

Client Alert

March 2015

France – The Highest Administrative Court Annuls Parts of Sunshine Decree and Circular

In 2011, France adopted a ‘sunshine’ law that imposes transparency of the interactions between, on the one hand, pharmaceutical, medical device and cosmetic companies and, on the other, health care professionals and organizations (‘Sunshine Law’).¹ Transparency applies to agreements entered, and benefits granted, from 1 January 2012.

The Sunshine Law was implemented by a governmental decree (‘Sunshine Decree’)² and an administrative circular (‘Circular’).³ On 24 February, the *Conseil d’Etat*, the highest administrative court, annulled parts of the Sunshine Decree and Circular.

The Court generally extends the transparency obligations and therefore increases the administrative burden imposed on companies. The decision applies not only to future but also to past interactions, which means that companies should correct the disclosures made since 2012. Hopefully, the French enforcement authority will adopt a pragmatic approach in regards to past disclosures.

The most important rulings are the following:

- **More Extensive Disclosure Requirements for Cosmetic Companies:** The Sunshine Law imposes transparency of agreements entered into by pharmaceutical and medical device companies (‘health companies’) as well as cosmetic, non-corrective contact lens and tattoo companies (‘non-health companies’). However, for non-health companies, the Sunshine Decree limits the disclosure to agreements related to safety evaluation, vigilance or biomedical research. The Court annulled this limitation.
- **Purchase of Goods or Services by Health Care Professionals or Organizations:** The Sunshine Law exempts purchase and service agreements from the disclosure obligation. The Court clarified that this exemption is limited to the purchase of goods or services *made by* health care professionals or organizations from companies and not the other way around.
- **Compensation for Services to be Disclosed:** The Sunshine Law requires companies to disclose the benefits granted to health care professionals or organizations and the agreements entered into with health care professionals or organizations. Under the Circular, compensations paid to health care professionals or organizations pursuant to a work or service agreement did not have to be disclosed except if they were manifestly disproportionate. The Court specified that all compensations

¹ 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*” or “*Loi Bertrand*”).

² Decree No 2013-414 on Transparency of Benefits Given by Companies Manufacturing or Marketing Health and Cosmetic Products for Human Use (“*décret relatif à la transparence des avantages accordés par les entreprises produisant ou commercialisant des produits à finalité sanitaire et cosmétique destinés à l’homme*”).

³ Circular DGS/PF2/2013/224 on application of Article 2 of Law No 2011-2012 (“*circulaire du ministre des affaires sociales et de la santé n° DGS/PF2/2013/224 du 29 mai 2013 relative à l’application de l’article 2 de la loi n° 2011-2012 du 29 décembre 2011 relative au renforcement de la sécurité sanitaire du médicament et des produits*”).

paid under work or service agreements must be disclosed except those made pursuant to labor agreements.

- **Transparency Obligations Apply Only to Companies:** The transparency obligations apply only to companies; they do not apply to organizations of health care professionals, even if they transfer the benefits granted by a company to their members.

Contacts

Geneviève Michaux

gmichaux@hunton.com

Nicolas Herbatschek

nherbatschek@hunton.com

© 2015 Hunton & Williams LLP. Attorney advertising materials. These materials have been prepared for informational purposes only and are not legal advice. This information is not intended to create an attorney-client or similar relationship. Please do not send us confidential information. Past successes cannot be an assurance of future success. Whether you need legal services and which lawyer you select are important decisions that should not be based solely upon these materials.