



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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**Best expertise vs. conflicts of interest:
Striking the right balance**
Academia (human medicines)

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Drug Commission of the German Medical Association





Drug Commission of the German Medical Association (DCGMA) –

How managing relationships (of ~ 140 experts) with industry?

- **Independent scientific non-profit organization**
- **Mission/main tasks**
 - Information on rational pharmacotherapy and drug safety
 - Regular announcements in the “Deutsche Ärzteblatt”, various flyers (“Wirkstoff AKTUELL”, “Neue Arzneimittel”), book “Drug prescriptions”, ISDB-journal, Evidence-based treatment guidelines
 - advising the GMA in fundamental questions of pharmacopolitics
 - official expert for the ‘benefit assessment of pharmaceuticals’
 - reporting, documentation and assessment of adverse drug reactions
- **Conflict of interest (CoI) disclosure**
 - Obligatory declaration of CoI before membership, before participation for the last 3 years; yearly update; paid/unpaid activities
 - 7 closed questions: employment; consultancy; fees; third party funds; shares, patents, business shares; (guest/ghost) authorship; intellectual CoI
 - DCGMA policy how to manage CoI

CoI: Declaration and Management

Status quo (academia)

- Collaborations between physicians and industry integral to medical research
- „Commitment to maintaining trust by managing CoI“
- Potential impact on integrity of research and public confidence in professional judgement
- CoI no clear-cut ethical breach of duty („red flag“)
- (great) variation in definition, disclosure and management of CoI
- Prevalence of financial relationships decreasing
- Substantial deficiencies in the adequacy of CoI disclosures
- Academic authors with financial ties ► greater scientific contributions
- Impact of professional relationships on design, outcomes, and reporting as well as interpretation of research findings (industry-funded research)
- Severity of CoI dependent on value (of secondary interest) and scope of CoI
- Unintended consequences of CoI disclosure (e.g., increased bias)
- **Research gaps:** no sufficient and systematic evidence how well CoI policies accomplish their goals

EMA policy concerning the handling of CoIs

Some questions and problems of the academia

- Revised EMA policy (2011/2012) ► more transparency and comprehensive management of experts' CoI
- Definition of CoI (primary/secondary interests; direct/indirect interests)?
- What about intellectual CoI and relationships between experts and, e.g., health insurances or HTA organizations?
- Base of risk levels and restricted involvement adequate?
- Clarification of inappropriate and/or intolerable relationships of experts?
- ‚Good‘ experts cannot contribute due to CoIs ► ‘expert witness concept‘
- Proactive approach for search of alternative experts
- Transparency of financial ties between institution (definition?) and industry
- Direct links of CHMP members/experts involved in EPARs, decision-making bodies, SAGs with their eDoI



Herausgeber:

Bernard Lo & Marilyn J. Field

,,...concerns are growing that wide-ranging financial ties to industry may unduly influence professional judgements involving the primary interests and goals of medicine. Such conflicts of interest threaten the integrity of scientific investigations, the objectivity of professional education, the quality of patient care, and the public's trust in medicine“.

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Steven C. Schachter et al.: Managing Relationships with Industry; AP, 2008.

**Marc A. Rodwin: Conflicts of Interest and the Future of Medicine;
Oxford University Press, 2011.**

Further relevant publications see list with references