

COLLEGIATE BOARD RESOLUTION – RDC No. 204 OF 27 DECEMBER 2017

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Provides for the prioritization of requests for marketing authorization, post-marketing authorization, and previous approval for clinical research of medicinal products.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, items III and IV, combined with Article 7, items III and IV, of Law no. 9782 of 26 January 1999, and Article 53, item V, paragraphs 1 and 3, of the Internal Regulation approved by Annex I of Collegiate Board Resolution – RDC no. 61 of 3 February 2016, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 12 December 2017, and I, the Director-President, determine its publication:

CHAPTER I

INITIAL PROVISIONS

Article 1. This Resolution approves the criteria and procedures to prioritize the requests for marketing authorization, post-marketing authorization, and previous approval for clinical research of medicinal products, according to public relevance, aiming at ensuring or increasing the access to pharmaceutical assistance, in the terms of this Resolution.

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

I – therapeutic alternative: medicinal products that contain different active pharmaceutical ingredients indicated for the same therapeutic or clinical objective, which present potentially the same therapeutic effect;

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

III – emerging or re-emerging diseases: new conditions of health status, usually of infectious origin, or conditions already known that acquire or re-acquire epidemiologic significance in public health;

IV – neglected diseases: diseases not economically attractive for the development of medicinal products, or because they affect mostly the population of developing countries;

V – rare disease: disease that affects up to sixty-five in one hundred thousand people, according to the definition established by the Brazilian Policy on Full Attention to People with Rare Diseases, based on official Brazilian data or, when inexistent, on data published in technical-scientific documentation;

VI – public health emergency: situation that requires urgent measures to prevent, control, and suppress risks, damages, and harm to public health in situations that may rise from epidemiology (outbreaks and epidemics), disasters, or neglect of healthcare to the population;

VII – medicinal product: pharmaceutical product, technically obtained or developed, for prophylactic, curative, palliative, or diagnosis purposes, as defined by Law no. 5,991 of 1973;

VIII – first-time generic drug: it corresponds to the first prescription generic drug granted a marketing authorization in Brazil, for a determined active pharmaceutical ingredient or combination, and pharmaceutical form;

IX – innovative medicinal product: medicinal product with improvements regarding a medicinal product already authorized in Brazil, including new salts, isomers or mixture of isomers, esters or ethers of molecules previously authorized;

X – new medicinal product: medicinal product with a new active pharmaceutical ingredient (API) in Brazil;

XI – significant improvement in efficacy or safety: when the medicinal product shows a better efficacy or safety profile confirmed by clinical outcome, compared to the already existing therapeutic alternative;

XII – Productive Development Partnership (PDP): program of the Health Ministry that involves cooperation by means of agreement among public institutions and between public institutions and private entities for the Brazilian development, transference, and absorption of technology, production, productive and technological capacity in strategic products to meet demands from the Unified Health System;

XIII – clone primary request: simplified request linked to the technical and clinical report of a matrix primary request, and it may diverge exclusively regarding the name of the medicinal product, package layout, and the legal information on leaflet and label.

CHAPTER II

GENERAL PROVISIONS

Article 3. The requests for marketing authorization for medicinal products shall be considered as priority when meeting one or more of the following criteria:

I – medicinal product used for neglected, emerging, or re-emerging disease, public health emergencies, or serious debilitating conditions, in situations where there is no therapeutic alternative available, or when it presents a significant improvement in safety, efficacy, or adherence to the treatment;

II – new medicinal product, new pharmaceutical form, new therapeutic indication, or new concentration destined to the pediatric population;

III – vaccines or hyperimmune sera to be included in the Brazilian Immunization Program of the Health Ministry;

IV – innovative or new medicinal product, for a new active pharmaceutical ingredient manufactured in Brazil;

V – the three (3) first requests of first-time generic medicinal product for each active pharmaceutical ingredient or association and pharmaceutical form, from different economic groups;

VI – medicinal product included in the list of strategic products, within the Unified Health System (SUS, in Portuguese), being object of Productive Development Partnership (PDP), by means of the complete initial submission of all documents and studies provided for by the regulation in force.

Paragraph 1. For priority requests of vaccines or hyperimmune sera, mentioned in item III of this Article, the company must present a document issued by the Health Ministry stating the intention to include the product in the Brazilian Immunization Program.

Paragraph 2. In addition to the 3 (three) first prioritized requests of first-time generic medicinal products, in accordance with item V of this Article, a fourth request of first-time generic medicinal product from a different economic group may be classified as priority, as long as none of the priority medicinal products authorized under this criterion has been commercialized in 365 (three hundred and sixty-five) days from the publication of the marketing authorization.

Paragraph 3. For the priority requests of medicinal products referred to in item V of this Article, the company must inform if the reference medicinal product is protected by a patent and, if so, it must inform the numbers of the related patent requests.

Paragraph 4. The requests for marketing authorization for medicinal products referred to in item V of this Article, the reference medicinal product of which is protected by a patent valid for more than 300 (three hundred) days from the date the request was submitted, shall not be classified as priority, except if the applicant is licensed by the patent holder, and the company must present the document confirming it, or in the case of compulsory licensing.

Paragraph 5. The requests for marketing authorization for medicinal products classified as clone primary request shall not be considered as priority.

Article 4. The requests for post-marketing authorization alteration of medicinal products meeting one or more of the following criteria shall be classified as priority:

I – new therapeutic indication or extended use destined to neglected, rare, emerging or re-emerging diseases, public health emergencies, or serious debilitating conditions, in situations where there is no therapeutic alternative available, or when it presents a significant improvement in safety or efficacy;

II – new therapeutic indication or extended use destined to the pediatric population;

III – vaccines or hyperimmune sera included in the Brazilian Immunization Program, when the risk of shortage in the Unified Health System is confirmed;

IV – only generic medicinal product authorized, commercialized under prescription only, for a certain active pharmaceutical ingredient or association, pharmaceutical form, and concentration, the priority analysis of which is essential to avoid market shortage of such generic medicinal product;

V – requests related to the production internalization process of a medicinal product included in the list of strategic products, within the Unified Health System (SUS) and object of productive

development partnership, by means of the complete submission of documents and studies provided for by the regulation in force;

VI – requests related to reference medicinal products, included in the Lists of Reference Medicinal Products made available at Anvisa’s website, which are unavailable in the Brazilian market because of post-authorization alterations waiting for analysis.

Sole paragraph. For priority requests of medicinal products mentioned in item III of this Article, the company must present a document issued by the Ministry of Health confirming the risk of shortage in the Unified Health System.

Article 5. Anvisa shall consider as priority the requests for previous approval in the Medicinal Product Clinical Development Dossier (DDCM, in Portuguese) process, in addition to substantial alterations, meeting one or more of the following criteria:

I – new medicinal product with all production phases carried out in Brazil;

II – medicinal product included in the Brazilian Immunization Program;

III – medicinal product on the list of strategic products, within the Unified Health System, which is object of a productive development partnership.

Article 6. Anvisa shall consider as priority the requests for previous approval in clinical research (Specific Clinical Trial Dossier – DEEC, in Portuguese) process, in addition to substantial alterations, meeting one or more of the following criteria:

I – medicinal product used for neglected, emerging, or re-emerging disease, public health emergencies, or serious debilitating conditions, in situations where there is no therapeutic alternative available;

II – clinical trial conducted exclusively in pediatric population;

III – phase I clinical trial, conducted exclusively within the Brazilian territory.

Article 7. In addition to the criteria established in articles 3 and 4, Anvisa may classify as priority the requests for marketing authorization and post-marketing authorization for prescription medicinal products when there is confirmation of the risk of shortage in the market impacting on public health.

Article 8. The medicinal products prioritized and authorized under the criteria in this regulation shall be commercialized in up to 365 (three hundred and sixty-five) days from the date the authorization is published.

Article 9. The new medicinal products classified as priority, in accordance with the criteria established in this Resolution, shall have up to 30 (thirty) days to submit the dossier of maximum price definition, counting from the first working day after the authorization is published.

Article 10. The classification as priority shall be defined at the moment the marketing authorization, post-authorization alteration, and clinical research previous approval requests are protocolled, which shall be object of prioritization.

Paragraph 1. The protocol referred to in the caption of this article may be carried out by companies duly recognized by Anvisa as responsible for the respective requests which the provisions in this Resolutions are intended to be applied to.

Paragraph 2. For the protocol of marketing authorization for priority new medicinal products, the provisions in Article 2 of Collegiate Board Resolution – RDC no. 20 of 10 April 2013 are not applicable.

Article 11. The moment the request is protocolled, the company must attach a document indicating which criteria established in articles 3, 4, 5, and 6 justify the classification as priority.

Sole paragraph. If the prioritization is not confirmed during the technical analysis, the request shall be rejected.

Article 12. The period for the final decision regarding the analysis of requests for marketing authorization and post-marketing authorization of medicinal products classified as priority shall be:

I – 120 (one hundred and twenty) days for medicinal product marketing authorization requests;

II – 60 (sixty) days for post-marketing authorization requests.

Paragraph 1. Those periods shall count from the date the priority request is protocolled.

Paragraph 2. Clarification requests or technical demands shall suspend the period counting determined in this Article until they are met.

Paragraph 3. The periods referred to in items I and II of this Article may be extended for up to one-third of the original period, only once, upon a justified decision issued at least fifteen working days before the end of the original period.

Article 13. The deadline for the first manifestation of the competent organizational units regarding the analysis of priority requests for previous approval of clinical development dossier process and for previous approval of medicinal product clinical research process, as well as the secondary requests referring specifically to the prioritized primary process, shall be of 45 (forty-five) days from the first working day after the priority request is protocolled.

CHAPTER III

FINAL PROVISIONS

Article 14. For the criteria provided for in this Resolution to be applied, the priority request for marketing authorization, post-marketing authorization, and previous approval of medicinal product clinical research shall be submitted with the whole documentation required in the legislation and regulation in force, failing which it shall be rejected.

Article 15. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, pursuant to Law no. 6,437 of 20 August 1977, without prejudice to the applicable civil, administrative, and criminal liabilities.

Article 16. This Resolution enters into force 60 (sixty) days after the date of its publication.

JARBAS BARBOSA DA SILVA JR.