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E-ALERT | Food & Drug

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FRANCE - A REVOLUTION FOR THE MEDICAL DEVICES INDUSTRY

New Advertising Rules

French Law No 2011-2012 of 29 December 2011 on the Strengthening of Health Protection for Medicinal and Health Products (*"loi relative au renforcement de la sécurité sanitaire du médicament et des produits de santé"*) (the 'New Law') will have a tremendous impact on the medical devices industry. The industry will now be subject to new advertising rules, sunshine-like obligations, stricter rules on conflicts of interest, and more.

A new chapter on advertising rules for medical devices has been inserted in the Public Health Code (*'Code de la santé publique'* or CSP) (Art. L. 5213-1 to L. 5213-7). In some aspects, the new legal regime is similar to the one for medicinal products: prohibition of advertising for non-CE marked devices; prohibition of advertising to the general public for medical devices subject to health insurance reimbursement, except for medical devices with a low risk to human health; prior approval for advertising for medical devices with an important health risk; and general criteria for advertisements. Violations of those rules by manufacturers, EU representatives, or importers are administratively and criminally sanctioned.

Another new chapter deals with in vitro diagnostic medical devices (IVDs). These rules are almost identical to those governing medical devices, except for those referring to reimbursement by health insurance (which is not available for IVDs).

The statutory rules will be applicable after the adoption of an implementing decree, which is expected in mid-2012. Meanwhile, companies should prepare if they have not already done so: they should set up a review committee, determine the review responsibilities and process, identify the relevant documents, and so on.

SUMMARY

The main difference in the requirements for advertising to the general public and advertising to healthcare professionals is determined by whether the medical device is subject to health insurance reimbursement and the potential risk to human health. The chart below summarises these differences:

	General Public	Healthcare Professionals
Non-CE marked MDs	No	No
MD covered by health insurance		
Low risk to health (official list)	Yes	Yes
No important risk to health	No	Yes
Important risk to health (official list)	No	Prior approval Medicines Agency

MD not covered by health insurance		
No important risk to health	Yes	Yes
Important risk to health (official list)	Prior approval Medicines Agency	Prior approval Medicines Agency
Contraceptives and condoms	Yes	Yes
Information on human health or diseases	Yes, unless a direct or indirect reference to a specific MD (if so, see rules above)	Yes, unless a direct or indirect reference to a specific MD (if so, see rules above)

Advertising

Like for a medicinal product, 'advertising' for a medical device is defined as any form of information, including canvassing, inducement to prescribe, deliver, sell, or use a MD. The following are not considered 'advertising':

- information given by hospital pharmacists
- labelling and instructions for use
- correspondance, including any non-promotional document, which is necessary to answer a specific question on a specific MD
- warnings, precautions of use, side effects, as well as sale catalogues and lists of processes if there is no information on the MD
- information on human health or diseases, provided that there is no direct or indirect reference to a MD.

The advertising rules do not apply to contraceptives or condoms.

Prohibition of Advertising for Non-CE Marked Medical Devices

None of the new rules expressly prohibits advertising of non-CE marked MDs. However, new Article L. 5213-2 specifies that advertising concerns MDs with a conformity certificate (and therefore CE-marked devices).

The wording of the provision is unclear and although an argument could be made that only CE-marked MDs are subject to the new rules, this interpretation conflicts with the legislative history and defies common sense. The objective of the law is to better protect consumer health; if non-CE marked MDs were subject only to common advertising rules (fair, balanced, substantiated, and non-misleading claims are allowed) and thus to a much more lenient regime than CE-marked devices, no added protection to consumer health would attach. Therefore, advertising of non CE-marked devices now seems restricted to scientific or technical meetings, fairs, or displays (Art. R 5211 - 13 CSP).

Prohibition of Advertising to the General Public for Medical Devices Covered by Health Insurance

MDs that are subject to health insurance reimbursement, in whole or in part, may not be advertised to the general public unless they carry a low risk for human health and are included in a list to be drawn up by the Ministry of Health.

In France, health insurance coverage concerns specific use. The new legal provision suggests that the coverage of one use is sufficient to prevent advertising of any use of the MD, whether reimbursable or not.

Prior Approval for Advertising for Medical Devices with Important Health Risks

Advertising for MDs that carry an important risk for human health and are included in a list to be drawn up by the Ministry of Health is subject to a prior approval by the French Medicines Agency. The approval, which may be granted for a maximum of five years, may be suspended or withdrawn by the Agency.

The applicable provision does not distinguish between MDs subject to health insurance coverage and MDs not subject to such coverage and so applies to both categories of MDs.

General Criteria for Advertisements

Advertising must present the MD, its functions, or its conformity to essential safety and health requirements as defined by the conformity certificate in an objective manner. It must also encourage the rational use of the product, not be misleading, and not endanger public health. These criteria are the same as for medicinal products.

Sanctions

Violations of the new requirements are subject to administrative and criminal sanctions. Besides ordering the company to withdraw or correct the advertisement or prohibit it, the Medicines Agency may impose an administrative fine up to 10% of the turnover 'generated' with a maximum of 1 million Euros and a daily penalty up to 2,500 Euros. The fine should be proportional to the seriousness of the infringement. The provision is unclear about how turnover is determined; this will be specified in the implementing decree.

Criminal courts could impose a fine up to 150,000 Euros on companies as well as up to two years of imprisonment and fine up to 30,000 Euros on individuals. Additional sanctions are also specified (publication of the decision, temporary closing of the facility, etc.).

Get Organised

Companies that are not yet organised should do so before the new rules become applicable with the implementing decree and adoption of list(s) of MDs with low or important risk to human health. In practice, this means, for example,

- determine the health insurance status of each MD
- identify, for each MD, the documents that qualify as promotional and their target audience
- identify, for each MD, the reference documents (instructions for use, technical file, opinions of the *Haute Autorité de Santé*, etc.)
- set up a review committee
- adopt a SOP to determine the review internal responsibilities and company procedures
- review each promotional document to ensure that it meets the general advertising criteria.

Moreover, companies should take steps, perhaps through the relevant trade associations, to avoid their MDs from being included in the list of MDs with important risks to human health.

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

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