

Observations' Index

This document explains e4ethics pre-assessments and is intended to provide **guidance with regard to the provisions of the ARPharM HCP Code**. It is a company's individual decision to sponsor/ participate in an event. Companies belonging to ARPharM 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.

Conclusions will appear in the pre-assessment report posted on the "Events Database" – followed by further clarification on the pre-assessment, referring to the relevant provisions in Directive 2001/83/CE and in the ARPharM HCP Code.

Conclusions of the pre-assessment will be posted on e4ethics with the following colour-code for each of the 5 areas (in contrast to a single composite assessment) covered by the ARPharM Article 9 HCP Code provisions:

Ø **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 9 of the ARPharM HCP Code. However, ARPharM members are invited to check the application of laws, regulations and/or rules of the jurisdiction where healthcare professionals carry out their profession.

Ø **ORANGE:** based on information available from the event's website (on the date indicated), arrangements may raise concern with regard to provisions of the ARPharM Article 9 HCP Code provisions. ARPharM members are asked to also check application of laws, regulations and/or rules of the jurisdiction where healthcare professionals carry out their profession.

Ø **BLUE:** ARPharM's pre-assessment process is ongoing.

In principle, the first pre-assessment with regard to ARPharM HCP Code provisions will be conducted no later than 3 months prior to the start of the event. The final pre-assessment will be conducted 1 month prior to the event.

ARPharM can update the information included in e4ethics at any time till the 1 month prior to the event period. Please therefore consult the website regularly. Pre-assessments are based on information accessible on the event's website or information provided by the organiser of the event, a supplier or any other third party. ARPharM member-companies are welcomed to provide any available information as soon as they are reached by the event organisers to sponsor/ participate in event. The date when information on the event's website(s) was accessed shall be indicated.

I. Scientific Programme Schedule / Structure

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 3 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 or departure of participants).

Criteria / Observations	Directive 2001/83/CE	ARPharM 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 3 months in advance of the event, at the latest.	Article 94	Article 9 – Section 9.1
2. The programme on the event's website is incomplete. - The full programme should be available 3 months in advance of the event, at the latest. The detailed programme must include a timetable, the themes; the speakers, and the duration of any breaks.	Article 94	Article 9 – Section 9.1
3. The programme on the event's website is preliminary. - The full programme should be available 3 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 9 – Section 9.1
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	Action 9 – Section 9.1; 9.6; 9.8.2; 9.8.3;
5. The total duration of the event – Events in the territory of the Republic of Bulgaria, should not have duration of above three twenty-four hour periods. International events should not continue more than four twenty-four hour periods.	Article 94	Action 9 – Section 9.8.2; 9.8.3;
1. ARPharM is considering assessment of the event upon request of (one of) its member(s). – An ARPharM member requested this event be pre-assessed with regard to ARPharM 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.		
4. An event being held within less than 3 months - 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 3 months in advance of the event; at the latest		Article 9 – Section 9.1

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 and can provide hospitality that is appropriate and complies with the code of ethics. . Member states shall prohibit the advertising to the general public of prescription-only medicines.

Criteria / Observations	Directive 2001/83/CE	ARPharM HCP Code
1. It is recommended to check the rules prevailing under applicable national codes.		
1. Extravagant and luxurious venues – Hospitality, in which the participants in the event are accommodated in extravagant and luxurious hotels, which are associated mainly with entertainment activities, is considered inappropriate. Extravagant and luxurious hotels for the purposes of this Code are all 5 star hotels, located in year-round resort destinations, as well as all hotels, regardless of the class, located in seasonal resort destinations during the summer or winter tourist season respectively; wine tourism complexes, regardless of their class and location.	Article 94	Article 9 – Section 9.1.1
2. 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 9 – Section 9.1
3. 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. ARPharM is considering assessment of the event upon request of (one of) its member(s). – An ARPharM member requested this event be pre-assessed with regard to ARPharM 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.		

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 exceeding the officially declared duration of the event, unless the arrival on the previous day or the departure on the next is necessary for the effective planning of the trip; 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	ARPharM HCP
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 9 – Section 9.1; 9.6
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 exceeding the officially declared duration of the event, unless the arrival on the previous day or the departure on the next is necessary for the effective planning of the trip. 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 9 – Section 9.6
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 9 – Section 9.6
1. ARPharM is considering assessment of the event upon request of (one of) its member(s). – An ARPharM member requested this event be pre-assessed with regard to ARPharM 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.		

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	ARPharM 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 9 – Section 9.7
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 9 – Section 9.7
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 9 – Section 9.7
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 9 – Section 9.7
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 9 – Section 9.7
1. ARPharM is considering assessment of the event upon request of (one of) its member(s). – An ARPharM member requested this event be pre-assessed with regard to ARPharM 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.		

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	ARPharM 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 9 – Section 9.5
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 9 – Section 9.5
3. The program of the event allows the presence of non-medical professionals/accompanying persons - The necessary measures should be taken to avoid promotional activities related to prescription-only medicines targeted at the general public.	Article 88	
1. ARPharM is considering assessment of the event upon request of (one of) its member(s). – An ARPharM member requested this event be pre-assessed with regard to ARPharM 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.		