Ministry of Health - MS

National Health Surveillance Agency - ANVISA

COLLEGIATE BOARD RESOLUTION - RDC No. 204, OF DECEMBER 27, 2017

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Provides for the inclusion in the priority category of registration, post-registration and prior consent petitions in clinical drug research.

The **Collegiate Board of the National Health Surveillance Agency,** using the powers conferred on it by art. 15, III and IV combined with art. 7th, III, and IV, of Law No. 9,782, of January 26, 1999, and art. 53, V, §§ 1 and 3 of the Internal Regulations approved in accordance with Annex I of the Resolution of the Collegiate Board of Directors - RDC No. 61, of February 3, 2016, resolves to adopt the following Resolution of the Collegiate Board of Directors, as resolved at the meeting held on December 12, 2017, and I, Chief Executive Officer, determine its publication:

CHAPTER I - INITIAL PROVISIONS

Art. 1 The criteria and procedures for the purpose of classifying petitions for registration, post-registration and prior consent in clinical drug research, according to public relevance, in the priority category, are hereby approved, aiming to guarantee or expand access to pharmaceutical assistance, under the terms of this Resolution.

Art. 2 For the purposes of this Resolution, the following definitions are adopted:

I - therapeutic alternative: medicines that contain different active pharmaceutical ingredients indicated for the same therapeutic or clinical objective, which potentially have the same therapeutic effect;

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

III - emerging or re-emerging diseases: new health conditions, generally of infectious origin, or already known conditions that acquire or re-acquire epidemiological significance in public health;

IV - neglected diseases: diseases that do not present economic attractiveness for the development of drugs, or because they affect populations predominantly from 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 for Comprehensive Care for People with Rare Diseases, based on official national data or, when non-existent, on data published in technical-scientific documentation;

VI - public health emergency: situation that demands the urgent use of measures to prevent, control and contain risks, damages and harm to public health in situations that may be epidemiological (outbreaks and epidemics), disasters, or of lack of assistance to the population;

VII - medicine: pharmaceutical product, technically obtained or prepared, with prophylactic, curative, palliative or diagnostic purposes, as defined by Law No. 5,991, of 1973;

VIII - new generic medicine: corresponds to the first generic medicine sold under medical prescription to be registered in the country, for a specific active pharmaceutical ingredient or association, and pharmaceutical form;

IX - innovative medicine: medicine with the development of improvements in relation to a medicine already registered in the country, including new salts, isomers or mixtures of isomers, esters or ethers of previously registered molecules;

X - new medicine: medicine with new active pharmaceutical ingredient (IFA) country;

XI - significant improvement in efficacy or safety: when the medicine presents a better efficacy or safety profile demonstrated by clinical outcome, compared to the existing therapeutic alternative;

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

XIII - clone primary petition: simplified petition linked to the technical and clinical report of a matrix primary petition and may differ exclusively in the name of the medicine, packaging layout and legal information present in the leaflet and labeling.

CHAPTER II - GENERAL PROVISIONS

Art. 3 Petitions for registration of medicines that meet one or more of the following criteria will be classified as priority:

I - medicine used for neglected, emerging or re-emerging diseases, public health emergencies or serious debilitating conditions, in situations where there is no therapeutic alternative available or when there is a significant improvement in safety, efficacy or adherence to treatment;

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

III – vaccines or hyperimmune serums to be incorporated into the National Health Program Immunization from the Ministry of Health;

IV – innovative or new medicine, for active pharmaceutical ingredient manufactured in the Country;

V – the first three (3) petitions for new generic medicine for each input active pharmacist or association and pharmaceutical form, from different economic groups;

VI – medicine included in the list of strategic products, within the scope of the Unified Health System – SUS that is the subject of a Productive Development Partnership (PDP), through the complete initial submission of all documents and studies provided for in current regulations.

§ 1 For priority requests for vaccines or hyperimmune serums, covered by item III of this article, the company must present a document issued by the Ministry of Health declaring the intention of incorporation into the National Immunization Program.

§ 2 In addition to the first 3 (three) priority petitions for unpublished generic medicine, according to item V of this article, a fourth petition may be classified as priority of new generic medicine from a different economic group, provided that none of the priority medicines registered by this criterion have been marketed within 365 (three hundred and sixty-five) days, counting from the publication of the registration.

§ 3 For priority petitions for medicines covered by item V of this article, the company must inform whether the reference medicine is protected by patent and, if so, it must inform the numbers of the related patent applications.

§ 4 Petitions for registration of medicines covered by item V of this article, whose reference medicine is protected by a patent valid for more than 300 (three hundred) days, counting from the date of the petition protocol, will not be classified as priority, except if the applicant is licensed by the patent holder, and must present the supporting document, or in the case of compulsory licensing.

§ 5 Petitions for registration of medicines classified as primary petitions clone will not be classified as priority.

Art. 4 Petitions for post-registration changes to medicines that meet one or more of the following criteria will be classified as priority:

I - new therapeutic indication or expansion of use for diseases neglected, rare, emerging, re-emerging, public health emergencies or

serious debilitating conditions, in situations where there is no therapeutic alternative available or when there is a significant improvement in safety or effectiveness;

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

III – vaccines or hyperimmune serums included in the National Immunization Program when the risk of SUS shortages is proven;

IV - single registered generic medicine, sold under medical prescription, for a specific active pharmaceutical ingredient or association, pharmaceutical form and concentration, whose priority analysis is essential to avoid market shortages of this generic medicine;

V – petitions related to the process of internalizing the production of medicines included in the list of strategic products, within the scope of the Unified Health System – SUS and subject to a productive development partnership, through the complete submission of documents and studies provided for in current regulations;

VI – petitions related to reference medicines, part of the Reference Medicine Lists available on the Anvisa Portal, which are unavailable on the national market as a result of post-registration changes awaiting analysis.

Single paragraph. For priority requests for medicines covered by section III of this article, the company must present a document issued by the Ministry of Health proving the risk of shortages in the Unified Health System.

Art. 5 Petitions for prior consent in the drug clinical development dossier process (DDCM) and substantial modifications falling within one or more of the following criteria will be classified as priority:

I - new medicine with all production stages carried out in the country;

II – medicine that is part of the National Immunization Program;

III - medicine included in the list of strategic products, within the scope of the System Unified Health System – SUS that is the subject of a productive development partnership.

Art. 6 Petitions for prior consent in the clinical research process (Specific Clinical Trial Dossier – DEEC) and substantial amendments falling within one or more of the following criteria will be classified as priority:

I - medicine used for neglected, emerging or re-emerging diseases, public health medical emergencies or serious debilitating conditions, in situations where there is no therapeutic alternative available;

II - clinical trial conducted exclusively in the pediatric population;

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

Art. 7 In addition to the criteria established in arts. 3rd and 4th, Anvisa will be able to classify priority should be given to petitions for registration and post-registration of medicines sold under medical prescription, when there is a risk of market shortages with an impact on public health.

Art. 8 Medicines prioritized and registered using the criteria of this standard must be sold within a period of up to 365 (three hundred and sixty-five) days, counting from the date of publication of the registration.

Art. 9th. New medicines falling into the priority category, as a result of the criteria established in this Resolution, will have a period of up to 30 (thirty) days to submit the maximum price definition dossier, counting from the first business day after publication of the registration.

Art. 10. Classification in the priority category must be carried out at the time of filing the registration petition, post-registration amendment and prior consent for clinical research, which will be subject to prioritization.

§ 1 The protocol referred to in the *caput* can only be carried out by companies duly recognized by ANVISA as responsible for the respective petitions to which the provisions of this Resolution are intended to be applied.

§ 2 The provisions of art do not apply to the registration protocol for new priority medicines. 2nd of the Collegiate Board Resolution – RDC nº 20, of April 10, 2013.

Art. 11. When filing the protocol, the company must attach a document indicating which criteria(s) established in arts. 3rd, 4th, 5th and 6th justify classification in the priority category.

Single paragraph. If classification in the priority category is not confirmed during the technical analysis, the petition will be rejected.

Art. 12. The deadline for a final decision regarding the analysis of registration and post-registration petitions for medicines classified as priority will be:

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

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

§ 1. The deadlines will be counted from the protocol of the priority petition.

§ 2. Requests for clarification or technical requirements will suspend the count deadlines determined in this article until they are met.

§ 3. The deadlines mentioned in items I and II of this article may be extended by up to one third of the original deadline, once, through a reasoned decision issued at least fifteen working days before the end of the original deadline.

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

CHAPTER III - FINAL PROVISIONS

Art. 14. In order for the criteria set out in this resolution to be applied, the priority application for registration, post-registration and prior consent in clinical drug research must be accompanied by all the documentation required by legislation and regulations in force, under penalty of rejection.

Art. 15. Failure to comply with the provisions contained in this resolution constitutes a health infraction, under the terms of Law No. 6,437, of August 20, 1977, without prejudice to applicable civil, administrative and criminal responsibilities.

Art. 16. This Resolution comes into force 60 days after the date of its publication.

JARBAS BARBOSA DA SILVA JR.