RESOLUTION – RDC N. 23, OF 04 APRIL, 2012

Rules to mandatory implementation and reporting of field actions by registration holders of health products in Brazil.

The Collegiate Board of the National Health Surveillance Agency, in the exercise of the attributions granted by the item IV of the art. 11 of the Regulation approved by Decree n° 3029 of April 16, 1999, and in view of the provisions of item II and1st and 3rd Paragraph of Article 54 of Internal Rules approved pursuant to Annex I of the ANVISA Ordinance No. 354, of August 11, 2006, republished in the Federal Official Gazette of August 21, 2006, in a meeting held in January 24, 2012, adopts the following Board of Directors Collegiate Resolution and I, President-Director, determine its publication:

CHAPTER I
INITIAL PROVISIONS
Section I
Purpose

Art. 1 This resolution defines the situations in which are mandatory to registration holders of health product in Brazil to implement and report field actions, setting its minimum requirements.

Art. 2 Registration holder of health product means the holder of health product registration at Anvisa.
Sole paragraph. The registration holder, as well as the other agents involved from the production to the use of the product, or disposing of this when applied, are jointly and severally responsible for the maintenance of the quality, safety and efficacy of health products up to the final consumer.

Section II
Definitions

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 health product;

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

IV. Serious adverse event: adverse event that fits in at least one of the following situations:
(a) cause death;

(b) cause disability or permanent damage to a body structure;
(c) require medical or surgical intervention to prevent injury to a permanent structure or function of the body;
(d) requires patient hospitalization or prolongation of hospitalization; and
(e) leads to disruption or fetal risk, fetal death or congenital anomaly;

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

CHAPTER II
THE OBLIGATION OF PERFORMING FIELD ACTIONS

Art. 4 Registration holder should start, as soon as possible, a field action whenever there is sufficient evidence or proof that a health product does not meet the essential requirements of safety and effectiveness applicable to this product.
§1 The field action must be planned and performed with the objective of minimizing the health risk effectively and timely.
§2 It is up to the registration holder indicate the need for the suspension of marketing/batch import or series affected, unless defined by National Health Surveillance System (SNVS).
Art. 5 The registration holder shall establish, implement and maintain updated written operational procedures for the actions of its responsibility.
Art. 6 SNVS shall establish, when identified risk to health, implementation of field actions that deems appropriate, regardless of the initiatives taken by the registration holder.

CHAPTER III
THE ALERT MESSAGE

Art. 7 The registration holder should disclose, as soon as possible, alert message for field actions of its responsibility, expressed clearly and objectively and containing, at less, information about:
I-The problem;
II-The product (registration number/registration, product name, model, and serial/lot affected);
III-The risk associated to the problem;
IV-Guidelines for health professionals, patients, users, regulated industry, other interested or the community as a whole.
Sole paragraph. It is up to the registration holder to select and use the most effective communication means for the dissemination of the alert message.

CHAPTER IV
THE PRIOR INFORMED CONSENT OF THE ALERT MESSAGE

Art. 8 In case of need to use mass media vehicle to the alert message, the registration holder shall submit such message to Anvisa's prior consent, according to the art. 41-B of the law 9782/99, within 5 calendar days from the decision to start the field action.
§1 The submission of the information covered in this article shall be held in a specific form defined by Anvisa.

§2 The form must also be sent to the e-mail recall.utvig@anvisa.gov.br, with the prediction of the date of disclosure of the message in mass circulation media.
§3 After receive the form, Anvisa can approve the alert message content or point the necessary corrections.
§4 After Anvisa approval, the registration holder should promote immediately the airing of the message alert.
§ 5 The prior informed consent does not exempt the company to send the notification form field action, provided for in art. 9° of this resolution.

CHAPTER V
FIELD ACTION REPORTING

Art. 9 The registration holder shall notify Anvisa on carrying out field action involving health product of its responsibility, in accordance with the following terms and conditions:
I- In up to 3 days, in case of need to use wide circulation media vehicle to the alert message;
II- In up to 3 days, in case of serious threat to public health;
III- Up to 10 calendar days, when identified risk of occurrence of serious adverse event and the situation does not fit in sections I or II of this article;
IV- Up to 30 calendar days, when the situation does not fit in items I, II or III of this article.
§ 1 The days defined in this article shall be counted from the decision to start up the field action.
§ 2 The notification shall be made by means of a specific form, defined by Anvisa.
§. 3 Anvisa may request the review, change or addition of information submitted by the registration holder.

CHAPTER VI
REPORTS

Art. 10 The registration holder shall submit to Anvisa monitoring reports and completion report of its field actions.
§1 These reports shall be sent in accordance with the dates declared in the notification form's action plan submitted by the registration holder.
§2 Along with the completion report shall be sent a copy of evidentiary documentation regarding the completion of the field action, or a declaration that such documentation is in the company (registration holder).
§3 Monitoring reports of field action should be sent as the model defined by Anvisa.

Art. 11 Anvisa may request submission of reports on different dates of those reported in the company's action plan.

CHAPTER VII
TRANSITIONAL AND FINAL PROVISIONS

Art. 12 The health products distributors should forward to the registration holder, in a timely fashion, the distribution map and other requested information to the notification and implementation of actions.

Art. 13 In situations where the health product subject to field action was or is still being used, the registration holder should assist users, patients or other persons involved, in order to make acceptable the risk associated with the use of the product and to reduce the effects of the damage that has already occurred.

Art. 14 Recalled products must be identified and segregated in separated and safe areas, until the definition of its final destination.
Sole paragraph. In cases where the field action does not require withdraw, the target product of this field action must be properly identified and segregated when applicable, to avoid improper use.

Art. 15 Destruction of recalled health products, when required, is a registration holder responsibility, in compliance with the regulations concerning the waste disposal.
Sole paragraph. The destruction of a recalled product implies in its mischaracterization as a health product.

Art. 16 The registration holder shall keep an updated file of documents and records relating to its field actions, structured in such a way to ensure the traceability of information and the rapid recovery of data and information.
Sole paragraph. Should be a part of the referred file the records of sending and receiving correspondence, as well as the records and supporting documents for completion of field actions initiated by the registration holder.

Art. 17 The breach of the provisions contained in this resolution constitutes infringement health, in accordance with law No. 6437, August 20, 1977, without prejudice to the civil, administrative and criminal responsibility applicable, including those established by law No. 8078, September 11, 1990.

Art. 18 It is up to Anvisa and other entities of the National Health Surveillance System (SNVS), within their competences and by pact responsibilities, the adoption of measures and procedures in cases not foreseen in this Resolution.

Art. 19 It is established a period of 360 (three hundred and sixty) days for registration holders of health products adopt necessary measures for the application of this Resolution.

Art. 20 This Resolution enters into force on the date of its publication.

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