

ORDINANCE 1/2015 ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 7 OF THE PHARMIG CODE OF CONDUCT (EVENTS)

Events for healthcare professionals, such as symposia, scientific congresses, workshops, lectures and the like, also smaller-scale events, are recognised vehicles for the dissemination of knowledge and experience on medicinal products and therapies as well as recognised means of training and continuing education.

As regards the organisation, implementation or support of events, invitations to events or the assumption of participants' costs for these events, it is mandatory to comply with the provisions of the Medicinal Products Act (Arzneimittelgesetz or AMG), the provisions of the Pharmig Code of Conduct (CoC), in particular the provisions set forth in Article 7 CoC, and the provisions of any other laws as may be applicable.

Pursuant to Article 16 CoC, the board of Pharmig adopts, in respect of Article 7.1 through 7.4 CoC and in conformity with Article 7.9 CoC, the following

ORDINANCE ON ARTICLE 7 COC:

Firstly, it should be noted that the assessment of an event in accordance with Article 7 CoC has to consider all elements characterising the event. It is particularly important that the overall picture of the event does not give the impression that undue influence is being exerted over healthcare professionals.

1. The purpose of an event is exclusively to provide scientific information and/or further specialisation in accordance with Article 7.1 CoC. Leisure and/or social programmes taking place in a close timely correlation to the event run counter to this purpose. Close timely correlation is defined as leisure and/or social programmes taking place during the event or within 24 hours before or after the event. This is independent of whether the leisure and/or social programme is organised, held or supported by the pharmaceutical company.
2. The assumption of costs for these events shall, pursuant to Article 7.2 CoC, be restricted to travel costs, room and board as well as the original admission fee and shall be appropriate. What costs are actually reimbursed depends on the agreement between the pharmaceutical company and the respective participant.
 - 2.1. If pharmaceutical companies support an event, they have to ensure that the support provided serves exclusively to provide scientific information and/or further specialisation or that they are used for this purpose. The organiser has to confirm that the support provided by pharmaceutical companies is used in conformity with the law and the CoC.

In this context, the board of Pharmig adopts the "Sample confirmation on the use of support provided by pharmaceutical companies in conformity with the law and the CoC", which is annexed to this document as SCHEDULE ./1 CoC Ordinance Article 7 (Events).

Use of SCHEDULE ./1 is not mandatory; however, if a pharmaceutical company does not use SCHEDULE ./1, it has to ensure that the confirmation it uses fully maps the content as shown in SCHEDULE ./1.

- 2.2. In accordance with Article 7.2 CoC, organising or supporting leisure and/or social programmes for the participants of the event in any way is not permitted. This is independent of whether the leisure and/or social programme has been organised and/or is being held by the organiser, HCl, HCP or a third party.

Inadmissible leisure and/or social programmes are any kind of programmes which do not serve the purpose of providing scientific information and/or further specialisation and give the impression that the event is of a private and entertaining nature (e.g. musical performances, cultural excursions, sports events or similar activities). This is independent of whether the leisure and/or social programme takes place during, before or after the scientific programme.

- 2.3. Appropriate travel costs in accordance with Article 7.2 CoC are the costs in the amount of the official kilometre allowance for individual travel by car, the costs for a first class train ticket for travel by train, the costs for an economy ticket for flights within Europe (continental flights) and the costs for a business class ticket for flights outside Europe (intercontinental flights) for travel by air.

- 2.4. Board in connection with an event has to be adequate. Care must be taken that the board itself or the selection and/or arrangement thereof is not of any entertaining nature whatsoever.

Concerning adequate cost reimbursement for board (meals and beverages), we refer to the ORDINANCE ADOPTED BY THE BOARD OF PHARMIG ON ARTICLE 7 AND ARTICLE 8 OF THE PHARMIG CODE OF CONDUCT ARTICLE ON VALUE LIMITS FOR BOARD AND HOSPITALITY.

- 2.5. Overnight accommodation or lodging within the meaning of Article 7.2 CoC is considered appropriate if the hotel or the conference centre features adequate infrastructure and the necessary technical equipment and rooms for holding the event and does not have leisure and entertainment areas and/or does not offer leisure or entertainment activities which exceed standard facilities and/or offers and if the venue as such is not particularly luxurious and/or extravagant (e.g. conference hotels, seminar hotels, training facilities).

In terms of assessing a hotel or seminar centre, it is important that inviting the participants to assume the cost for their overnight accommodation or lodging does not give the impression that undue influence is being exerted over healthcare professionals and is not likely to influence how they issue prescriptions and/or distribute medical products.

3. As specified in Article 7.4 CoC, the conference venue has to be chosen solely based on objective factors. Objective factors are, for example, the geographical location in consideration of the participants' place of departure and the contents of the event as well as its accessibility for participants. The recreational value of a conference venue is not to be considered as an objective factor.

This ordinance shall come into force on 01/09/2015.

SAMPLE CONFIRMATION ON THE HOLDING OF AN EVENT AND THE USE OF SUPPORT PROVIDED BY PHARMACEUTICAL COMPANIES IN CONFORMITY WITH THE LAW AND THE COC

CONFIRMATION

Details of the organiser:

(hereinafter referred to as "Organiser")

Details of the pharmaceutical company:

(hereinafter referred to as "Pharmaceutical Company")

Details of the event:

(hereinafter referred to as "Event")

Description of the support or reimbursement provided by the Pharmaceutical Company:

(hereinafter referred to as "Support Provided")

The Organiser hereby confirms that the Event organised or to be held by them exclusively serves to provide scientific information and/or further specialisation and that no leisure and/or social programmes take place in connection with the Event. Support Provided by the Pharmaceutical Company exclusively serves one, several or all of the following purposes:

- Admission fees for one/several participants and/or costs for holding and organising the scientific event
- Travel costs for one/several participants
- Board for one/several participants
- Room for one/several participants

The provisions of the Pharmig Code of Conduct in respect of Article 7 and the related Ordinance (Schedule 1) are hereby acknowledged and agreed to and it is hereby confirmed that the Event meets the conditions mentioned above and that the Support Provided by the Pharmaceutical Company is used in accordance with the provisions of the CoC.

If the Event is not held in conformity with the law and the CoC and/or if the Support Provided is used by the Organiser in breach of this agreement, the Pharmaceutical Company is expressly entitled to withdraw from this agreement and to have any Support Provided refunded to it in full. The Organiser undertakes to pay back to the Pharmaceutical Company any Support Provided within 7 days following the declaration of withdrawal.

Date, (company) signature of the Organiser
