

Observations' Index (March 2015)

This document explains e4ethics pre-assessments and is intended to provide **guidance with regard to the provisions of the EFPIA HCP Code**. It is a company's individual decision to sponsor / participate in an event. Companies belonging to EFPIA should be mindful of the rules and provisions that apply when deciding on their sponsorship, participation or collaboration in an event.

The pre-assessment of events provided on e4ethics cannot, under any circumstance, be interpreted as a judgment on the quality or content of the scientific programme, or on the quality of the speakers.

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.

Conclusions of the pre-assessment will be posted on e4ethics with the following color-code for each of the 6 areas (in contrast to a single composite assessment) covered by the EFPIA Article 10 HCP Code provisions:

∅ **GREEN**: based on information available from the event's website (on the date indicated), arrangements would not raise concern with regard to provisions of Article 10 of the EFPIA HCP Code. However, EFPIA members are invited to check the application of laws, regulations and codes that may apply in the country where the event takes place and/or rules of the jurisdiction where healthcare professionals carry out their profession.

∅ **ORANGE**: based on information available from the event's website (on the date indicated), arrangements may raise concern with regard to provisions of the EFPIA Article 10 HCP Code provisions. EFPIA members are asked to also check application of laws, regulations and codes that may apply in the country where the event takes place and/or rules of the jurisdiction where healthcare professionals carry out their profession.

∅ **BLUE**: EFPIA's pre-assessment process is ongoing.

In principle, the first pre-assessment with regard to EFPIA HCP Code provisions 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.

A draft pre-assessment with regard to EFPIA HCP Code provisions will be sent to the event's organiser and the national association of the country where the event takes place to allow for their comments during a ten day period prior to its publication for EFPIA membership guidance.

Where the Member Association of the event's hosting country provides comments regarding stricter national laws, regulations and/codes, these will be shared with the organiser and reflected in the sixth areas of the pre-assessment report: National Code Provisions.

EFPIA can update the information included in e4ethics at any time. Please therefore consult the website regularly. Pre-assessments are based on information available on the event's website, be it provided by the organiser of the event, a supplier or any other third party. The date when information on the event's website(s) was accessed shall be indicated.

I. Scientific Programme Schedule / Structure		
<p>The programme should demonstrate that the event has a genuine scientific purpose. The pre-assessment cannot, under any circumstance, be interpreted as a judgement on the quality or content of the scientific programme, or on the quality of the speakers. 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. Unnecessary duplication in the scientific programme must be avoided and scientific activities must take up the majority of the time allocated to each day (i.e. minimum 6 hours for a full day event; 3 hours for a half-day event, when the remainder of the day facilitates the arrival and departure of participants).</p>		
Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
1. It is recommended to check the rules prevailing under applicable national codes.		
1. No scientific programme could be found on the event's website. - The full programme should be available 6 months in advance of the event, at the latest.	Article 94	Article 10 – Section 10.01
2. The programme on the event's website is incomplete. - 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.	Article 94	Article 10 – Section 10.01
3. The programme on the event's website is preliminary. - The full programme should be available 6 months in advance of the event, at the latest. The programme posted on the event's website at the time of the assessment does not provide enough detail to allow a valuable pre-assessment.	Article 94	Article 10 – Section 10.01
4. There is an imbalance between the time dedicated to the scientific programme and the total duration of the event. - Scientific activities must take up the majority of the time allocated to each day (i.e. minimum 6 hours for a full day event; 3 hours for a half-day event, when the remainder of the day facilitates the arrival and departure of participants).	Article 94	Article 10 – Section 10.01
1. EFPIA is considering assessment of the event upon request of (one of) its member(s). – An EFPIA member requested this event be pre-assessed with regard to EFPIA HCP Code provisions and the pre-assessment process is now ongoing.		
2. The event's organisers have communicated changes to the programme and/or arrangements relating to the event. – Re-evaluation process upon the event's organisers' request is ongoing.		
3. Information that would allow pre-assessment is not yet available on the event's website. – The information available on the event's website at the time of the pre-assessment doesn't provide enough detail to allow a valuable pre-assessment.		Article 10 – Section 10.01
4. Only a preliminary programme is available. – The scientific programme posted on the event's website at the time of assessment does not provide enough detail to allow a valuable pre-assessment; the detailed scientific programme should be available 6 months in advance of the event; at the latest.		

II. Venue and Exhibition Area

All promotional, scientific or professional meetings, congresses, conferences, symposia and other similar events (including, but not limited to, advisory board meetings, visits to research or manufacturing facilities, and planning, training or investigator meetings for clinical trials and non-interventional studies) organised or sponsored by or on behalf of a company must be held in an appropriate location (city) and venue (building) that are conducive to the main purpose of the event. Member states shall prohibit the advertising to the general public of prescription-only medicines.

DISCLAIMER: Based on prior application of the EFPIA Code to the e4ethics pre-assessment process, most locations did not raise concern. Locations must, however, be conducive to the main purpose of the event, ensuring logistics are easily provided.

Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
1. It is recommended to check the rules prevailing under applicable national codes.		
1. The venue chosen may bring discredit upon, or reduce confidence in, the pharmaceutical industry. – The venue where the event takes place must be appropriate and conducive to the main purpose of the event. Companies should avoid using venues that are renowned for their entertainment facilities or are extravagant.	Articles 94 & 95	Article 10 – Section 10.01, Section 10.08
2. The event's programme permits attendance of non-healthcare professionals to the exhibition area. – Please adopt the necessary measures to avoid promotional activity relating to prescription-only medicines to people other than HCPs.	Article 88	
1. EFPIA is considering assessment of the event upon request of (one of) its member(s). – An EFPIA member requested this event be pre-assessed with regard to EFPIA HCP Code provisions and the pre-assessment process is now ongoing.		
2. The event's organisers have communicated changes to the programme and/or arrangements relating to the event. – Re-evaluation upon the request of the event's organisers is ongoing.		
3. Information that would allow pre-assessment is not yet available on the event's website. – The information available on the event's website at the time of the pre-assessment doesn't provide enough details to allow a valuable pre-assessment.		Article 10 – Section 10.01

III. Hospitality Provided (Directly or Indirectly) to HCPs

HCP includes 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. Hospitality includes travel, accommodation, meals, drinks and genuine registration fees. Hospitality must be reasonable. Local rules and local prices should be assessed and taken into consideration in order to ensure the application of reasonable hospitality costs. Hospitality arrangements that include accommodation must do so in an appropriate venue. Hospitality provided (directly or indirectly) to HCPs must not cover any period of stay beyond the official duration of the event; no extra overnight stay may be covered. Companies shall not participate in extending the stays for personal reasons of participants and shall not contribute to the financial costs thereby incurred. Any healthcare professional who wishes to extend his / her stay must organise it personally and pay for all the associated costs of travel and accommodation.

Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
1. It is recommended to check the rules prevailing under applicable national codes.		
1. Hospitality may not be reasonable. - Hospitality includes: travel, accommodation, meals and drinks. Hospitality must remain reasonable. Local rules and local prices should be assessed and taken into consideration in order to ensure the application of reasonable hospitality costs. Hospitality arrangements that include accommodation must do so in an appropriate venue which may not seem extravagant.	Articles 94 & 95	Article 10 – Section 10.05 & 10.07
2. Accommodation is (directly or indirectly) provided beyond the duration of the scientific programme. - Hospitality provided (directly or indirectly) to HCPs must not cover any period of stay beyond the official duration of the event; no extra overnight stay may be covered. Companies shall not participate in extending the stays for personal reasons of participants and shall not contribute to the financial costs thereby incurred. Any healthcare professional who wishes to extend his / her stay must organise it personally and pay for all the associated costs of travel and accommodation.		Article 10 – Section 10.04
3. Hospitality provided may bring discredit upon, or reduce confidence in, the pharmaceutical industry. – Hospitality must in no way prejudice the industry’s reputation.	Articles 94 & 95	Article 10 – Section 10.07
1. EFPIA is considering assessment of the event upon request of (one of) its member(s). – An EFPIA member requested this event be pre-assessed with regard to EFPIA HCP Code provisions and the pre-assessment process is now ongoing.		
2. The event’s organisers have communicated changes to the programme and/or arrangements relating to the event. – Re-evaluation process upon the event’s organisers’ request is ongoing.		
3. Information that would allow pre-assessment is not yet available in the event’s website. – The information available on the event’s website at the time of the pre-assessment doesn’t provide enough details to allow a valuable pre-assessment.		Article 10 – Section 10.01

IV. Other Activities Hospitality provided (directly or indirectly) to HCPs must be limited to registration fees, travel expenses, meals, overnight stay. Hospitality shall not include sponsoring or organising sporting or leisure events or other entertainment events.		
Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
1. It is recommended to check the rules prevailing under applicable national codes.		
1. Sightseeing tours are organised in connection with the event. – Hospitality shall not include sponsoring or organising entertainment events (e.g., sightseeing tours).	Articles 94 & 95	Article 10 – Section 10.08
2. Pre-congress and/or post-congress sightseeing tours are organised in connection with the event. – Hospitality shall not include sponsoring or organising entertainment events (e.g., pre-congress sightseeing tours or post-congress sightseeing tours).	Articles 94 & 95	Article 10 – Section 10.04 & 10.08
3. Entertainment activities are organised in connection with the event. – Hospitality shall not include sponsoring or organising entertainment (e.g., concerts, theatre or similar spectacles) events.	Articles 94 & 95	Article 10 – Section 10.08
4. Leisure activities are organised in connection with the event. – Hospitality shall not include sponsoring or organising entertainment (e.g., museum visits) events.	Articles 94 & 95	Article 10 – Section 10.08
5. Sporting activities are organised in connection with the event. – Hospitality shall not include sponsoring or organising entertainment (e.g., sporting) events.	Articles 94 & 95	Article 10 – Section 10.08
1. EFPIA is considering assessment of the event upon request of (one of) its member(s). – An EFPIA member requested this event be pre-assessed with regard to EFPIA HCP Code provisions and the pre-assessment process is now ongoing.		
2. The event’s organisers have communicated changes to the programme and/or arrangements relating to the event. – Re-evaluation process upon the event’s organisers’ request is ongoing.		
3. Information that would allow pre-assessment is not yet available in the event’s website. – The information available on the event’s website at the time of the pre-assessment doesn’t provide enough details to allow a valuable pre-assessment.		Article 10 – Section 10.01

V. Accompanying Persons Hospitality may only be extended to persons who qualify as participants in their own right. Hospitality provided (directly or indirectly) to HCPs must be limited to participation in registration fees, travel expenses, meals, overnight stay.		
Criteria / Observations	Directive 2001/83/CE	EFPIA HCP Code
1. It is recommended to check the rules prevailing under applicable national codes.		
1. Accompanying persons shall not be invited to the event or activities organised in connection with it. – Hospitality may only be extended to persons who qualify as participants in their own right.	Article 95	Article 10 – Section 10.06
2. An alternative programme is proposed for accompanying persons. – 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.	Article 95	Article 10 – Section 10.06
1. EFPIA is considering assessment of the event upon request of (one of) its member(s). – An EFPIA member requested this event be pre-assessed with regard to EFPIA HCP Code provisions and the pre-assessment process is now ongoing.		
2. The event’s organisers have communicated changes to the programme and/or arrangements relating to the event. – Re-evaluation process upon the event’s organisers’ request is ongoing.		
3. Information that would allow pre-assessment is not yet available on the event’s website. – The information available on the event’s website at the time of the pre-assessment doesn’t provide enough details to allow a valuable pre-assessment.		Article 10 – Section 10.01

VI. National Code Provisions
<p>Promotion and interaction which take place within Europe must comply with applicable laws and regulations. The EFPIA Code sets out the minimum standards which EFPIA considers must apply. Member Companies shall also be responsible for the obligations imposed under any relevant Applicable Code. In a manner compatible with their respective national laws and regulations, member associations must, at a minimum, adopt in their national codes provisions no less rigorous than the provisions contained in the EFPIA Code. Member associations are encouraged to tailor their national codes to adapt to national conditions and to adopt additional provisions which extend further than the minimum standards included in the EFPIA Code. In the event of a conflict between the provisions of EFPIA member association’s national codes, the more restrictive of the conflicting provisions shall apply (except for the host country principle - Article 10.05 and the HCPs sponsorship - Article 13.01).</p>
<p>In order to provide guidance as complete as possible to EFPIA membership through the e4ethics platform, EFPIA’s member association of the country where the event is to take place is included in the pre-assessment process. Comments, up to 500 characters, provided by the Member Association of the event’s hosting country regarding arrangements that may raise concern due to stricter national laws, regulations and/or codes will be reflected in this area of the report.</p>