

## **RESOLUTION - RDC NO. 23, FROM APRIL 4, 2012**

It addresses the compulsory execution and notification of field actions by the registration holders for health products in Brazil.

The Collegiate Director Board of *Agência Nacional de Vigilância Sanitária* (National Health Surveillance Agency), using its attribution granted by subsection IV of article 11 of the Regulation approved by Decree No. 3,029, from April 16, 1999, and considering what is provided in subsection II and §§ 1<sup>st</sup> and 3<sup>rd</sup> of article 54 of the Internal Rules of Procedure approved according to Annex I of Ordinance No. 354 of ANVISA, from August 11, 2006, and republished in the Official Federal Gazette from August 21, 2006, at a meeting held on January 24, 2012, adopts the following Collegiate Director Board Resolution, and I, the President Director, determine its publication:

### **CHAPTER I**

#### **ON INITIAL PROVISIONS**

##### **Section I**

##### **Object**

Article 1<sup>st</sup> This Resolution defines the situations when enforcing and notifying field actions that are mandatory by the registration holders for health products in Brazil, setting its minimum requirements.

Article 2<sup>nd</sup> Registration holder for health product is understood as the holder of the “registro”/”cadastro””registro”/”cadastro” of a health product at Anvisa.

Single paragraph. The registration holder, as well as the other agents involved since the product manufacturing to its use or disposal, when applicable, are jointly responsible for maintaining the quality, safety, and efficacy of health products up to the final consumer.

##### **Section II**

##### **Definitions**

Article 3<sup>rd</sup> The following definitions are adopted for this Resolution:

I - Field Action: action performed by the manufacturer or registration holder of a health product, aiming to reduce the risk of occurrence of an adverse event related to the use of the already commercialized health product;

II - Alert Message: communication made by the registration holder for healthcare providers, patients, users, regulated sector, other concerned parties, or general community, whose purpose is to inform on the risk of occurrence of an adverse event related to the use of the health product;

III - Adverse Event: any undesirable effect in humans coming from the use of products under sanitary surveillance;

IV - Severe Adverse Event: adverse event that is fitted in at least one of the following situations: (a) causes death; (b) causes permanent disability or harm to a body structure; (c) requires medical or surgical intervention in order to prevent a permanent compromise of a body function or structure; (d) requires hospitalization or extends the hospitalization of a patient; and (e) causes fetal disturbance or risk, fetal death, or congenital anomaly;

V - Serious Threat to Public Health: any type of occurrence that results in imminent risk of death, severe injury, or serious disease requiring a fast corrective measure.

## **CHAPTER II**

### **ON THE OBLIGATORINESS OF PERFORMING FIELD ACTIONS**

Article 4<sup>th</sup> The registration holder must always start, as fast as possible, a field action when there are sufficient indications or proof saying that a health product does not meet the essential safety or efficacy requirements applicable to that product.

§ 1<sup>st</sup> The field action must be planned and performed aiming to minimize the health risk effectively and timely.

§ 2<sup>nd</sup> The registration holder is responsible for indicating the need for suspension of the commercialization/importation of the affected lot or series, except when it is defined by the *Sistema Nacional de Vigilância Sanitária* (National Health Surveillance System) (SNVS).

Article 5<sup>th</sup> The registration holder must elaborate, apply and keep updated all operational procedures written for field actions under its responsibility.

Article 6<sup>th</sup> Once a health risk is identified, SNVS will determine the performance of field actions it deems as proper, regardless of the measures taken by the registration holder.

### **CHAPTER III**

#### **ON THE ALERT MESSAGE**

Article 7<sup>th</sup> The registration holder must issue, the faster as possible, an alert message referring to the field action under its responsibility, clearly and objectively expressed and containing at least information on:

I - The problem;

II - The product (“registro”/”cadastro” number, product name, model, and affected lot/series);

III - The risk related to the problem;

IV - Orientation for healthcare providers, patients, users, regulated sector, other concerned parties, or general community.

Single paragraph. The registration holder is responsible for selecting and using the most effective communication medium (media) to spread the alert message.

### **CHAPTER IV**

#### **ON THE PREVIOUS AGREEMENT ON THE ALERT MESSAGE**

Article 8<sup>th</sup> In case of need for using a great circulation media vehicle to spread the alert message, the registration holder must submit such message to previous agreement by Anvisa, according to what

article 41-B of Law 9,782/99 sets, in up to 5 consecutive days counted from the decision on performing the field action.

§ 1<sup>st</sup> The submission of the information addressed in this article must be performed in a specific form defined by Anvisa.

§ 2<sup>nd</sup> The form must be also sent to the e-mail [recall.utvig@anvisa.gov.br](mailto:recall.utvig@anvisa.gov.br), with a preview for the date of spreading the message in great circulation media.

§ 3<sup>rd</sup> After submitting the form, Anvisa may approve the content and form of the alert message or may indicate needed corrections.

§ 4<sup>th</sup> After Anvisa's consent, the registration holder must immediately promote the spread of the alert message.

§ 5<sup>th</sup> A previous consent does not exempt the company of sending the field action notification form, which was determined in article 9<sup>th</sup> of this Resolution.

## **CHAPTER V**

### **ON FIELD ACTION NOTIFICATION**

Article 9<sup>th</sup> The registration holder must notify Anvisa about the performance of a field action involving a health product under its responsibility, according to the following terms and conditions:

I - In up to 3 consecutive days, in case of need for using a great circulation media vehicle for spreading the alert message;

II - In up to 3 consecutive days, in case of serious threat to public health;

III - In up to 10 consecutive days, once a risk of occurrence of a severe adverse event is identified and the situation does not fit in subsections I or II of this article;

IV - In up to 30 consecutive days, once the situation does not fit in subsections I, II, or III of this article.

§.1<sup>st</sup> The terms defined in this article must be counted from the decision on performing the field action.

§.2<sup>nd</sup> The notification must be done by a specific form defined by Anvisa.

§.3<sup>rd</sup> Anvisa might ask a review, alteration, or complementation of the information presented by the registration holder.

## **CHAPTER VI**

### **ON REPORTS**

Article 10 The registration holder must present monitoring reports and a report on the field action's closure to Anvisa.

§ 1<sup>st</sup> The reports must be sent on the dates claimed in the action plan in the notification form presented by the registration holder.

§ 2<sup>nd</sup> A copy of a corroborating documentation on the field action's closure or a statement saying that such documentation is in the company (registration holder) must be sent together with the final report.

§ 3<sup>rd</sup> Reports on field action monitoring must be sent according to a model defined by Anvisa.

Article 11 Anvisa might ask the presentation of reports in different dates from the ones informed in the company action plan.

## **CHAPTER VII**

### **ON FINAL AND TRANSIENT PROVISIONS**

Article 12 Health product distributors must forward the distribution map and other information requested for notification and performance of field actions to the registration holder in timely manner.

Article 13 In situations when the health product subjected to the field action was or is still being used, the registration holder must provide assistance to users, patients, or other involved persons, in order to turn the risk associated to the product use acceptable and to reduce the already incurred harm effects.

Article 14 Recalled products must be identified and segregated in separated and safe areas until the definition of its final destination.

Single paragraph. In cases when the field action does not require recall, the product targeted by that action must be duly identified, and segregated when applicable, in order to prevent inadvertent use.

Article 15 When needed, the destruction of recalled health products is responsibility of the registration holder, considering the rules in effect related to waste destination.

Single paragraph. The destruction of a recalled product implies its full uncharacterization as health product.

Article 16 The registration holder must keep an updated file of documents and registries referring to its field actions, structured in order to ensure information traceability and fast data and information recovery.

Single paragraph. Corroborating records of mail sending and receiving, as well as corroborating records and documents on the field actions's closure started by the registration holder must be part of the file cited in the head of this article.

Article 17 Noncompliance with the provisions contained in this Resolution constitutes sanitary infraction, under the terms of Law no. 6,437, from August 20, 1977, without disregarding the applicable civil, administrative, and penal responsibilities, including those set by Law no. 8,078, from September 11, 1990.

Article 18 Anvisa and the other SNVS bodies, in the ambit of their competences and by agreement on responsibilities, are responsible for adopting measures or procedures for cases not foreseen in this Resolution.

Article 19 The term of 360 (three hundred and sixty) days is set for the registration holders for health products be adjusted to this Resolution.

Article 20 This Resolution takes effect on the date of its publication.

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