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Integrated
Business
Solution

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RESOLUTION - RDC NO. 551 OF AUGUST 30th 2021

Establishes mandatory execution and notification of field actions by medical device registration holders in Brazil.

The Collegiate Board of the National Health Surveillance Agency, in the use of the powers conferred on it by art. 15, III and IV, together 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 Collegiate Board Resolution - RDC No. 255, of December 10, 2018, resolves to adopt the following Resolution, as resolved at a meeting held on August 30, 2021 and I, Chief Executive Officer, determine its publication.

Art. 1 This Resolution defines the situations in which the execution and notification of field actions by medical device registration holders in Brazil are mandatory, establishing its minimum requirements.

Art. 2 The medical device registration holder is the medical device registration/notification holder with Anvisa.

Single paragraph. The registration holder, as well as the other agents involved from the production to the use of the product, or disposal of the product, when applicable, are jointly responsible for maintaining the quality, safety and effectiveness of the medical devices until the end consumer.

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

I - field action: action taken by the manufacturer or registration holder of health product, in order to reduce the risk of occurrence of the adverse event related to the use of an already marketed health product;

II - alert message: communication done by the registration holder to health professionals, patients, users, regulated sector, other stakeholders or wider community, whose goal is to inform about the risk of occurrence of the adverse event related to the use of a medical device;

III - adverse event: any undesirable effect in humans, resulting from the use of products under sanitary surveillance;

IV - serious adverse event: adverse event that falls into at least one of the following situations:

a) causes death;

b) causes disability or permanent damage to a body structure;

c) requires medical or surgical intervention in order to prevent permanent injury of a function or structure of the organism;

d) requires patient hospitalization or extension of hospitalization; and

e) leads to fetal disruption or fetal risk, fetal death or congenital anomaly;

V - serious threat to public health: any kind of occurrence that results in imminent risk of death, serious injury or serious illness that requires rapid corrective measure.

Art. 4. The registration holder must initiate, as soon as possible, a field action whenever there is sufficient evidence or proof that a medical device does not meet the essential safety and effectiveness requirements applicable to this product.

§ 1 The field action must be planned and executed with the objective of minimizing the risk to health in an effective and timely manner.

§ 2 It is up to the registration holder to indicate the need to suspend the marketing/import of the affected lot or series, except when defined by the National Health Surveillance System (SNVS).

Art. 5 The registration holder must prepare, apply and keep up-to-date written operational procedures for field actions under his responsibility.

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Art. 6 The SNVS will determine, when a health risk is identified, the execution of field actions it deems appropriate, regardless of the initiatives taken by the holder of record.

Art. 7 The registration holder must disclose, as soon as possible, an alert message regarding the field action under his/her responsibility, expressed in a clear and objective manner and containing, at least, information on:

I - The problem;

II - The product (registration/notification number, product name, model and batch/series affected);

III - The risk related to the problem;

IV - Guidelines for health professionals, patients, users, the regulated sector, other interested parties or the community as a whole.

Single paragraph. It is up to the registration holder to select and use the most effective communication means for the dissemination of the alert message.

Art. 8 In case of need to use a large circulation media vehicle for the dissemination of the alert message, the registration holder must submit such message to the prior consent of Anvisa, as established in art. 41-B of Law 9,782 of January 26, 1999, within 5 (five) calendar days from the decision to carry out the field action.

§ 1 The submission of information dealt with in this article must be carried out in a specific form defined by Anvisa.

§ 2 After the registration of the form, Anvisa can approve the content and form of the alert message or point out the necessary corrections.

§ 3 After the consent of Anvisa, the holder of registration must immediately promote the placement of the warning message.

§ 4 The prior consent does not exempt the company from sending the field action notification form, provided for in art. 9 of this Resolution.

Art. 9. The registration holder must notify Anvisa about the performance of a field action involving the medical device under his/her responsibility, according to the following terms and conditions:

I - Within 3 (three) calendar days, in case of need to use a large circulation media vehicle for the dissemination of the alert message;

II - Within 3 (three) calendar days, in case of serious threat to public health;

III - Within 10 (ten) calendar days, when the risk of occurrence of a serious adverse event is identified and the situation does not fit into items I or II of this article;

IV - Within 30 (thirty) calendar days, when the situation does not fit into items I, II or III of this article.

§ 1 The deadlines defined in this article must be counted from the decision to carry out the field action.

§ 2 The notification must be made through a specific form, defined by Anvisa.

§ 3 Anvisa may request the revision, alteration or complementation of the information presented by the registration holder.

Art. 10. The registration holder must submit monitoring reports and field action completion report to Anvisa.

§ 1 The reports must be sent on the dates stated in the action plan of the notification form presented by the registration holder.

§ 2 Along with the conclusion report, a copy of documentation proving the completion of the field action or a declaration that such documentation is in the company (registration holder) must be sent.

§ 3 The field action monitoring reports must be sent according to the model defined by Anvisa.

Art. 11. Anvisa may request the presentation of reports on dates different from those informed in the company's action plan.

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Art. 12. The distributors of medical devices must forward to the holder of record, in a timely manner, the distribution map and other requested information for the notification and execution of field actions.

Art. 13. In situations where the medical device subject to field action has been or is still being used, the registration holder must provide assistance to users, patients or other persons involved, in order to make the risk associated with the use of the product and reduce the effects of damage that has already occurred.

Art. 14. The collected products must be identified and segregated in separate and safe areas, until their final destination is defined.

Single paragraph. In cases where the field action does not require collection, the target product of this action must be properly identified, and segregated when applicable, to avoid inadvertent use.

Art. 15. The destruction of the collected medical devices, when necessary, is the responsibility of the registration holder, respecting the rules in force regarding the disposal of waste.

Single paragraph. The destruction of the collected product implies in its complete mischaracterization as a medical device.

Art. 16. The registration holder must keep an updated file of documents and records referring to their field actions, structured in such a way as to ensure the traceability of information and the quick retrieval of data and information.

Single paragraph. The supporting records for sending and receiving correspondence, as well as the records and supporting documents for the completion of field actions initiated by the record holder, must be part of the file mentioned in the caput of this article.

Art. 17. Failure to comply with the provisions contained in this Resolution constitutes a health infraction, pursuant to Law No. 6,437, of August 20th, 1977, without prejudice to the applicable

civil, administrative and criminal liabilities, including those established by Law No. 8.078, of 11 September 1990.

Art. 18. It is incumbent upon Anvisa and other SNVS entities, within the scope of their powers and upon agreement of responsibilities, to adopt measures or procedures for cases not provided for in this Resolution.

Art. 19. The following are revoked:

I - the Resolution of the Collegiate Board of Directors - RDC No. 23, of April 4th, 2012, published in the Official Gazette No. 68, of April 9th, 2012, Section 1, p. 77; and

II - the Resolution of the Collegiate Board of Directors - RDC No. 501, of May 27th, 2021, published in the Official Gazette No. 103, of June 2nd, 2021, Section 1, p. 119.

Art. 20. This Resolution enters into force on October 1st, 2021.