PDG Avocats

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POSSIBLE CHANGES IN ADVERTISING AND COMPLIANCE REGULATIONS IN FRANCE

The French government has decided to review the current French Health Product system and in particular the provisions relating to safety of health products (« *Projet de loi relatif au renforcement de la sécurité sanitaire du médicament et des produits de santé* »). This bill of law is the outcome of several evaluation reports conducted by actors in the pharmaceutical field.

According to the Minister of Health, the bill of law aims in particular at restoring the confidence in the decisions taken and the transparency in the relationships between the industry and experts.

The bill of law proposes a modification of the some articles of French Public Health Code (CSP) regarding industry/health professional relationships (I.) and advertising of medicinal products (II.).

A first draft of bill of law has been presented to the Council of Ministers on 1st August 2011. The text has not been reviewed by the Parliament yet. It should be examined by the Parliament in September 2011. (Bill of Law N° 3714 registered by the French Parliament (Assemblée Nationale) on 1st August 2011).

Please find below a short overview of the changes proposed by the bill of law for these two subject-matters. We are at your disposal for any additional questions.

I. Compliance: Industry/health professional relationships

New provisions regulating to the granting of advantages by pharmaceutical companies (both medicinal products and medical devices) to health professionals may be introduced in the CSP by the above-mentioned bill of law.

Indeed, in addition to the existing provisions of Article L.4113-6 of the CSP prohibiting the granting of advantages to health professionals, pharmaceutical companies will have to disclose the existence of conventions that they concluded with:

- health professionals,
- associations of health professionals,
- students in medicine and odontology,
- associations of patients,
- health establishments,
- foundations,
- press organs for health professionals;
- learned societies.

Above a limit that will be fixed by Decree, the same obligation will apply to the advantages in nature or in money granted by pharmaceutical companies to the above listed recipients.

A Decree will also set down the conditions of application of this article and in particular determine which information will have to be disclosed, the timing of disclosure and the modalities of publication.

Finally, please note that Article L.4113-6 of the CSP will also apply to students in medicine and odontology.

Sanctions in case of violation of these provisions (fines and imprisonment) have been foreseen for all actors (pharmaceutical companies and above listed recipients).

II. Advertising of pharmaceutical products

The bill of law modifies the some existing provisions of the CSP on advertising of medicinal products (2.1.) and introduces new provisions on advertising of medical devices (2.2.).

2.1. Advertising of medicinal products

The bill of law modifies the CSP regarding advertising of medicinal products.

One modification is the prohibition of advertising a medicinal product when the said medicinal product is under benefit/risk re-evaluation further to a pharmacovigilance signal.

Another main modification is the need for pharmaceutical companies to obtain the authorisation for advertising to professional prior to its launch. For the time being, advertising to professionals must be notified to AFSSAPS within an eight-day period after its launch. It is consequently assessed by the AFSSAPS after being released. This will be a significant change for pharmaceutical companies.

2.2. Advertising of medical devices

Article 23 of the bill of law includes in the CSP provisions relating to advertising of medical devices. Currently, the CSP does not regulate advertising of medical device. General provisions of the French Consumer Code apply to advertising of medical device and no notification to the French Agency (AFSSAPS) is foreseen.

Advertising of medical device is defined as "*any form of information including canvassing, prospecting or enticement aiming at promoting the prescription, the delivery, the sale or the use of medical devices, except the information given by pharmacists within the framework of their activities in hospital pharmacies*".

It is not considered as advertising:

- The labeling and notice of use;
- The answer to a precise question on a specific medicinal product;
- Information on warnings, precautions for use and adverse reactions within the framework of pharmacovigilance activities and on sales catalogues or lists of prices if there is no information on the medical device on them.

- Information on human health or diseases if they do not include reference even indirectly to a medical device.

This definition is very similar to the definition of advertising of medicinal products.

Similarly to medicinal products, the advertising of medical devices would have to be objective and be in compliance with the CE mark obtained.

Medical device covered or financed even partially by the Health Insurance cannot be advertised to general public. Consequently only non-reimbursed medical device can be the subject of an advertisement to general public.

A prior authorisation of the French Agency (which will be renamed "*Agence Nationale de Sécurité du Médicament et des Produits de Santé*" (ANSM) – National Agency for Safety of Medicinal Products and Health Products) will have to be obtained for medical device presenting a high level of risk. A list of these medical devices will be fixed by the Ministry of Health. This authorisation will be delivered for renewable 5-year period but can be suspended or withdrawn by decision of the French Agency.

Sanctions for violation of these provisions (fines and imprisonment) are inserted in the CSP.

Please keep in mind that it is the beginning of the legislative process and changes may still occur.

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