OFFICIAL FEDERAL GAZETTE

Published: 08/17/2022 | Issue: 156 | Section: 1 | Page: 102
Body: Ministry of Health/National Health Surveillance Agency/Collegiate Board of Directors

RDC RESOLUTION – No. 741, OF AUGUST 10, 2022

Provides for the general criteria for the admissibility of analysis carried out by an Equivalent Foreign Regulatory Authority in a health surveillance process with Anvisa (National Health Surveillance Agency) through an optimized analysis procedure.

The Collegiate Board of Directors of the National Health Surveillance Agency, in the use of the powers conferred upon it by Art. 15, III and IV, allied to Art. 7, III and IV of Law No. 9.782, of January 26, 1999, and to Art. 187, VI, § 1 of the Internal Regulations approved by Resolution of the Collegiate Board of Directors – RDC No. 585, of December 10, 2021, hereby decides to adopt the following Resolution, as resolved at a meeting held on August 9, 2022, and I, the Chief Executive Officer, hereby determine its publication.

CHAPTER I

INITIAL PROVISIONS

Art. 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 with Anvisa through an optimized analysis procedure.

Sole Paragraph. The specific conditions for the admissibility of analysis carried out by Equivalent Foreign Regulatory Authorities in the different health surveillance processes or product categories shall be defined by specific normative acts.

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

I – Equivalent Foreign Regulatory Authority (AREE): foreign regulatory authority or international entity that has regulatory practices aligned with those of Anvisa, responsible for ensuring that products authorized for distribution have been properly assessed and meet recognized standards of quality, safety, and effectiveness, and that shall be deemed by Anvisa as a practice of regulatory trust.

II – instructional documentation: information presented through reports, bulletins, opinions, or technical or legal documents of decision-making, auxiliary, or opinion nature, issued by the Equivalent Foreign Regulatory Authority specified in specific normative acts for use in the optimized analysis procedure;

III – optimized analysis procedure: technical assessment mechanism at Anvisa, facilitated by practices of regulatory trust, using technical analysis or instructional documentation issued by an Equivalent Foreign Regulatory Authority as a unique or complementary reference;

IV – health surveillance process: activities, acts, or practices of a conclusion nature, such as authorization, registration and post-registration, qualification, accreditation, certification, inspection, monitoring, supervision, and health control;

V – recognition: practice of regulatory trust, in which the decision of another regulatory authority or international entity is automatically adopted by Anvisa; and

VI – collaborative work: practice of regulatory trust, in which two or more regulatory authorities share activities to carry out a specific regulatory task.

Sole Paragraph. The collaborative work referred to in item VI may involve the joint assessment of health surveillance processes and the exchange of information between authorities, in order to share their analysis, benefit from each one’s knowledge, and discuss any deficiencies in the assessed data.

CHAPTER II

ADMISSIBILITY OF ANALYSIS CARRIED OUT BY AN EQUIVALENT FOREIGN REGULATORY AUTHORITY

Art. 3 The analysis carried out by an AREE may be admitted for the purpose of adopting an optimized analysis procedure facilitated by practices of regulatory trust, such as collaborative work and mutual or unilateral recognition, among others.

Art. 4. Specific criteria and procedures for the definition of Equivalent Foreign Regulatory Authorities shall be established in specific normative acts, according to each type of health surveillance process or product category.

§1 In addition to meeting the specific requirements provided for in the specific normative acts, the AREEs shall have a transparent management system guided by good regulatory practices.

§2 The admissibility of the AREE shall be made through decision by the Collegiate Board of Directors of Anvisa, upon the consideration of technical opinions prepared by the respective technical area and by the organizational unit responsible for the coordination and supervision of international affairs, in accordance with specific normative acts.

§3 The requirements set out in §2 do not apply to the AREE defined by Anvisa for practices of regulatory trust in progress before the effectiveness of this Resolution.

§4 Anvisa shall disclose the admitted AREEs, according to the type of health surveillance process or product category.

Art. 5 In order to maintain the admissibility of the AREE by Anvisa, the AREE shall maintain the conditions and requirements that led to its admissibility.

§1 The admissibility of the AREE shall be monitored and reassessed continuously and periodically, in accordance with criteria and procedures provided in specific normative acts.

§2 The admissibility of the AREE by the Collegiate Board of Directors of Anvisa may be revoked at any time when the conditions set out in this Resolution and in the respective specific normative acts are not met.

CHAPTER III

OPTIMIZED ANALYSIS PROCEDURE

Art. 6 The practice of the optimized analysis procedure shall be based on the instructional documentation prepared by the Equivalent Foreign Regulatory Authority, as established in specific normative acts.

Art. 7 For purposes of adopting the optimized analysis procedure, the instructional documentation of the Equivalent Foreign Regulatory Authority shall:

I – prove that the product under the instructional documentation is essentially identical to the one submitted for assessment by Anvisa;

II – have been prepared using standards consistent with those used by Anvisa, to ensure that it has the same scope; and

III – be presented in its complete form, including the questions and guidelines that have been made during the analysis of the Equivalent Foreign Regulatory Authority, unless excepted in specific normative acts.

§1 The instructional documentation 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 information, data, and privacy protection.

§2 When there is a difference between the parameters of the health surveillance process or the corresponding product assessed in the instructional documentation of the Equivalent Foreign Regulatory Authority and the intended parameters, this shall be justified by the applicant for purposes of assessment by Anvisa, and the same level of health protection shall be ensured.

§3 Whenever necessary, complementary documentation or additional information may be requested from the applicant in order to complete information gaps in the instructional documentation of the Equivalent Foreign Regulatory Authority.

Art. 8 The optimized analysis procedure may start from a specific request petitioned by the interested party prior to the beginning of the analysis of the petition or at Anvisa’s initiative.

§1 The instructional documentation may be used in whole or in part as a complementary reference to Anvisa's technical analysis.

§2 The specific criteria and procedures for the instructional documentation protocol referring to the optimized analysis procedure, including the steps and flows required by the health surveillance process or product category, shall be defined through specific normative acts.

CHAPTER IV

FINAL PROVISIONS

Art. 9 Regardless of the documentation to be filed for the optimized analysis procedure, the applicant shall submit the full technical and legal documentation provided for in the current health regulations, unless excepted in specific normative acts.

§1 The documentation mentioned in the head provision shall meet all requirements, criteria, and specifications established by Anvisa for the corresponding health surveillance process.

§2 The submission of simplified documentation instead of full documentation is allowed if provided for in the current specific regulation.

§3 The optimized analysis procedure does not prevent the assessment of the full or simplified documentation filed with Anvisa.

Art. 10. When requesting the optimized analysis procedure, the most recent instructional documentation issued by the Equivalent Foreign Regulatory Authority shall be presented.

Sole Paragraph. The acceptable deadline for issuing the instructional documentation for its admissibility in the optimized analysis procedure may be defined in specific normative acts considering the time of approval of the health surveillance process by the Equivalent Foreign Regulatory Authority, in addition to the results of post-market control, if applicable.

Art. 11. The optimized analysis procedure shall follow the prerogatives of transparency adopted by Anvisa's technical areas for each health surveillance process or product category.

Art. 12. The regularization or approval objects filed under this Resolution may be verified on site, and may result in alteration of the decision, request for additional evidence and any other necessary health measure, without prejudice to other applicable legal measures.

Art. 13. Anvisa shall be responsible for the decision on the claim made, regardless of the decision rendered by the Equivalent Foreign Regulatory Authority.

Art. 14. The provisions of this Resolution do not prevent the adoption of other practices of regulatory trust established by specific regulations, including through regulatory harmonization and convergence practices agreed upon and operationalized between foreign authorities, and also the use of documentation from multilateral organizations, international institutions, or a third-party agency, in accordance with the guidelines and regulations of specific programs and mechanisms to which Anvisa is a party.

Art. 15. This Resolution enters into force on September 1, 2022.

ANTONIO BARRA TORRES
Chief Executive Officer