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E-ALERT | Life Sciences

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FRANCE - PRIOR APPROVAL FOR ADVERTISING FOR MEDICAL DEVICES AND IVDS

French Law No 2011-2012 of 29 December 2011 on the Strengthening of Health Protection for Medicinal and Health Products has been inserted into the Public Health Code ('*Code de la santé publique*' or CSP). It includes new advertising rules for medical devices (MDs) and in vitro diagnostic medical devices (IVDs). See our previous e-alert (France - A Revolution for the Medical Devices Industry New Advertising Rules). The Law has been supplemented by the implementing Decree No 2012-743 of 9 May 2012 that details the prior approval system for advertisements for certain MDs (those carrying an important risk to human health) and IVDs. The approval (so-called 'visa') is granted by the French Medicines Agency (ANSM), for a maximum of five years. The MDs and IVDs concerned had to be determined by the Ministry of Health. This is done - the Ordinances listing the MDs and IVDs the advertising of which is subject to prior approval have been published today in the French official journal.

Ordinance of 24 September 2012 on MDs Carrying an Important Risk to Human Health

Advertisements to general public	Dermal fillers*
Advertisements to HCPs	o Cardiology - implantable heart defibrillator - implantable heart defibrillating catheter - implantable heart stimulator and its accessories - implantable heart stimulating catheter - coronary stent o Repair Surgery - breast implant - dermal fillers o Orthopedics - Traumatology - ankle prosthesis - knee prosthesis - hip prosthesis - shoulder prosthesis o Ophthalmology: intraocular lens o Medical and Surgery Specialty: surgery laser generator o Neurology and Neurosurgery: intracranial stent

*Under the Commission's proposal for a regulation on medical devices, certain implantable or other invasive products are considered medical devices, regardless of whether or not they are intended by the manufacturer to be used for a medical purpose. Those products, which are listed in Annex XV to the future Regulation, include dermal fillers.

Ordinance of 24 September 2012 on IVDs

Advertisements to general public	IVDs for auto diagnosis
Advertisements to HCPs	o Reactive agents (including associated measurement and control materials) for determining the following blood groups: system ABO, rhesus (C, c, D, E, e) anti-kell. o Reactive agents (including associated measurement and control materials) for detecting, confirming and quantifying markers of HIV (HIV 1 et 2), HTLV I and II as well as hepatitis B, C and D in human specimens. o IVDs for detection, diagnostic and confirmation of the variant of Creutzfeldt-Jakob disease.

Decree No 2012-743 and the Ordinances apply as from 1 January 2013. Any advertisement for a listed MD or IVD needs the ANSM's visa if (i) it is disseminated as from 1 January 2013 or (ii) it was disseminated before 1 January 2013 and continues to be used after that date. Unlike for medicinal products, no specific timeslots have been set by the ANMS for visa applications. Visa applications are deemed accepted if the ANSM does not take a decision within two months of the submission of the application. The ANSM may also grant the visa within a shorter period.
These rules will continue to apply despite the planned adoption of new EU rules on medical devices and IVDs, unless the EU Parliament and Council add specific advertising rules to the current Commission's proposals (the proposals do not contain advertising rules).

If you have any questions concerning the material discussed in this client alert, please contact the following members of our life sciences practice group:

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