

Fédération Européenne d'Associations et d'Industries Pharmaceutiques

EFPIA CODE OF PRACTICE FOR THE PROMOTION OF MEDICINES

QUESTIONS & ANSWERS("Q&A") With respect to Articles 9 & 10

- Events and Hospitality, Gifts and Inducements -

EFPIA and its **MISSION**

The European Federation of Pharmaceutical Industries and Associations ("EFPIA") represents the pharmaceutical industry operating in Europe. Through its direct membership of 29 national associations and 43 leading pharmaceutical companies, EFPIA is the voice on the EU scene of over 585,000 employees committed to researching, developing and bringing to patients new medicines that improve health and the quality of life.

The pharmaceutical industry makes a substantial contribution to public health by its research and development, and by making available and optimising the use of pharmaceutical products to prevent, diagnose and treat diseases and disabilities. Besides contributing to social progress and improving public health, the pharmaceutical industry is a major industrial asset to the European economy, generating economic growth and delivering innovation.

INTRODUCTION

In the course of the implementation of the revised EFPIA Code of Practice for the Promotion of Medicines, a number of questions have been raised with respect to the interpretation of Articles 9 ("Events and Hospitality") and 10 ("Gifts and Inducements"). In this context, as requested by our members, we provide below some guidance as put together by the members of the EFPIA Code of Practice Committee at its Meeting of 26 October 2005. The guidance concerns mainly the interpretation of "venues renowned for their entertainment facilities", the level of acceptability of "entertainment" at scientific and professional events and of "inexpensive gifts related to the practice of medicine or pharmacy". This document is not a formal part of the Code, it is merely intended to provide a "benchmarking" of the solutions allowed by the national codes, through an exchange of experience. It will be kept under review.

QUESTIONS & ANSWERS ("Q&A")

1. Venues for Events and Hospitality: Interpretation on the Choice of Venues for Scientific and Similar Events (Article 9)

Code / Section 9.01 provides that:

"All promotional, scientific or professional meetings, congresses, symposia, and other similar events (each, an "event") organized or sponsored by a company must be held in an appropriate venue that is conducive to the main purpose of the event and may only offer hospitality when such hospitality is appropriate and otherwise complies with the provisions of any applicable code(s)."

Code / Section 9.06:

'Hospitality shall not include sponsoring or organizing <u>entertainment</u> (e.g. sporting or leisure) events. Companies should avoid using <u>venues that are renowned for their entertainment facilities</u>."

QUESTION: How to interpret the notions of "appropriate venue", "entertainment", and "venue renowned for their entertainment facilities"?

ANSWER:

A. <u>Venues and Locations</u>: It is not possible to draw up a list of <u>venues / locations</u> that are "per se" acceptable or not depending on entertainment facilities. The Code Committee advises that Sections 9.01 and 9.06 should be read jointly. In other words, any venue with a high profile should not be ruled out automatically, the assessment as to its appropriateness will depend on the specific circumstances of each event (calendar, logistics, strategic needs, country of origin of invitees, etc...). The invitations to such events should be carefully worded, with a reference to all applicable mandatory rules establishing restrictions (law, self-regulation, etc). The examples set out below may be helpful in assessing borderline cases.

B. Entertainment: The restriction on offering entertainment, follows the following rule: i.e., all associations prohibit stand-alone entertainment (such as an evening at the opera). Some associations apply a stricter standard and ban also so-called "secondary entertainment", ("secondary" to the main scientific, professional or promotional event, such as having musical background during a dinner hosted in the course of a scientific event). Associations assess the situations with respect to the circumstances surrounding the event.

Examples

Would hospitality offered, for example, at Disneyland in Paris, be considered an "appropriate venue"? No, it is not considered acceptable. What about Munich? It is not acceptable during the traditional tourist season, such as the beer festival period, but may be acceptable outside this period. Hotels in some venues are renowned whereas other hotels maybe less renowned but could in fact be more luxurious: the choice of the former would be acceptable provided there were no renowned sporting events taking place at the same time (such as gold tournaments, tennis competitions, ...). Associations are advised to look carefully at the programme of the events proposed, as some promotional events, while not offering lavish entertainment, might offer luxurious hospitality (such as the leisure of "spa centers",..). What about skiing resorts? Hospitality at skiing resorts (such as Davos) is not acceptable in the winter, but may be acceptable in the summer. For example, "Winter meetings" in Spanish skiing resorts in the winter are prohibited by Farmaindustria. Answers to such questions may also depend on strategic needs. For instance, the choice of a given venue may be objectively justified by logistical reasons (need to accommodate a large number of participants (300- 400,...)). Associations already comply with the rule that no meetings may be held abroad if most participants are from the home country (a meeting convening mainly Swiss doctors may only take place in Switzerland). It was agreed that it is justified that some regular large scale international events are held in certain big cities. One association asks its member companies to

include in their invitation a mandatory text reminding participants of the limitations imposed by law, by the Code of Practice and by the Ministry of Health.

2. Gifts and Inducements: Interpretation of Inexpensive Gifts Relevant to the Practice of Medicine or Pharmacy (Article 10)

<u>Code / Section 10.01:</u> "No gift, pecuniary advantage or benefit in kind may be supplied, offered or promised to a healthcare professional as an inducement to prescribe, supply sell or administer a medicinal product."

Code / Section 10.02: "Subject to Section 10.01 above, where medicinal products are being promoted to healthcare professionals, gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons only if they are inexpensive and relevant to the practice of medicine or pharmacy."

QUESTION: How to interpret the notions of "inexpensive gift, relevant to the practice of medicine or pharmacy"?

<u>ANSWER</u>: As explained below, there are different practices in terms of the acceptability of gifts, grants and whether or not they are "related to the practice of medicine or pharmacy". While the assessment should be left to the national associations, the double condition set out above must be complied with: any gift must be both inexpensive <u>and</u> related to the practice of medicine or pharmacy. Companies must adhere to the local definitions. The examples set out below may be helpful in assessing specific cases.

Examples: The value of "inexpensive" gifts varies from 1.5 euros, to 6 euros, 12 euros or 6 sterling L (UK), and up to 25 or 30 euros, depending on the country concerned. Most national associations allow pharmaceutical companies to offer gifts to physicians with a higher value if it is in the form of medical books or medical devices (such as a stethoscope). In some countries, a gift in the form of medical devices is expressly permitted by the Ministry of Health as such devices directly benefit the patients. In some cases a financial ceiling is set (for example 100 euros for a medical book), in others it is not. One association permits an annual lump-sum value of gifts per doctor, including medical books. A financial ceiling may be imposed for tax reasons (tax relief applicable for gifts below the said amount). Some associations distinguish between gifts and grants (such as medical equipment). The latter may only be given to hospitals, institutions, not to individual medical doctor's practice. They must be strictly for the benefit of patient care and must be free of product promotion. Some associations do not allow grants under any form. Any gifts with a potential dual use should be banned (professional and private use, such as a cell phone). One association will shortly introduce the notion of "perceived value" of a gift, in comparison with the receipted value.

Useful Internet Link

The EFPIA Code of Practice for the Promotion of Medicines (November 2004) as well as the national Codes of Practice may be accessed directly from EFPIA's website at the following address (look up "Publications" and "Guidelines (Code of conduct – Code of Practice)"):

EFPIA www.efpia.org