LATINI GROUP
Integrated
Business
Solution

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RESOLUTION OF THE COLLEGIATE BOARD OF DIRECTORS – RDC No. 478, OF MARCH 12, 2021

Provides for monitoring economical of medical devices

The Collegiate Board of the National Health Surveillance Agency, in use of the attributions conferred by art. 15, III and IV, combined with art. 7, III and IV of Law no. 9,782, of January 26, 1999, and to art. 53, VI, §§ 1 and 3 of the Internal Regulations approved by the Resolution of the Collegiate Board of Directors - RDC No. 255, of December 10, 2018, decides to adopt the following Resolution, as decided at a meeting held on March 11, 2021, and I, the Chief Executive Officer, determine its publication.

CHAPTER I
DAS DISPOSIÇÕES INICIAIS

Seção I
Object

Art. 1 This Resolution provides for the economic monitoring that are subject to medical devices registered with the National Surveillance Agency Sanitary (Anvisa), in regulation to item XXV of Law No. 9,782, of January 26 of 1999.

Section II
Scope

Art. 2 The economic monitoring dealt with in this Resolution will be carried out for medical devices selected by Anvisa, according to the attached list the specific Normative Instruction, to be published and updated according to the criteria set out in this Resolution.

Section III
Definitions

Art. 3 For the purposes of this Resolution, the following shall be considered definitions:

I - medical device: medical product, as defined by the Resolution of Collegiate Board of Directors - RDC nº 185, of October 22, 2001, or its updates;

II - technical attribute: technical specification, also comprising its possible variations, relating to a medical device, selected by Anvisa for mark the grouping of medical devices with technical characteristics Similar;

III - information asymmetry: market failure that occurs when there is a difference in the information that the parties involved in a transaction have about a product or service, particularly when that difference may cause imbalances in the market and affect the result of the transaction; and

IV - economic monitoring of medical devices: continuous monitoring of the prices of medical devices, as well as others economic data that is relevant to reducing information asymmetry in the medical device market.

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CHAPTER II
OF ECONOMIC MONITORING

Section I
Objective

Art. 4 The economic monitoring referred to in this objective Resolution contribute to the reduction of information asymmetry in the market, through:

I - the dissemination of statistics on the history of prices charged by the monitored medical devices;

II - the definition and dissemination of technical attributes of the devices monitored physicians; and

III - the disclosure of other information that Anvisa considers relevant to the reduction of information asymmetry, safeguarded the information protected by legal secrecy.

Section II
Requirements

Art. 5 The following are requirements for economic monitoring:

I - The selection, by Anvisa, of the medical devices subject to monitoring, in accordance with Section I of Chapter III of this Resolution;

II - The definition, by Anvisa, of the set of technical attributes for grouping the selected medical devices, according to Section I of Chapter IV of this Resolution;

III - The collection, by Anvisa, of the historical prices charged in the market, as well as other data to be monitored, according to Section I of Chapter V of this Resolution; and

IV - Information regarding the technical attributes for grouping each model of medical device with valid registration from Anvisa, to be provided by applicants or holders of medical device registration, according to Section II of Chapter V of this Resolution.

Single paragraph. Whenever necessary, the economic information provided for in item VII of article 16 of Law No. 6,360, of September 23, 1976, may be requested for the purposes of the monitoring provided for in this Resolution.

Section III
Implementation

Art. 6 The economic monitoring will be implemented by Anvisa for the registered medical devices, selected gradually and incrementally.

§ 1 - The order of implementation of the economic monitoring of medical devices included in the list published through the specific Normative Instruction referred to in article 2 of this Resolution shall take into account the complexity for the definition of the set of technical attributes, in order to ensure that monitoring is implemented for the largest number of medical devices of interest in the shortest possible time.

§ 2 The implementation schedule of the economic monitoring of medical devices shall take into account the technical and operational feasibility of Anvisa.

§ 3 The beginning of the economic monitoring of each medical device will occur from the publication, by Anvisa, of its set of technical attributes in the annex to the Normative Instruction referred to in article 16 of this Resolution.

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Section IV
Findings

Art. 7 The results of the economic monitoring of medical devices should contribute to the reduction of information asymmetry in the market, through the disclosure of technical attributes that allow the grouping of products with similar technical characteristics and the dissemination of statistics of the historical prices practiced.

Art. 8 The results of economic monitoring may be used to assist in the definition of price benchmarks for public or private purchases of medical devices.

CHAPTER III
MEDICAL DEVICES

Section I
Selection criteria

Art. 9 For the selection of medical devices subject to economic monitoring, Anvisa will consider the following criteria:

I - the financial impact for the Single Health System (SUS);

II - the financial impact on the supplementary health system; and III - the relevance to public health, duly substantiated.

§ 1 - The financial impact for the SUS will be evaluated considering at least the percentage represented by the medical device in the total expenditure on public purchases, according to information obtained from the Ministry of Health.

§ 2 - The financial impact for the supplementary health system shall be evaluated considering at least the percentage represented by the medical device in the total expenses by health plan operators, according to information obtained from the National Agency for Supplementary Health.

Art. 10. Only medical devices with valid registration with Anvisa may be selected for the economic monitoring referred to in this Resolution.

Section II
Dissemination and updating of selected medical devices

Art. 11. The medical devices selected for economic monitoring by Anvisa will be disclosed through a list attached to the specific Normative Instruction referred to in article 2 of this Resolution.

Art. 12. The updating of the list of medical devices selected for economic monitoring will be carried out at the initiative of Anvisa, in order to ensure constant compliance with the criteria set forth in Section I of Chapter III of this Resolution.

Sole paragraph The update referred to in the caput may result in the inclusion or exclusion of a medical device in the scope of economic monitoring

CHAPTER IV
OF THE TECHNICAL ATTRIBUTES
Section I
Definition of the set of technical attributes

Art. 13. The set of technical attributes of medical devices selected for economic monitoring will be defined by Anvisa.

Single paragraph. To define the set of technical attributes, Anvisa It will consult the agents who are interested in or affected by the topic.

Art. 14. Technical attributes should be selected from those that are related to the functionality of the medical device.

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Art. 15. The set of technical attributes must allow the grouping ofMedical devices with similar technical characteristics available on the market.

Section II
Dissemination and updating of the set of technical attributes

Art. 16. The set of technical attributes defined for the devices physicians selected for economic monitoring should be disclosed through: of specific Normative Instruction.

Art. 17. Updating the technical attribute set of devices selected physicians, when necessary to maintain effective monitoring economic, will be carried out at the initiative of Anvisa, which may change, include or exclude technical attributes, as well as their variations.

§ 1 - The exclusion, alteration or inclusion of a technical attribute, including its variations may be suggested to Anvisa, by any interested party, through electronic form available on Anvisa's website.

§ 2 - In all cases, the suggestion must be accompanied by justification technique that underpins the importance of updating the set of technical attributes, considering the relationship between the technical attribute and the functionality of the device medical device and the possibility of allowing the grouping of medical devices with similar technical characteristics.

§ 3 - To update the set of technical attributes of the device's physicians selected for economic monitoring, Anvisa will consider the suggestions received and will consult the agents who have an interest or who are affected by the topic.

§ 4 - Suggestions that are not instructed with all the required information.

CHAPTER V
FROM THE COLLECTION OF THE DATA NECESSARY FOR MONITORING

Section I
Data collection by Anvisa

Art. 18. The data necessary for the economic monitoring of the selected medical devices may be collected by Anvisa through:

I - active research to the available databases;

II - the sharing of information by other public agencies;

III - technical-scientific publications; or

IV - of application to the holders of registration of medical devices or to other economic agents that operate in this market.

Single paragraph. Depending on the specifics of the economic monitoring of each group of medical devices, other sources may be used.

Art. 19. The data used in economic monitoring should be as up-to-date as possible, considering the sources of collection available for use by Anvisa.

Section II
Submission of information by registrants or registrants

Art. 20. It is the responsibility of the holder of the registry to send Anvisa the information regarding the technical attributes of each model of the medical device object of economic monitoring.

Art. 21. The information referred to in article 20 will be sent to Anvisa, through a specific petition:

I - for new medical devices, within sixty days after the publication of the registration;

II - for medical devices already registered:

a) when requested by Anvisa, pursuant to the sole paragraph of this article 21;

b) at the time of revalidation of the registration; or

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c) whenever post-registration changes are made that include new models, change or include information regarding the technical attributes of the medical device, within sixty days after the approval of the post-registration change.

Single paragraph. For medical devices with valid registration that are included in the list published through the specific Normative Instruction referred to in article 2 of this Resolution, and whose registration holders have not yet sent the information regarding the technical attributes, Anvisa will request this submission in its own instrument, which will define a period of not less than sixty days for presentation.

CHAPTER VI
DISSEMINATION OF THE RESULTS OF ECONOMIC MONITORING

Art. 22. The results of cost-effective medical device monitoring will be disclosed by Anvisa on its website, protected confidentiality legal and guaranteed information as to the sources of the data used.

§ 1 - Anvisa will make available, on its website, a tool updated to allow the consultation of statistics of the history of prices charged by grouping of medical devices with similar technical characteristics, according to the technical attributes reported for each model.

§ 2 - The updating of the results of the economic monitoring of medical devices must be performed at least quarterly by Anvisa.

§ 3 Anvisa will adopt measures to avoid the identification of prices of medical devices, as well as for the safeguarding of other Sensitive business information.

§ 4 - The dissemination of the results of the economic monitoring shall be performed using price information from monitored medical devices lagged in time by at least three months.

CHAPTER VII
OF THE FINAL PROVISIONS

Art. 23. Failure to comply with the provisions contained in this Resolution, as well as as the falsity in the information provided, constitutes a health infraction subject to the penalties provided for in Law No. 6,437, of August 20, 1977, without prejudice to the applicable civil or criminal sanctions.

Art. 24. This Resolution will be revised after three years from the its validity, based on the results achieved by economic monitoring, determined through the Monitoring and Evaluation of Regulatory Results (M&ARR).

Art. 25. The following are hereby repealed:

I - Collegiate Board Resolution - RDC No. 185, of October 13, 2006, published in the Official Gazette No. 198, of October 16, 2006, Section 1, p. 69; and

II - Resolution - RE No. 3,385, of October 13, 2006, published in the Diário Union Officer No. 198, October 16, 2006, Section 1, p. 77. Art. 26. This Resolution takes effect on April 1, 2021.

ANTONIO BARRA TORRES
Chief Executive Officer