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The new French Decree: Advertising visa for high risk medical devices

The French decree regarding the list of medical devices for which advertising to healthcare professionals shall obtain a prior authorization of ANSM (National Safety Agency of Medicines and Health Products), has been published on October 03, 2012. Such authorization is referred to as ‘’visa de publicité’’ *(*advertising visa*)* and is applicable to all advertising materials utilized after January 1st 2013, meaning that all manufacturers required submitting their current marketing materials to ANSM.

So, is subject to prior authorization by ANSM all advertising directed at health professionals for the following medical devices:

- Cardiology: Implantable heart defibrillators; Implantable heart defibrillating leads; Implantable heart pacemakers and accessories; Implantable heart stimulating leads; Coronary Stents.
- Repair Surgery: Breast implants; Dermal fillers.
- Orthopedics and Traumatology: Ankle prosthesis; Knee prosthesis; Hip prosthesis; Shoulder prosthesis.
- Ophthalmology: Intraocular lenses.
- Medical and surgical specialty: Laser generators for surgery
- Neurology and Neurosurgery: Intracranial stents

ANSM will have a period of 2 months from the date of receipt of the application to notify the company of a favorable opinion or a refusal. Beyond this period and if no response from ANSM, the application is considered accepted. The validity of the visa is five years.

Where an advertisement is communicated for these devices without having obtained the advertising visa or if this authorization was terminated or refused, the penalties are a maximum of two years of imprisonment and a fine of up to 30,000 Euros.

However, on October 26, writing this article, ANSM indicates that the modalities of submission for this visa are not yet ready and will be published later on their website: *http://ansm.sante.fr/Activites/Publicite-pour-les-dispositifs-medicaux-et-autres-produits-de-sante/Publicite-pour-les-dispositifs-medicaux/(offset)/0*

The modalities will include probably the documents to provide with the visa request such as the IFU, the CE Certificates and the results of the clinical investigations. We know that the new proposed EU medical devices regulations of last September 26 include the creation of a Medical Device Coordination Group (MDCG) who will review the safety and performance of all new high risk medical devices, which may delay their marketing launch of 90 days, but the new regulations should not be effective before at least 2017. One consequence of this ‘’advertising visa” could be to delay the launch of the new devices included into the above mentioned list by 60 days without waiting 2017.

One other consequence is that for devices such as Orthopedic prosthesis, manufacturers should take care to remove any advertising into their surgical technique manuals or videos in order to avoid the need for this “advertising visa”.

It has been reported that, even without knowing the submission modalities, more than 1500 visa requests have been already sent to ANSM !

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