

RESOLUTION – RDC N. 67, OF 21 DECEMBER, 2009

Provisions regarding post-market surveillance applicable to registration holders of health product 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 and 1st 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 December 16, 2009, 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 establishes general requirements for post-market surveillance to be implemented by registration holders of health product based in the national territory.

Art. 2 – For the purposes of this Resolution, post-market surveillance is understood to mean a system of surveillance of adverse events and malfunctions involving health products in the post-market phase, with the view to recommend the adoption of measures to ensure the protection and promotion of the health of the population.

Art. 3 – For the purposes of this Resolution, registration holder of health products is understood to mean holder of health product registrations at ANVISA.

Sole paragraph. Registration holder is legally responsible for the product registered under its name in Brazil, and as such shall respond, to health authorities, about any malfunctions, adverse events, situations presenting a serious threat to public health, alerts, field actions, and other events that represent a health risk and that are related to its products.

Section II Definitions

Art. 4 – For the purposes of this Resolution, the following definitions are adopted:

I – alert: written communication directed at health professionals, patients, users, the regulatory sector, and general communications, having for objective to inform with respect to the risk of occurrence of adverse events in relation to a health product;

II – field action: action performed by the manufacturer or holder of a health product registration, having for objective to reduce the risk of occurrence of adverse events related to the use of a marketed health product;

III- adverse event: any undesirable effect to humans resulting from the use of products subject to health surveillance;

IV – serious adverse event: an adverse event that meets at least one of the following:

- (a) leads to death;
- (b) causes a disability or permanent damage in a structure of the body;
- (c) requires medical or surgical intervention to prevent permanent harm to a function or structure of the body;
- (d) requires hospitalization of a patient or a prolongation of hospitalization;
- (e) leads to a disturbance or risk to a fetus, fetal death, or a congenital anomaly.

V – non serious adverse event: any other adverse event not included in the definition of a serious adverse event;

VI – risk management: systemic application of policies, procedures and practices with the objective to analyse, assess and control risks;

VII – instructions for use: manuals, brochures and other documents accompanying a health product that contain technical information about the product;

VIII – notification: the act of informing health authorities, or other organizations, about the occurrence of adverse events or malfunctions involving health products, by the registration holder;

IX – health product: a product falling into one of the following two categories:

- (a) medical product – a product, such as equipment, device, material, article or system having a use or application that is medical or dental or for laboratory use, that is intended to prevent, diagnose, treat, rehabilitate, or for contraception, and that does not rely on pharmaceutical, immunological, or metabolic means to achieve its primary function in humans, but may however be assisted by such means;
- (b) *in-vitro* diagnostic product: reagents, standards, calibrators, controls, materials, articles and instruments along with their instructions for use, used to perform a qualitative, quantitative, or semi-quantitative determination on a sample derived from the human body and is not intended to perform an anatomical, physical, or therapeutic function, nor to be ingested, injected or inoculated into humans, but is to be solely used to provide information about a sample derived from a human;

X – malfunction: notification of suspected adulteration or irregularity of a product or company in relation to technical or legal aspects, and that could, or not, cause harm to individual and collective health;

XI – traceability: the ability to describe the history, application, processes and the location of a product, in a particular organization, by means of records and identification;

XII – risk: the combination of the probability of occurrence of harm and the severity of the harm;

XIII – serious threat to public health: any type of occurrence that results in an imminent risk of death, serious lesions or serious disease, that requires rapid corrective measures;

XIV – National System of Health Surveillance (SNVS): constituted of the Ministry of Health, the National Health Surveillance Agency (ANVISA), and the Health Surveillance Centres of the States, Territories, and the Federal District.

CHAPTER II POST-MARKET SURVEILLANCE IN THE COMPANY

Art. 5 – The registration holder shall designate, in a written document, at least one professional with college-level training, as responsible for post-market surveillance in the company.

Art. 6 – The registration holder shall organize and implement a system of post-market vigilance in its company, in order to:

- I – predict and provide the resources necessary to fulfill the provisions of this Resolution;
- II – standardize and ensure the effective implementation of post-market surveillance processes and procedures, in accordance with the company’s quality system;
- III – ensure the effective management of risks associated with its products;
- VI – ensure that all professional roles and responsibilities are formally described, communicated, and understood by persons involved in post-market surveillance activities;
- V – develop, implement, monitor, and continuously evaluate training for professionals involved in activities described in this Resolution;
- VI – make available, processes, procedures, reports and other documents related to post-market vigilance, when requested by the National System of Health Surveillance (SNVS);
- VII – receive and document information regarding malfunctions, adverse events, situations presenting a serious threat to public health, counterfeiting, alerts, and field actions related to products registered in its name;
- VIII – evaluate information regarding malfunctions, adverse events, situations presenting a serious threat to public health, counterfeiting, alerts, and field action related to products registered in its name, in order to investigate these occurrences according to the severity and risk of each situation;
- IX – notify the SNVS of malfunctions, adverse events, situations presenting a serious threat to public health, and counterfeiting related to health products, that it becomes aware of, in accordance with the requirements of Article 8 of this Resolution;
- X – maintain an up-to-date and properly documented records of notifications related to malfunctions, adverse events, situations presenting a serious threat to public health, counterfeiting, alerts, and field actions related to products registered in its name, so as to ensure traceability of the information related to post-market surveillance actions performed in the company, including the rapid retrieval of data;
- XI – present its conclusions of the investigation to the notifier of the occurrence of malfunctions, adverse events, serious threats to public health or counterfeiting of health products, in writing, when requested by the notifier or health authorities, describing the relevant evidence; and
- XII – comply with other legislation pertinent to the surveillance of health products.

Sole paragraph: All records required by item X above shall be maintained for a period of time equivalent to the expected lifetime of the product, but not less than two years from the date of receipt of the notification by the registration holder.

Art. 7 – For the purposes of post-market surveillance, the registration holder shall conduct a priority review of the following occurrences in relation to a health product involving a patient, user, or other person:

- I – serious threat to public health;
- II- death;
- III – serious adverse event not leading to death;
- IV – malfunction having the potential to cause death or a serious adverse event;

V – non-serious adverse event;

VI – malfunction having the potential to cause a non-serious adverse event; and

VII - counterfeiting

CHAPTER III MANDATORY NOTIFICATION

Art. 8 – The registration holder shall notify the SNVS as quickly as possible, in accordance with the following deadlines:

I – No later than 72 (seventy-two) hours after becoming aware of the following verified events within the national territory that are associated with health products registered in its name:

- a) death;
- b) serious threat to public health;
- c) counterfeiting.

II – No later than 10 (ten) days after becoming aware of the following verified events within the national territory that are associated with health products registered in its name:

- a) serious adverse events not involving death;
- b) non-serious adverse events, the re-occurrence of which has the potential to cause a serious adverse event to a patient, user, or other person.

III – No later than 30 (thirty) days after becoming aware, of a verified malfunction within the national territory and associated with a health product registered in its name, that could lead to a serious adverse event in a patient, user, or other person, provided that one of the following conditions applies:

- a) the possibility of re-occurrence of the malfunction is not remote;
- b) an event of the same type has caused or contributed to a death or serious harm to health in the last three years;
- c) the registration holder of the product needs, or needed, to perform an action to prevent danger to health;
- d) the possibility that an use error was caused by deficient design, labelling, or instructions.

IV – No later than 10 (ten) days after becoming aware, of the following verified events occurring in other countries and associated with health products registered in its name in Brazil:

- a) death;
- b) serious risk to public health;
- c) counterfeiting.

§ 1 – The registration holder shall notify where there is confirmation or strong suspicion that its health product caused, or contributed, to the event.

§ 2 – The notification of international events to which refers item IV of this Article is only applicable in cases where the registration holder, or a distributor authorized by the registration holder, has imported into Brazil lots or serial numbers affected by the same problem as the original event.

Art. 9 – The registration holder shall maintain the information referred in the notifications sent to the SNVS up-to-date, in accordance with the development of each case.

Art. 10. The adverse events and malfunctions described in Article 8 of this Resolution are exempt from notification requirements when one of the following verified conditions apply:

I – the malfunction is normally detectable by the user prior to using the product, independent of existing precautions contained in the instructions for use provided with the product;

II – the registration holder has information that the adverse event was caused by the condition of the patient, whether pre-existing or acquired during the use of the health product under investigation;

III – the sole cause of the adverse event or malfunction is the use of the product after the expiry date or beyond the useful life established by the manufacturer;

IV – the product features a mechanism to prevent faults conditions that present a risk to the patient, user, or other person, and the fault-prevention mechanism functioned correctly to prevent the occurrence of a serious adverse event;

V – the events are planned and expected by the manufacturer or registration holder, are clearly identified in the labelling or instructions for use of the products, and are functionally or numerically predictable when the product is used in accordance with indications;

VI – the product is not used in accordance with the intended uses declared by the manufacturer, the instructions and warning contained in the labelling and instructions for use of the product, and did not cause a serious adverse event; and,

§ 1 – A situation described in item I of this Article is not applicable in cases where the adverse event is due to product non-conformity.

§ 2 – In order to justify situations found in item II, the registration holder shall have available sufficient information to conclude that the product did not cause or contribute to cause the adverse event.

§ 3 – The registration holder shall notify the SNVS about malfunctions, adverse events or other occurrences that, regardless of their inclusion in the conditions contained in items I to VI of this article, are related to a serious threat to public health.

§ 4 – In situations described in the previous paragraph, the deadline for notification is 72 hours, in accordance with item I of Article 8 of this Resolution.

Article 11 – For the purposes of notifying the SNVS of events in accordance with Article 8 of this Resolution, the holder of the registration shall use the SNVS electronic information system defined by ANVISA.

CHAPTER IV FINAL AND TRANSITIONAL PROVISIONS

Article 12 – Adverse events and malfunction arising from use of health products, quoted in the notification to SNVS, and which may constitute a violation of federal health legislation will be investigated by appropriate administrative process.

Sole paragraph: The reporting of adverse events or malfunction to SNVS does not imply immediate responsibility of the registration holder by events causing harm to other due to the use of health products quoted in the notification.

Article 13 – Without damage of others legal sections, including criminal penalties, that are punishable its technical and legal guardians, the company will respond administratively and civilly for health infringements arising from failure of this Resolution and additional rules, under Law n° 6.437/77.

Article 14 - It's up to ANVISA and the others SNVS members, within their competence and through pacts of responsibility, to adopt measures or procedures for cases not provided in this Resolution.

Article 15 – It is established a period of 180 (a hundred and eighty) days for ANVISA provide the required tools and systems to compliance with the determinations set forth in this Resolution.

Article 16 – It is established a period of 360 (three hundred and sixty) days to registration holders of health products adopt necessary measures for the application of this adopt necessary measures for the application of this Resolution.

Article 17 – This Resolution enters into force on the date of its publication.

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