

RDC RESOLUTION # 204, OF DECEMBER 27, 2017

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Features on the framework in the priority category, petitions of registration, post- registration and prior consent in clinical research of drugs.

The Collegiate Board of the Brazilian Health Surveillance Agency, in the use of the assignment that confers the art. 15. III and IV together with the Art. 7, III, and IV, of Law n. 9,782, of 26 January 1999, art. 53, V, §§ 1 and 3 of internal rules adopted pursuant to Annex I of resolution of the Board - RDC n 61 of 3 February 2016, resolves to adopt the following Resolution of the Board, as discussed in the meeting held on 12 December 2017, and I, the CEO, determine its publication.

CHAPTER I - INITIAL PROVISIONS

Art. 1 Are approved the criteria and procedures for the purpose of framing in the priority category of petitions of registration, post-registration and prior consent in clinical research of drugs, according to the public relevance, in order to guarantee or expand access to pharmaceutical assistance, in accordance to this resolution.

Art. 2 For the purpose of this resolution is adopted the following definitions:

I - Alternative therapy: drugs that contain different active pharmaceutical supplies indicated for the same therapeutic objective or clinical, which are potentially the same therapeutic effect;

II - Serious debilitating condition: disease or condition associated with irreversible morbidity or high probability of death, unless the course of the disease is interrupted;

III - Emerging or reemerging diseases: new conditions of health status, generally of infectious origin, or conditions already known to acquire or regain epidemiological significance in public health;

IV - Neglected diseases: diseases that do not show economic attractiveness for the development of drugs, or to achieve population predominantly in developing countries;

V - Rare disease: one that affects up to sixty-five people in every one hundred thousand individuals, as defined by the National Policy of Integral care to people with rare diseases, based on official national data or, when absent, in data published in scientific-technical documentation;

VI - Emergency in public health: a situation that requires the urgent employment measures for the prevention, control and containment of risks, damages and injuries to public health in situations that may be epidemiological studies (outbreaks and epidemics), disasters, or lack assistance to the population;

VII - Drug: pharmaceutical product, technically obtained or prepared, with prophylactic purpose, curative, palliative or diagnostic purposes, as defined by Law n. 5,991, of 1973;

VIII - Unprecedented generic drug: corresponds to the first generic drug for sale under medical prescription to be registered in the country, for a given active pharmaceutical supply or association, and pharmaceutical form;

IX - Innovative drug: drug with development of improvements in relation to a drug already registered in the country, including new salts, isomers or a mixture of isomers, esters and ethers of molecules previously registered;

X - New drug: drug with active pharmaceutical ingredients (API) new country;

XI - Significant improvement of efficacy or safety: when the drug present a better profile of efficacy or safety demonstrated by clinical outcome, compared to existing therapeutic alternative;

XII - Productive Development Partnership (PDP): program of the Ministry of Health, which involves cooperation by agreement between institutions Government and between public institutions and private entities for the development, transfer and absorption of technology, production, productive and technological capacity of the country in strategic products for attending to the demands of the SUS;

XIII - Primary Petition clone: Simplified linked to a technical and clinical report of a primary petition may differ matrix exclusively in the name of drug, the layout of packaging and in legal information present in the leaflet and labelling.

CHAPTER II – GENERAL PROVISIONS

Art. 3 Shall be classified as priorities the petitions of drug registration related to one or more of the following criteria:

I - Drug used for neglected disease, emerging or reemerging, public health emergencies or seriously debilitating conditions, in situations in which there is no therapeutic alternative available or when presenting a significant improvement of safety, efficacy or adherence to treatment;

II - New Drug, new pharmaceutical form, new therapeutic indication or new concentration intended for the pediatric population;

III - Vaccines or hyperimmune serums to be incorporated in the National Immunization Program of the Ministry of Health;

IV - Innovative drug or new, for active pharmaceutical supply manufactured in the Country;

V - The three (3) first petitions of unprecedented generic drug for each active pharmaceutical supply or association and pharmaceutical form, distinct economic groups;

VI - Drug as part of the list of strategic products, in the context of the Unified Health System – (SUS) that is the subject of Productive Development Partnership (PDP), upon the initial submission of all documents and studies provided for in the current legislation.

§ 1 to the petitions of priority vaccines or hyperimmune serums, framed in item III of this article, the company shall submit a document issued by the Ministry of Health stating the intention of incorporating the National Immunization Program.

§ 2 besides the three (3) first priority petitions of unprecedented generic drug, according to item V of this article may be classified as priority a fourth petition of unprecedented generic drug of distinct economic group, provided that none of the priority drugs registered by this criterion, have been commercialized within 365 (three hundred and sixty-five) days, counted from the date of publication of the registry.

§ 3 to the priority's petitions of drugs classified in item V of this article, the company shall inform if the reference medicinal product is protected by patent, and if so, should inform the numbers of requests of patents as related.

§ 4 the petitions of registration of drugs classified in term V of this article, whose reference medicinal product is protected by a patent of validity exceeding 300 (three hundred) days, counted from the date of the protocol of the petition, will not be classified as priority, except if the applicant is licensed by the patent holder, should present the evidentiary document, or in the case of compulsory licensing.

§ 5 the petitions for registration of drugs classified as primary petition clone will not be considered as a priority.

Art. 4 shall be classified as priority the petitions of alteration after registration of drugs classified in one or more of the following criteria:

I - new therapeutic indication or extension of use for neglected diseases, rare, emerging and reemerging diseases, public health emergencies or serious debilitating conditions, in situations in which there is no therapeutic alternative available or when presenting a significant improvement of safety or efficacy;

II - new therapeutic indication or extension of use intended for the pediatric population;

III - vaccines or hyperimmune serums members of the National Immunization Program when demonstrated the risk of shortages of SUS;

IV - generic drug only registered, commercialized with sale under medical prescription, for a given active pharmaceutical supply or association, pharmaceutical form and concentration, whose priority analysis is essential to avoid the shortages in the market of this generic drug;

V - petitions related to the process of internalization of production of drug as part of the list of strategic products, in the context of the Single Health System - SUS and object of partnership of productive development, upon the submission of documents and studies provided for in the legislation;

VI - petitions related to reference medicinal product, members of drug list of references available at the Anvisa's website, that are unavailable in the national market as a result of post-record changes that are awaiting analysis.

Sole Paragraph. For priority petitions of drugs classified in item III of this article, the company must submit document issued by the Ministry of Health, proving the risk of shortages of the Single Health System (SUS).

Art. 5 shall be classified as priorities the petitions of prior consent in the process of the dossier of clinical development of drug (DDCM) and substantial modifications incorporated in one or more of the following criteria:

I - New drug with all the stages of production carried out in the Country;

II - Drug as part of the National Immunization Program;

III - Drug as part of the list of strategic products, in the context of the Single Health System -(SUS) that is the subject of a development partnership productive.

Art. 6 shall be classified as priority the petitions of prior consent in clinical research process (Specific Dossier of Clinical Trial - DEEC) and substantial amendments related to one or more of the following criteria:

I - drug used for neglected disease, emerging or reemerging, medical emergencies in public health or serious debilitating conditions, in situations in which there is no therapeutic alternative available;

II - clinical trial conducted exclusively in the pediatric population;

III - clinical trial phase I, conducted exclusively in national territory.

Art. 7 in addition to the criteria laid down in articles 3 and 4, Anvisa may classify as priority the petitions of registration and post-registration of drugs for sale under medical prescription, when is configured the risk of shortages in the market with an impact on public health.

Art. 8 The drugs prioritized and recorded through the criteria of this norm shall be commercialized within 365 (three hundred and sixty-five) days, counted from the date of publication of the registry.

Art. 9 The new drugs related to the priority category, in accordance to the criteria established in this resolution, will have within up to 30 (thirty) days to submit the dossier of definition of maximum price, counted from the first day after the publication of the registry.

Art.10 the framework in the category of priority shall be made at the time of the protocol of the petition for registration, alteration after registration and prior consent in clinical research, which will be object of prioritization.

§ 1 of the Protocol referred to in the caput may only be done by companies duly recognized by ANVISA as responsible for their petitions for which you want to apply the provisions of this Resolution.

§ 2 for the registration protocol of new drugs priority do not apply the provisions related to the art. 2 of the Resolution of the Collegiate Board - RDC N 20, of 10 April of 2013.

Art. 11. In the act of the protocol the company shall attach a document indicating what criteria(s) established(s) in arts. 3, 4, 5 and 6 base(s) the framework in the priority category.

Sole Paragraph. If the framework in the category of priority is not confirmed during the analysis technique, the petition will be rejected.

Art. 12. The deadline for final decision regarding the examination of petitions of registration and post-registration of drugs classified as priority will be to:

I - 120 (one hundred and twenty) days for petitions of registration of drug;

II - 60 (sixty) days for petitions of post-registration.

§ 1 the deadlines shall be counted from the protocol of the priority's petition.

§ 2 the requests for clarification or technical requirements will suspend the counting of the deadlines specified in this article until they are attended.

§ 3 the time limits referred to in terms I and II of this article may be extended by up to one third of the original term, once only, by reasoned decision issued in at least 15 working days before the end of the original term.

Art. 13. The deadline for the first manifestation of competent organizational units regarding the analysis of priority petitions prior consent in the process of the dossier of clinical development, and prior consent in the process of clinical research of drug, as well as the secondary petitions relating specifically to the primary process prioritized, will be of 45 (forty-five) days, counted from the first day after the protocol of the priority petition.

CHAPTER III – FINAL PROVISIONS

Art.14. So that they can be applied the criteria presented in this resolution, the priority petition of registration, post-registration and prior consent in clinical research of drug must be accompanied by all the documentation required by legislation and regulations, under penalty of refusal.

Art.15. The noncompliance with the provisions contained in this resolution constitutes violation of sanitary ware, in terms of Law n. 6,437, of 20 August of 1977, without prejudice to the responsibilities of civil, administrative and criminal sanctions.

Art. 16. This Resolution comes into effect in 60 days from the date of its publication.

JARBAS BARBOSA DA SILVA JR.