Prepared for the New Transparency Requirements?

On 1 November 2014, new Danish regulation on the cooperation between the Danish health care professionals ("HCPs") and the pharmaceutical and medical device companies comes into force. The regulation provides for a much higher degree of transparency including HCPs' affiliation with pharmaceutical and medical companies, and the economic benefits to HCPs.

On 20 May 2014, the Danish Parliament passed an act, thus amending the Danish Medicines Act, the Danish Medical Devices Act, and the Danish Health Act. The new act introduces a new chapter in the Danish Health Act, namely chapter 61a. This chapter sets out the rules for lawful affiliation of HCPs with pharmaceutical and medical device companies. Particularly for medical device companies, the regulation is entirely new. The general rule stipulates that the HCPs may not be affiliated with pharmaceutical or medical device companies unless the HCPs have obtained a prior permit from the Danish Health and Medicines Authority ("DHMA").

As an explicit derogation from the permission regime, the HCPs are allowed for certain forms of activities merely to report the cooperation to the DHMA. Examples are lecturing and research activities, clinical trials and non-intervention trials, along with the ownership of shares of a value not exceeding DKK 200,000 in any pharmaceutical or medical device company.

Affiliation in the form of consultancy and other economic affiliation, including ownership of shares of a value exceeding DKK 200,000, will require a permit from the DHMA.

Assessing Affiliation and Economic Benefits

The DHMA will issue specific criteria for the assessment of the different categories of affiliation. Each permit application will be subject to an individual assessment. According to the preparatory works and interpretative notes, the main criteria when assessing an affiliation will be:

For consultancy activities

- Whether the consulting activities can be presumed to be consistent with the applicant's work with patients;
- Whether the work or service performed by the HCP does not contain an incentive to promote consumption of a specific product, including ordination and sale; and
- Whether the remuneration is proportionate to the work conducted – and whether it is reasonable.

For ownership of shares

- Whether the ownership in a particular company can be presumed to be consistent with the applicant's clinical work – this shall be assessed in relation to the company's nature and the economic value of applicant's share in the compan
- Ownership in companies producing medicine and medical devices is generally acceptable as long as the products are not being marketed. If the products are marketed later, the DHMA shall assess ownership, including a potential liquidation of assets; and
- Ownership is not permitted in companies, which commercially are marketing products which can be chosen or used by the HCP in his or her clinical work.

Furthermore, the HCPs shall now have the duty to notify the DHMA, when receiving economic benefits from pharmaceutical and medical device companies for the purpose of participation in professional events outside of Denmark. This provision refers to economic benefits offered to the HCP's quid pro quo and also includes sponsorship of professional conferences as well as travel and accommodation expenses.

On their website, the DHMA shall publish all the permits and notifications given as described above.

At the moment, an executive order on the details of these new transparency requirements is drafted for public consultation and is expected to be passed on 1 October 2014.

New Obligations for the Industry and the Patient Associations

Under the new act, pharmaceutical and medical device companies have an obligation to inform the HCPs of the HCPs' duty to either apply for the DHMA's prior permission or to notify the Authority as described above. The specific rules about the companies' duty to inform, including the DHMA's disclosure of the records obtained on this subject, will be set out in the pending executive order.

Particularly for medical device companies, to which the act is completely new, the amended Danish Medical Devices Act stipulates that manufacturers and owners of specialist shops established in Denmark, that are selling or distributing medical devices in risk group II a, II b, III, or active implantable medical devices on Danish territory, have an obligation to notify the DHMA of their business activity. Representatives established in Denmark and acting for such manufacturers and owners have also a duty to inform the DHMA of their business activity in Denmark.

The purpose of the new obligation of notification is to give the DHMA the opportunity to register companies, so that the DHMA can publish a full list with a clear identification of all the companies subject to the rules on industry affiliation with the HCPs.

Patient associations, whose function is to safeguard the interests of patients, are as of 1 November 2014 under an obligation to publish all economic benefits that they receive from pharmaceutical and medical device companies. Any kind of gifts and/or amount received shall be published.

Effective Date – for new and existing cooperation

The described amendments regarding affiliation of the HCPs with pharmaceutical and medical device companies shall take effect as of 1 November 2014. This includes all new cooperation as of this date, whereas already existing cooperation and affiliations shall be notified to the DHMA as of 1 April 2015.