Observations Index

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

The pre-assessment is based on the information retrieved from public sources, in particular the events' websites, other sources on the Internet or through ARPharM membership. In principle, a first pre-assessment will be conducted no later than 3 months prior to the start of the event. A second pre-assessment will be conducted 1 month prior to the event, which will be based on updated / additional information available after the first pre-assessment.

Criteria / Observations	Directive 2001/83/CE	ARPharM Code
I. Scientific programme schedule / structure		
1. No scientific programme is available - 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; unnecessarily duplications in the scientific programme must be avoided.	Article 94	Article 9 – Section 9.1
2. The programme available 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 that speakers will address, and the duration of any breaks; unnecessarily duplications in the scientific programme must be avoided.	Article 94	Article 9 – Section 9.1
3. With the event taking place within less than 3 months, only a preliminary programme is available – the programme available at the time of assessment does not provide enough detail to allow a valuable pre-assessment; the full detailed programme should be available 3 months in advance of the event, at the latest.	Article 94	Article 9 – Section 9.1
4. There is an imbalance between the time dedicated to scientific programme and the total duration of the event – scientific activities must take up the majority of the time allocated each day (i.e. minimum 6 hours for a full day event.	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;

Criteria / Observations	Directive 2001/83/CE	ARPharM Code
II. Location and Venue		
1. Extravagant and luxurious venues – Hospitality, in which the participants in the event are accommodated in extravagant and luxurious hotels, is considered inappropriate. Extravagant and luxurious hotels for the purposes of the Code are all 5 star hotels, located in resort destinations.	Article 94	Article 9 – Section 9.1
2. The venue chosen may bring into disrepute the good reputation of the pharmaceutical industry – the venue where the event takes place may seem extravagant.		

Criteria / Observations	Directive 2001/83/CE	ARPharM Code
III. Hospitality provided (directly or indirectly) to Healthcare Professionals (HCP) 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.		
1. Hospitality is not reasonable – hospitality may include travel, accommodation, meals and drinks; hospitality must remain reasonable – the hospitality arrangements should not include accommodation in an location / venue that is extravagant. The hospitality costs should be reasonable considering the prices and rules which are custom at the venue where the event takes place.	Articles 94 & 95	Article 9 – Section 9.1; 9.6
2. Accommodation is provided beyond the duration of the scientific programme – hospitality provided (directly or indirectly) to HCP must not cover any period of stay beyond twenty-four hour period prior to the beginning or after the ending of the event. 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.		Article 9 – Section 9.6;

3. Hospitality provided may bring into disrepute the good reputation of the pharmaceutical industry – hospitality must in no way prejudice the industry's reputation.	Articles 94 & 95	Article 9 – Section 9.6

Criteria / Observations	Directive 2001/83/CE	ARPharM Code
IV. Other activities		
1. Entertainment, sporting or leisure events are organised in connection with the event – 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.	Articles 94 & 95	Article 9 – Section 9.7
V. Accompanying persons		
1. Hospitality should not be provided by companies to non-healthcare professionals /accompanying persons' in regards to participation in the event – 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 non-healthcare professionals / 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 event's programme permits attendance of non-healthcare professionals / accompanying persons to the exhibition area. Please adopt the necessary measures to avoid carrying out any promotional activity related to prescription-only medicines directed to public at large.	Article 88	

	Bulgarian Legislation
The ARPharM Code of Ethics sets out minimum standards which ARPharM considers must apply. Bulgarian legislation may include more rigorous provisions than those contained in the ARPharM Code of Ethics.	

Criteria / Observations	Directive 2001/83/CE	ARPharM Code
Pending		
1. ARPharM 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 available at the time of assessment does not provide enough details to allow a valuable pre-assessment; the detailed scientific programme should be available 3 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 – pre-assessment process will start when relevant information is available.		Article 9 – section 9.01