Update 25.10.19

EphMRA Code of Conduct 2019 – Changes since September 2019

Denmark
Point 4.45.1 of the EphMRA Code:

4.1.1 **In Denmark** legislation stipulates that any non-double-blinded (i.e. the identity of the commissioning client company in not known to the HCP market research subject and the identity of the HCP is not known to the commissioning client company) and the contact between a HCP and a pharmaceutical company or manufacturer of medical devices must be declared to the Danish Health authorities as consultancy. The registration of contact must be made by both the HCPs and the end-client (Pharmaceutical Company or Medical Device Manufacturer).

Is to be substituted with the FULL articles 15 and 16 of the ENLI code

Denmark:
ENLI 2017 The Pharmaceutical Industry's Code of Practice on Promotion etc., of Medicinal Products aimed at Healthcare Professionals
Article 15 – The use of consultants/professional services
Section 15.01. It is permitted to use healthcare professionals as consultants and advisors, whether in groups or individually, for services such as speaking at and chairing meetings, involvement in medical/scientific studies, clinical trials or training services, participation at advisory board meetings, and participation in market research, also when this participation involves remuneration and/or travel activity. A written contract or agreement must be concluded prior of the commencement of the services, specifying the nature of the services and, subject to clause (f) below, the basis of payment for these services. In addition, the following criteria, to the extent relevant, must be met: a) a legitimate need for the services must be clearly identified prior to requesting the services and entering into arrangements with the prospective consultants; b) the criteria for selecting consultants must be directly related to the identified need and the persons responsible for the selection of consultants must have the expertise necessary to assess, whether the particular healthcare professionals meet the criteria; c) the number of healthcare professionals retained must not exceed the number reasonably necessary to achieve the identified need; d) the contracting company must keep a record of, and make appropriate use of, the services provided by consultants; e) the hiring of the healthcare professional to provide the relevant service must not be an inducement to recommend, prescribe, purchase, supply, sell or administer a particular medicinal product; and f) the compensation for the services must be reasonable and reflect the fair market value of the services provided. In this regard, token consultancy arrangements must not be used to justify compensating healthcare professionals. g) Payment must only be offered in the form of actual payment, and not as a set-off, benefit in kind or by other indirect means.
Section 15.02. Employment arrangements of general practitioners, dentists and pharmacists with a pharmaceutical company require prior notification to or permission from the Danish

Health and Medicines Authority as per the Danish Health Act section 202 (a). Pharmaceutical companies must inform the healthcare professionals thereof as well as inform the Danish Health and Medicines Authority of the doctors, dentist and pharmacists who are associated with the company, as per this code's Art. 16, section 16.02
Section 15.03.Anonymous surveys, where the study is carried out by a third party and where the anonymity between respectively the underlying company and the pharmacist, doctor or dentist will be maintained after the implementation of the study, is not covered by section 15.02. It is a requirement that the company and the pharmacist, doctor or dentist does not become aware of each other.
Section 15.04. Limited market research, such as one-off phone interviews or post/email/internet surveys is not covered by this provision, except for Art. 15, section 15.01, sub-sections c), e), f) and g) and section 15.02, provided that the healthcare professionals are not consulted in a recurring manner (either with respect to the frequency of calls generally or of calls relating to the same research) and that the remuneration is minimal and in proportion to the service, cf. section 15.01, sub-section f). Such research must not constitute disguised promotion. Section 15.05. If a healthcare professional attends an event (an international event or otherwise) in a consultant or advisory capacity, the relevant provisions of Art. 13 shall apply.

Article 16 - Transparency
Section 16.01. Lif, IGL and PFL, and their members have signed up to "EFPIA's CODE ON DISCLOSURE OF TRANSFERS OF VALUE FROM PHARMACEUTICAL COMPANIES TO HEALTHCARE PROFESSIONALS AND HEALTHCARE ORGANISATIONS" (Disclosure Code). In Denmark, EFPIA's Disclosure Code is embodied within the framework of Sec. 4.02 and 4.03, which state that national variations are permissible in those countries where so required in national legislation.

Section 16.02. Accordingly, companies in Denmark are obliged to comply with: 1) The requirements laid down within the framework of the registration/approval and Disclosure Regulation laid down in Danish legislation (Medicines Act, Pharmacy Act and Danish Health Act) and the associated Executive Orders (Executive Order on Relations between Healthcare Professionals and Pharmaceutical and Medical Technology Companies and the Executive Order on Advertising of Medicinal Products) with effect from November 1, 2014. 2) The disclosure requirements arising from the pharmaceutical industry's other ethical rules on collaboration.