European Federation of Pharmaceutical Industries and Associations

LEGAL AND ETHICAL RULES GOVERNING MEDICAL CONGRESS

How to set up a medical congress?

Introduction

The objective of this document is to explain the legal and ethical rules applying to medical congresses that are sponsored by EFPIA Member Companies.
The primary intended audience for this document is the medical societies and other organisations that may be unfamiliar with European legislation and the EFPIA Code.
The document includes the minimum standards of rules applying at the European level. National laws and regulations can be stricter; therefore, we recommend always verifying the national framework applying to medical congresses.

Structure of a medical congress

Medical congresses are generally organised in two parts:
1) The scientific program covers up to 95% of the entire program, is exclusively managed by the medical society without any pharmaceutical industry input. It typically includes keynote lectures, debates, plenary sessions, abstract, and poster presentations. This must be the main reason to attend the event.
To ensure the scientific purpose of the medical congress, there must be an independent scientific board that is responsible for the program review.

2) The pharmaceutical industry takes on the responsibility for satellite activities, including industry symposia and exhibitions, which complement the main congress agenda. These activities allow the industry to present their innovations and engage with healthcare professionals, while remaining separate from the core educational content led by the medical societies. The industry activities should represent a minor part of the entire program.

The faculty who is, in general, composed of the speakers, moderators or anyone involved in the scientific program of the medical congress may access sessions in which they have an active role even if they are not qualified as HCPs.

Definitions and legal provisions relevant for medical congress

Directive 2001/83/EC[1] regulates the interaction between pharmaceutical companies and person that can prescribe or supply medicinal products. The Directive also mentions information that can be shared with the public. Interactions with patients/Patient Organisations are not mentioned. Therefore, the provisions applicable to the public apply to these interactions.

[1] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0083

Title VIII in Directive 2001/83/EC[2] sets the rules on advertising. It prohibits the advertising of prescription products to the general public[3].

Advertising of medicinal products is any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; including visits by medical sales representatives, the supply of samples, sponsorship of promotional meetings, sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith.[4]

Non-promotion, as per the definition in the Directive[5], is the labelling and the accompanying package leaflets, correspondence to answer a specific question about a particular medicinal product, factual, informative announcements and reference material, trade catalogues and price lists, statements relating to human health or diseases, provided there is no reference, even indirect, to medicinal products.

Definitions included in the **EFPIA Code of Practice**[6]:

Healthcare Professional (HCP): any natural person that is a member of the medical, dental, pharmacy or nursing professions[7] or any other person who, in the course of his/her professional activities, may prescribe, purchase, supply, recommend or administer a Medicinal Product and whose primary practice, principal professional address or place of incorporation is in Europe. For the purpose of this Code, the definition of HCPs includes: (i) any official or employee of a government, agency or other organisation (whether in the public or private sector) that may prescribe, purchase, supply, recommend or administer Medicinal Products and (ii) any employee of a Member Company whose primary occupation is that of a practising HCP, but excludes (x) all other employees of a Member Company and (y) a wholesaler or distributor of Medicinal Products.

Healthcare Organisation (HCO): any legal person/entity (i) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form) such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for POs within the scope of article 21) whose business address, place of incorporation or primary place of operation is in Europe or (ii) through which one or more HCPs provide services.

Self-regulation provisions related to medical congress

Article 10 of the EFPIA Code defines the requirements applicable to pharmaceutical companies when organising events (all professional, promotional, scientific, educational meetings, congresses, conferences, symposia, and other similar events organised or sponsored by or on behalf of a Member Company) and/or providing hospitality during these events (paying for travel, meals, accommodation and genuine registration fees).

[2] Art. 86 – 100, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0083
[3] Ibid. art. 88
[4] Ibid. Art. 86
[5] Ibid. Art. 86 paragraph 2
[6] EFPIA Code of Practice, https://www.efpia.eu/relationships-code/the-efpia-code/
[7] Local restrictions may apply i.e. in some countries, nurses are not considered as HCPs

In addition, Member Company must submit or verify that the European congresses they organise or sponsor has been assessed by e4ethics and has received a positive assessment.

Self-regulation provisions related to the interactions between the pharmaceutical sector and the POs

The EFPIA Code includes a recognition of these interactions between the pharmaceutical sector and the Patient Organisations.[8]
It applies to **Patient Organisations**: non-for-profit legal person, mainly composed of patients and/or caregivers, that represents and/or supports the needs of patients and/or caregivers and to **POs representatives:** a person mandated to represent and express the collective views of a PO on a specific issue or disease area.

Questions

1. Which category of participants generally attend medical congresses?

- Healthcare Professionals
- Healthcare Organisations
- PO, patient advocates, patients
- Member of the public
- Journalists
- Staff of supporting companies and exhibitors
- Researchers, academic representatives
- Students[9]

2. Which type of activity are accessible for each category?

a. Exhibition area (with direct or indirect promotion)

- Healthcare Professionals
- Exhibitors

b. Medical society scientific session (without direct or indirect promotion)

- All registered delegates

c. Industry satellite symposia

- Healthcare Professionals
- Staff of the company organising the symposia

3. Why are non-HCP delegates unable to access some congress activities?

As mentioned above, Directive 2001/83/EC only regulates interactions with person qualified to prescribe or purchase a Medicinal Product or communication with the public. Interactions with patients/POs are not mentioned. Therefore, for communication to patients/POs, it is the provisions for public that apply.

[8] EFPIA Code of Practice, https://www.efpia.eu/relationships-code/the-efpia-code/
[9] Local specificities may apply as in some countries, students are considered as HCPs.

Title VIII in Directive 2001/83/EC[10] sets the rules on advertising and prohibits any promotional communication of prescription products to the general public[11].
As described above, some parts of the medical congress include promotional information and can only be accessible to person qualified to prescribe or purchase a Medicinal Product.

4. Are non-HCPs allowed to visit or to have a booth in the exhibition area?

As described above, it is not acceptable to have non-HCPs visiting the exhibition area.

To ensure patient organisations have access to medical congresses, and whilst respecting the prohibition of promotion to public, some medical congresses have two different exhibition areas: one part with materials intended for HCPs (which may include promotional material) and another part with material intended also for the public (without any form of direct or indirect promotion).

As an example, a PO can have a booth with materials intended for public/patients as long as the booth is in a separate non-promotional exhibition area.

5. What safeguards can medical congress organisers put in place to respect laws and regulation?

Medical societies must ensure that non-HCP delegates are not exposed to promotional materials.
As an example, they can provide different coded lanyards/badges so that non-HCP delegates do not enter promotional areas or organise two separate exhibition spaces (if any exhibitors have materials intended for the public).

[10] Art. 86 – 100, Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32001L0083
[11] Ibid. art. 88