

E-ALERT | Health Care

January 20, 2012

FRANCE - A 'SUNSHINE ACT' FOR THE HEALTHCARE INDUSTRY

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"), creating Articles L. 1453-1 and L. 1454-3 to L. 1454-5 of the French Code of Public Health ("Code de la santé publique" or 'CSP')

On December 29, 2011, the French legislature adopted new rules imposing disclosure requirements on a broad section of the life sciences industry, including pharmaceutical, medical devices, and cosmetics companies as well as distributors. The rules also cover providers of related services and more specialised players such as entities marketing organs, tissues and cells, and certain software providers. Contractual arrangements with, or any benefits granted to, a wide range of healthcare actors, including healthcare professionals, hospitals, patient associations, or providers of medical software, must be disclosed; written and spoken press and online publications are also covered. Infringements are subject to criminal sanctions. Additional details will be set forth in an implementing decree (the 'Decree') which is not expected before late 2012. The new obligations will only become enforceable after the adoption of the Decree, but they may be retroactively applied to agreements and benefits as from 1 January 2012.

Many details remain unclear and there will be extensive debate on key points, such as the protection of business secrets, the proportionality of the obligations, compliance with EU law, and the possible retroactive effect. There will also be numerous interpretation problems such as the applicability to companies based outside France or to relationships with entities based outside France.

The new French law follows similar laws adopted in the UK and the Netherlands, but those laws are applicable to the pharmaceutical industry only.

SCOPE OF APPLICATION

Activities – The transparency obligations apply to (i) any agreements and (ii) from a certain level, any benefits, direct or indirect, in kind or in cash.

The concept of 'benefit' is not legally defined by the New Law, but Article L. 4113-6 CSP can be referenced for guidance. Article L. 4113-6 expressly prohibits any benefit to individual healthcare professionals (HCPs), either direct or indirect, in kind or in cash, and in any form whatsoever. Although 'benefit' is not defined in this provision, the term is interpreted very broadly to cover any type of payment, goods, or services, such as free medical equipment, hospitality for spouses, or excessive fee for service. A few benefits are exempted from the prohibition set forth in Article L; 4113-6 (i.e., fees for services, hospitality, sponsoring of continuing medical education, gifts of low value, donations to legal entities, and rebates/discounts), but still must be disclosed under new Article L. 1453-1.

Companies – Companies that manufacture or commercialise health products or associated services are subject to the transparency obligations.

The health products concerned are the 19 categories of products which are under the French Medicines Agency's supervision, such as medicinal products, medical devices, cosmetic products, essential oils, human and animal tissues or cells, contact lenses, tattoo products, test devices, etc. (see Article L. 5311-1(II) CSP). The term 'associated services' products is vague and thus potentially has a very broad coverage, including distributors, advertising companies, logistics companies, etc.

Recipients – Covered companies must disclose all the agreements entered with, and benefits given to, nine categories of healthcare actors, including healthcare professionals (doctors, veterinarians, dentists, pharmacists, nurses, mid-wives), associations of healthcare professionals, healthcare students, patients associations, hospitals, non-profit associations (foundations, societies), companies providing advice in relation to health products, companies running a press, radio, television or online public communication services, or legal entities providing or participating in the initial training of healthcare professionals.

Overall, the scope of Article L. 1453-1 is much broader than that of Article L. 4113-6 CSP, which is expressly limited to services and health products which are subject to social security reimbursement and healthcare professionals.

CONDITIONS OF DISCLOSURE (WHAT? HOW? WHEN?)

The details of the scope of application of the transparency obligations, the information to be disclosed, the time limits and conditions of publication, the updating of the information, and the national associations' involvement in such publication will have to be specified in an implementing decree. In all likelihood, certain provisions of the New Law will be challenged before the French Constitutional Court and the upcoming French presidential election may trigger a political change which could affect the application of the New Law. It may be the last quarter of 2012 before the Decree is adopted.

Nevertheless, some guidance is included in new Article L. 1453-1 CSP as it already specifies that the disclosure will be limited. First, disclosure will be limited to the existence of agreements and will not require disclosure of the subject-matter or specific terms. (Note that compensation paid under the agreements may still have to be disclosed as it qualifies as benefits.) Second, the benefits must be disclosed only if they exceed a 'level' to be fixed by the Decree. The legislative history suggests that the level will be low: an amount of 150 Euros was suggested in the early drafts. Determining whether the level has been exceeded will be easy to check for monetary benefits but may prove difficult for benefits in kind.

SANCTIONS

Companies that 'knowingly' violate the transparency obligations may be subject to a criminal fine up to €225,000 and may face ancillary sanctions, such as a ban on participating in public tenders, the suspension of business activities, or the closing of facilities. Individuals may face sanctions such as the public communication of the sentence, a bar from a public office or conduct business activities, or the prohibition to manufacture, import and market health products. (see Articles L. 1454-3 to L. 1454-5 CSP).

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