RESOLUTION - RDC NO. 67, FROM DECEMBER 21, 2009

It addresses technovigilance rules applicable to 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 §§ 1st and 3rd of article 54 of the Internal Rules of Procedure approved according to Annex I of Administrative Rule no. 354 of ANVISA, from August 11, 2006, and republished in the Official Federal Gazette from August 21, 2006, at a meeting held on December 16, 2009, adopts the following Collegiate Director Board Resolution, and I, the President Director, determine its publication:

CHAPTER I

ON INITIAL PROVISIONS

Section I

Object

Article 1st This Resolution sets the general technovigilance requirements to be adopted by all registration holders for health products based in the national territory.

Article 2nd For this Resolution, technovigilance is understood as a surveillance system for adverse events and technical complaints related to health products in post-marketing phase, aiming to recommend the adoption of measures to ensure people's health protection and promotion.

Article 3rd For this Resolution, registration holder for health product is understood as the holder of the registration of a health product at Anvisa.

Single paragraph. The registration holder is the legal responsible for the health product registered under its name in Brazil and, as such, must respond to the sanitary authorities about any technical complaints, adverse events, situation of serious threat to public health, alert, field action, and other occurrences representing sanitary risk and that are related to its products.

Section II

Definitions

Article 4th The following definitions are adopted for this Resolution:

I - alert: written communication oriented to healthcare providers, patients, users, regulated sector, and general community, aiming to inform on the risk of occurrence of an adverse event related to the use of a health product;

II - 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 product health product that is already on the market;

III - adverse event: any undesired 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 prolongation of hospitalization for a patient; and (e) causes fetal disturbance or risk, fetal death, or congenital anomaly;

V - non severe adverse event: any other adverse event that is not included in the severe adverse event criteria;

VI - risk management: systematic application of policies, procedures, and practices aiming to analyze, evaluate, and control risks;

VII - instructions for use: manuals, brochures, and other documents accompanying the health product, containing technical information on that product;

VII - notification: act of reporting the occurrence of an adverse event or technical complaint involving health products to the registration holders, sanitary authorities, or other organizations;

VIII - health product: product fitted in at least one of the two categories described below: (a) medical product - health product such as equipment, device, material, item, or system for medical,

odontological, or laboratorial use or application, destined to prevention, diagnosis, treatment, rehabilitation, or contraception and that does not use pharmacological, immunological, or metabolic means to perform its main function in human beings and that, however, can be aided in its functions by such means; (b) diagnosis product for *in vitro* use - reagents, standards, calibrators, controls, materials, items, and instruments, together with its instructions for use, which contribute to perform a qualitative, quantitative, or semiquantitative determination of a sample coming from the human body and that are not destined to perform any anatomic, physical, or therapeutic function, that are not ingested, injected, or inoculated in human beings, and that are uniquely used to provide information on samples obtained from the human body;

IX - technical complaint: any notification on suspicion of alteration/irregularity of a product/company related to technical or legal aspects and that might or might not cause harm to the individual and collective health;

X - traceability: ability to describe history, application, processes, and location of a product, at a certain organization, by records and identification;

XI - risk: combination of the probability of occurrence of harm and its severity;

XII - 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; and

XIII - *Sistema Nacional de Vigilância Sanitária* (National Health Surveillance System) (SNVS): constituted by Ministry of Health, *Agência Nacional de Vigilância Sanitária* (Anvisa), and state, federal district, and municipal *Centros de Vigilância Sanitária* (Sanitary Surveillance Centers) (VISAs).

CHAPTER II

ON TECHNOVIGILANCE IN THE COMPANY

Article 5th The registration holder for a health product must designate, by a written document, at least one professional with university degree and registered in a professional council, as responsible for the technovigilance area of the company.

Article 6th The registration holder of a health product must structure and implant a technovigilance system in its company, in order to:

I - forecast and provide the resources needed to meet the provisions in this Resolution;

II - standardize and ensure the compliance with the performable protocols and procedures in the technovigilance area, according to the company quality system;

III - ensure an effective management of risks associated to its products;

IV - ensure that all professional attributions and responsibilities are formally described, communicated, and understood by the persons involved in technovigilance activities;

V - elaborate, implement, follow, and permanently evaluate the education for the professionals involved in the activities described in this Resolution;

VI - make technovigilance-related protocols, procedures, reports, and other documents available whenever requested by *Sistema Nacional de Vigilância Sanitária* (SNVS);

VII - receive and document information referring to technical complaints, adverse events, situations of serious threat to public health, falsifications, alerts, and field actions related to products registered under its name;

VIII - evaluate information referring to technical complaints, adverse events, situations of serious threat to public health, falsifications, alerts, and field actions related to products registered under its name, in order to investigate those occurrences according to the severity and risk of each situation;

IX - inform the SNVS on technical complaints, adverse events, situations of serious threat to public health, and falsifications related to health products that come to its knowledge and are fitted in the criteria set in Article 8th of this Resolution;

X - keep an updated and duly documented file of notifications referring to technical complaints, adverse events, situations of serious threat to public health, falsifications, alerts, and field actions related to products registered under its name, in order to ensure the traceability of information related to technovigilance actions performed by the company, as well as a fast data recovery;

XI - present the written investigation conclusion to the notifier of the occurrence of technical complaint, adverse event, serious threat to public health, or falsification of health products when requested by that notifier or sanitary authority, describing the respective evidence; and

XII - meet the other legislations related to sanitary surveillance of health products.

Single paragraph. All records of the file determined in subsection X must be stored for a time period equal to the lifetime expected for the product, but in no case for less than two years since the date when the registration holder received the notification.

Article 7th For technovigilance, the following occurrences related to health products and involving patients, users, and other persons must be primarily evaluated by the registration holder:

I - serious threat to public health;

II - death;

III - severe adverse event that did not lead to death;

IV - technical complaint with potential to cause death or severe adverse event;

V - non severe adverse event;

VI - technical complaint with potential to cause non severe adverse event; and

VII - falsification.

CHAPTER III

ON MANDATORY NOTIFICATION

Article 8th The registration holder for a health product must notify SNVS as rapidly as possible, meeting the following terms:

I - Maximum term of 72 (seventy-two) hours after being notified, the following occurrences verified in national territory and associated to the health product registered under its name:

a) death;
b) serious threat to public health; and
c) falsification.

II - Maximum term of 10 (ten) calendar days after being notified, the following occurrences verified in national territory and associated to the health product registered under its name:

a) severe adverse event, without associated death;
b) non serious adverse event, whose recurrence has potential to cause a severe adverse event to a patient, user, or other person.

III - Maximum term of 30 (thirty) calendar days after being notified, the following occurrences verified in national territory and associated to the health product registered under its name, which can lead to a severe adverse event in a patient, user, or other person, provided that at least one of the conditions below are verified:

a) the possibility of technical complaint recurrence is not remote;
b) an occurrence of the same type has already caused or contributed to death or serious harm to health in the last two years;
c) the registration holder for the product needs or would need to perform an action to prevent a health hazard;
d) there is a possibility of misuse induced by precarious design, labeling, or instructions.

IV - Maximum term of 10 (ten) calendar days after being notified, the following occurrences verified in other countries and associated to the health product registered under its name in Brazil:

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

§ 1st The registration holder must notify whenever there is confirmation or strong suspicion that its health product is the cause, or one of the causes, of the occurrence.

§ 2nd The notification of the international occurrences that subsection IV of this article refers to is only applied in cases where the registration holder, or a distributor authorized by the registration holder, has imported, to Brazil, a lot or serial number affected by the same problem that originated the occurrence.

Article 9th The registration holder for the health product must keep the information referring to notifications forwarded to SNVS updated, according to the development of each case.

Article 10. Adverse events and technical complaints that are fitted in Article 8th of this Resolution are exempted from notification when at least one of the following conditions is verified:

I - the technical complaint is usually detectable by the user before using the product, regardless of the existence of precautions described in the instructions for use provided together with the product;

II - the registration holder has information saying that the adverse event was caused by the patient conditions, either preexistent or acquired during the use of the health product under investigation;

III - the single cause for the occurrence of the adverse event or technical complaint was the product use after the validity or lifetime set by the manufacturer expires;

IV - the product presents a protection device against failure, which represents a risk to the patient, user, or other person, and the protection correctly worked, avoiding the occurrence of a severe adverse event;

V - there are occurrences foreseen and expected by the manufacturer or registration holder, which are clearly identified on the product labeling or instructions for use and have numerical or functional predictability when the device is used according to what is indicated;

VI - the product is used in disagreement with the intended use stated by the manufacturer, instructions, and warnings presented on the product labeling and instructions for use and has not caused a severe adverse event; and

§ 1st The condition described in subsection I of this article does not apply in case of occurrence of an adverse event caused by product non conformity;

§ 2nd In order to justify the classification under subsection II, the registration holder must have available and sufficient information to conclude that the product did not cause, or did not contribute to cause, the adverse event;

§ 3rd The registration holder must notify SNVS about technical complaints, adverse events, or other occurrences that, in spite of being fitted in at least one of the criteria set in subsections I to VI of this Article, are related to a situation of serious threat to public health.

§ 4th In the hypothesis of the previous paragraph, the term for notification is 72 hours, according to what is set in Article 8th, subsection I, of this Resolution.

Article 11 In order to notify occurrences according to what is set in Article 8th of this Resolution, the registration holder must use the electronic information system of the SNVS defined by Anvisa.

CHAPTER IV

ON FINAL AND TRANSIENT PROVISIONS

Article 12. Adverse events or technical complaints caused by the use of the health products cited on the notification to SNVS that may represent infraction to the federal sanitary legislation will be investigated by the due administrative process.

Single paragraph. The notification of adverse events or technical complaints to SNVS does not imply the immediate responsibility of the registration holder for harmful events caused to other parties due to the use of the health product(s) cited on the notification.

Article 13. Without disregarding other legal comminations, even penal ones, the technical and legal responsible parties are susceptible to, the company will be administratively and civilly responsible for sanitary infraction caused by non compliance with this Resolution and other complementary rules under the terms of Law no. 6,437/77.

Article 14. Anvisa and the other members of SNVS, in the extent of their competences and by responsibility agreement, will be in charge of the adoption of measures or procedures for the cases not predicted in this Resolution.

Article 15. The term of 180 (one hundred and eighty) days is set for Anvisa to make the needed tools and systems available for compliance with the determinations set in this Resolution.

Article 16. The term of 360 (three hundred and sixty) days is set for the registration holders of health products to be adjusted to this Resolution.

Article 17. This Resolution takes effect on the date of its publication.

DIRCEU RAPOSO DE MELLO