



Industry and corporate standards - transparency

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Background

- Top priority during Vasella's IFPMA Presidency
- New EFPIA President (Arthur Higgins, Bayer Schering): « Trust is our licence to operate »
- Renewed attention by WHO
- Issue with compliance world-wide (CEE, SE Asia, MEA, Central and Latin America...)
- EU focus on post-marketing studies and support to patient organisations
- Debate on influence on doctors (CME, medical journals...)
- Looming US legislation...





The NEW ENGLAND JOURNAL of MEDICINE

SPECIAL ARTICLE

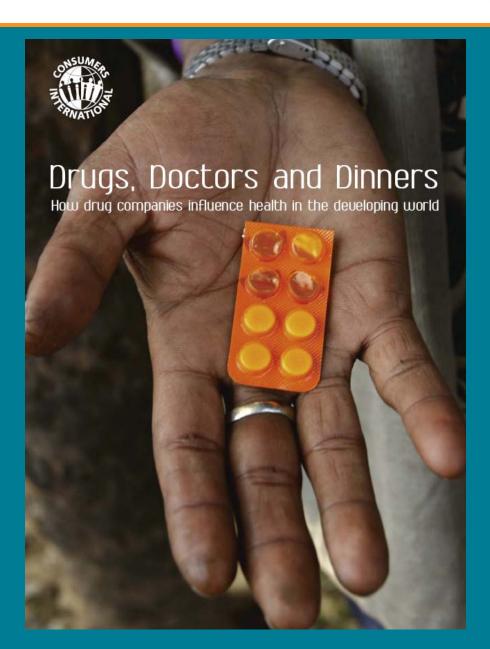
A National Survey of Physician–Industry Relationships

Eric G. Campbell, Ph.D., Russell L. Gruen, M.D., Ph.D., James Mountford, M.D., Lawrence G. Miller, M.D., Paul D. Cleary, Ph.D., and David Blumenthal, M.D., M.P.P.

RESULTS

Most physicians (94%) reported some type of relationship with the pharmaceutical industry, and most of these relationships involved receiving food in the workplace (83%) or receiving drug samples (78%). More than one third of the respondents (35%) received reimbursement for costs associated with professional meetings or continuing medical education, and more than one quarter (28%) received payments for consulting, giving lectures, or enrolling patients in trials. Cardiologists were









New IFPMA Code

- New Code with global reach
- In line with updated Codes in regulated markets
- Focus on interactions with health care professionals
- Commitment to prevention
- Revamped Complaint Procedure
- Publicity of breaches: « Name and shame »
- Code and complaint information readily accessible through internet





Main features of new IFPMA Code

- Restrictive rules on international events (Art 7.1) and company sponsorship (Art 7.2)
 - travel only allowed for logistical (majority from abroad) or security reasons
 - spouses not allowed
- Restrictive rules regarding hospitality provision by companies, including provisions largely restricting entertainment (Art 7.5)
 - specific amounts for meals
 - extravagant venues to be avoided
 - ban on self-standing social activities
- New provisions defining the extent to which gifts may be offered to healthcare professionals (Art 7.6)
 - cash never allowed
 - cultural courtesy gifts to be clearly defined (occasions and values)





IFPMA Code Compliance Network

- To exchange best practices in code compliance and implementation;
- To facilitate prevention of breaches by encouraging communication and networking among companies and associations officers;
- To create a forum for positive communication around industry self-regulation activities;
- To create a resource pool of experts in code compliance for needs of the IFPMA complaints procedure
- To stimulate discussions about new challenges related to industry's promotion and marketing practices





New IFPMA Complaint Procedure

IFPMA procedure directly applicable in countries where there are no Codes.

Complaints sent to IFPMA in Geneva

- Step 1 the complaint is sent to CEO of the company in alleged breach, with request for clarification; results are communicated to the complainant.
- Step 2 where the company disputes allegation, IFPMA will rule on the case. Director General with 3 members of the Code Compliance Network make a decision.
- Step 3 appeal procedure in case of further dispute; final decision is made by 5 members of the Code Compliance Network.

All decisions are made public on the website and summarized in an annual report





New (2007) EFPIA Code

- Latest national implementation date: July 1, 2008
- New chapters on
 - Non-interventional studies
 - Consultants
 - Grants and donations vs. fees for service
- Separate rules on sponsorship of patient organisations
- Covers 3rd party contractors
- Unlike the IFPMA Code, rules on foreign travel and Events (incl. ban on social activities) cover <u>all</u> meetings with HCPs (incl. clinical trial meetings, advisory boards...)
- EFPIA Code Steering Group to provide guidance on interpretation





Challenges

- Not all countries covered
- Not all sectors covered
- Need all stakeholders aligned
 - working with WMA and FIP
- Congress organisers and medical associations key to success





On the horizon (I)



BETTER HEALTH THROUGH RESEARCH AND INNOVATION



28 March 2008

Medicines Australia sets world-first in transparency





On the horizon (II)



Editorials represent the opinions of the authors and JAMA and not those of the American Medical Association.

Impugning the Integrity of Medical Science

The Adverse Effects of Industry Influence

Catherine D. DeAngelis, MD, MPH
Phil B. Fontanarosa, MD, MBA

to note that for some of the referenced publications listed in the Table of the article by Ross et al, 1 some of the authors either did not actually receive financial support from the company; were





The only way

Accountability and transparency