Visibility of funding of Continuing Medical Education

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Disclosure of Interests

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• Member of the Rome Group

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• Independent consultant
Financial or other kind of contributions given by a commercial organization which is used to pay all or part of the costs of a CME/CPD activity
Compliance : Definition

com·pli·ance (km-plns)n.
1.a. The act of complying with a wish, request, or demand; acquiescence.


2. A disposition or tendency to yield to the will of others.

3.a. Extension or displacement of a loaded structure per unit load.

b. Flexibility.
Sources of bias

— Commercial support
— Insurances – payers
— Healthcare Management Organizations
— Authorities
— Academia
— Patient organizations
The main objective of Commercial Support Regulation

- To ensure the independence of CME/CPD activities by preventing the commercial bias

- CoI is not bias but a “tendency” toward bias (M. Davis)
Link between Conflict of Interest and Bias
Rationale for commercial support regulation

Commercial support accounts for more than 60% of CME/CPD offer in Europe and the USA.

Commercial support is essential to assure the access of physicians to qualified CME/CPD, complementing the resources allocated by employers and the health administration (in many European countries).
Financing of CME

CME is paid by patients

- insurance premiums
- hospital and other bills
- fees of doctors and other professionals
- taxes
- prices pharmaceutical products
- outside funding is the exception
How do we manage industry support?

Pragmatic solution

Complete ban  No control at all
Codes of Conduct

Initially

Industry

Health Care Professionals

Regulators
Codes of Conduct
Now

Industry

Health Care Professionals  Regulators
Codes of Conduct

Ideally

Industry

Health Care Professionals

Regulators
At Stakeholder level

Initially
At Stakeholder level

Now
At Stakeholder level

Ideally

1

2

3
Categories of Educational Activities

Commercial Support

Marketing activity  Product information

Social gathering  Accredited event

Educational Value
Standard for Commercial Support

Independence of the scientific programme

Independence of the faculty/speakers (Disclosure)

Control of the promotional and educational materials

Control of logos
Regulations

National

• UK : ABPI - Federation of Royal Colleges of Physicians
• Belgium : Mdeon
• Spain : SACME
• USA : ACCME Standards on Commercial Support - FCPA
• Canada : Canadian Medical Association
• UK : Bribery Act

Global

• Europe : Joint declaration CPME - EFPIA
• Europe : UEMS-EACCME Standards on Commercial Support
• Europe : EFPIA and EUCOMED codes
• Worldwide : Rome Group Guidelines on Commercial Support
EU Directive 2001/83

Regulates the interactions between the Pharmaceutical Industry and the Health Care Professionals

Has to be implemented in National Legislation

• has not been done in all EU Member States yet
• small amendments can be introduced nationally
1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than health-care professionals.  (Dir. 2004/27)
3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.

4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by paragraphs 1, 2 and 3.
Unrestricted grant

Problems to assess this
Some possible solutions?

Mdeon
• Independent body “regulating” the sponsoring of events
• Is mandated by the government
• Organized by the three main partners
  – Industry
    • Pharmaceutical Industry (pharma.be)
    • Industry of the Generic Products (Febelgen)
    • Medical Devices (Unamec)
  – Pharmacists
  – Doctors
    • General Practitioners
    • Specialists
Common Ethical Healthplatform

Industry

Veterinaries

Physicians

Nurses

Physiotherapists

Paramedicals

Hospital technicians

(Hospital) Pharmacists

Dentists

25 MEMBERS
European Initiatives about Transparency

- EFPIA
- Eucomed CVS
- CPME Declaration on Transparency
Purpose of the Eucomed Code

- Covers all types of interactions, including research and consulting agreements, gifts as well as the sponsorship of healthcare professionals to attend company events and third party professional and educational conferences based on:
  - Principle of Separation
  - Principle of Transparency
  - Principle of Equivalence
  - Principle of Documentation
The need for a single system

- Third party conferences, are an essential part of the education and training of healthcare professionals
- It is critical that sponsoring is conducted in the most ethical, consistent and transparent manner
- Eucomed Board created a centralised decision-making system to approve Eucomed member sponsorships
The Eucomed Compliance Panel

Nancy Russotto, European Affairs Advisor

John Mc Loughlin, Chair Attorney

Arthur Muratyan, ETHICS

Christine Sainvil, Compliance Officer
The Compliance Panel

- Independent body created by Eucomed to ensure consistent interpretation of the Eucomed Code of Ethical Business Practices

- Its role in the Conference Vetting System:
  - Supervise the Compliance Officer
  - Ensure treatment of requests in full compliance with competition policy rules
  - Hear appeals of decisions (procedure to be defined at the end of the pilot phase)
The Conference Vetting System (CVS)

- The system operates independently of Eucomed to ensure objectivity in conference assessments.
- Separate website & visual identity: [www.ethicalmedtech.eu](http://www.ethicalmedtech.eu)
- The CVS will review compliance of third party educational conferences with the ethical rules established by the Eucomed Code.
- Pilot phase: March 21, 2012
- Duration: +/- 6 months
- Conference assessments: recommendations only (pilot phase)
- When the CVS becomes final, decisions of the Compliance Officer will be binding upon the industry, no longer recommendations.
Transparency
EFPIA’s initiative

• European Federation of Pharmaceutical Industries and Association

• Publishing all money transfers between Industry and HCP’s
  – Directly as well as indirectly
  – Money, advantages or other

• Not
  – Meals and drinks
  – Small gifts
  – Samples
Transparency
EFPIA’s initiative

- On yearly basis *(following the previous 6 months)*
- Individually or Aggregated
- Template will be provided
- Through common web platform
What to be published
Based on three categories

• Research and Development
  – Non clinical studies
  – Clinical Trials
  – Non interventional activities
    • Aggregated

• Health Care Organization

• Health Care Professional
What to be published

Based on three categories

• Research and Development

• Health Care Organization
  – Donations and subsidies
  – Support of scientific activities
  – Registration fees
  – Travel and accommodation
  – Consultancy fees
    • Individually (except Privacy legislation)

• Health Care Professional
What to be published

Based on three categories

• Research and Development

• Health Care Organization

• Health Care Professional
  – Support of scientific activities
  – Travel and accommodation
  – Consultancy fees
  – Costs related to consultancy
    • Individually (except Privacy legislation)
EFPIA Protocol

Implementation

Implemented in:

- Austria
- Hungary
- Slovenia
- Belgium
- Ireland
- Spain
- Bulgaria
- Italy
- Sweden
- Cyprus
- Latvia
- Switzerland
- Czech Republic
- Lithuania
- United Kingdom
- Estonia
- Malta
- Turkey
- Finland
- Norway
- Germany
- Poland
- Greece
- Romania
EFPIA Protocol
Regulated by National Legislation

- Denmark
- France
- Portugal
- Slovakia

Co-regulation

- Netherlands
Funding from third parties, such as the pharmaceutical industry, must comply with openness and transparency and should only be permitted in accordance with national and international guidelines.
Key Words

Distinction between Promotion and Education
Unrestricted grants
Independence of organizers
Independence of evaluators
Transparency
Conclusions

CME without Industry support is nearly impossible

Industry ban is not the solution

Clear rules are much more effective

Rules have not only to be drafted but also applied strictly
Thank you

Merci

Muito obrigado

Vielen Dank

Gracies

Dank U

Muchas gracias

Dank U

Grazzi

Dank U

Διαγνωστείτε

Много спасибо

Благодарю

*bopahstay*

*Thek vo luh*

Thank you