

NORMATIVE INSTRUCTION - IN No. 4, OF JUNE 15th, 2012

Establishes rules for providing instructions for use of healthcare products in non-printed formats.

The Collegiate Board of Directors of the Brazilian National Health Surveillance Agency (ANVISA), in the exercise of the powers vested by Article 11, subsection IV, of ANVISA Regulation approved by Decree no. 3,029, of April 16th, 1999, and in view of the provisions of Article 54, paragraphs 1 and 3, and Article 55, subsection II, of the Internal Statute approved under the terms of Annex I of Anvisa Ordinance no. 354, of August 11th, 2006, republished on the Brazilian Official Gazette of August 21st, 2006, in meeting held on June 14th, 2012, hereby resolves:

Article 1. This Normative Instruction hereby establishes the necessary requirements for providing, in non-printed formats, instructions for use of healthcare products subject to *cadastro* or *registro* registration and used by qualified professionals or in healthcare service environments.

Sole Paragraph. The healthcare products referred to thereof comprise medical products, regulated by RDC no. 185, of October 22nd, 2001, and in-vitro diagnostic products, regulated by RDC no. 206, of November 17th, 2006.

Article 2. It is hereby forbidden to provide instructions for use exclusively in non-printed formats for the following products:

I - healthcare equipment intended for:

- a) overall domestic use, including those intended for use in homecare services (SAD);
- and
- b) being operated by laypeople, regardless of the location;

II - healthcare materials used by laypeople;

III - in-vitro diagnostic products, comprising:

- a) self test products;
- b) products used for remote laboratory testing; and
- c) patterns and calibrators.

Article 3. Instructions for use in non-printed formats may be provided in CDs, DVDs, online, or in any other format that contemplates all requirements laid down herein.

Article 4. The following are requirements for providing instructions for use in non-printed formats:

I – information on the external label about how to obtain the respective version of the instructions for use of the supplied product;

II – indication of Customer Service to which the printed version of the instructions for use may be requested with no additional cost (including mailing expenses);

III - to ensure the availability of the instructions for use throughout the period of time that the product is marketed; and

IV – specifications of the required resources so that the user may have access to the instructions for use.

Paragraph 1. Should the dimensions of the external label not allow, the information required thereof may be included in a document enclosed to the product.

Paragraph 2. Manufacturers or registration holders of healthcare equipment shall consider the period of time indicated in subsection III as being the lifetime specified for the product, counted from the date the last unit was commercialized.

Article 5. The instructions for use provided in non-printed formats shall contain:

I - all information required in item 3.2 of the Annex of RDC 206, of November 17th, 2006, if in-vitro diagnostic products;

II - all information required in the annex of RDC no. 185, of October 22nd, 2001, and in specific regulations, when applicable, if healthcare products;

III - identification of the version of the instructions for use corresponding to the respective product;

IV - a warning to the user so that the correlation between the version of the instructions for use and the acquired product may be observed; and

V - indication of how to obtain the printed version of the instructions for use without any additional cost.

Article 6. In order to provide the instructions for use online, the following requirements shall be met, in addition to those laid down in Articles 4 and 5 hereof:

I - to provide, along with the product, clear orientation on how to find its corresponding and updated instructions for use on the electronic address available on the Internet;

II - to ensure the basic requirements for safety of the electronic address;

III - to provide the instructions for use on the electronic address as a non-editable, read-only file;

IV - to provide, on the electronic address, free access and the program required for reading the instructions for use; and

V - to ensure that the document provided on the electronic address be identical to the printed version supplied by the manufacturer or registration holder, when requested.

Article 7. Failure to observe the determinations hereof shall constitute a health violation, being the offender hereby subject to the punishments laid down in Law no. 6,437, of August 20th, 1977.

Article 8. This Normative Instruction shall come into force on the date of its publication.

DIRCEU BRÁS APARECIDO BARBANO