Resolution RDC No. 3, February 2nd, 2010

Sets forth the chronological criteria for reviews of registro and cadastro applications of medical devices at ANVISA.

The Collegiate Board of Directors of Anvisa, using the powers vested by Subsection IV of Article 11 of the Regulation approved by Decree no. 3,029, of April 16th, 1999, and in view of the provisions of Subsection II, Paragraphs 1 and 3, of Article 54 of the Internal Statute approved in accordance with Annex I of Anvisa Ordinance no. 354, of August 11th, 2006, republished on the Official Gazette on August 21st, 2006, in meeting held on November 9th, 2009, hereby adopts the following Resolution and I, Director-President, determine its publication:

Article 1. The general criterion adopted for reviewing applications for registro, post-registro, cadastro or post-cadastro of health products is hereby chronological, pursuant to the date and time of submission.

Article 2. For the purpose of chronological organization, applications shall be grouped into four distinct groups upon submission:

I - registro applications, referring to the first registro application of a particular product or product family.

II - cadastro applications, referring to the first cadastro application of a particular product or product family.

III - post-registro applications, referring to revalidations, changes, archiving or expiration of the registro of a product or product family.

IV - post-cadastro applications, referring to revalidations, changes, archiving or expiration of the cadastro of a product or product family.

Article 3. For chronological organization of applications of the four groups listed in the previous Article, separate lists shall be adopted for different types of products, according to the following subgroups:

I - Subgroup I - In-Vitro Diagnostic Products:

a) In-vitro diagnostic products intended for immunohematology and blood-borne diseases;

b) other in-vitro diagnostic products.

II - Subgroup II - Materials for health use:
a) orthopedic prostheses and orthoses;
b) other materials for health use.

III - Subgroup III – Equipment:

a) electrical medical equipment with mandatory certification of conformity with technical standards;
b) equipment without mandatory certification.

Article 4. Products enclosed by one or more of the following conditions shall supersede the chronological criterion in order to organize the line in each group or subgroup:

I - Products identified as priorities by the Ministry of Health and that are the object of:

a) strategic actions related to the population’s health:
b) projects or processes of technological development receiving funds from government agencies or with partnerships that involve governmental bodies;

II - applications originated from the requirement for splitting registro or cadastro applications of health products;

III - applications with regard to products that are complementary to others under review;

IV - applications referring to the same subject, submitted by the same applicant, and that may be reviewed together.

Sole Paragraph. The indication of priority products, in accordance with Subsection I of this Article, shall observe the issuance of acts by the Ministry of Health, along with the motivation for each case.

Article 5. This Resolution shall come into force 30 days after its publication.

DIRCEU RAPOSO DE MELLO