COLLEGIATE BOARD RESOLUTION – RDC No. 741 OF 10 AUGUST 2022

Provides for the general criteria for the admissibility of analysis carried out by an Equivalent Foreign Regulatory Authority in a health surveillance process at Anvisa, through an optimized analysis procedure.

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, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraphs 1 of Anvisa Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, in a meeting held on 9 August 2022, adopts the following Collegiate Board Resolution and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Article 1. This Resolution defines the general criteria for the admissibility of analysis carried out by an Equivalent Foreign Regulatory Authority (EFRA) in a health surveillance process at Anvisa, through an optimized analysis procedure.

Sole paragraph. The specific conditions for the admissibility of analyses carried out by Equivalent Foreign Regulatory Authorities in the different health processes or product categories shall be established in specific regulations.

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

I – Equivalent Foreign Regulatory Authority (EFRA): foreign regulatory authority or international organization with regulatory practices aligned with Anvisa's, which is responsible for ensuring that the products authorized for distribution were appropriately assessed and meet recognized standards of quality, safety, and efficacy, and which shall be considered by Anvisa in a practice of regulatory reliance.

II – application documents: information presented through reports, opinions, or technical/ legal documents of decision-making, auxiliary, or opinionative nature issued by the Equivalent Foreign Regulatory Authority established through specific regulations for use in the optimized analysis procedure;

III – optimized analysis procedure: technical assessment mechanism at Anvisa, facilitated by regulatory reliance practices, which uses technical analysis or application documents issued by an Equivalent Foreign Regulatory Authority as sole or complementary reference;

IV – health surveillance process: activities, acts, or practices of definitive nature, such as approval, marketing and post-marketing authorization, licensing, accreditation, certification, inspection, monitoring, supervision, and health control;

V – recognition: regulatory reliance practice, in which the decision made by another regulatory authority or international organization is automatically adopted by Anvisa; and

VI – work-sharing: regulatory reliance practice, in which two or more regulatory authorities share activities to carry out a specific regulatory task.

Sole paragraph. The work-sharing referred to in item VI may involve the joint assessment of health surveillance processes and the exchange of information between the authorities, in order to share their analyses, benefit from each other's knowledge, and discuss any deficiencies of the data assessed.

CHAPTER II

ADMISSIBILITY OF ANALYSIS CARRIED OUT BY AN EQUIVALENT FOREIGN REGULATORY AUTHORITY

Article 3. The analysis carried out by an EFRA may be admitted for the purposes of adopting an optimized analysis procedure facilitated by regulatory reliance practices, such as work-sharing and mutual or bilateral recognition, among others.

Article 4. The specific criteria and procedures for the definition of Equivalent Foreign Regulatory Authorities, in accordance with each type of health surveillance process or product category, shall be established in specific regulations.

Paragraph 1. In addition to the compliance with specific requirements provided for in specific regulations, the EFRAs must have a transparent management system guided by the good regulatory practices.

Paragraph 2. The EFRA admissibility shall be confirmed through a decision by Anvisa Collegiate Board, through the analysis of technical reports elaborated by the respective technical office and by the organizational unit responsible for coordinating and supervising international affairs, in accordance with specific regulations.

Paragraph 3. The requirements provided for in Paragraph 2 do not apply to the EFRAs defined by Anvisa for the regulatory reliance practices in progress before this Resolution enters into force.

Paragraph 4. Anvisa shall publicize EFRA admissions, in accordance with the type of health surveillance process or product category.

Article 5. In order to maintain the EFRA admissibility by Anvisa, the EFRA must maintain the conditions and requirements that gave cause to its admissibility.

Paragraph 1. The EFRA admissibility must be monitored and reassessed on a continuous and regular basis, in accordance with the criteria and procedures provided for in specific regulations.

Paragraph 2. The EFRA admissibility may be revoked by Anvisa Collegiate Board at any time, when the conditions provided for in this Resolution and the respective specific regulations are not complied with.

CHAPTER III

OPTIMIZED ANALYSIS PROCEDURE

Article 6. The practice of optimized analysis procedure shall be based on the application documents elaborated by the Equivalent Foreign Regulatory Authority, in accordance with the provisions established in specific regulations.

Article 7. For the purposes of adopting the optimized analysis procedure, the Equivalent Foreign Regulatory Authority application documents must:

I – confirm that the product object of the application documents is essentially identical to the one submitted to Anvisa for assessment;

II – have been elaborated using standards consistent with the ones used by Anvisa, in order to ensure it has the same scope; and

III – be presented in its complete form, including the questions made and the guidance occurred during the analysis by the Equivalent Foreign Regulatory Authority, except if exempted in specific regulations.

Paragraph 1. The application documents shall be subject to the management of public access to information, observing its availability, authenticity, and integrity, as well as the due legal treatment of protection of information, data, and privacy.

Paragraph 2. When there is a difference between the parameters of the health surveillance process or the corresponding product assessed in the application documents from the Equivalent Foreign Regulatory Authority and the parameters intended, such difference must be justified by the applicant for the purposes of assessment by Anvisa, and the same level of health protection must be ensured.

Paragraph 3. Whenever necessary, complementary documentation or additional information may be requested to the applicant, in order to fill up information gaps in the application documents from the Equivalent Foreign Regulatory Authority.

Article 8. The optimized analysis procedure may start from a specific requirement petitioned by the interested party, before the application analysis start, or on the initiative of Anvisa.

Paragraph 1. The application documents may be totally or partially used as a reference complementary to Anvisa's technical analysis.

Paragraph 2. The specific criteria and procedures to protocol the application documents related to the optimized analysis procedure, including the stages and workflows required per health surveillance process or product category, shall be established in specific regulations.

CHAPTER IV

FINAL PROVISIONS

Article 9. Regardless of the documentation to be protocoled for the optimized analysis procedure, the petitioner must submit the whole technical and legal documentation provided for in health regulations in force, except if exempted in specific regulations.

Paragraph 1. The documentation referred to in the caption of this article must meet all requirements, criteria, and specifications established by Anvisa for the corresponding health surveillance process.

Paragraph 2. The submission of a simplified documentation in place of the whole documentation is allowed, as long as it is provided for in specific regulations in force.

Paragraph 3. The optimized analysis procedure does not hinder the assessment of the whole or simplified documentation submitted to Anvisa.

Article 10. The optimized analysis procedure petition must present the most recent application

documents issued by the Equivalent Foreign Regulatory Authority.

Sole paragraph. Specific regulations may establish the acceptable time limit to issue the application documents for the Equivalent Foreign Regulatory Authority's admissibility in the optimized analysis procedure, considering the time it takes to approve the health surveillance process, in addition to the results of post-market control, when applicable.

Article 11. The optimized analysis procedure must follow the transparency prerogatives adopted by Anvisa's technical offices for each health surveillance process or product category.

Article 12. The objects of regularization or approval protocoled in the terms of this Resolution may be verified *in loco*, and such verification may result in decision alteration, requirement of additional evidence, and any other necessary health measure, without prejudice to other applicable legal measures.

Article 13. Anvisa shall be responsible for the decision regarding the application presented, regardless of the decision made by the Equivalent Foreign Regulatory Authority.

Article 14. The provisions in this Resolution do not prevent the adoption of other regulatory reliance practices established by specific regulations, including regulatory harmonization and convergence practices agreed and made operational between foreign authorities, as well as the use of documentation from multilateral organizations, international institutions, or third-party organizations, in accordance with directives and regulations of specific programs and mechanisms Anvisa is part of.

Article 15. This Resolution enters into force on 1 September 2022.

ANTONIO BARRA TORRES

Director-President