COLLEGIATE BOARD RESOLUTION – RDC No. 954 OF 20 DECEMBER 2024

Provides for the simplified procedure for applications for the marketing authorization, post-marketing authorization and renewal of marketing authorization of medicinal products and gives other provisions.

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 item VI, paragraphs 1 and 3 of Article 187 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Resolution, as decided upon in a meeting held on 19 December 2024, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1. This Resolution establishes the criteria for the simplified procedure for the marketing authorization, post-marketing authorization and renewal of marketing authorization of generic, similar, specific, dynamized, herbal, and radiopharmaceutical medicinal products, as well as biological products classified in accordance with this Resolution.

Section II

Scope

Article 2. This Resolution applies to applications for the marketing authorization, post-marketing authorization and renewal of marketing authorization of generic, similar, specific, dynamized, herbal, and radiopharmaceutical medicinal products, as well as biological products linked to a primary parent application or secondary parent application of a medicinal product already given marketing authorization of a company in the same economic group, according to the list of economic groups defined by the Medicinal products Market Regulation Chamber (CMED, in Portuguese), or companies from Productive Development Partnerships (PDP) and medicinal product technology transfer processes.

Section III

Definitions

Article 3. For the purposes of this Resolution, the following definitions are adopted:

I – complete dossier: set of all administrative and technical documents provided for in the specific regulations in force that address the granting, renewal of marketing authorization, and post-marketing authorization changes of generic, similar, specific, dynamized, herbal, and radiopharmaceutical medicinal products, as well as biological products;

II – therapeutic equivalent: medicinal product that has proven pharmaceutical equivalence and, when applicable, bioequivalence with the reference medicinal product through studies evaluated and approved by Anvisa at the time of marketing authorization, renewal, or post-marketing authorization change analyzed and approved by Anvisa;

III – primary parent application: application referring to a medicinal product already granted marketing authorization in which all the information and documents required for the marketing authorization of a medicinal product are included;

IV – simplified primary application: application linked to a primary parent application in which the applicant requests the granting of marketing authorization of a medicinal product or biological product, through the simplified procedure; it must have the same pharmaceutical form(s), concentration(s), and presentation(s) as the parent primary application;

V – parent secondary application: secondary application linked to a parent primary application, which contains all the information and documents required for the renewal of marketing authorization or post-marketing authorization change of a medicinal product;

VI – simplified secondary application: secondary application linked to a simplified primary application and a parent secondary application, which must have the same pharmaceutical form(s), concentration(s), and presentation(s) as the parent secondary application;

VII – electronic application: application made online, using the application form available on the Anvisa electronic portal, FP1 and FP2, identified by a transaction number, the subject of which is subject to control and inspection by Anvisa;

VIII – simplified procedure: procedure related to the assessment of applications for marketing authorization, renewal of marketing authorization, or post-marketing authorization changes of generic, similar, specific, dynamized, herbal, and radiopharmaceutical medicinal products, as well as biological products, that are linked to the technical and clinical reports of a parent application of a medicinal product already granted marketing authorization;

IX – clinical report: documentation for the purpose of proving the safety and efficacy required for the product category;

X – technical report: documentation for the purpose of proving the quality required for the product category.

CHAPTER II

ELIGIBILITY

Article 4. For the marketing authorization of medicinal products through the simplified procedure, the primary application must meet the following conditions:

I – be related to a medicinal product with marketing authorization in force;

II – be related to a medicinal product included in Anvisa list of reference medicinal products, in force when submitting the simplified primary application; or

III – be related to a medicinal product therapeutically equivalent to the reference medicinal product chosen by Anvisa at the time of conducting the bioequivalence studies, if applicable, and pharmaceutical equivalence studies, approved by Anvisa, as well as the applications linked to them; or

IV – be related to a medicinal product granted marketing authorization or renewed in accordance with the regulatory frameworks established in this Resolution;

V – not have an application for renewal of marketing authorization denied, including in the appeal phase;

VI – be related to a new or innovative medicinal product, generic, similar, specific, dynamized, herbal, or radiopharmaceutical medicinal product, or biological product.

Sole paragraph. For the purposes of the provisions in items II and III of the caption of this article, the reference medicinal product cannot have been excluded from the reference list for reasons of quality, efficacy, and safety.

Article 5. When the primary parent application refers to a new or innovative medicinal product, the medicinal product that is the object of the simplified primary application must be a generic or similar medicinal product.

Article 6. When the primary parent application refers to a generic or similar medicinal product, the medicinal product that is the object of the simplified primary application must be a generic or similar medicinal product.

Article 7. When the primary parent application refers to a specific medicinal product, the object of the simplified primary application must be a specific medicinal product.

Paragraph 1. The specific medicinal product in the primary parent application must have been granted marketing authorization or have had its marketing authorization renewal assessed in accordance with Resolution RDC No. 24 of 14 June 2011, or its updates.

Paragraph 2. In cases of medicinal products previously granted marketing authorization in a category but reclassified as a specific medicinal product, the simplified primary application shall follow the category of specific medicinal product.

Article 8. When the primary parent application refers to a dynamized medicinal product, the object of the simplified primary application must be a dynamized medicinal product.

Sole paragraph. The dynamized medicinal product of the primary parent application must have been granted marketing authorization or have had its marketing authorization renewal assessed in accordance with Resolution RDC No. 238 of 25 July 2018, or its updates.

Article 9. When the primary parent application refers to an herbal product, the object of the simplified primary application must have the same classification as the object of the primary parent application, in accordance with Resolution RDC No. 26 of 13 May 2014, or its updates.

Paragraph 1. The herbal medicinal product or traditional herbal product of the primary parent application must have been granted marketing authorization or had its marketing authorization renewal assessed in accordance with Resolution RDC No. 26 of 13 May 2014, or its updates.

Paragraph 2. For cases of medicinal products previously granted marketing authorization as herbal medicines, reclassified as traditional herbal products, the simplified primary application shall follow the traditional herbal product category.

Article 10. When the object of the parent primary application refers to a new biological product or biological product, the object of the simplified primary application must be a biological product.

Sole paragraph. The biological product of the parent primary application must have been granted marketing authorization or had its marketing authorization renewal assessed in accordance with Collegiate Board Resolution – RDC No. 315 of 26 October 2005 or Collegiate Board Resolution – RDC No. 233 of 17 August 2005 or Collegiate Board Resolution – RDC No. 323 of 10 November 2003, or Collegiate Board Resolution – RDC No. 187 of 8 November 2017, or their updates.

Article 11. When the object of the primary parent application refers to a new radiopharmaceutical medicinal product or radiopharmaceutical medicinal product, the object of the simplified primary application must be a radiopharmaceutical medicinal product.

Paragraph 1. The radiopharmaceutical medicinal product of the primary parent application must have been granted marketing authorization or had its marketing authorization renewal assessed in accordance with Collegiate Board Resolution – RDC No. 64 of 18 December 2009 or its updates.

Paragraph 2. Radiopharmaceutical medicinal products granted marketing authorization in accordance with Collegiate Board Resolution – RDC No. 263 of 4 February 2019 may not have a linked simplified primary application.

CHAPTER III

PETITIONING

Article 12. Simplified primary and secondary applications are subject to petitioning and submission of documents exclusively electronically.

Sole paragraph. In the event of proven unavailability of Anvisa's electronic petitioning system, simplified primary and secondary applications may be submitted physically, exclusively as an exception.

Article 13. The marketing authorization process object of a simplified primary application, in accordance with this Resolution, shall be linked to the marketing authorization process for the parent primary application, and there may be no discrepancies between marketing authorizations, except with regard to labeling, name of the medicinal product, intended sale, and legal information in the package insert.

Article 14. The company petitioning for the marketing authorization object of a simplified primary application is responsible for the correct petitioning and linking of the simplified applications to the parent application.

Sole paragraph. The simplified primary or secondary application that has not been linked or has been incorrectly linked to the parent application shall be closed.

CHAPTER IV

MARKETING AUTHORIZATION

Article 15. For marketing authorization purposes, the simplified primary application must be accompanied by the following documents:

I – electronic application forms FP1 and FP2 duly completed and signed, according to the model available on Anvisa's website;

II – technical justification for choosing the parent application, indicating in which applications the evidence required to prove therapeutic equivalence is found, when applicable;

III – declaration of link to the parent application, according to the model attached to this Resolution;

IV – name of the medicinal product and differential complement, when applicable to the regulatory category of the medicinal product, accompanied by a technical rationale according to current legislation regarding medicinal product names;

V – labeling layout per pharmaceutical form, concentration, and intended use;

VI – proposed models of package insert with the legal wording of the simplified primary application.

Article 16. The company requesting marketing authorization through the simplified procedure must have an Operation Authorization (AFE, in Portuguese) for an activity compatible with the marketing authorization of the medicinal product.

Paragraph 1. For medicinal product marketing authorizations with one or more manufacturing stages in Brazilian territory, except packaging, the company requesting marketing authorization of the medicinal product through a simplified primary application must have authorization in its AFE to manufacture medicinal products.

Paragraph 2. For medicinal product marketing authorizations with one or more manufacturing or packaging stages outside Brazilian territory, the company requesting marketing authorization through a simplified primary application must have an AFE for the activity of importing medicinal products.

Article 17. The Good Manufacturing Practices Certification (GMPC) of the companies responsible for the manufacturing and packaging stages of the medicinal product must be valid at the time of analysis of the simplified primary application.

Sole paragraph. When the establishment object of Certification is located outside Brazilian territory, the GMPC, in accordance with the caption of this article, must be issued in the name of the company requesting marketing authorization of the simplified primary application.

Article 18. In the case of imported medicinal products granted marketing authorization through the simplified procedure provided for in this Resolution, quality control must be performed exclusively by the company(ies) authorized in the parent marketing authorization process.

Article 19. Marketing authorization granted through the simplified procedure shall be cancelled if the requirements and deadlines established in this Resolution are not met.

Paragraph 1. If the marketing authorization of the presentation(s) of the primary parent application is cancelled, the presentation(s) of the simplified primary application(s) linked to it shall be automatically cancelled.

Paragraph 2. If the marketing authorization of the parent primary application is cancelled, the marketing authorization(s) of the simplified primary application(s) linked to it shall be automatically cancelled.

Paragraph 3. If there is any change in the primary parent application that cannot be replicated in the simplified primary application(s) linked to it, it/they shall be cancelled.

CHAPTER V

POST-MARKETING AUTHORIZATION AND RENEWAL CHANGES

Article 20. The following requests for post-marketing authorization changes may be filed in the simplified primary application, regardless of whether the same protocol exists in the primary parent application:

I – Cancellation of medicinal product marketing authorization;

II – Correction of data in the database;

III – New destination;

IV – Information on the package insert for immediate implementation;

V – Permanent discontinuation of manufacturing or import;

VI – Temporary discontinuation of manufacturing or import;

VII – Reactivation of manufacturing or import;

VIII – Change of medicinal product trade name;

IX – Rectification of publication;

X – Change of labeling;

XI – Transfer of marketing authorization ownership.

Article 21. For all the other post-marketing authorization changes requested in the primary parent application, the company holding the marketing authorization granted through the simplified procedure must request the same post-marketing authorization changes within 30 (thirty) days from the filing of the respective changes in the parent application process, with the following documents:

I – electronic application form duly completed and signed, according to the model available on Anvisa's website;

II – declaration of link between the simplified secondary application and the secondary parent application, according to the model attached to this Resolution.

Paragraph 1. Failure to file all relevant post-marketing authorization changes within the period established in the caption of this article shall result in cancellation of the marketing authorization granted through the simplified procedure.

Paragraph 2. The post-marketing authorization changes provided for in the caption of this article must be petitioned using a specific subject code.

Paragraph 3. All post-marketing authorization changes provided for in the caption of this article must be individually requested in the simplified primary application, regardless of whether they are the result of requirements set forth by Anvisa during the analysis of parent applications.

Article 22. After the simplified primary application has been granted, if there are any requests for post-marketing authorization changes pending for the primary parent application, the holder of the marketing authorization granted through the simplified procedure must request the same changes for his/her process within 30 (thirty) days after the granting of his/her marketing authorization.

Sole paragraph. Failure to comply with the provisions established in the caption of this article shall result in cancellation of the marketing authorization granted through the simplified procedure.

Article 23. The request for renewal of the marketing authorization granted through the simplified procedure must be filed, considering the expiration date of its marketing authorization itself, using the subject "Renewal of medicinal product marketing authorization – simplified procedure", exclusively electronically, accompanied by the following documents:

I – electronic application form duly completed and signed, according to the model available on Anvisa’s website;

II – proof of marketing of the medicinal product granted through the simplified procedure.

Article 24. The filing of the Product Change History (HMP, in Portuguese) related to the marketing authorization granted through the simplified procedure, when required for the primary parent application, must occur within 30 (thirty) days after the filing of the HMP of the primary parent application, regardless of the expiration date of the marketing authorization granted through the simplified procedure.

Sole paragraph. Failure to comply with the provisions established in the caption of this article shall result in cancellation of the marketing authorization granted through the simplified procedure.

CHAPTER VI

DELINKING

Article 25. Marketing authorization processes granted through the simplified procedure may be delinked from their respective parent processes and continue as independent processes in three situations:

I – When requested by the Public Partner holding the marketing authorization granted through the simplified procedure within the scope of the Productive Development Partnership (PDP);

II – When requested by the holder of the marketing authorization granted through the simplified procedure, after the conclusion of the technology transfer process for the production of medicinal products considered strategic by the Ministry of Health, involving public and private entities;

III – When requested by the holder of the marketing authorization granted through the simplified procedure, in cases where the renewal of the marketing authorization of the medicinal product of the primary parent application is denied for reasons unrelated to failures in efficacy, safety, and quality.

Paragraph 1. In the case of item II, the company holding the marketing authorization of the medicinal product granted through the simplified procedure, in addition to proving the completion of the technology transfer, must prove that the situation is not just a matter of licensing or authorization to use the marketing authorization dossier, but rather a process of technology absorption.

Paragraph 2. In the case of item III, the company holding the marketing authorization of the medicinal product granted through the simplified procedure must file a specific application subject in accordance with its regulatory category within 60 (sixty) days from the publication of the denial of the renewal of the marketing authorization of the parent medicinal product in the Federal Official Gazette (DOU, in Portuguese).

Paragraph 3. After the deadline established in Paragraph 1 of the caption of this article, failure to file the specific application in accordance with this Resolution shall result in the cancellation of the marketing authorization(s) of the simplified primary application(s) linked to the marketing authorization of the presentation(s) of the canceled primary application(s).

Article 26. The application for delinking must be accompanied by the following documents:

I – Duly completed Application Forms 1 and 2;

II – Proof of payment, or exemption, of the Health Surveillance Inspection Fee (TFVS, in Portuguese), through a specific Federal Collection Form (GRU, in Portuguese);

III – Copy of all documentation contained in the parent process, from the granting of the initial marketing authorization to the date of the filing of the request for delinking;

IV – Declaration of veracity of the information provided;

V – Declaration by the companies holding the marketing authorization granted through the simplified procedure and the parent company attesting that the copy of the marketing authorization documentation of the parent process was completely and faithfully delivered to the company holding the marketing authorization granted through the simplified procedure, in order to be part of the process that will be delinked.

Sole paragraph. The delinking must refer to all presentations of the simplified primary application.

Article 27. The process of marketing authorization granted through the simplified procedure shall continue as an independent process only after the publication of the approval of the request for delinking in the Federal Official Gazette.

Article 28. The company holding the marketing authorization granted through the simplified procedure must comply with the deadlines and the form of filing requests for post-marketing authorization changes provided for in this Resolution until the publication of the delinking.

Article 29. After the publication of the delinking, the company holding the marketing authorization of the delinked medicinal product is responsible for keeping the marketing authorization dossier updated in accordance with the regulations in force for the regulatory category of the product, except for the HMP, which shall follow the filing dates practiced prior to the delinking.

Paragraph 1. To allow the filing of post-marketing authorization changes of the marketing authorization granted through the simplified procedure, the link with the parent process shall be maintained for 30 (thirty) days after the delinking is granted.

Paragraph 2. The delinking shall not imply a change in the number of the process of the marketing authorization granted through the simplified procedure, nor shall it result in the granting of a new marketing authorization number for the presentations granted marketing authorization.

CHAPTER VII

FINAL AND TRANSITIONAL PROVISIONS

Article 30. Any adjustments to the marketing authorization process of the parent application required by Anvisa must be presented in the simplified application, in accordance with the deadline established for the parent application.

Article 31. To comply with this Resolution, companies holding marketing authorizations for all medicinal products approved through the simplified procedure must have knowledge of and full access to the complete and updated dossier of the parent medicinal product.

Article 32. At any time, Anvisa may request that the company holding the marketing authorization granted through the simplified procedure send the complete dossier or parts thereof, within 60 (sixty) days from receipt of the request.

Sole paragraph. Unjustified failure to comply with the request shall result in cancellation of the marketing authorization granted through the simplified procedure.

Article 33. Article 32 of this Resolution shall come into effect on 22 June 2025. **(New wording given by Anvisa Resolution no. 960 of 17 January 2025).**

Article 34. Administrative appeals may be filed in the simplified primary application, regardless of whether the same protocol exists in the primary parent application.

Article 35. Simplified primary applications filed before the effective date of this Resolution, including those under analysis, shall be assessed in accordance with the Resolutions in effect at the time of filing.

Article 36. Marketing authorizations of medicinal products already granted in accordance with RDC No. 31 of 29 May 2014, which do not fall within the scope of this Resolution, shall be maintained.

Paragraph 1. The company holding the marketing authorization must comply with the provisions of this Resolution to request post-marketing authorization changes and renewal of marketing authorization in the process linked to the primary parent application.

Paragraph 2. The company holding the marketing authorization may avail itself of the delinking only in the cases provided for in this Resolution.

Article 37. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, in accordance with Law No. 6,437 of 20 August 1977, without prejudice to applicable civil, administrative, and criminal liabilities.

Article 38. Collegiate Board Resolution – RDC No. 31 of 29 May 2014, published in the Federal Official Gazette No. 102 of 30 May 2014, Section 1, page 131, is hereby revoked; and

Article 39. Collegiate Board Resolution – RDC No. 43 of 19 September 2014, published in the Federal Official Gazette No. 182 of 22 September 2014, Section 1, page 41, is hereby revoked.

Article 40. This Resolution shall come into effect on 21 January 2025.

ANTONIO BARRA TORRES

Director-President

ANNEX I

DECLARATION OF LINK TO THE PARENT APPLICATION

"The Legal and Technical Representatives of the Companies [name of the company requesting marketing authorization of the medicinal product through the simplified procedure] and [name of the company holding the marketing authorization of the medicinal product that is the object of the primary parent application] hereby declare, for the purposes of exemption from analysis, in accordance with Collegiate Board Resolution – RDC No. 954 of 20 December 2024, that this request for marketing authorization or post-marketing authorization change regarding the subject [subject of the application through the simplified procedure] is linked to the process (or application, in the case of post-marketing authorization) no. [number of the process or parent application (in the case of post-marketing authorization) to which it is linked], regarding the subject [subject of the process or parent application (in the case of post-marketing authorization)].

I declare that the information in the package insert text of the aforementioned applications is the same, and it may differ only in terms of the legal statements of the marketing authorization holder and name of the medicinal product.

The Responsible Parties declare that they are aware that any change made to the marketing authorization of the parent process must also be made to the marketing authorization process(es) granted through the simplified procedure, incurring cancellation of the marketing authorization(s) linked to it, if the change is not petitioned within the period established in Collegiate Board Resolution – RDC No. 954 of 20 December 2024.

[signature]

Name of the Legal Representative of the Company – process/application of the simplified procedure (duly registered with Anvisa at the time of analysis or accompanied by a power of attorney)

CPF number of the Legal Representative

[signature]

Name of the Technical Manager – process/application of the simplified procedure (duly registered with Anvisa at the time of analysis or accompanied by a power of attorney)

CPF number of the Technical Manager

[signature]

Name of the Legal Representative of the Company – parent process/application (duly registered with Anvisa at the time of analysis or accompanied by a power of attorney)

CPF number of the Legal Representative

[signature]

Name of the Technical Manager – parent process/application (duly registered with Anvisa at the time of analysis or accompanied by a power of attorney)

CPF number of the Technical Manager

ANNEX II

DELINK DECLARATION OF THE MARKETING AUTHORIZATION PROCESS GRANTED THROUGH THE SIMPLIFIED PROCEDURE AND VERACITY OF THE INFORMATION PROVIDED

The Legal and Technical Representatives of the Companies [name of the company holding the marketing authorization granted through the simplified procedure] and [name of the parent company] undersigned declare that the Productive Development Partnership (PDP) will continue in accordance with the Term of Commitment [number and name of the document] signed between the parties involved, according to the approved schedule, and that they agree that the medicinal product marketing authorization processes may continue independently from this moment on.

They also declare, for the purposes of exemption from analysis, that the copy of the parent process [number of the parent process] was completely and accurately delivered to the company holding the marketing authorization granted through the simplified procedure, in order to be part of the process [number of the process of the marketing authorization granted through the simplified procedure] that will be delinked, under penalty of cancellation of the marketing authorization. Under these terms, Anvisa is also authorized to replicate in its computerized systems the aforementioned primary parent application, particularly the complete dossier, for the aforementioned marketing authorization process granted through the simplified procedure.

Or

The Legal and Technical Representatives of the Companies [name of the company holding the marketing authorization granted through the simplified procedure] and [name of the parent company] undersigned declare that the internalization and/or technology transfer process was finalized according to the Term of Commitment [number and name of the document] entered into between the parties involved, and may therefore continue as independent medicinal product marketing authorization processes.

They also declare, for the purposes of exemption from analysis, that the copy of the parent process [number of the parent process] was completely and faithfully delivered to the company holding the marketing authorization granted through the simplified procedure, in order to be part of the process [number of the process of the marketing authorization granted through the simplified procedure] that will be delinked, under penalty of cancellation of the marketing authorization. Under these terms, Anvisa is also authorized to replicate in its computerized systems the aforementioned primary parent application, particularly the complete dossier, for the aforementioned marketing authorization process granted through the simplified procedure.

Or

The Legal and Technical Representatives of the Companies [name of the company holding the marketing authorization granted through the simplified procedure] and [name of the parent company] undersigned declare that the documentation presented refers in its entirety to the documentation in Anvisa's possession regarding the process (primary parent application) to delink the process (primary simplified application) and may continue as independent medicinal product marketing authorization processes.

They also declare, for the purposes of exemption from analysis, that the copy of the parent process [number of the parent process] was completely and faithfully delivered to the company holding the marketing authorization granted through the simplified procedure, in order to be part of the process [number of the process of the marketing authorization granted through the simplified procedure] that will be delinked, under penalty of cancellation of the marketing authorization. Under these terms, Anvisa is also authorized to replicate in its computerized systems the aforementioned primary application, particularly the complete dossier, for the aforementioned marketing authorization process granted through the simplified procedure.

[signature]

Name of the Legal Representative of the Company – marketing authorization process granted through the simplified procedure (duly registered with Anvisa at the time of analysis or accompanied by a power of attorney)

CPF number of the Legal Representative

[signature]

Name of the Technical Manager – marketing authorization process granted through the simplified procedure (duly registered with Anvisa at the time of analysis or accompanied by a power of attorney)

CPF number of the Technical Manager

[signature]

Name of the Legal Representative of the Company – parent process (duly registered with Anvisa at the time of analysis or accompanied by a power of attorney)

CPF number of the Legal Representative

[signature]

Name of the Technical Manager – parent process (duly registered with Anvisa at the time of analysis or accompanied by a power of attorney)

CPF number of the Technical Manager.

SUBJECT CODES

11488 – DYNAMIZED – Medicinal Product Marketing Authorization Delink

11489 – SPECIFIC – Medicinal Product Marketing Authorization Delink

11490 – HERBAL MEDICINE – Medicinal Product Marketing Authorization Delink

11491 – GENERIC – Medicinal Product Marketing Authorization Delink

11492 – BIOLOGICAL PRODUCT – Medicinal Product Marketing Authorization Delink

11493 – SIMILAR – Medicinal Product Marketing Authorization Delink

11494 – TRADITIONAL HERBAL PRODUCT – Medicinal Product Marketing Authorization Delink