LETTER TO THE EDITOR

Medical devices registration by ANVISA (Agência Nacional de Vigilância Sanitária)

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Dear Editor,

The term ''medical devices'' covers a wide range of health or medical instruments used directly or indirectly in medicine, dentistry, physical therapy, and laboratory practice for the diagnosis, rehabilitation, therapy, and monitoring of human beings, as well as for aesthetic purposes.

The National Health Surveillance Agency (Agência Nacional de Vigilância Sanitária – ANVISA)[1] is responsible for the registration of medical devices in Brazil and assigns a unique 11-digit identification number to each device, according to specific resolutions.

According to ANVISA,[1] all medical devices are regulated by the Brazilian Ministry of Health, under Article 12 of Law No. 6360 of September 23, 1976, published in the Official Gazette of September 24, 1976. This Article regulates the manufacture, use, and sale of medical devices in Brazil.

All medical devices have to be registered and/or listed with ANVISA.

Listing is the first step in the registration process of all medical devices. This is a simple process that applies to medical devices classified according to the first paragraph of Article 25 of Law No. 6360 as Class I and Class II, which do not require registration under Resolution RDC ANVISA 24 of May, 1999.

On the other hand, some medical devices require registration, even if classified as Class I or Class II, because of the potential risk involved, as indicated in Resolution RDC ANVISA 185 of October 22, 1999, and other complementary regulations also used in this process.

The requirement for medical device registration and/or listing with ANVISA is determined by the classification of the device into four risk classes (I to IV) based on 18 classification rules. Classes I, II, III and IV represent low-, medium-, high- and very-high-risk devices, respectively.

Thus, medical devices classified as Class I and Class II may or may not require registration depending on their use, because they pose a low risk to the patient. Class III and Class IV devices require listing and registration, and all the parameters and specifications of the device have to be given during the registration process.

The classification rules for the registration of medical devices are based on the evaluation of risks arising from the application and use of the devices.

Medical devices used in physical therapy are considered active devices, meaning that a power supply is required for their operation. These devices can be classified based on four rules, of which the most important one (Rule 9) refers to ''active therapeutic devices intended to deliver energy to or exchange energy with the human body'', including electrophysical agents used in the clinical practice to facilitate wound healing, analgesia, edema reduction, and modulation of the inflammatory process.

Most of the electrophysical instruments used in physical therapy for tissue repair are classified as Class II devices and only require to be listed. Examples of Class II devices include equipment used in ultraviolet phototherapy, ultrasound therapy, pulsed electromagnetic field therapy, electric stimulation therapy, laser therapy, and light-emitting diode therapy.

Regardless of their therapeutic use and classification, all medical devices should necessarily be registered with the provision of clear specifications, and their safety for use in the clinical practice should be determined on the basis of clinical trials.

Therefore, even devices for aesthetic treatments or those used by technicians, such as estheticians, should have reliable operating parameters, allowing them to be tested in scientific studies.

The search for agents that can influence the wound-healing process by accelerating the different phases of wound healing and reducing healing time, and that can improve functional and aesthetic results, is still a challenge in the field of surgery.

Experimental studies have indicated that the use of medical devices have a beneficial effect on the healing of skin wounds, contributing to the modulation of the inflammatory process,[2,3] stimulation of angiogenesis,[2,4] proliferation of fibroblasts[2,3,5] and myofibroblasts,[6–8] deposition of collagen,[3] and proliferation of keratinocytes.[9]

From these studies, it was possible to advance to clinical trials and adjust the specifications of these devices for use in clinical practice.

As an example, there is an electrophysical device available in the market, called the ''high-frequency machine'', which has been used for many years for facial and body aesthetic treatments. The literature and manufacturers suggest that this device produces therapeutic effects similar to those obtained from the topical application of

ozone, and is indicated for the healing of skin wounds, surgical wound dehiscence, and treatment of fungal lesions.[10–15] However, scientifically rigorous studies are necessary to determine the veracity of these claims, because the reported performance of this device is based on unreliable studies, and to date no study on this device has been published in the peer-reviewed medical literature.

According to ANVISA, the high-frequency machine is classified as a Class I device, meaning that it is a device for aesthetic treatments and is considered to pose a low risk to the patient. Therefore, the manufacturer is not required to register this device and disclose all technical specifications in order to standardize its applications, even though there may be risks and contraindications associated with its use.

Thus, like other medical devices for therapeutic use, the registration and control of the specifications and parameters of such a device would be of considerable importance. Moreover, the registration of all medical devices should be mandatory.

All these biophysical agents have specific indications and contraindications, have the potential to produce skin lesions, such as burns, and may negatively impact the health of patients with pacemakers, malignant tumors or thrombophlebitis, among other things.

On the basis of the classification system (classes I to IV) for medical devices, ANVISA does not require scientific studies to be performed to determine the actual effects and risks of Class I and Class II devices. This trivializes their use and allows non-medically qualified practitioners to operate them.

Therefore, the goal of this *Letter to the Editor* is to alert the community to the current system of risk categorization of medical devices used by ANVISA, which can result in losses and harm to the patient caused by the use of a device.

In conclusion, we believe that it is important to call the attention of health officials to the need for standardization of the parameters and specifications of medical devices, so that their therapeutic use can follow guidelines developed on the basis of scientifically rigorous studies, providing increased safety to patients treated with such devices.

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