EFPIA Compliance and Codes Committees Update n°2

Welcome to this new edition of the EFPIA ComCom & CodCom Update.
Our aim is to inform Members about the latest issues and initiatives in the compliance arena.
We would welcome your feedback on the update and your recommendations of topics you would like to see covered in future additions.

The focus of this issue will be the publication of European Generic Medicines Association Code of Conduct on Interactions with the Healthcare Community and the related questions & answers, the national transparency laws and regulations' initiatives and an update about German criminal sanctions for self-employed doctors bill.

1. Publication of EGA Code of conduct

The EGA Code was adopted by its General Assembly on 9th December 2014 and published in March 2015.
This Code is related to the interactions with the Healthcare Community including Healthcare Professionals, Healthcare Organisations, patients and Patient Organisations.
This Code applies to prescription-only medicines and to EGA Members, so EGA national associations need to adopt the EGA Code.
The principles set forth in the EGA Code are mandatory and shall be implemented by all EGA members. However, where Applicable rules and requirements related to EGA Members are more stringent than the principles in the EGA Code; those Applicable rules and requirements shall prevail.

The content of the Code includes guidelines related to:

- Relations with patients and Patients Organisations: there are the same guidelines as the one set in the EFPIA Patient Organisation Code excluding the template.

- Fees for services and Consultancy for expert advice and support by HCPs and HCOs (e.g. expert on advisory boards, speaking engagements, participating in research, in focus group or market research, training and educating on products.): legitimate need, pay the correct price, appropriate number of experts, fair selection.

- Meetings and Hospitality: meetings for educational, scientific, research and promotional purposes with reasonable hospitality in connection with these meetings. Concerning travel, the Code states the economic class for flights as

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the rule (with a compensation for business class in exceptional circumstances).

- Educational Support for HCPs: providing educational support by paying registration costs, travel and accommodation and reasonable hospitality for company-organised events or for congresses and conferences organized by third parties. These meetings should be in therapeutic areas in which the HCP currently practices and are directly related to the company's therapeutic areas.

- Site Visits in Company's manufacturing and R&D facilities with an educational value could be provided to HCPs.

- Sponsorship of Events: Company have to be sure that the sponsored funds will only be used for the stated purpose. No sponsorship for recreational or entertainment activities for HCPs.

- Social Contributions for recognized charities, civic organisations and not-for-profit institutions (excluding natural persons or for-profit entities). These contributions could be financial or in-kind donations for the purpose of supporting scientific research, medical education, patient education, patient access to healthcare, and the overall development of healthcare system. Unrestricted contributions to HCOs that are not tied to a specific project or activity are prohibited.

- Educational Materials, Medical Utility Items and Inexpensive Gifts may be provided to HCPs if they are relevant to HCPs professional duties and ultimately benefit patients, patient care or practice of medicine or pharmacy. But, these items may not offset the costs of operating a HCP's practice and the items used for the day-to-day practice are prohibited.
    - This rule regarding inexpensive gifts is different from EFPIA HCP Code, which introduces a ban of gift in June 2013.

- Samples could be provided on an exceptional basis to help HCPs to familiarize themselves with certain products.
    - This provision is consistent with Article 96 of Directive 2001/83/EC which states that "*Free samples shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:*
        - *(a) the number of samples for each medicinal product each year on prescription shall be limited;*
        - *(b) any supply of samples shall be in response to a written request, signed and dated, from the prescribing agent;*
        - *(c) those supplying samples shall maintain an adequate system of control and accountability;*

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- *(d) each sample shall be no larger than the smallest presentation on the market;*
- *(e) each sample shall be marked 'free medical sample — not for sale' or shall show some other wording having the same meaning;*
- *(f) each sample shall be accompanied by a copy of the summary of product characteristics;*
- *(g) no samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied…"*

  - In practice, this provision despite its difference with the EFPIA HCP Code establishing the rule of 4x2 will have limited impact.

- Promotional Materials and Information: Companies cannot promote prescription medicines and products to patients, the public or any other person although they can promote their corporate brand, their company and the generic industry.

- Transparency for engagements, payments and other transfers of value to HCPs and HCOs and should encourage the recipients of the transfers of value to disclose them if they could potentially pose a conflict of interest. This disclosure should be compatible with data protection legislation.

- Data protection: This disclosure and any other processing of Healthcare Community's personal data should be compatible with data privacy legislation.

The Code describes the enforcement procedures' provisions and sets some definitions.
This Code is accompanied by a Questions & Answers document.

You will find the Code and the Q&A in the EGA website and in attachments (Annexes 1a&b).

2. National transparency laws and regulations' initiatives
Romania

On 23rd February 2015 was published the Ordinance n° 194 containing rules of implementation for disclosure obligations under Emergency Ordinance n° 2/2014 for amending and supplementing the Law n° 95/2006 (article 799). As legal standards now differ from the EFPIA Code requirements, the Romanian R&D Association ARPIM may benefit from a deviation to implement the EFPIA Code, to be assessed by EFPIA.

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These rules of implementation set the principle of an annual declaration by Marketing Authorization Holders (or their representatives in Romania, included wholesalers and retail distributors) of all sponsorship activities and other expenses to healthcare professionals, professional organisations, patient organisations and any other organisations active in human health, healthcare or pharmaceutical.
This declaration shall be made to the National Drug and Medical Devices Agency (ANMDM) up to 31st March of the current year in a template form.
The same obligation applies to beneficiaries of the sponsorship, doctors, nurses, professional organisations, patient organisations and any other organisations that have human health activities, healthcare or pharmaceutical.

The information declared shall be published on ANMD site and on the sites of the sponsoring entity and the beneficiaries in the second quarter of the previous year.

For 2014, the first declaration should be made before 30th June and the first publication before 30th september.

You will find attached, for your information, a translation of the ordinances (Annex 2a), the template (Annex 2b) and the ordinance 194/2015 (Annex 2c) and the template (Annex 2d) as published in the Official Gazette (in Romanian).

Lithuania
The national member association updated EFPIA about a new law issued by Ministry of Health.
It sets a partial disclosure of contribution to costs related to HCP sponsorship to events. The scope of the law is to report sponsorship of HCP to local and international events (disclosing registration fees, meal expenses, separately travel and accommodation expenses).
This new law should come into force by 1st May 2015.

The national member association has informed the MoH on the Disclosure Code and its requirements and collaborates in implementation of the new law and synchronizing the information requested to disclose by the new law according to EFPIA Disclosure Code.
The national member association will keep us informed on further progress of this topic.

3. Greek Code's amendments

The national member association updated his code in several provisions.
This update is related to, for example, the Host Country Principle transposition, clarification in some topics, harmonization with the Law and implementation of new rules for patient education and training programs.

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These amendments of the SFEE Code of Ethics will be effective as from the 1st May 2015. In the meanwhile, you will find attached the comparison table provided by the Greek national association (Annex 3).

4. German criminal sanctions for self-employed doctors bill

The German national member association informed EFPIA of a draft bill of the German Federal Ministry of Justice and Consumer Protection on fighting corruption in the healthcare system.

A decision of the German Federal Court of Justice (*Bundesgerichtshof*) stated in 2012 that the provisions of German criminal law in force do not support criminal sanctions regarding self-employed doctors, and that the development of new sanctions is reserved for future legislative action.

At the end of January 2015, the Ministry of Justice and Customer Protection issued a first working draft of a new provision to be added to the German Criminal Code.

The vfa member companies cooperate with all kinds of HCPs following the same strict anti-corruption rules established in 2004 by the FSA (Freiwillige Selbstkontrolle für die Arzneimittelindustrie). The legislator`s intention to include self-employed doctors in the circle of possible offenders under the German Criminal Code is therefore welcome, says the vfa, but the new section 299a will need to make sure not to interfere with legitimate cooperation between industry and HCPs.

You will find attached the latest information letters of the vfa (Annexes 4a&b).

5. Upcoming events / meetings

EFPIA Compliance team will attend the following meetings and congresses:

- Disclosure code speech in the 5th Annual Global Transparency Reporting Congress on **15th & 16th April** (*London*)
- European Generic Medicines Association Compliance Committee on **17th April** (*Brussels*)
- IFPMA CCN Meeting on **21st & 22nd April** (*Geneva*)
- 9th International Pharmaceutical Compliance Congress on **11th – 13th May** (*Brussels*) – You will find in attachment the program (Annex 5)
- EFPIA Codes Committee meeting for national pilot's implementation on **27th May** (*Madrid*)

The next Compliance Committee is scheduled on **July 3rd from 9:00 to 16:00** (*Brussels*).

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