

COLLEGIATE BOARD RESOLUTION – RDC No. 625 OF 9 MARCH 2022

It provides for the minimum requirements regarding the obligation, on the part of companies that are holders of marketing authorization for medicinal products, of notification on the implementation of medicinal products recall action to the competent health authorities and consumers, in the event of sufficient evidence or proof of quality deviation representing risk, aggravation, or consequence to health, as well as in the event of cancellation of marketing authorization related to safety and efficacy.

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 15, item III, and Article 7, items III and IV of Law no. 9,782 of 26 January 1999, and Article 187, item VI, Paragraph 1 of the Internal Regulation approved by Collegiate Board Resolution – RDC no. 585 of 10 December 2021, adopts the following Collegiate Board Resolution, as decided upon in a meeting held on 9 March 2022, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective

Article 1. This Resolution establishes the minimum requirements regarding the obligation, on the part of companies that are holders of marketing authorization for medicinal products, of notification to the competent health authorities and consumers on the implementation of medicinal products recall action, in the event of sufficient evidence or proof of quality deviation representing risk, aggravation, or consequence to health, as well as in the event of cancellation of marketing authorization related to safety and efficacy.

Sole paragraph. The companies holding marketing authorization, as well as the other agents, from production to consumption, are jointly responsible for maintaining the quality, safety, and efficacy of the products until the final consumer, in order to avoid risks and adverse effects to health.

Section II

Definitions

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

I – prior consent of advertising message: procedure through which the marketing authorization holder submits the warning message addressed to consumers to the prior analysis by the Brazilian Health Regulatory Agency (Anvisa), by means of a specific form, informing the batch(es) of the medicinal product unsuitable for use, whatever are the forms and means for its dissemination;

II – health risk classification: determination of classes – I, II, and III – of risk qualification related to health to which a population is exposed after the use of the medicinal product with sufficient evidence or proof of quality deviation, or whose marketing authorization has been canceled due to absence of safety and efficacy, pursuant to the terms established in Article 3 of this Resolution;

III – notice of quality deviation/ marketing authorization cancellation: document that must be presented by the marketing authorization holders to Anvisa, as well as to their distribution chain, informing the reason for the deviation, the risk classification, the aggravation, or the consequence to health, among other information relevant to the quality deviation detected;

IV – quality deviation: divergence from the quality parameters established for a product;

V – receiving establishments: hospitals, clinics, drugstores, pharmacies, and other establishments provided for by law, which have medicinal products in stock;

VI – recall: action aimed at the immediate and effective withdrawal of specific batch(es) of medicinal product from the market, with sufficient evidence or proof of quality deviation, or due to cancellation of marketing authorization related to product safety and efficacy, to be implemented by the marketing authorization holder and distributors of the medicinal product involved in the recall action; and

VII – monitoring report on the recall of medicinal products: periodic document to be presented by the marketing authorization holder to Anvisa informing on the recall action progress, until its conclusion.

Section III

Health risk classes

Article 3. For the purposes of this Resolution, the following classes are established for the classification of health risk:

I – class I: situation in which there is a high probability that the use of or exposure to a medicinal product may cause health risk leading to death, threat to life, or permanent damage;

II – class II: situation in which there is a high probability that the use of or exposure to a medicinal product may cause a temporary health aggravation or a reversible aggravation through medicinal treatment; and

III – class III: situation in which there is a low probability that the use of or exposure to a medicinal product may cause adverse consequences to health.

CHAPTER II

RECALL

Section I

Voluntary recall

Article 4. The recall provided for in this Resolution shall be mandatorily implemented by the company holding the marketing authorization, in situations framed in classes I and II of the health risk classification, provided for in Article 3, items I and II of this Resolution, and implies in the immediate suspension of the commercialization of the respective batch(es) of the medicinal product and segregation of the stock in the company holding the marketing authorization, distributors, and receiving establishments.

Article 5. The medicinal product marketing authorization holder must inform Anvisa and the competent state, district, or municipal Health Surveillance body about sufficient evidence or proof of quality deviation, in situations framed in classes I and II of the health risk classification, provided for in Article 3, items I and II of this Resolution, and this procedure must be conducted in the following ways:

I – through electronic means, published on Anvisa website, immediately from the knowledge of sufficient evidence or proof of quality deviation or the publication of the marketing authorization cancellation due to the absence of safety and efficacy, informing the name of the product, marketing authorization number, presentation, batch number(s), manufacturing and expiration dates, manufactured or imported amount of the medicinal product(s) involved in the recall, and description of the type of deviation detected; and

II – by means of the appropriate form, submitted to Anvisa, within 48 (forty-eight) hours, from the awareness of sufficient evidence or proof of deviation or publication of the marketing authorization cancellation due to the absence of safety and efficacy.

Paragraph 1. The appropriate form referred to in item II of this article must include the following information:

I – corporate name and trade name, if any, of the marketing authorization holder, including its respective registration in the Brazilian Registry of Legal Entities (CNPJ);

II – full address of the marketing authorization holder, including district, Municipality, Federative Unit, and Zip Code;

III – name of the medicinal product, according to Anvisa marketing authorization, including its respective marketing authorization number, active ingredient, presentation, batch number(s) involved in the recall, in addition to the respective manufacturing and expiration dates;

IV – medicinal product manufacturing location;

V – date of awareness of sufficient evidence or proof of quality deviation, or publication of marketing authorization cancellation;

VI – health risk classification, pursuant to Article 3 of this Resolution, in addition to a detailed description of the evidence or quality deviations observed;

VII – manufactured or imported amount of each batch, if there is more than one, of the recall medicinal product;

VIII – number of units distributed by the marketing authorization holder in each Federative Unit, including the corporate names and respective registrations in the CNPJ of each distributor; and

IX – name of the Technical Responsible officer of the company holding the marketing authorization, in addition to telephone number and e-mail address.

Paragraph 2. The medicinal product marketing authorization holder must send to Anvisa, together with the form referred to in item II of the caption and in Paragraph 1 of this article, the respective proof of information that it has effectively communicated all companies involved in the distribution chain, through the same form referred to in this article.

Paragraph 3. Anvisa may, at any time, request additional or complementary information regarding the medicinal product recall action.

Section II

Recall determined by Anvisa

Article 6. Anvisa may, at any time, regardless of the initiative of the marketing authorization holder, in situations representing an imminent health risk to consumers, determine the recall of a certain medicinal product with sufficient evidence or proof of quality deviation, regardless of the health risk classification established in Article 3 of this Resolution.

Paragraph 1. Anvisa may delegate to the States and the Federal District the determination of the recall provided for in the caption of this Article, as well as the monitoring of the procedures adopted.

Paragraph 2. The provisions set forth in Section I, Voluntary Recall, of this Resolution, are applicable to cases of recall determined by Anvisa.

CHAPTER III

WARNING MESSAGE TO CONSUMERS

Article 7. The marketing authorization holder must send a warning message to consumers informing them of the danger or harmfulness of the medicinal product batch(es) placed on the market, in the cases defined in classes I and II of the health risk classification established in Article 3 of this Resolution.

Sole paragraph. The warning message referred to in the caption of this article must be conveyed in an understandable way to consumers, describing the type of deviation and the inherent risks.

Article 8. The proposal for a warning message to consumers must be submitted to Anvisa's prior consent, within 72 (seventy-two) hours from the awareness of sufficient evidence or proof of deviation, as established in Article 41-B of Law No. 9,782 of 26 January 1999, and other criteria for consent available on Anvisa website.

Paragraph 1. The proposal for a warning message to consumers submitted to Anvisa's prior consent must include the following information:

I – corporate name and trade name, if any, of the marketing authorization holder, including its respective CNPJ registration number;

II – full address of the marketing authorization holder, including district, Municipality, Federative Unit, and Zip Code;

III – name of the medicinal product according to the marketing authorization with Anvisa, including its respective marketing authorization number, active ingredient, presentation, number(s) of the batch(es) involved in the recall, in addition to the respective manufacturing and expiration dates;

IV – warning message to be conveyed and period of its advertising;

V – specification of the communication means to be used by the marketing authorization holder;

VI – contact information for the marketing authorization holder so that consumers can clarify their doubts, such as telephone number, e-mail address, among others; and

VII – name of the Technical Responsible officer and Legal Representative of the company holding the marketing authorization.

Paragraph 2. The company holding the marketing authorization must convey the warning message to consumers within the deadline and under the conditions previously established by the health authority, so that it effectively reaches the product distribution areas.

Paragraph 3. After the filing by the marketing authorization holder of the proposal for a warning message to consumers, Anvisa has a period of up to 48 (forty-eight) hours to consent or inform the necessary corrections.

Paragraph 4. After Anvisa's consent, the marketing authorization holder must immediately promote the dissemination of the warning message to the population.

Article 9. Anvisa shall determine, when it deems necessary, the dissemination of a warning message to the population in cases of marketing authorization cancellation of a medicinal product that is being marketed and used, when related to absence of safety and efficacy.

CHAPTER IV

RECALL MONITORING

Section I

Responsibilities of distributors and receiving establishments

Article 10. The distributor must send to the marketing authorization holder the distribution map for the medicinal product to be recalled and the following information:

I – corporate name and trade name, if any, of the distributor, including its respective state and CNPJ registration number;

II – full address of the distributor, including district, Municipality, Federative Unit, and Zip Code;

III – name of the distributor's Technical Responsible and registration number with the Professional Class Council;

IV – name of the medicinal product according to the marketing authorization with Anvisa, including its respective marketing authorization number, active ingredient, presentation, number(s) of the batch(es) involved in the recall, and number of the Invoice issued by the marketing authorization holder;

V – amount purchased by the distributor of the medicinal product classified in item IV of this article, as well as the remaining amount in its respective stock;

VI – amount distributed to each establishment receiving the medicinal product classified in item IV of this article, as well as the remaining amount in their respective stocks; and

VII – signatures of the distributor's Technical Responsible officer and Legal Representative.

Article 11. The distributor must send the information provided for in Article 10 within a period of up to 48 (forty-eight) hours from the receipt of the notice, and this procedure may be carried out through electronic means.

Article 12. It is up to the distributor to inform its receivers about the recall, requesting from the receiving establishments the amount in stock, to complete the information to be passed on to the marketing authorization holder provided for in Article 10.

Article 13. It is up to the receiving and distributing establishments to adopt and enable measures ensuring, to the marketing authorization holder, compliance with the deadlines established in this Resolution for the recall of the respective batch(es) of the medicinal product.

Section II

Recall monitoring reports

Article 14. The marketing authorization holder must periodically submit to Anvisa the recall monitoring reports.

Paragraph 1. The monitoring reports must necessarily include, without prejudice to other information considered by the marketing authorization holder as relevant, the following information:

I – corporate name and trade name, if any, of the marketing authorization holder, including the respective CNPJ registration number;

II – full address of the marketing authorization holder, including district, Municipality, Federative Unit, and Zip Code;

III – name of the medicinal product according to the marketing authorization with Anvisa, including its respective marketing authorization number, active ingredient, presentation, number(s) of the batch(es) involved in the recall, in addition to the respective manufacturing and expiration dates;

IV – manufactured or imported amount of each batch, if there is more than one, of the recall medicinal product;

V – amount of each batch distributed, if there is more than one;

VI –health risk classification, pursuant to Article 3 of this Resolution;

VII – quantity of units of each batch recalled in the period, if there is more than one;

VIII – number of units recalled from each batch per Federative Unit, if there is more than one;

IX – number of units recalled as a percentage related to the total batch introduced on the market at state level;

X – number of units recalled as a percentage related to the total batch introduced on the market at national level; and

XI – number of units recalled as a percentage related to the total batch introduced on the market at international level, when applicable.

Paragraph 2. The first monitoring report of the recall must be sent to Anvisa within 30 (thirty) days from the notice provided for in Article 5 of this Resolution, and the subsequent ones also within equal periods.

Section III

Conclusive recall reports

Article 15. The marketing authorization holder must submit a conclusive recall report to Anvisa, within a maximum period of 60 (sixty) days, for situations fitting in class I of the health risk classification, and 120 (one hundred and twenty) days for class II, counting from the notice provided for in Article 5 of this Resolution.

Paragraph 1. The conclusive recall report must necessarily include, without prejudice to other information considered by the marketing authorization holder as relevant, the following information:

I – corporate name and trade name, if any, of the marketing authorization holder, including the respective CNPJ registration number;

II – full address of the marketing authorization holder, including district, Municipality, Federative Unit, and Zip Code;

III – name of the medicinal product according to the marketing authorization with Anvisa, including its respective marketing authorization number, active ingredient, presentation, number(s) of the batch(es) involved in the recall, in addition to the respective manufacturing and expiration dates;

IV – manufactured or imported amount of each batch, if there is more than one, of the recall medicinal product;

- V – amount of each batch distributed, if there is more than one;
 - VI – amount of each batch recalled, if there is more than one;
 - VII – health risk classification, pursuant to Article 3 of this Resolution;
 - VIII – date of communication to Anvisa regarding the recall;
 - IX – date of final submission of the final recall report;
 - X – number of units recalled from each batch, if there is more than one, per Federative Unit;
 - XI – number of units recalled as a percentage related to the total batch introduced on the market at state level;
 - XII – number of units recalled as a percentage related to the total batch introduced on the market at national level;
 - XIII – number of units recalled as a percentage related to the total batch introduced on the market at international level, when applicable;
 - XIV – number of units recalled by each foreign country, when applicable;
 - XV – date of the conclusive recall report;
 - XVI – investigative and corrective measures implemented by the marketing authorization holder, when applicable.
- Paragraph 2. Anvisa may request the submission of monitoring reports, as well as the conclusive recall report, in a frequency lower than that stipulated in Paragraph 2 of Article 14 and in the caption of this article, respectively.

Section IV

Recalled medicinal product destruction

Article 16. The marketing authorization holder is responsible for the destruction of recalled medicinal products, in compliance with the regulations in force on waste disposal.

Sole paragraph. The destruction referred to in the caption of this article must be communicated to the local health authority, without the need for prior authorization, and the respective documentation must be filed at the establishment.

CHAPTER V

FINAL PROVISIONS

Article 17. The list of medicinal products in recall processes shall be made available by Anvisa on its website.

Article 18. Omitted cases or cases not provided for in this Resolution shall be analyzed by Anvisa.

Article 19. Failure to comply with the provisions included 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 20. Collegiate Board Resolution – RDC No. 55 of 17 March 2005, published in the Federal Official Gazette No. 54 of 21 March 2005, Section 1, page 82, is hereby revoked.

Article 21. This Resolution shall enter into force on 1 April 2022.

ANTONIO BARRA TORRES