COLLEGIATE BOARD RESOLUTION – RDC No. 894 OF 27 AUGUST 2024

Provides for the Good Cosmetovigilance Practices for companies holding regularization of cosmetic products with the Brazilian Health Regulatory Agency (Anvisa).

The Collegiate Board of Directors of the Brazilian Health Regulatory Agency, in the use of the attributions vested in it under Article 7, item III, and Article 15, item III 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 Collegiate Board Resolution, as decided upon in a meeting held on 22 August 2024, and I, Director-President, determine its publication.

CHAPTER I

INITIAL PROVISIONS

Section I

Objective and Scope

Article 1. This Resolution establishes the Good Cosmetovigilance Practices for companies holding the regularization of cosmetic products with the Brazilian Health Regulatory Agency (Anvisa).

Paragraph 1. Good Cosmetic Surveillance Practices encompass a set of minimum requirements and activities necessary to ensure the implementation, organization, operation, and maintenance of Cosmetovigilance Systems to be complied with by companies holding regularization of cosmetic products.

Paragraph 2. The term "cosmetic product(s)" in this Resolution encompasses personal hygiene products, cosmetics, and perfumes, excluding products intended for non-human use.

Section II

Definitions

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

I – Corrective action: action planned and implemented with the objective of eliminating the cause(s) of an identified non-conformity or any other undesirable situation that may compromise consumer safety in the use of cosmetic products;

II – Communication action: set of measures adopted by the company with the purpose of informing consumers and the general public about the safety of the cosmetic products they market, when risks to the consumer's health are identified. These measures may include the publication of safety alerts, advertising campaigns, dissemination on social media, press releases, and information on the company's communication channels;

III – Preventive action: planned and implemented proactive action aimed at eliminating or reducing the likelihood of possible non-conformities or other undesirable situations that may compromise consumer safety in the use of cosmetic products;

IV – Safety alert: communication directed at professionals, consumers, or the community in general, intended to inform about the risk of an imminent or potential serious adverse event related to the use of or exposure to a cosmetic product;

V – Causality analysis: systematic and careful process that aims to determine the probability of a causal relationship between a specific cosmetic product and one or more reported adverse events. This analysis is carried out individually for each report and considers several factors, such as temporality, biological plausibility, and the presence of other possible contributing factors. The result of this analysis, considering all the information available in the report, may result in a general conclusion for the case in terms of levels of probability of the causal relationship;

VI – Master File of the Cosmetovigilance System: document that describes and specifies, in detail, the entire Cosmetovigilance System of a company, such as procedures, policies, responsibilities, workflows, resources, and applicable regulatory requirements;

VII – Cosmetovigilance Audit: systematic, disciplined, independent, and documented process based on the analysis of evidence with the objective of verifying compliance with Good Cosmetovigilance Practices by a company, with a view to identifying opportunities for improvement;

VIII – Health authority: competent authority for the exercise of public health duties, with the prerogative of applying health legislation. The following are health authorities: Anvisa and health surveillance entities/agencies of the States, Federal District, and Municipalities;

IX – Database: structured set of data and information regarding reports of adverse events related to cosmetic products, which are evaluated, coded, and stored. It serves as a repository of information on adverse events, including details on the cosmetic product involved, description of the adverse events, reporter details, and other relevant information;

X – Causality: relationship between the use of or exposure to a cosmetic product and the subsequent emergence of an adverse event;

XI – Communication: act of informing, quickly and through an official communication channel, the health authority about any problem related to cosmetic products that, due to its severity, urgency, or potential risk to public health, may require the immediate adoption of corrective or preventive actions;

XII – Consumer: any individual who uses a cosmetic product or who has been exposed to such product, whether occupationally or not. The term "consumer" includes both direct users of cosmetic products, as well as other people exposed to the products, such as health professionals, beauticians, and individuals who may have indirect contact with the product;

XIII – Cosmetovigilance: includes activities related to the identification, notification, evaluation, investigation, monitoring, communication, and prevention of adverse reactions resulting from the use of cosmetic products under normal or reasonably foreseeable conditions. The ineffectiveness of cosmetic products, their misuse, exogenous poisoning, occupational exposure, and technical complaints that resulted in harm to the health of the consumer are also adverse events of interest to Cosmetovigilance. Cosmetovigilance is the term used to designate the post-marketing/post-use surveillance and monitoring of cosmetic products regulated in Brazil;

XIV – Company Holding the Regularization of Cosmetic Products (or Company): refers to the legal entity responsible for regularizing the cosmetic product with the competent health authority, which is responsible for administrative, civil, and criminal liability;

XV – Efficacy: the ability of a cosmetic product to achieve the expected results in terms of benefits attributed to the product on the label;

XVI – Adverse event: any undesirable or unexpected experience that is harmful to health that occurs after the use of or exposure to a cosmetic product and that does not necessarily have a cause-and-effect relationship;

XVII – Serious adverse event: an adverse event is considered serious when it results in one or more of the following outcomes: a) death: when there is suspicion that the adverse event contributed to the death of the individual; b) risk to life: when there is suspicion that the adverse event has placed the individual at substantial risk of death at the time of the occurrence; c) hospitalization (initial or prolonged): when there is suspicion that the adverse event has led the individual to hospitalization or prolonged hospitalization; d) permanent or significant disability or damage: when there is suspicion that the adverse event has resulted in a substantial interruption in the individual's ability to perform normal functions of daily living, resulting in a significant, persistent, or permanent change in the individual's body function/structure, physical activities, and/or quality of life; e) congenital anomaly/defect: when there is suspicion that exposure to a cosmetic product before conception or during pregnancy may have resulted in an adverse event in the child's development or health; and f) other clinically significant events: when the clinical condition resulting from the adverse event does not fit into the previous outcomes, but represents a threat to the individual's health, and may require medical care or surgical intervention;

XVIII – Non-serious adverse event: any adverse event that does not qualify as serious, but is important for monitoring and transparency purposes, and may include manifestations such as mild signs and symptoms, temporary discomfort, low-intensity adverse reactions, among other similar occurrences;

XIX – Occupational exposure to cosmetic product: exposure to a cosmetic product that occurs as a direct result of professional activity from its handling to application;

XX – Safety signal management: set of systematic and continuous activities that involve the identification, validation, confirmation, analysis, prioritization, evaluation, communication, and adoption of actions in the face of a safety signal related to cosmetic products;

XXI – Ineffectiveness: inability of a cosmetic product to achieve the expected results in terms of benefits attributed to the product on the label;

XXII – Cosmetovigilance Inspection: inspection action conducted by health authorities to verify and evaluate compliance with the Good Cosmetovigilance Practices established in this

Resolution by companies. This type of health inspection consists of document analysis, interviews, visits to the company's facilities, database reviews, among other activities;

XXIII – Instructions for use: set of information provided by the company to guide the consumer on the intended purpose and proper use of the cosmetic product, including details on relevant warnings and precautions;

XXIV – Exogenous poisoning: refers to harmful effects on health resulting from intentional or unintentional exposure to cosmetic products, as a result of the unpredictable use of these products, including accidental ingestion, application to inappropriate areas of the body, simultaneous use with incompatible products or substances, and use contraindicated for a specific health condition;

XXV – Investigation of adverse events: process of collecting accurate and comprehensive information on serious adverse events and non-serious adverse events of interest, including the circumstances involved, aiming to conclusively or exploratorily identify the causes that contributed to the occurrence of the adverse events in question;

XXVI – Non-compliance: refers to non-compliance with provisions provided for in health legislation;

XXVII – Notification: act of informing health authorities, through official notification channels, of any suspected serious adverse event related to the use of or exposure to a cosmetic product;

XXVIII – Standard operating procedure: written document containing detailed information to ensure uniformity in the execution of a specific Cosmetovigilance activity;

XXIX – Cosmetic product: encompasses products of interest to Cosmetovigilance, which are: personal hygiene products, cosmetics, and perfumes. The definition of each of these products can be found in specific health legislation;

XXX - Technical complaint: any suspected change, irregularity, or deviation related to technical, quality, or legal aspects of a cosmetic product or company. When the technical complaint results in harm to human health, it is considered an adverse event of interest to Cosmetovigilance;

XXXI – Adverse reaction: refers to a harmful reaction to human health that occurs as a result of the normal or reasonably foreseeable use of a cosmetic product;

XXXII – Benefit-risk ratio: assessment of the beneficial effects of a cosmetic product in relation to the risks associated with its use. The benefit-risk ratio considers the expected or desired benefits of the cosmetic product, such as aesthetic improvement, hydration, and sun protection, among others, compared to the potential risks that may arise from its use;

XXXIII – Report: refers to the communication of any adverse event to human health related to the use of or exposure to a cosmetic product to the company. This report may be made by consumers, health professionals, or other interested parties;

XXXIV – Reporter: person who contacts the company to report suspected adverse events related to the use of or exposure to a cosmetic product, which may be the consumer or third parties;

XXXV – Safety signal: refers to the emergence of new information that may modify the safety assessment of a cosmetic product or require further investigation. A signal generally arises from an unexpected change in a pre-existing level of reporting rates of adverse events related to the product. Validation of an identified safety signal may lead to appropriate measures being taken,

such as in-depth investigations, communication to health authorities, and corrective and communication actions, aiming to protect consumer health and public health;

XXXVI – Cosmetovigilance System: system adopted by a company to comply with legal obligations regarding Cosmetovigilance. This System is designed to monitor, investigate, and evaluate the safety of its cosmetic products regulated in Brazil, identifying and recording adverse events, as well as detecting any change in the benefit-risk ratio of the products. It covers the collection, analysis, investigation, evaluation, communication, and management of information on adverse events related to cosmetic products, aiming at consumer safety and compliance with applicable regulations;

XXXVII – Improper use: refers to the intentional use of a cosmetic product in disagreement with its intended use and with the instructions and warnings provided by the company.

CHAPTER II

COMPANY'S COSMETOVIGILANCE SYSTEM

Section I

General provisions

Article 3. The company must have a Cosmetovigilance System that allows it to fulfill its responsibilities regarding the safety of the products it commercializes and ensure the adoption of timely measures, when necessary.

Sole paragraph. The companies' Cosmetovigilance Systems are part of the Cosmetovigilance activities carried out, on a permanent and continuous basis, by the health authorities.

Article 4. The company's Cosmetovigilance System must be located in Brazilian territory.

Sole paragraph. The company is allowed to have the requirements and activities of the Cosmetovigilance System developed in other countries by companies of the same business group or by contracted third parties, provided that this outsourcing does not compromise the operational capacity to identify and monitor problems related to the safety of its cosmetic products that occur in Brazlian territory, in compliance with the provisions of Article 18 of this Resolution.

Section II

Objectives of the Cosmetovigilance System

Article 5. The objectives of the companies' Cosmetovigilance System are:

I – To comply with the legal obligations related to Cosmetovigilance;

II – To prevent harm to human health resulting from adverse events associated with the use of cosmetic products regulated under the terms provided for in Brazilian health legislation, including those resulting from occupational exposure;

III – To promote the safe and effective use of cosmetic products; and

IV – To contribute to the protection of consumers and public health.

Sole paragraph. The company must adopt appropriate measures to achieve the objectives established in this article.

Section III

Requirements for the implementation, organization, operation, and maintenance of the Cosmetovigilance System

Article 6. The minimum mandatory requirements for the implementation, organization, operation, and maintenance of a Cosmetovigilance System in a company are:

I – To have a form or other similar instrument that allows the collection of data and information on adverse events related to cosmetic products;

II – Establish and maintain a database to record and store data and information on adverse events related to cosmetic products;

III – Implement procedures for managing safety signals;

IV – Designate and have a qualified professional responsible for the Cosmetovigilance System, as well as his/her substitute, when necessary;

V – Maintain a master file of the Cosmetovigilance System; and

VI – Implement communication actions.

Subsection I

Form or other similar instruments for collecting data and information on adverse events to cosmetic products

Article 7. The company must have a form or other similar instrument that allows the collection of data and information on adverse events related to its cosmetic products.

Paragraph 1. The company must establish and maintain a direct and easily accessible communication channel with consumers to receive and respond to reports of adverse events related to its cosmetic products.

Paragraph 2. The service data provided for in letter "c" of item II of Article 13 of Collegiate Board Resolution – RDC No. 752 of 19 September 2022 must include the communication channel referred to in Paragraph 1 of this article.

Article 8. The form or other similar instrument for collecting data and information on adverse events to cosmetic products must contain at least the following data:

I – Identification of the consumer (name or initials; gender; age or date of birth);

II – Description of the adverse event(s) (signs and symptoms that motivated the report, including the [approximate] onset date of the signs and symptoms and whether the adverse event(s) resulted in medical/dental care);

III – Identification of the suspected cosmetic product (trade name, product regularization number at Anvisa, expiration date, and batch number);

IV – (Approximate) date of use of the suspected cosmetic product;

V – Identification of the company responsible for the regularization of the cosmetic product (name and CNPJ [Brazilian Record of Legal Entities]); and

VI – Identification of the reporter (name and contact information: e-mail and/or telephone).

Paragraph 1. The data and information collected must be treated with secrecy and confidentiality by the company.

Paragraph 2. The disclosure of personal data collected in adverse event reports by the company must only be done with the express consent of the person concerned, in compliance with the data protection legislation in force.

Subsection II

Database for recording and storing data and information on adverse events

Article 9. The company must have a database for recording and storing reports of adverse events related to its products, including its use for reviewing the benefit-risk relationship of the products.

Paragraph 1. The database must be structured in such a way as to ensure the integrity, confidentiality, and availability of the information, in accordance with the data protection legislation in force.

Paragraph 2. The reports referred to in the caption of this article must be traceable and kept secure under the responsibility of the company for at least 5 (five) years (counting from the date the report is received by the company), even after the cancellation and/or expiration of the authorization to regularize the product in the country.

Article 10. The company must implement procedures and controls to ensure the correct maintenance, updating, and integrity of the data and information stored in the database, including periodic review of the data, identification of inconsistent or incomplete information and adoption of measures to correct or update the data and information.

Subsection III

Procedures for the management of safety signals

Article 11. The company must have documented procedures for the management of safety signals.

Paragraph 1. The procedures referred to in the caption of this article must clearly and precisely describe all the steps from the identification of the possible safety signal to, when necessary, its communication to the competent health authorities.

Paragraph 2. The company must establish a formal process for the periodic review and updating of safety signal management procedures, ensuring that they are aligned with best practices in Cosmetovigilance and in compliance with alterations in current regulations.

Article 12. In cases where safety signals imply situations of risk to the health of the consumer, the company must take rapid and effective measures to reduce and mitigate the risks, even before more in-depth analyses are completed.

Article 13. The communication of safety signals by the company to the health authorities must be proportional to the severity and potential risk of the signal being identified and must not exceed 15 (fifteen) business days.

Article 14. The company must adopt measures to monitor the effectiveness of the actions taken in response to safety signals, in order to assess their adequacy and make any adjustments when necessary.

Article 15. The company must keep records of all actions related to the management of safety signals, including the measures adopted, the dates of implementation and the results obtained for the purposes of health inspections and audits for up to 5 (five) years.

Article 16. The company must establish a system for continuous monitoring of safety signals, including regular analysis of data and information from reports of adverse events.

Subsection IV

Professional responsible for Cosmetovigilance

Article 17. The company must provide the appropriate means for the professional responsible for Cosmetovigilance to perform his/her duties for the development of Cosmetovigilance activities.

Article 18. The professional responsible for Cosmetovigilance of each company must:

I – Be responsible for the Cosmetovigilance System; and

II – Reside in Brazilian territory and be available whenever necessary.

Article 19. The professional responsible for Cosmetovigilance in each company must have sufficient authority and autonomy to:

I – Implement changes in the Cosmetovigilance System, aiming to promote, maintain, and improve compliance with regulatory requirements;

II – Respond, within a maximum period of 10 (ten) business days, which may be extended for the same period upon request and justification, to any request for information from health authorities on the safety of cosmetic products under the company's responsibility;

III – Notify or ensure notification of serious adverse events of cosmetic products commercialized in Brazil (manufactured locally or imported) to the health authority; and

IV – Collaborate with health authorities in the investigation and assessment of cosmetic product safety issues.

Article 20. The professional responsible for Cosmetovigilance must have appropriate training for the role (technical or higher level).

Paragraph 1. The company must designate an official replacement for the professional responsible for Cosmetovigilance in cases of absence or unavailability.

Paragraph 2. The replacement professional must have similar qualifications and be available to assume responsibilities temporarily.

Article 21. The teams involved in Cosmetovigilance activities must receive adequate training to correctly perform their functions and responsibilities.

Sole paragraph. The training records must be kept by the company for the purposes of health inspections and audits for up to 5 (five) years.

Subsection V

Cosmetovigilance System master file

Article 22. The company must have a document that describes and specifies, in detail, the entire Cosmetovigilance System, containing information regarding its organizational structure, interfaces, work processes and procedures, responsibilities, and activities related to risk management, including its operation and performance evaluation and records of health inspections and audits.

Article 23. The company must perform regular reviews of the Cosmetovigilance System master file to ensure that the information is up to date and faithfully reflects the current status of the System.

Sole paragraph. The reviews referred to in the caption of this article must be documented, including the date of the review, the alterations made (if any) and the justification for the alterations.

Article 24. The Cosmetovigilance System master file must contain a management procedure for dealing with crisis situations, emergencies, or serious problems related to the safety of cosmetic products.

Article 25. The Cosmetovigilance System master file must contain a training plan for employees involved in Cosmetovigilance activities, including employees of partner and outsourced companies.

Sole paragraph. The training plan must address the technical and legal aspects of Cosmetovigilance, as well as individual responsibilities in relation to the System.

Article 26. The Cosmetovigilance System master file must contain a detailed description of the procedures for communication with health authorities, including deadlines and formats for sending required information.

Article 27. The Cosmetovigilance System master file must reference the document that addresses data protection and the confidentiality of information related to adverse events.

Article 28. The Cosmetovigilance System master file must be kept in a safe and easily accessible location for employees involved in Cosmetovigilance activities and be available for health inspections and audits.

Subsection VI

Implementation of communication actions

Article 29. The company must implement communication actions to inform consumers and the general public about the safety of the cosmetic products they sell, whenever situations of risk to the consumer's health are identified.

Paragraph 1. Communication actions must include raising awareness of the importance of reporting adverse events to the company.

Paragraph 2. The company must monitor the effectiveness of communication actions through specific performance indicators, including the number of reports received and the volume of products placed on the market and their trends.

Paragraph 3. The company must keep records of all communication actions carried out, including the date, the content disclosed, the channels used, and the results achieved, for the purposes of health inspections and audits for up to 5 (five) years.

Paragraph 4. In crisis or emergency situations, the company must adopt measures to ensure prompt and accurate communication with consumers, including the dissemination of safety alerts and recommendations for the safe use of products until the problem is duly clarified.

Article 30. The company's communication channel, referred to in Paragraph 1 of Article 7, may be designated to receive and respond to consumers' questions and concerns about the risks and serious adverse events related to its cosmetic products.

Article 31. The company may also promote, at its discretion, educational campaigns on the importance of Cosmetovigilance and the need for consumers to report adverse events.

Section IV

Management of reports on adverse events to cosmetic products

Article 32. The company must record in its database reports of individual cases of adverse events related to the use of or exposure to cosmetic products, even if unconfirmed, relating to:

I – Adverse reaction;

II – Total or partial ineffectiveness;

III – Interactions between cosmetic products and other products;

IV – Exogenous poisoning;

V – Improper use;

VI – Technical complaint; and

VII – Other situations relevant to Cosmetovigilance.

Article 33. The company must notify the health authority of all serious adverse events related to the use of or exposure to cosmetic products that occur in Brazilian territory, reported spontaneously or upon request.

Paragraph 1. The notification of serious adverse events must be made to the health authority within a maximum period of 20 (twenty) calendar days, counted from the date of knowledge of the event.

Paragraph 2. Failure to comply with the deadline established in Paragraph 1 does not exempt the company from the obligation to subsequently send the notification to the health authority.

Article 34. For the notification of serious adverse events to be considered valid and reportable to the health authority, it must contain as much information as possible, including at least the following data:

I – Identification of the consumer (name or initials, sex, age or date of birth);

II – Description of the adverse event(s);

III – Identification of the suspected cosmetic product (name of the product and regularization number); and

IV – Time interval, which may be approximate, between the use of the suspected cosmetic product and the onset of signs and symptoms.

Paragraph 1. The absence of any of this information on serious adverse events makes the initial report incomplete, requiring the company to actively search for the missing data.

Paragraph 2. Information received after the initial notification of the case must be provided within the maximum period established in Paragraph 1 of Article 33.

Article 35. In exceptional cases, in which the notification of serious adverse events involves circumstances that result in missing or non-retrievable data, the submission of the notification to the health authority will not be invalidated.

Sole paragraph. In the cases addressed in the caption of this article, the company must provide the maximum available details about the product, the adverse event and any other relevant information that may facilitate the assessment by the health authority.

Article 36. The company must keep updated records of the actions taken in response to reports of serious adverse events, including the corrective and preventive actions implemented.

Sole paragraph. The records must be available to the health authorities, upon request, for up to 5 (five) years.

Article 37. Companies are authorized to notify the health authority of non-serious adverse events related to the use of or exposure to cosmetic products.

Paragraph 1. Companies must keep internal records of non-serious adverse events related to their products for a minimum period of 5 (five) years from the date the event was discovered.

Paragraph 2. The company must keep non-serious adverse events in its database, which must be available for continuous analysis and monitoring.

Paragraph 3. The company must provide access to internal records of non-serious adverse events to health authorities, upon request.

Article 38. The company must follow the rules set forth in current data protection legislation to ensure the confidentiality, secrecy, and privacy of the people involved in reporting adverse events.

Subsection I

Causality analysis of serious adverse events to cosmetic products

Article 39. The causality analysis of reports of serious adverse events to cosmetic products made to the company must consider as much information as possible, covering at least the following criteria:

I – Temporality, which may be approximate, between the use of the cosmetic product and the onset of the adverse event;

II – Individual characteristics of the consumer, such as age, sex, medical history, and health conditions;

III – Characteristics of the adverse events reported; and

IV – Characteristics of the cosmetic product, including ingredients, formulation, and method of use.

Paragraph 1. Any alteration in health occurring in the first 30 (thirty) days after the use of or exposure to a cosmetic product must be considered a suspected consequence of the use of or exposure to the product.

Paragraph 2. Adverse events occurring after 30 (thirty) days do not automatically exclude a possible causal relationship.

Article 40. The causality analysis may result in one of the following conclusions:

I – Very likely, when there is a high probability that the cosmetic product is the cause of the adverse event, based on available evidence and information;

II – Probable, when there is a reasonable probability that the cosmetic product is related to the adverse event, but other factors may also be involved;

III – Not clearly attributable, when it is not possible to establish a causal relationship due to lack of sufficient information or evidence;

IV – Unlikely, when there is no evidence to support a causal relationship between the cosmetic product and the adverse event; and

V – Exclusionary, when it is proven, based on available evidence and information, that the cosmetic product is not related to the adverse event.

Paragraph 1. After receiving the report of a serious adverse event to a cosmetic product, the company must perform the causality analysis diligently and in a timely manner.

Paragraph 2. During the causality analysis period, the company must adopt the necessary measures to ensure consumer safety, including, where applicable, the temporary suspension of the commercialization of the cosmetic product in question.

Paragraph 3. The causal relationship established may be reviewed periodically based on new evidence or information available.

Article 41. All causality analyses of reports of serious adverse events must be duly documented and substantiated, including the evidence and information used to conclude the analyses.

Sole paragraph. The results of the causality analyses of reports of serious adverse events must be duly recorded and included in the company's database, in order to guarantee transparency and accessibility of the information by health authorities.

Section V

Other responsibilities of the company

Article 42. The company must have written standard operating procedures covering all Cosmetovigilance activities, including the flow of capturing individual cases of serious adverse events, their analysis and investigation, notification to the health authority, adoption of preventive, corrective and communication actions, until the conclusion and archiving of the case.

Paragraph 1. The standard operating procedures must be updated in accordance with technical-scientific information and current legislation, and a historical file with their updates must be maintained.

Paragraph 2. The standard operating procedures must be reviewed and approved in accordance with the quality management processes defined by the company, ensuring that the professional responsible for Cosmetovigilance can guarantee their implementation.

Paragraph 3. The standard operating procedures must be part of the qualification and training process of professionals directly involved in the Cosmetovigilance System.

Article 43. The company must present any and all information on Cosmetovigilance within the deadline defined by the health authority.

Paragraph 1. If the company is unable to submit the information within the established deadline, a request for an extension of the deadline accompanied by justification must be submitted in a timely manner.

Paragraph 2. Partial data may be submitted within the deadline established by the health authority, with justification and a plan for submitting all the requested information.

Article 44. The company must carry out an assessment of the benefit-risk relationship of its cosmetic products regularized by Anvisa that present potential risks to the health of the consumer.

Sole paragraph. In cases where the assessment of the benefit-risk relationship identifies new information that may negatively influence the overall assessment of the benefit-risk relationship of the cosmetic product, the company must communicate these findings to the health authority within 15 (fifteen) business days.

Article 45. The company must ensure a physical and/or digital archiving system that allows for the proper preservation of all documentation related to the responsibilities and activities of Cosmetovigilance.

Article 46. The company may transfer the execution of Cosmetovigilance requirements and activities described in this Resolution to third parties.

Paragraph 1. The person responsible for Cosmetovigilance and his/her substitute may not be outsourced.

Paragraph 2. In cases of outsourcing of Cosmetovigilance requirements and activities, the contracting company is jointly and severally liable for the legal and health obligations related to its products.

Paragraph 3. The contracting company must provide the appropriate means to ensure that the outsourced company complies with all the health requirements set forth in this Resolution.

Paragraph 4. In cases of outsourcing Cosmetovigilance requirements and activities, there must be clear and descriptive contractual documentation defining the specific responsibilities and duties of those involved in each Cosmetovigilance requirement and activity, and subcontracting is prohibited.

Paragraph 5. The execution of Cosmetovigilance requirements and activities between companies in the same group, for the purposes of this Resolution, is not considered outsourcing.

Paragraph 6. The relationship between companies in the same group referred to in Paragraph 5 of this article must be included in documents or procedures related to the Cosmetovigilance of the companies involved.

Paragraph 7. In cases of outsourcing Cosmetovigilance requirements and activities, duplication of notification submissions of individual cases to the health authority must be avoided.

Paragraph 8. Companies must establish in the outsourcing contract the continuity of Cosmetovigilance requirements and activities in the event of interruption of outsourced services.

Paragraph 9. The outsourcing contract referred to in this article must provide for the possibility of Cosmetovigilance inspections at the facilities of contracted third parties, at the discretion of the health authorities.

Article 47. The company must preferably carry out 1 (one) audit of the Cosmetovigilance System per year, not exceeding the period of 2 (two) years for its completion, keeping the record of this activity in its possession for up to 5 (five) years, as a way of proving that all activities are carried out in accordance with this Resolution.

Paragraph 1. The result of each audit must be recorded in a report for verification purposes with the health authorities.

Paragraph 2. Corrective actions must be established for each of the deficiencies observed, with documentation on the monitoring of their implementation.

Article 48. Companies have the autonomy to employ artificial intelligence technologies in the identification, analysis, investigation, and monitoring of serious adverse events related to cosmetic products and in other Cosmetovigilance activities.

Paragraph 1. The use of artificial intelligence technologies must be guided by transparency, ethics and be in compliance with current legislation.

Paragraph 2. Companies that choose to adopt artificial intelligence technologies in Good Cosmetovigilance Practices must maintain updated documentation, including a description of the algorithms used, methods for validating artificial intelligence models and results obtained.

Paragraph 3. The health authority reserves the right to inspect the artificial intelligence processes applied within the scope of the companies' Cosmetovigilance Systems.

Article 49. The company must carry out continuous monitoring to identify possible recurring problems in its cosmetic products to implement, when necessary, appropriate corrective and preventive actions.

CHAPTER III

FINAL PROVISIONS

Article 50. The company is subject to Cosmetovigilance inspections conducted by the health authorities, whether announced or not, to assess compliance with this Resolution.

Sole paragraph. The company must provide all documentation and information requested by health authorities, make its personnel available for interviews and grant access to its database, in order to allow verification of compliance with legal requirements.

Article 51. Anvisa and other health authorities must adopt measures or procedures for cases not provided for in this Resolution, within the scope of their powers and through an agreement on responsibilities.

Article 52. This Resolution incorporates, in more detail, into the Brazilian legal system, Resolution GMC MERCOSUR No. 19/05 and its updates.

Article 53. Failure to comply with the provisions of this Resolution constitutes a health infraction in accordance with Law No. 6,437 of 20 August 1977, subject to the applicable civil, administrative, and criminal liabilities.

Article 54. Collegiate Board Resolution – RDC No. 332 of 1 December 2005, published in Federal Official Gazette No. 231 of 2 December 2005, Section 1, page 65, is hereby revoked.

Article 55. This Resolution shall come into force 12 (twelve) months after the date of its publication.

ANTONIO BARRA TORRES

Director-President