

**Hungarian
Pharmaceutical
Manufacturers
Association**

**Association of
Innovative
Pharmaceutical
Manufacturers**

**Union of Hungarian Generic
Pharmaceutical
Manufacturers and
Distributors**

**"Immunity" Vaccine
and Immunobiology
Manufacturers and
Distributors**

Joint Committee for Ethical Communication (JCEC)

JCEC Statement 1/2015 (March 26)

on the extent of hospitality services provided at events organized for professional, scientific and educational purposes or related to pharmaceutical research and the promotion of medicinal products solely for Healthcare Professionals

PRELIMINARIES

Event organization and implementation is a key area with a significant impact on the daily practices of member companies. Besides, it is a highly visible activity for the authorities as well as for our partners, so it greatly influences the general image of the entire industry. Therefore the correct interpretation and application of the legal and ethical regulations is of utmost importance. Considering the fact that each company's practice is based on different logical concepts, the harmonization and alignment of the different practices seems necessary.

Even though there is a common intention to develop a lawful practice, it is not easy to define the behavioural patterns that are considered appropriate. In order to help member organizations to remain in line with the Code of Ethics ("Code"), JCEC issued this statement to interpret the rules related to the organization and sponsorship of events for medical professionals as well as for the sponsorship of participation in such events. In the interpretation process, we have considered the specific wording of the Code and the general basic interpretations as guidelines which we attempt to align and harmonize with the terms used in the industry. The categorization of events was governed by their contents and objectives rather than their names.

This statement neither replaces nor overrules the legal interpretation of the law enforcement agencies. The audit practice of the competent state administration organizations and the court verdicts arising from potential legal disputes will complete the picture.

The Code categorizes events based on the following definitions:

Independent Events Independent professional-scientific events and programs, including events organized by Patient Organizations, which are neither organized by a Company, nor initiated or organized on behalf of or in the interest of a Company, and where the Companies have no influence on deciding about the professional program or the contents of the program.

Company Events Programs, events or conventions initiated or organized by a Company or for a Company or sponsored by a Company for Healthcare Professionals, organizations of Healthcare Professionals, patients, Patient Organizations and/or their members. Company Events include, in particular, promotional events, symposia, scientific meetings, factory visits, advance training, meetings attended by principal investigators of clinical trials and non-interventional studies.

I. COMPANY events related to or having the purpose of medicinal product promotion

Company events must be held in an appropriate venue that is consistent with the main objectives of the event. In selecting venues those renowned for their entertainment establishments or extravagant

venues offering extraordinary experiences that are not compatible with the Company event's key objectives shall be avoided. .

1. Company Events supporting Medicinal Product Promotion, legal reference: Paragraph (2) of Section 14 of Act XCVIII of 2006 on the General Provisions Relating to the Reliable and Economically Feasible Supply of Medicinal Products and Medical Aids and on the Distribution of Medicinal Products ("the Medicine Act")

Features:

- The primary purpose of such events is to promote the particular medicinal products based on Paragraph (1) of Section 12 of the Medicine Act, even if the programme of the event contains other professional, scientific or educational information transfer that are clearly distinguishable from the specific promotional information transfer. Events supporting medicinal product promotion are considered as commercial practice.
- Regulations pertaining to the person(s) actively involved in the promotion:
The personal attendance and contribution of a registered medical sales representative is required for the implementation of the commercial practice. Upon the Company's request, Healthcare Professionals contracted by healthcare service providers to conduct healthcare activities or contribute thereto may hold lectures in which they present and share their knowledge and professional experience with the audience within the framework of scientific freedom. Thus the Company may request physicians to present e.g. their views on a particular therapeutic area, diagnosis, or their therapeutic experience with the medical therapy, in line with the summary of product characteristics of the medicinal product. In this quality, the invited lecturers (authors) conduct a scientific activity, therefore they cannot be regarded as promoters, In such cases the Company must conclude a contract with the invited physicians prior to the event in compliance with the rules on service provision and remuneration laid out in the Code.

Applicable rules:

- If possible, the Company Promotional Event should be the workplace of the Healthcare Professional.
- If the workplace of the Healthcare Professional involved in the Company Promotional Event is not suitable for the event, then the necessity and suitability of the other selected venue should be justified and documented. The non-workplace venue must be of secondary importance compared to the main objective of the event (venues specifically designed for hospitality services must be avoided), and the Company must aim to minimize the costs arising from the use of the venue.
- The daily amount of hospitality provided to participants must not exceed the amount laid out in the legal regulation (currently it is 5% of the minimum wage). Compared to the main objective of the event (i.e. promotion), hospitality services must be of secondary importance.
- Sponsorship granted in-kind for participation are not allowed (therefore: no reimbursement of accommodation and travel expenses).

2. Sponsored Company Events for professional and scientific purposes (Paragraph (3) of Section 14 of the Medicine Act) This category includes a) Company events, programmes and meetings (e.g. symposia) with a purely professional-scientific purpose held as part of an independent

professional-scientific event (e.g. conference) sponsored directly or indirectly by the Company and b) events organized by the Company for solely or primarily professional and scientific purposes. Programmes (programme components) solely designed for professional/scientific purposes and organized by the Company or directly or indirectly sponsored by the Company shall not be regarded as medicinal product promotion.

Features:

- The main objective of the event is e.g. an exchange of experience between healthcare professionals interested in a particular disease or medical area, or the education of such healthcare professionals.
- In addition to the professional-scientific programme, promotional activities are also allowed as long as they are clearly separated. Clear separation means a separation from the professional-scientific programme in space or time in a way that enables Healthcare Professionals to freely decide whether or not to receive information constituting medicinal product promotion.
- Organizational costs may arise; travel and accommodation expenses may also occur.

Applicable rules:

- There is no limit in terms of the Company's own financial resources allocated to the organization of the Company Event for professional and scientific purposes. Sponsorship is limited by the degree of justification by the scientific objectives.
- Healthcare professionals may receive sponsorship granted in-kind for participation in the event (travel expenses, meal allowance, accommodation expenses, participation fee), and the amount of such payments is not limited, but payments for entertainment or reward purposes are not allowed.
- Organizational expenses may be considered subordinate as long as it can be proven that they were completely allocated to ensuring the conditions essential for organizing the event.

Regulations pertaining to contributing persons:

The personal attendance and contribution of a registered medical sales representative of the sponsor Company is not obligatory but recommended in the case of purely professional-scientific events, programmes and meetings. Upon the Company's request, Healthcare Professionals contracted by healthcare service providers to conduct healthcare activities or contribute thereto may hold lectures in which they present and share their knowledge and/or professional experience with the audience within the framework of scientific freedom. Thus the Company may request physicians to present e.g. their views on a particular therapeutic area, diagnosis, or their therapeutic experience with the medical therapy. In this quality, the invited lecturers (authors) conduct a scientific activity. In such cases the Company must conclude a contract with the invited physicians prior to the event in compliance with the rules on service provision and remuneration laid out in the Code. In case of medicinal product promotion separated from the professional and scientific programmes, the regulations laid out in Paragraph 1 above shall logically apply.

3. Presentation of a manufacturing plant (factory visit)

This category includes visits to the Company's manufacturing plants in Hungary or abroad, during which Healthcare Professionals are given an insight into the manufacturing process of medicinal products. The presentation of manufacturing plants must not be centred on hospitality services. In

order to ensure that, visits of Healthcare Professionals to the Company's manufacturing plants may solely be organized for professional, scientific or educational purposes. The purpose and the programme of the visit to the manufacturing plant must be documented by the Company prior to the visit. Companies are not allowed to perform medicinal product promotion during the visit to the manufacturing plant. The maximum length of time to be allocated for the visit of one manufacturing plant is one working day. One trip may comprise visits to no more than three manufacturing plants - located in the same country or geographical area (e.g. member state). The duration of a trip organized or sponsored by the Company for the purposes of a factory visit, i.e. the duration of travelling to and staying at the site combined may not exceed 5 days in the case of travelling within Europe and 7 days in the case of travelling to a manufacturing plant outside Europe.

Applicable rules:

- The amount of own financial resources allocated to the organization of a factory visit is not limited. Sponsorship is limited by the degree of justification by the scientific objectives.
 - Healthcare professionals may receive sponsorship granted in-kind participation in the factory visit (travel expenses, meal allowance, accommodation expenses), and the amount of such payments is not limited, but payments for entertainment or reward purposes are not allowed.
 - Organizational expenses may be considered subordinate as long as it can be proven that they were completely allocated to ensuring the conditions essential for organizing the factory visit.

II. INDEPENDENT professional/scientific events and courses sponsored by Companies

Features:

- Events not initiated and organized by Companies, e.g. annual scientific conferences of Professionals/ Societies/Associations in a Hungary or abroad.

Companies are allowed to sponsor these events in the following manners:

- The event may be sponsored.
- The participation of healthcare professionals in the event may be sponsored in the form of sponsorship granted in-kind.
- It is permitted to purchase services which provide the conditions for a promotion activity (exhibition stand, symposium time, and advertising place) as long as the promotion is clearly separated from the professional/scientific event.

Applicable rules:

- Event sponsorship:
 - Reasonable extent (5% of the minimum wage/person). It must be defined in advance, based on the expected number of attendees.
 - It can be proven that the amount provided by the sponsor was completely allocated to ensuring the conditions essential for organizing the event.
 - The amount provided by the sponsor is used for holding the event but not for facilitating the participation of healthcare professionals. Therefore, the limit of sponsoring amount shall not include the sponsorship granted in-kind for

participation provided for healthcare professionals at the event (travel expenses, meal allowance, accommodation expenses, participation fee).

- Sponsorship of participation:
 - In the form of sponsorship granted in-kind for participation to cover expenses directly related to event participation (travel expenses, meal allowance, accommodation expenses, participation fee). The amount of such payments is not limited, but payments for entertainment or reward purposes are not allowed. This amount must be in line with the typical prices of the particular country and secondary to the main objective of the event.

- Purchasing services:
 - Considering the fact that it does not constitute sponsorship as it is a purchase of services, it is not limited. The limit on the sponsorship of independent professional conferences does not include the cost of promotions purchased at list price (exhibition stands, symposia) or the cost of any other related services (e.g. exhibition stand building, advertisements, and presentations). The daily amount spent on hospitality services provided by the Company must not exceed 5% of the minimum wage in connection with the medicinal product promotion performed separated from the professional-scientific programme at events organized for professional and scientific purposes.

III. Professional-scientific or educational events related to pharmaceutical research and not related to commercial practices

Such events may only be held in venues that are in compliance with the key objectives of the particular event. When selecting the venue, extravagant venues that are famous for their entertainment facilities or offer special programmes and are incompatible with the key objectives of the event must be avoided.

Sponsorship granted in-kind for participation to cover expenses directly related to event participation (travel expenses, meal allowance, accommodation expenses, and participation fee) are allowed. The amount paid to sponsor the organization of such events and the participation of healthcare professionals therein is not limited, but it is recommended to consider the relevant regulations laid out in Section I/2; e.g. payments for entertainment or reward purposes are not allowed.

1. Events held in relation to clinical studies, non-interventional studies (hereinafter: Studies)
e.g. Advisory board meeting(protocol, etc.), meeting of R/D investigators, Investigators' meeting. The common features of these events are:
 - These events are solely organized in connection with study products and the implementation of clinical studies.
 - These events are only attended by staff assigned to or involved in the implementation of the Study (including e.g. medical department, clinical investigation department, drug safety department).

- The list of participants must not include individuals other than the organizers and the healthcare professionals participating in the Study (i.e. the individuals whom or whose employers the organizing Company has contracted or plans to contract in connection with the given clinical study). The participants shall certify their attendance by signing the Attendance Sheet, which will be archived by the Company.
- Healthcare professionals may not be paid a daily rate or any other financial contribution for their participation in the event. Based on priorly concluded contracts, lecturers and chairpersons of meetings may be paid a fee in compliance with the Code's regulations on the services and remunerations.

2. Advisory board

e.g. Advisory Board Meeting (with service contract) The common features of these events are:

- If possible, the meetings of the Advisory Board must be held in the Hungarian head office of the Company. If it is impossible for some reason, or it poses disproportionately large difficulties or if it is logistically justifiable, then the meeting may be held in an external venue as well. The Company is recommended to document the reasons in a protocol.
- Participation of physicians in the meeting of the Advisory Board is recommended to be limited to Healthcare Professionals who have the appropriate professional competencies and are expected to provide sufficiently high-quality information to the Company.
- It is usually the invited physicians/consultants who speak at the Advisory Board Meetings, hence they are providing services. During its subsequent activities, the Company will use the advice given and will document them accordingly.
- Medicinal product promotion is not allowed in these events.
- There is no limitation defined by legal regulations on meal expenses - although the observation of the limit may be reasonable in order to ensure the scientific integrity of such meetings.
- The expenses related to contractual performance (e.g. travelling to the venue of the advisory board , accommodation, meal) may be reimbursed.

Other definitions/interpretations:

- Hospitality service is a special commercial activity by which we mean the provision of meals (food, beverages, tips, including VAT/person/day).