

Local implementation of the EDMA/Eucomed “Direct Sponsorship Phase-out” recommendation: Challenges for national associations in Europe

**Peter Ellingworth, CEO Association of British Healthcare
Industries**



Speakers

- Anna Lefevre Skjöldebrand, CEO, Swedish Medtech & Chairwoman of the Eucomed National Associations Network
- Gerry Livadas, General Secretary, SEIV
- Lorenzo Fracassi, Consigliere Delegato, Dasit Group S.p.A. & Member of the EDMA Board
- Alphie Moran, Senior Ethics, Compliance & Training Officer - EMEA, Cook Medical



Anna Lefevre Skjöldebrand,

CEO, Swedish Medtech

Chairwoman of the Eucomed National Associations Network



The Agreement in Sweden



- An agreement between industry (MD incl. IVD) and the Association of Local Authorities and Regions.
- Includes also the Medical Association and a private hospital corp through special agreement.
- Includes all publicly employed HCP and many privately employed HCP
- Includes all medical device companies in Sweden (dental in a separate agreement)



Direct sponsorship of HCP

- Not regulated until 2006
- 50 % rule until the 1st of Jan 2015
- Today no direct sponsorship of HCP
- Very strict rules on indirect sponsorship
- Signed by the Swedish Medical Association and the Swedish Association of Health Professionals

Challenges for national associations in Europe

Gerry Livadas, SEIV General Secretary





- Too many doctors attend too many congresses
- Economic situation urges for reduction in expenses
- Great need for support of medical education
- Small companies won't agree with phase-out direct sponsorship
- National Association may loose members

The Italian Way



Lorenzo Fracassi, Managing Director - Dasit Group S.p.A., Milano - Italy

Assobiomedica Member of the EDMA Board





General Rules

Law 231/2001 & Assobiomedica Ethical Code

Pursuant to the Italian provision on the “**administrative liability of legal entities deriving from offences**” contained in Legislative Decree no. 231 of June 8, 2001 (hereinafter, “Legislative Decree no. 231 of 2001”), legal entities – including limited companies – may be held liable, and consequently subject to money penalties and/or interdiction, for any offences¹ committed or any attempts to commit offences – in Italy or abroad – in the interest or to the advantage of the company itself:

- by individuals who are representatives, directors or managers of the company or of one of its organizational unit that has financial and functional independence, or by individuals who are responsible for managing or controlling the company (individuals in apical positions or “apicals”);
- by individuals who are managed or supervised by an individual in an apical position (individuals under the command of others).

- Sponsorship can be limited to enrollment, travelling and lodging or some of them but:
- The educational time during the event must be prevalent vs recreational time
- NO 5 ***** stars hotel lodging allowed
- NO congresses in locations/resort areas during high season and/or difficult to reach
- NO entertainment *per se* allowed
- NO « illogical » pleasure programs
- NO other guests (i.e. spouse, partners, kids, etc.) sponsored



Sponsorship rules in Italy for Public HCP's (mandatory) and Private HCP's (strongly suggested)

Moderator/ Speaker

- ECM Events (Continuing Medical Education): direct sponsorship is forbidden (it is up to the provider)
- No ECM Events: Invitation letter with the name of the moderator/speaker to obtain permission from the Hospital

Non speaker guests (ECM and no ECM events)

1. Invitation letter without names to the General Manager of the Hospital
2. The Hospital replies and provides the names of the HCP's to be invited
3. The company bears enrollment, travel and lodging costs.





Alphie Moran – Senior Ethics, Compliance & Training Officer
Cook Medical



Challenges for National Associations – An Industry Perspective



- HCO's
 - Communication to date, buy-in, what message, transparency...
- PCO's
 - Will HCO's use them, they have expertise
- HCP's
 - Selection criteria, 'Golden Circle'
- Industry
 - Admin burden, due diligence, lack of financial traceability