

## Observations Index

It is the company's individual decision to sponsor / participate in the event. Companies belonging to the EFPIA membership should be mindful of the rules and provisions that apply when deciding sponsorship, participation or collaboration in an event.

Sentences in blue will appear in the pre-assessment report posted on the "Events Database" – the text in black provides further clarification on the pre-assessment, referring to the relevant provisions in Directive 2001/83/CE and in the EFPIA HCP Code.

The pre-assessment is based on the information available on the event's website. In principle, a first pre-assessment will be conducted no later than 6 months prior to the start of the event. A second pre-assessment will be conducted 3 months prior to the event, which will be based on updated / additional information posted on the event's website after the first pre-assessment.

Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
<b>I. Scientific programme schedule / structure</b>		
<b>1. No scientific programme could be found on the event's website</b> - the full programme should be available 6 months in advance of the event, at the latest; the detailed programme must include a timetable, the themes that speakers will address, and the duration of any breaks; unnecessarily duplications in the scientific programme must be avoided.	Article 94	Article 9 – Section 9.01
<b>2. The programme on the event's website is incomplete</b> – the full programme should be available 6 months in advance of the event, at the latest; the detailed programme must include a timetable, the themes that speakers will address, and the duration of any breaks; unnecessarily duplications in the scientific programme must be avoided.	Article 94	Article 9 – Section 9.01
<b>3. With the event taking place within less than 6 months, only a preliminary programme is available</b> – the programme posted on the event's website at the time of assessment does not provide enough detail to allow a valuable pre-assessment; the full detailed programme should be available 6 months in advance of the event, at the latest.	Article 94	Article 9 – Section 9.01
<b>4. There is an imbalance between the time dedicated to scientific programme and the total duration of the event</b> – scientific activities must take up the majority of the time allocated each day (i.e. minimum 6 hours for a full day event; 3 hours for an half-day event, considering the remainder of the day is to facilitate arrival and departure of participants.	Article 94	Action 9 – Section 9.01

Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
<b>II. Location and Venue</b>		
<p><b>1. The location is renowned for entertainment</b> – venue mainly promoted as sport resort, theme park, wine hotels, etc. – the location chosen for the event and the travel arrangements to the event must be justified</p> <p>It is recommended to check the rules prevailing under applicable national codes.</p>	Article 94	Article 9 – Section 9.01
<p><b>2. In the season when the event takes place, location renowned as a destination for vacation (ski-resort in winter; beach-resort in summer)</b> – the place and date of the event must not lead to any confusion regarding the scientific nature of the event</p> <p>It is recommended to check the rules prevailing under applicable national codes.</p>	Article 94	Article 9 – Section 9.01
<p><b>3. Travelling abroad may not be justified since the international nature of the event does not arise from the scientific programme</b> – participation of HCPs in events outside their country must be justified; the international nature of an event can arise from the countries of origin of the speakers, and must be clearly stated in the programme; travel abroad must be justified on reasons linked to the purpose of the scientific event</p>	Article 94	Article 9 – Section 9.02
<p><b>4. The venue chosen may bring into disrepute the good reputation of the pharmaceutical industry</b> – the venue where the event takes place may seem extravagant.</p> <p>It is recommended to check the rules prevailing under applicable national codes.</p>		

Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
<b>III. Hospitality provided (directly or indirectly) to Healthcare Professionals (HCP)</b> HCP include any member of the medical, dental, pharmacy or nursing professions or any other person who in the course of his/her professional activities may prescribe, purchase, supply or administer a medicinal product.		
<p><b>1. Hospitality is not reasonable</b> – hospitality includes: travel, accommodation, meals and drinks; hospitality must remain reasonable – the hospitality arrangements include accommodation in a location / venue that may seem extravagant</p> <p>Local rules and local prices should be assessed and taken into consideration in order to ensure the application of reasonable hospitality costs.</p>	Articles 94 & 95	Article 9 – Section 9.06
<p><b>2. Accommodation is provided beyond the duration of the scientific programme</b> – hospitality provided (directly or indirectly) to HCP must not cover any period of stay beyond the official duration of the event; no extra overnight stay may be covered</p> <p>Companies shall not participate in the organisation of extending of stays for personal reasons by participants and shall not contribute to the financial costs thereby incurred. Any healthcare professional who wishes to extend his / her stay must organise personally and pay for all costs of associated travel / accommodation arrangements.</p>		Article 9 – Section 9.04
<p><b>3. Hospitality provided may bring into disrepute the good reputation of the pharmaceutical industry</b> – hospitality must in no way prejudice the industry's reputation.</p>	Articles 94 & 95	Article 9 – Section 9.06

Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
<b>IV. Other activities</b>		
<p><b>1. Entertainment, sporting or leisure events are organised in connection with the event</b> – hospitality provided (directly or indirectly) to HCP must be limited to participation in registration fees, travel expenses, meals, overnight stay; hospitality shall not include sponsoring or organising of sporting or leisure events or other entertainment events.</p>	Articles 94 & 95	Article 9 – Section 9.07
<p><b>EXHIBITIONS</b> – please read carefully the provisions of the EFPIA HCP Code and the additional guidance –</p>		Article 9 – Section 9.03
<b>V. Accompanying persons</b>		
<p><b>1. Non-healthcare professionals / accompanying persons shall not be invited to the event</b> – hospitality may only be extended to persons who qualify as participants in their own right</p> <p>It is recommended to check the rules prevailing under applicable national codes.</p>	Article 95	Article 9 – Section 9.05
<p><b>2. An alternative programme is proposed for non-healthcare professionals / accompanying persons</b> – no alternative programme shall be prepared for those accompanying participants to the event; no activities shall be organised for individuals accompanying participants, even if these individuals would bear the cost of such activities</p>	Article 95	Article 9 – Section 9.05
<p><b>3. The event’s programme permits attendance of non-healthcare professionals / accompanying persons to the exhibition area.</b> Please adopt the necessary measures to avoid carrying out any promotional activity related to prescription-only medicines directed to public at large.</p>	Article 88	



### National Codes

EFPIA's member association in the event hosting country draws attention to local provisions regarding the promotion of medicines and interaction with healthcare professionals. Arrangements may raise concern in regard of these provisions.

The EFPIA HCP Code sets out minimum standards which EFPIA considers must apply. National laws and regulations, or national codes provisions may include more rigorous provisions than those contained in the EFPIA HCP Code.

Where rules prevailing in the event hosting country raises concern, comments of the member association will be signalled, using the orange colour-code.

Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
<b>Pending</b>		
1. EFPIA is considering assessment of the event upon request of (one of) its member(s) – evaluation process is ongoing		
2. Only a preliminary programme is available – the scientific programme posted on the event's website at the time of assessment does not provide enough details to allow a valuable pre-assessment; the detailed scientific programme should be available 6 months in advance of the event, at the latest.		
3. The event's organisers have communicated changes to the programme and / or arrangements relating to the event – re-evaluation process is ongoing		
4. Information that would allow pre-assessment is not yet available on the event's website – pre-assessment process will start when relevant information is available on the event's website		Article 9 – section 9.01