one) from the National Bank of Economic and Social Development (acronym BNDES);

V – 1 (one) from FINEP – Innovation and Research; and

VI – 1 (one) from the ANVISA.

Paragraph 1. Each member will have a replacement that will substitute him in its eventual or permanent absence.

Paragraph 2. The Coordination of each Technical Commission will be made by the representatives of the SCTIE/MS.

Paragraph 3. The members will be indicated by the top directors of its respective organs and entities to the Ministry of Health.

Paragraph 4. The participation of the organs and entities listed in the items II to VI of the main clause will be formalized after answer to the invitation directed to them by the State Minister of Health.

Paragraph 5. Act of the Secretary of Science, Technology and Strategic Ingredients will constitute the Technical Evaluation Commission, with the definition of its subject and term for its duration.

Paragraph 6. Each Technical Evaluation Commission shall evaluate one or more proposals of PDP projects, depending on the object defined in the terms of the act mentioned in the previous paragraph.

Paragraph 7. The Coordination of the Commission can invite representatives of other entities and organs, public or private, as well as specialists in matters related to the theme, whose presence is considered necessary for the fulfillment of the disposed in this Ordinance.

Paragraph 8. The representatives and specialists mentioned in the previous paragraph will sign the term of confidentiality and declaration of conflict of interest to participate in the activities to which they have been invited by the Coordination of the Commission.

Article 18. Deliberative Committee will:

I - analyze and validate the reports of the Technical Evaluation Commissions;

II – approve or reprove the proposals of PDP project, by means of a conclusive opinion;

III - define the terms, criteria and specific conditions to the execution of the proposals of PDP projects and the PDPs;

IV – analyze and validate the degree of productive integration in the Brazilian territory of the product object of PDP, for the application of the rules herein foreseen;

V – Analyze and validate the terms of development and technological absorption, including the regulatory steps, compatible with the schedule proposed;

VI – establish the conditions of economy of the PDP and advantage of the PDP;

VII – indicate, with reasons, the necessity of submission of the proposals of PDP project to the new evaluation by the Technical Evaluation Commission "ad hoc", whose members are designated by the act of the Secretary of Science, Technology and Strategic Input, with the definition of its object and term of duration; and

VIII – other competences that have been attributed in the terms of this Ordinance.

Sole Paragraph. The members of this Technical Evaluation Commissions "ad hoc" mentioned in item VII will sign the term of confidentiality and declaration of inexistence of conflict of interest with a view to the analysis of the PDP project proposals.

Article 19. The Deliberative Committee will be composed by members of the following:

I – 1 (one) from the Ministry of Health;

II – 1 (one) from the Ministry of Industrial Development and External Trade (MDIC); and

III – 1 (one) from the Ministry of Science, Technology and Innovation (MCTI).

Paragraph 1. Each member will have a substitute that will replace him in its eventual or permanent absence.

Paragraph 2. The Coordination of the Deliberative Committee will be made by the Ministry of Health.

Paragraph 3. The members will be indicated by the top directors of its respective entities to the Ministry of Health and they shall be different from the one who integrate the Technical Evaluation Commission.

Paragraph 4. The participation of the entities listed in the items II to VI of the 'caput' will be formalized after answer to the invitation directed to them by the Minister of Health.

Paragraph 5. An act of the Minister of Health will constitute the Deliberative Committee.

Paragraph 6. The Coordination of the Committee can invite representatives of other entities, public or private, as well as specialists in matters related to the theme, whose presence is considered necessary for the fulfillment of the disposed in this Ordinance.

Paragraph 7. The representatives and specialists mentioned in the previous paragraph will sign the term of

confidentiality and declaration of inexistence of conflict of interest to participate in the activities to which they have been invited to by the Coordination of the Committee.

Article 20. The functions of the members of the Technical Evaluation Commission, the Technical Evaluation Commission "ad hoc" and the Deliberative Committee will not be paid and its exercise will be considered relevant public service.

Article 21. The Deliberative Committee will elaborate its internal regiment and also the internal regiment of the Technical Evaluations Commission, to be approved by act of the Minister of Health.

Sole Paragraph. The Technical Evaluation Commission "ad hoc" will have its activities established by the internal regiment of the Technical Evaluation Commission.

Subsection III
The Criteria of Analysis of the PDP proposal project

Article 22. The following Criteria will be considered in the analysis of the merit of the PDP project proposal:

I - Compliance with the guidelines and the requirements foreseen in article 14;

II – Goals of the proposal consonant to the public policy developed in the SUS, for the promotion, prevention and attendance to the health.

III – importance of the PDP for the reduction of the economic and technological vulnerability of the SUS, as well as contribution to the scientific, technologic and socioeconomic development of the Country.

IV – Lack or insufficiency of the national production or risk of shortage of supply of the finished product and/or the API or critical technological component, contributing to the productive integration in the scope of the CEIS and for the reduction of the trade deficit in health;

V - Clarity of the general goal to be reached, the specific objectives and the phases or products that, in the whole, define what is sought with the PDP;

VI - Adequacy of the schedule to the complexity of the technology involved and to the regulatory and sanitary requirements;

VII - rationality of the investments foreseen, with indication of the source, physical and financial schedule compatible with the evolution of the activities and with the necessity of resources;

VIII - Compliance to current intellectual property legislation;

IX - Degree of productive integration compatible with the product object of the PDP and to the development of the national productive plants;

X – Potential of the public institution in relation to the human resources necessary to the execution of the project,

productive area installed or project of adequacy of the area approved by the instance of the financing, compatibility of the nature of the project with the activities executed by the public institution and the capacity of the institution to absorb the technology of the partner;

XI - Correct delimitation of the abilities and competences of the private entities and the public institutions, productive lines necessary and existent in each industrial plant, analysis of risk and term of effectiveness presented;

XII - Compatibility of execution and obtaining of the previsions of registration and certification before the bodies and competent entities;

XIII - Projection of foreign exchange balance and of annual economy generated for SUS in the acquisitions of the product with a view to the last acquisition by the system;

XIV - Presence in the planning project of capacitation for innovation, trainings of the public institution by the partners for the absorption and transferring of the technology, development of the platforms of knowledge and productive in the Country and contribution to the local and regional development; and

XV - Integral acceptance of the monitoring and evaluation procedure and methodologies of defined in this Ordinance.

Sole Paragraph. It will be prioritized the distinct PDP projects proposals, by the same partners, that involve products of high value and products for diseases and neglected populations of interest of the Ministry of Health.

Article 23. The following tiebreaker criteria will be used when the number of proposals of PDP projects approved as per the merits, on the terms of article 22, for the same product is superior to the number of proposals supcetible to approval, according to sanitary matters, and the technical and economical viability:

I – Adequacy of the products and procedures to the requirements of the programs and actions of the Ministry of Health, in order to attend to the necessities of the SUS and the population;

II – Public institution with manufacturing line adequate to the product subject of the PDP;

III – Investments applied by the private partner for the execution of the PDP Project;

IV – Smaller term for the internalization of the technology;

V – Proposal of price that have higher potential of economy for the Ministry of Health;

VI – License of operation and Special License of Operation, when applicable, active for the private partner producer of the finished product;

VII – License of operation and Special License of Operation, when applicable, active for the private partner producer of the active pharmaceutical ingredient (IFA) or critical technological component;

VIII – Technic-operational condition or GMP valid for the manufacturing line of the product subject of the PDP project proposal for the public institution or sanitary inspections report with the proof of fabrication conditions;

IX - for the line of production of the product subject of the PDP project proposal for the private partner producer of the finished product or sanitary inspections report with the proof of fabrication conditions;

X - Technic-operational condition or GMP valid for the line of production of the product subject of the proposal of PDP for the private partner producer of the active pharmaceutical ingredient or critical technological component or sanitary inspections report with the proof of fabrication conditions;

XI – Additional presentation of innovation related to the product subject to PDP; additional presentation of innovation related to the product subject to the PDP

XII – Relative contribution of the technology for the development of the CEIS;

XIII – private entities with production line in the Country adequate to the product subject to the PDP;

XIV – technological development of the product subject to the PDP in the Country; and

XV – Contribution for the competition and technological balance of the Market.

Article 24. It will be considered in the analysis of the division of responsibilities of the public institutions, in cases of approval of more than one PDP Project proposals for a same product, the following criteria:

I – stimulation to the competition in the Market;

II – installed capacity for offer of the product;

III – programmed capacity according to the Project of construction, extension and/or reformation of the physical structure for the offer of the product in attendance to the schedule of the proposal;

IV – demand of the SUS; and

V – economic-financial balance of the product.

Subsection IV
The Instruction of the Administrative Procedure of PDP Project Proposal

Article 25. The SCTIE/MS will instruct the administrative procedure of the PDP project proposal.

Article 26. The proposals of PDP filed in the SCTIE/MS will be docketed, and sent to the Department of Industrial Complex and Health Innovation (DECIIS/SCTIE/MS) by means of order of the Secretary of Science, Technology and Strategic Ingredient.

Sole Paragraph. Before the sent of the dockets to the DECIIS/SCTIE/MS, the Secretary of Science, Technology and Strategic Ingredient will classify the information in the proposal of PDP project in a level of confidentiality in the terms of the Ordinance No. 1.583/GM/MS, of July 19, 2012.

Article 27. The DECIIS/SCTIE/MS will send the dockets to the General-Coordination of the Chemistry and Biotechnology (CGBQB/DECIIS/SCTIE/MS) or to the General-Coordination of medical devices (CGEMS/DECIIS/SCTIE/MS), depending on the area of the product, in view of the analysis of the proposal.

Article 28. The General-Coordination mentioned in article 27, will be responsible for the analysis of the proposal, will make a technical note in order to verify if the proposal of the new PDP project complies with every requirement and guidelines in the model of the executive project that is established in the sole paragraph of article 11.

Article 29. The proposal of PDP project will be forwarded by the General-Coordination responsible to the DECIIS/SCTIE/MS and, following it will be forwarded to the Office of the Secretary of Science, Technology and Strategic Ingredient, including the technical note that is referred to in the article 28 for means of evaluation and adoption of the necessary measures for the implementation of the competences of the Ministry of Health regulated on articles 17 and 19.

Article 30. After being established the Technical Evaluation Commission, the SCTIE/MS will send to it the PDP project proposal and the technical note that is referred to in the article 28 in order to attend the provisions of article 16.

Article 31. After the progress in the Technical Evaluation Commission, the proposal of the PDP project, including the respective documents produced in the scope of the SCTIE/MS and the Commission itself, will be sent for appreciation, discussion and decision by the Deliberative Committee in order to attend the provisions of article 18.

Subsection V
The Process of Evaluation and Decision of the PDP Project Proposal

Article 32. The Public institution will be summoned by the SCTIE/MS for oral presentation of the proposal of the PDP project before the Technical Evaluation Commission and, when applicable, before the Deliberative Committee.

Sole Paragraph. Only the public institution will take part in the oral presentation of the proposal, having to respond to the questions of the Technical Evaluation Commissions and the Deliberative Committee about the PDP project proposal.

Article 33. The Technical Evaluation Commission will analyze the PDP project proposal and will demand from the public institution adjustments in its content for compatibility with the provisions of article 14.

Paragraph 1. The PDP Project proposal readjusted by the public institution on the terms of the “main clause” shall be forwarded to the SCTIE/MS on a maximum term of 15 (fifteen) days after receiving the formal communication mentioned in the “main clause”.

Paragraph 2. The PDP Project proposal will be analyzed by the Technical Evaluation Commission, which will issue a report with the final opinion to be forwarded, passing by the SCTIE/MS, to the Deliberative Committee.

Article 34. After receiving the documents mentioned in article 33, the Deliberative Committee will adopt the measures provisioned in article 18.

Article 35. The PDP project proposals approved will be formalized by means of the terms of commitment subscribed by the public institution and by the Ministry of Health, by means of the SCTIE/MS, and declaration of agreement by

the private partners attached to the term of commitment.

Sole Paragraph. The terms of commitment will be subscribed and announced in meetings of the GECIS until the end of the year in which they were presented and the respective PDP project proposals.

Article 36. The abstract of the term of commitment of the PDP project proposal approved will be published in the Federal Register (acronym DOU).

Article 37. After the signature of the terms of commitment, the DECIIS/SCTIE/MS will send a copy of the act to the public institution and to Anvisa, including a copy of the technical notes produced by the SCTIE/MS, the Technical Commission of Evaluation and the Deliberative Committee.

Article 38. The PDP project proposals that are not approved by the Deliberative Committee will be communicated by the Ministry of Health, by means of the SCTIE/MS to the public institution, with the respective motivation.

Article 39. It is allowed for the public institution to have the right to file an administrative appeal against the decision of rejection of the proposal of PDP, based on the reasons of legality and merit, in sole and last instance, directed to the Ministry of Health.

Paragraph 1. The term for the filing of an administrative appeal is of ten days, without suspensory effects, counted from the divulgation of the decision in the Ministry of Health's website, available at www.saude.gov.br.

Paragraph 2. The administrative appeal will be sent to the office of the Minister (GM/MS), for the SCTIE/MS for the elaboration of a technical brief that will, after, send it to the Attorneys Office (acronym CONJUR/MS) for the elaboration of a legal brief in order to support the decision by the State Ministry of Health.

Paragraph 3. In case of the granting of the administrative appeal, the proposal of PDP will be sent to the SCTIE/MS for the reevaluation by a new Technical Evaluation Commission and by the Deliberative Committee, observing the same procedural flow provisioned in this Ordinance.

Article 40. The lists containing the PDPs project proposal not approved will be published, together with the respective motivation, at the Ministry of Health's website in www.saude.gov.br.

Article 41. Article 40. The approval of the PDP project proposals does not bind the Ministry of Health to the financing of investments and costs of the expenses of the public institution.

Article 42. The internal regiment of the Technical Evaluation Commissions and the Deliberative Committee will define in complementary character the procedures, terms, documentation, the methodology to be used in the ponderation of the criteria of analysis and competences for the process of evaluation and decision of the PDP project proposals.

Section II
The PDP Project

Article 43. After the signature of the term of commitment, begins the PDP project phase.

Article 44. In the phase related to the PDP project, the compliances with the commitments, responsibility and conditions of the project will be under the responsibility of the public institution and the private entity.

Article 45. Until the beginning of the PDP phase, the public institution and the private entity will formalize the agreement or the contract of development, transference and absorption of the technology of the product subject to the PDP, complying with the criteria, guidelines and orientation of this Ordinance, without interference of the Ministry of Health.

Sole Paragraph. The existence of the agreement or the contract of development, transference and absorption of technology of the product subject to the PDP and its submission to the Ministry of Health by the public institution is required for the formalization of the first supply of the product subject to the PDP.

Article 46. Any needs for amendments in the schedule of the project must be officially requested by the public institution, with substantive motivation, to the SCTIE/MS for its appreciation and, when it refers to the sanitary regulating aspects, to Anvisa's Technical Regulatory Committee (acronym CTR).

Sole Paragraph. The SCTIE/MS and, when relevant, Anvisa's CTR will decide about the request, "ad referendum" of the Deliberative Committee.

Article 47. The public institution may present proposal of amendments of their partners involved or the technologies in the PDP project will be officially presented by the public institution, with the respective substantive motivation, to the SCTIE/MS for its appreciation, by the Technical Evaluation Commission and by the Deliberative Committee.

Sole Paragraph. The decision of the request will be made by the Deliberative Committee, which will decide if the new PDP project proposal will be forwarded or not for the evaluation pf the Technical Evaluation Committee and for the mentioned Committee.

Article 48. The public institution may present the proposal of amendments of the Technologies of the PDP project, with the respective substantive motivation to the SCTIE/MS, for its appreciation by the Technical Evaluation Committee and by the Deliberative Committee.

Sole Paragraph. The Deliberative Committee is authorized to, in a proper act, define the hypothesis in which the proposal of amendment of the Technologies of the PDP Project proposals can be evaluated only by the SCTIE/MS or by the SCTIE/MS and the Technical Evaluation Committee.

Article 49. The requests for amendments of the schedule, partners or technology will be officially answered by the SCTIE/MS to the claimer.

Article 50. The providing of information about the execution of the PDP project to the Ministry of Health will be performed by the public institution.

Sole Paragraph. The public institution will send, by ordinary means, a report of follow-up every four months to the Ministry of Health, that will be available for evaluation by the Technical Evaluation Commission and by the Deliberative Committee, observed in the Law No. 12.527, November 18, 2011, Decree No. 7.724, of May 16, 2012 and the Ordinance No. 1.583/GM/MS, July 19, 2012.

Section III
PDP

Article 51. The PDP begins with the demonstration by the public institution to the Ministry of Health regarding the start of the development, transfer and absorption technology, development, industrial and technological capability, together with the first supply of the product subject of the PDP to the Ministry of Health by the public institution.

Paragraph 1. The year 1 (one) of the PDP will start from the specific publication for the first supply of the product under PDP by public institution to the Ministry of Health in the Official Gazette.

Paragraph 2. A public institution will forward, ordinarily, a quarterly progress report to the Ministry of Health.

Article 52. The purchase of the product subject of the PDP by the Ministry of Health will be resumed only after the compliance all the steps described in Sections I and II of this Chapter and with the demonstration by the public institution of the beginning of the development, transference and absorption of technology, industrial and technological capability.

Paragraph 1. For PDP projects related to the same product, the PDP that first attends to the provisions of the "main clause" and has the capacity of supply may be responsible for the supply of the total demand of the Ministry of Health until the other PDPs attend the provisions of the "main clause" and the division of the responsibilities approved in each PDP project is started.

Paragraph 2. The product subject to the PDP will attend to the presentations, specifications, forms and quantities demanded by the Ministry of Health, respecting the sanitary regulation.

Paragraph 3. The definition of the centralization of the acquisition of the product must happen through a prior agreement in the Tripartite Interjectors Commission (CIT).

Article 53. For the first acquisition, the marketing authorization of the product subject of the PDP can be from the public institution or the private entity, since it is in the process of development, technology transfer and absorption, in terms of subsection XXXII of Article 24 of Law No. 8666 of June 21, 1993.

Paragraph 1. In case the product's marketing authorization is from the private entity and it is in the process of technology transfer, the public institution should have all the technical information and copy the entire data package of the said marketing authorization approved by ANVISA, as well as the documentation required for possible update.

Paragraph 2. From the first purchase of the product subject of the PDP, the public institution will have a term of 60 (sixty) days to submit the marketing authorization request to ANVISA, in your name, of the product subject of PDP, on the terms of the RDC No. 43/Anvisa, of May 29, 2014 and RDC No. 43/Anvisa, of September 19, 2014, when applicable, and Anvisa's remaining regulations.

Paragraph 3. The public institution will have a term of 30 (thirty) days from the expiration of the term mentioned in the preceding paragraph, to forward to the Ministry of Health a copy of this documentation submitted to ANVISA.

Article 54. After one year from the original purchase of the product under the PDP, the Ministry of Health will make

new purchases only upon evidence by the public institution regarding that it is holding a marketing authorization of the product and regarding the evolution of the steps of development, transfer and absorption of technology, according to the scheduled approved in the executive project and eventual alterations.

Article 55. The purchase of the product subject of PDP will take place between the Ministry of Health and the public institution, by means of specific agreement, and will be made after observing and reviewing the following items:

I - regarding the service capacity:
a) it will be verified the technical conditions of the public institution, together with the private entity, to deliver the product in the quantitative, terms and conditions recommended by the specific areas of the Ministry of Health; and
b) It will be verified the capacity of the public institution to provide the product in the pharmaceutical presentation and forms and technical specifications requested by the Ministry of Health;

II – It will be considered the demand of the Ministry of Health at the time of purchase of the product subject of the PDP; and

III – regarding the prices, economy, and advantage:
a) the prices established for the purchase of the product subject of PDP will consider the technological input associated with the internalization of the production and will decrease in real terms, and may vary regarding the periods and the relevant legislation in order to take into account the flow in the average prices of domestic and international market, the price change measured by the IPCA or official sector index, the variation of the exchange rate when it involves importation in the transfer period, considering economies and health care systems similar to those of Brazil and, where applicable, the standards and criteria adopted by CMED;
b) it will be considered in the price evaluation, when appropriate, estimates of market values for products that are near to the expiration of the patent term and the relevant reduction in market prices due competition strategies of companies; and
c) The economic and advantage viability of the process must be analyzed with reference of the guidelines established in section VIII of Article 14.

Paragraph 1. The analysis of the prices referred to in the PDP Project Proposal will only serve as referential for the definition of prices of purchase by the Ministry of Health.

Paragraph 2. The Secretary of the Ministry of Health responsible for the execution of the specific agreement related to the purchase of the product subject of the PDP of the public institution will, together with the Executive Secretary (SE/MS), perform the analysis of prices to be charged with the technical support of SCTIE/MS, in a separate administrative procedure.

Article 56. The administrative process for the purchasing of the product subject of the PDP will comply with the current legislation and will contain all required documentation to prove the existence and regularity of the PDP, including the abstract of the terms of commitment published in the Federal Register and the documents referred to in this Section.

Sole paragraph. The purchase of the product subject to the PDP will be implemented through a multi-year contract compatible with the schedule of the PDP, respecting the Law in force.

Article 57. When verified the public institution's ability to supply the product subject of the PDP and for the purpose of its purchase, SCTIE/MS will forward the following documents to the Secretary of the Ministry of Health responsible for the purchase:

I - a copy of the Federal Register containing the publication page of ANVISA Resolution concerning the marketing authorization of the product subject of the PDP;

II - copy the GMP of the manufacturing place contained in the marketing authorization;

III - copy of the abstract of the terms of commitment; and

IV - technical note prepared by SCTIE/MS containing at least the following items:
a) Public institution and private entity involved in the PDP;
b) Object and purpose of the PDP, specifying the product involved, the presentations, the pharmaceutical form and the stage of technology transfer;
c) The term of the public institution for the internalization of technology; and
d) Statement of the participants agreeing with the compliance of project objectives for the development, transference and absorption of technology under this Ordinance.

Sole paragraph. The Secretary of the Ministry of Health responsible for the purchase of the product subject to PDP may require SCTIE/MS, in case of possession or jurisdiction, other information and documents necessary for the proper instruction of the purchasing procedure.

Article 58. The proposal of alteration of the schedule of the PDP, when the process of acquisition is started, will be officially presented by the public institution, with substantive motivation, to the SCTIE/MS.

Sole Paragraph. In case the proposal of amendment implies in the extension of term of acquisition of the product subject to the PDP as seen in the existing schedule, the SCTIE/MS will forward the proposal to the Technical Evaluation Commission and the Deliberative Committee for the evaluation and the Executive-Secretary of the Ministry of Health (SE/MS) for the decision.

Section IV
Technology Internalization

Article 59. After finishing the PDP and completing the process of development, transference and absorption of technology by the industry and private entity, the purchase of the product subject of the PDP will no longer be under the steps provided in the previous Section.

Sole paragraph. In the cases of impossibility of the public institution to supply all the demand of the Ministry of Health, it will be made a public bid for the complementary quantitative needed by the Unified Health System (SUS)

Article 60. Once the internalization of the technology is proven, the public institution may, with due justification analyzed by the Ministry of Health, transfer the technology subject to the PDP to another public institution in order to attend the necessities of the SUS.

CHAPTER V
MONITORING AND EVALUATION

Article 61. Each PDP will be continuously monitored since the PDP project until the technology internalization for in order to verify the expected progress in the manufacturing process, development, transference and absorption of technology.

Article 62. The monitoring and evaluation of the PDP project and PDP will observe the occurrence or not of the:

I - compliance with the schedule established in the PDP executive project; and

II - fulfillment of the obligations and responsibilities set during the administrative procedure phases to establish the PDP.

Article 63. Monitoring of capacity, technological and productive activities, of the executive project and its schedule, the technical process of technology transfer and capacity development of public institutions to the new technological level within the PDP will be conducted by SCTIE / MS, with participation of ANVISA, through the agency of CTR, and based on specific instruments and methodologies, involving the following dimensions:

I - technical monitoring of capacity and technological and productive activities required for ANVISA's sanitary regulation, through the agency of CTR, and based on specific tools and methodologies;

II - monitoring the executive project, the technical transfer process and absorption of technology and the capacity development of public institution to the new technological level, based on specific instruments and methodologies, being subsidized by the activities provided in paragraph I of the "caput", in charge of SCTIE / MS;

III - analysis of the follow-up reports sent every four months by the public institution to the Ministry of Health; and

IV - conducting annual technical visits in public and private plants by the Ministry of Health and ANVISA.

Article 64. The PDP projects and PDP in non-compliance with the requirements, criteria, guidelines and orientations established and that are identified by the monitoring mechanisms established in this Ordinance will be suspended by SCTIE / MS for analysis of the Technical Evaluation Commission and decision of the Deliberative Committee as to its:

I - restructuration: if verified the serious non-compliance of the requirements, criteria, guidelines and orientations set in this Ordinance;

II - Extinction:
a) If there is any damage to Administration or its use is in violation of the goals specified in this Ordinance, that compromise the objectives of the PDP; or
b) If there is a relevant non-compliance with a risk of irreversibility of the schedule established in the PDP, including for implementation of the development, transference and absorption of the technology in terms of portability, without justifying the factors unrelated to the efforts of the participants.

Paragraph 1. The suspension referred to in the "caput" will be communicated by SCTIE / MS to the Secretary of the

Ministry of Health responsible for implementing the specific instrument of purchasing of a product under the PDP with the public institution.

Paragraph 2. The implementation of the measures provided in this Article will not exclude the application of other sanctions and penalty provided by law.

Article 65. The public institution and the private entity will be subject to administrative and judicial measures, in addition to penalties provided by law and in signed contracts, in case of the PDP that has initiated the acquisition of products by the Ministry of Health and the transfer of technology to the public institution turns to not be effective, especially when there is any damage to the national treasury.

Sole Paragraph. The provision of the main clause is not applicable to of casualties, force majeure situations or other hypothesis duly motivated in accordance with the legislation in force, approved by the Ministry of Health.

CHAPTER VI
INSTITUTIONAL COMPETENCE

Article 66. The Ministry of Health is responsible for the:

I - drafting and revising the list of strategic products for the SUS;

II – verify within the Tripartite Management Commission (acronym CIT), the viability of centralization of the purchase of strategic products for the SUS;

III - encouraging public institutions to submit PDP projects proposals that complies with the list of strategic products for SUS institutions;

IV - encouraging private entities to participate in initiatives that promote investment, technological development, innovation and the generation of income and employment in Brazil regarding the SUS strategic product, through their participation in PDP;

V - Receiving and formalizing the proposed PDP project, with the inclusion of its technical brief, when appropriate, for analysis of the Technical Evaluation Commission and discussion and decision by the Deliberative Committee;

VI - providing technical and administrative support to carry out the activities of the Technical Evaluation Commission and discussion and decision by the Deliberative Committee

VII – establishing the terms of commitment of each PDP project approved;

VIII - monitoring and evaluating PDP projects;

IX - attending the CTR meeting and requiring information and documents, including meetings, from the public and private entity for monitoring the PDP project implementation and suggest strategies for compliance;

X – Participating the PDP phase and fulfill the responsibilities and obligations under said phase; and

XI – disclosing in the Ministry of Health website, at www.saude.gov.br, public information regarding the PDP, containing at least the following data:
a) Laws, decrees, ordinances and resolutions related to the PDP;
b) Form of executive project of PDP;
c) Form of the monitoring report submitted by the public institution;
d) Annual list of PDP project proposals under review, approved or not approved; and
e) Annual list of projects of PDP and PDP and their "status" of implementation and execution; and
e) List of PDP products whose purchase was initiated by the Ministry of Health via PDP, with a copy of the abstract of publication in the Federal Register.
Sole paragraph. To monitor and evaluate the PDP project and the PDP, the Ministry of Health will count with the support of the agencies or government entities.

Article 67. ANVISA is responsible for:

I - concluding the analysis required under the PDP project and the PDP for marketing authorization and post-authorization change within 60 (sixty) days from the date of the request;

II - prioritizing the analyzes of products subject of PDP with respect to the compliance with sanitary regulation;

III - monitor, within the activities of the CTR, the attendance to the schedule for the achievement of the drug or medical device marketing authorization, as well as post-authorization amendments private entities participating in a PDP, in line with the approved term of commitment, provided they all comply with standards and sanitary requirements, formally agreed with SCTIE / MS and other Departments of the Ministry of Health whose product is part of its programs and actions;

IV - Monitor the schedule for obtaining or renewing the GMP, in line with the approved terms of commitment, since they all comply with standards and sanitary requirements, formally agreed with SCTIE / MS and other Departments of the Ministry of Health whose product is part of its programs and actions;

V - supporting SCTIE / MS with monitoring and evaluation activities of the technical development of PDP projects to meet the requirements of quality and internalization of production in the country, using appropriate methodologies for this purpose;

VI - holding annual technical visits in the plants of public and private entities, members of the PDP, with the Ministry of Health;

VII - technically monitor the capacity and the technological and productive activities required for the sanitary regulation of public and private entities in order to subsidize the production and technological internalization of the product under PDP, through the agency of CTR and other proactive activities that ANVISA may contribute to its results; and

VIII – being part of the Technical Evaluation Commission of PDP project proposals.

Article 68. The public institutions, which is a PDP applicant and executer, is responsible for:

I - preparing and submitting a PDP project proposal in compliance with the criteria, requirements, directives and guidelines of this Ordinance, containing at least the information requested in the executive project form;

II - demonstrating the manufacturing capacity, equipment and human resources necessary for execution of the PDP project in the public institution, making the relevant adjustments to the effective transfer of technology;

III – making the risk analysis of the project;

IV - sending the executive project of the PDP to SCTIE / MS for analysis, meeting deadlines defined in this Ordinance;

V - Orally present the project proposal to Technical Evaluation Commission and Deliberative Committee, after formal brief of the Ministry of Health;

VI – signing a term of commitment with the Ministry of Health;

VII – signing contracts or other legal instruments with employees and partners in the PDP project, following the criteria and guidelines of this Ordinance and the premises of the term of commitment made, with the addition of other necessary conditions for the proper care of the public interest, in compliance with the relevant legislation;

VIII – filing the data package related to the product marketing authorization before ANVISA, as specific rules of the entity and established schedule;

IX - ensuring, together with its private partner, the internalization of the national production of the API, critical technological component and, where applicable, compliance with rules of origin and/or PPB;

X – Tracking, monitoring and evaluating the actions performed by a private entity for the transfer of technology and for the effective fulfillment of technical and regulatory timeline;

XI - actively participate in the product development with the private entity, following-up the complete technological cycle;

XII - conducting capacity training of your team, coordinated together with private entity in order to absorb the necessary knowledge for the effective technology transfer of the product subject of a PDP, and maintaining its practical effectiveness periodically evaluated, keeping the records of training saved and the schedules formalized before the Ministry of Health and being available during technical visits;

XIII - participating in technical visits in private entity, together with the Ministry of Health and ANVISA;

XIV - asking the prioritization analysis before ANVISA after application for marketing authorization or post-authorization amendment;

XV – complying with the schedule set for the PDP project, communicating and justifying the Ministry of Health any changes needed;

XVI - sending to the Ministry of Health, specifically the SCTIE / MS, the follow-up reports of every 04 (four) months for PDP projects approved, showing the implemented project activities, ongoing and planned, presenting founded

explanation in case of schedule changes presented in the executive project ;

XVII - collaborating and providing the necessary documentation for the technical visit of the Ministry of Health and ANVISA in the public institution;

XVIII – attending meetings of the CTR and the Ministry of Health, whenever required;

XIX – conducting specific instrument with the Ministry of Health for providing products under the PDP, respecting the relevant legislation and the terms of this Ordinance; and

XX - ensuring the supply and delivery of products according to quantitative and schedule defined by the Ministry of Health.

Sole paragraph. The choice and contractual relationships with the private entity are the sole responsibility of the public institution that signed the PDP, including with respect to their qualification and regularity evaluation of their legal status and suitability.

Article 69. To participate in the PDP project proposal, the PDP project and of the PDP, the private entity shall:

I - participate in the PDP project proposal in compliance with the criteria, requirements, guidelines and orientations of this Ordinance, containing at least the information requested in the executive project form;

II - demonstrating the production capacity, equipment and human resources necessary for execution of the PDP project in the public institution, making the relevant adjustments to the effective transfer of technology;

III – establishing contracts or other legal instruments with the public institution and private partners in the PDP project, following the criteria and guidelines of this Ordinance and the premises of the term of commitment made, with the addition of other necessary conditions for the proper care of the public interest, in compliance with the relevant legislation;

IV – ensuring in the executive project, the internalization of the national production of the API, critical technological component and, where applicable, compliance with rules of origin and/or PPB;

V – Guaranteeing the technology transfer and the effective compliance with the technic-regulatory schedule;

VI - actively participate in the product development with the public institution and the private partners;

VII - conducting capacity training in order to transfer the necessary know-how to the effective development and technology transference of the product subject of the PDP, keeping the records of training saved and the schedules formalized before the Ministry of Health and being available during technical visits;

VIII – receive scheduled technical visits of the teams of the Ministry of Health and of ANVISA, in line with the used methodology, collaborating and providing the necessary documents;

IX – filing, when it is needed, the data package related to the product marketing authorization and post-authorization before ANVISA, as provided by the specific rules;

X - Complying with the schedule set for the PDP project, communicating and justifying to the public institution any changes needed;

XI – inform periodically to the public institution, in compliance with the defined schedule, the activities of the project already executed, the ones pending and the ones expected, helping the public institution in the elaboration of the follow-up reports of every 04 (four) months and presenting motivated justifications in case of amendments in the schedule, sending to the public institution documents about the development of the project and of the activities related to the project, aiming to meet the public interest and its goals , including the technology transfer, the guarantee of supply and local manufacture of the ingredient;

XII - ensuring the supply and delivery of products according to quantitative and schedule defined by the public institution in order to meet the Ministry of Health's demand.

XIII – stablishing the joint declaration of agreement with the terms of the PDP project proposal, according to the provisions of §3rd of article 14, and the declaration of agreement attached to the term of commitment, on the terms of article 35.

CHAPTER VII
FINAL PROVISIONS

Article 70. The guidelines, criteria, requirements, orientations and forms of monitoring and evaluation defined in this Ordinance are applicable, when possible, to the PDP already signed.

Paragraph 1. It is granted a term of 180 (one hundred eighty) days from the date of publication of this Ordinance, for the public institution and private entity, as applicable, to comply with the provisions of the established herein.

Paragraph 2. The SCTIE/MS will implement the classification of the PDPs in force according to the phases of establishment of the PDPs provisioned in article 10.

Paragraph 3. For the PDPs already signed of research and development that are in the development, transference and absorption of technology phase, the public institution may request to the SCTIE/MS its alterations for compatibility for the framing as a project of PDP or a PDP, on the terms of this Ordinance, for the analysis by the Technical Evaluation Commission and by the Deliberative Committee.

Paragraph 4. The PDP Project proposals in progress in the Ministry of Health, on the terms of the Ordinance No. 837/GM/MS, of April 18, 2012, and still lacking evaluation by the managing Commissions will be restored by the SCTIE/MS to the proposing institutions for the compatibility to the regulations of this Ordinance.

Article 71. In the hypothesis of existence of contracts in force between the Ministry of Health and the public institutions for the acquisition of strategic products until the date of publication of this Ordinance, the mentioned contracts will be compatible, when applicable, to the provisions of this Ordinance.

Article 72. In the hypothesis of existence of agreement or contract of development, transference and absorption of technology of the product subject of the PDP between the public institutions and the private entities until the date of

publication of this Ordinance, the mentioned agreements will be altered for compatibility, when applicable, to the provisions of this Ordinance.

Article 73. Specific act of the Minister of Health will establish the guidelines and criteria relating to PDP on research, development and innovation.

Article 74. Until the issuance of the new list of strategic products for the SUS, is established in Article 7, the current list defined under Article 6 of Ordinance No. 3089/GM/MS, of December 11, 2013 remains in force

Article 75. This Ordinance will enter into force on the date of its publication.

Article 76. It is revoked:

I - Ordinance No. 837/GM/MS, of April 18, 2012, published in the Official Gazette (DOU) No. 82, Section 1, of day 27 and following, p. 34; and

II - Ordinance No. 3089/GM/MS, of December 11, 2013, published in the Official Gazette No. 242, Section 1, of day 13 and following, p. 153.

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