

CME

INSTRUCTIONS FOR USE

Notwithstanding that both the regulation and the determinations later published by the National Committee do not fully clarify the many interpretative doubts

Confirming that Assobiomedica believes that the principle which the CME regulation is based on is unacceptable, namely that the relationship between health professionals and the corresponding industry is inherently opaque and is aimed at satisfying purely commercial interests

Confirming that member companies are always required to comply with the Association's Code of Ethics for any type of event, whether or not CME

Recalling that the relations between companies and Public Administration are regulated by Law 231/01, which also governs training/information activities offered to public employees, regardless of CME regulations

We have tried to identify the most relevant aspects of the regulation and to give companies an indication for each of them so as to ensure their good practice.

- Companies **cannot** sponsor participants and speakers directly at CME events, i.e. they **cannot** cover their travel/accommodation expenses and their registration for these events; however, according to the interpretation given in the determination of January 18, 2011, health professionals can benefit from **direct** sponsorships offered by companies for up to 1/3 of their total credits over the three-year period 2011-2013
- It is up to providers, medical councils, societies or associations which physicians are enrolled with to check and certify credits up to the said 1/3 threshold of their total number
- The definition of training courses and event programmes, the choice of lecturers, the invitations to participants, hospitality costs, organization, etc. are at the **sole** cost and responsibility of the provider
- Any company seeking to fund CME events must have **solely** economic relations with providers
- Companies **cannot** ask for – and **cannot** receive – the list of participants attending CME events
- Companies may directly organize workshops or seminars (**without** assigning CME credits) during a CME event but **not** while a CME session is held, in order to avoid any overlapping.
- Company booths, workshops and seminars must be held in a different area from that where CME courses take place.
- Promotional material **cannot** be distributed in the folders of CME events
- Company logos - let alone product advertising - **cannot** be projected or displayed in the rooms where CME courses are held
- Companies **are required** to comply with the regulation in force since January 1, 2011, **even where** the event has been accredited under the previous rules



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- International events held in Italy and/or abroad: if they grant CME credits, they are subject to the rules set out above in relation to hospitality, travel expenses, registration of Italian health professionals
- International events held in Italy and/or abroad that grant CME-type credits, though according to foreign regulations: they are considered **non-CME** events
- In the case of direct sponsorships, the mechanism of selection must satisfy the guarantee requirements laid down in Law 231/01 (this obligation is not mentioned in the CME regulation, though it is an important recommendation that Assobiomedica feels necessary to point out to its members)
- All the above obligations apply **ONLY** to CME events, i.e. they do not apply to non-CME events