SPONSORSHIP AND CONFLICT OF INTEREST

FRAMEWORK FOR GUIDELINE DEVELOPMENT

Introduction

The developments since the mid 20th century in the manufacturing of psychotropic drugs have been beneficial in the treatment of many patients with mental illness. These developments were partly made possible through the contacts of doctors with companies that develop, manufacture and distribute these drugs. This cooperation has improved the treatment of patients as well as their quality of life. The companies that manufacture these drugs have been financially successful, which enabled them to generously support activities of associations, individual healthcare professionals and patients organisations.

However, this close cooperation may have unwanted effects on the optimal treatment of individual patients and management of specific mental disorders. There is scientific evidence to support this statement. Although the pharmaceutical industry is the biggest sponsor of doctors and their associations, there are numerous other sponsors such as public healthcare, government, local authorities, hospital managers etc.

Most healthcare professionals are able to assess the conflicts of interest which may arise from accepting benefits from sponsors. There is however an agreement that more clarity and guidance would help associations as well as individuals to find their way.

The UEMS Section of Psychiatry at its autumn meeting in Ljubljana in 2009 decided to establish a working group, in collaboration with the European Federation of Psychiatric Trainees (EFPT), to develop a framework providing guidance on regulations for EU psychiatric organisations and healthcare professionals on their relations with sponsors (mainly commercial organisations such as pharmaceutical industries). The framework will recommend actions that should be taken to address the impact sponsors can have on psychiatric associations as well as on individual healthcare professionals. The framework is intended to retain the positive effects of sponsorship on psychiatric activities whilst minimizing its negative consequences.

It was agreed that the target recipients of the final report/recommendations should be:

1) National scientific psychiatric and medical associations
2) Individual medical practitioners, including trainees
3) Other service providers
4) Commercial organisations

To overcome potential difficulties with adopting the framework in all EU countries, the working group decided that the recommendations covered by the framework should have, where possible, three levels of implementation:

1. Basic practice – essential for everyone to apply
2. Good practice – desirable level
3. Best practice – aspirational goal

Level 3 implementation includes the criteria of level 1 and 2.

The evidence

The relationships between commercial organizations with medical organizations and individual doctors are extensive. Frequency of contacts, money spent in sponsorship and propaganda, payment for consulting services and other activities have been used as indicators to quantify these relationships. The results demonstrate a large variability across countries and settings but always involving in one way or another almost all organizations and individuals, including psychiatric associations and psychiatrists.

The scope of the unwanted consequences of sponsorship is wide and it has been repeatedly denounced in papers and books as well as disseminated through the media. However, some of these consequences are difficult or impossible to prove because of their complexity or because they result from an indirect influence of sponsoring, such as the contribution of the pharmaceutical industry to medicalisation, to disease-mongering or to the reinforcement of the biomedical model.

Other consequences are more susceptible to empirical research. Among these the influence of sponsorship on physician's prescribing has received particular attention. Several reviews have been published, one of them systematic, and some facts emerge as firmly established. Sponsorship has been found associated with higher prescribing frequency, higher costs, or lower prescribing quality. Even more important, no study has ever reported an improvement in prescribing as a result of sponsorship.

Another important issue is the influence of sponsorship on research. Some of the negative consequences described above are caused by the influence of sponsorship on research. The available evidence shows that in drug trials there is a greater likelihood of reporting outcomes that favour the drug produced by the companies supporting the trial. Clinical Practice Guidelines (CPGs) are known as a relatively objective way of translating research results into actual practice. However, it is very frequent that authors of CPGs have undisclosed relationships with companies whose drugs are considered in the guideline they authored. The same applies to the development of DSM IV-TR diagnostic criteria: one hundred percent of the members of the panels on 'Mood Disorders' and 'Schizophrenia and Other Psychotic Disorders' had financial ties to drug companies.

Doctor's attitudes particularly those of trainees are easily influenced by sponsorship. It has been shown that contact with sales representatives is associated with having positive opinions about interactions with pharmaceutical companies and with disavowing the potential negative effects of these interactions on prescribing. Interestingly, the majority of trainees feel they are not influenced by sponsorship and the minority that admit to this influence believe that others may be more influenced.

Accepting sponsorship, whether by individual psychiatrists or psychiatric organisations, affects the general credibility of psychiatry as a profession.

Definitions

Sponsorship is defined as funding from any external source, including funding of all or part of the costs of employing a member of staff, research, training, pharmaceuticals, equipment, meeting rooms, costs associated with meetings, meals, gifts, hospitality, accommodation and transport costs (including trips abroad), and provision of free services (speakers), buildings or premises. This definition includes purchasing exhibition space and advertising in journals (adapted from the Royal College of Psychiatrists 2008 and UK Department of Health 2000). In this document 'sponsor with commercial interest' refers to a commercial organisation such as pharmaceutical company, or a manufacturer of medical devices.

Conflict of interest occurs when a healthcare professional (or their relatives) is influenced by a secondary interest (i.e. a personal incentive) in their acts concerning one of the primary interests to which they are professionally committed. These primary interests are: the welfare of their patients, the progress of science, and the education of their students, residents or colleagues. The secondary interests that may influence doctors´ actions include material benefits such as financial gain for themselves (or their relatives) or for an institution.

Clinicians and researchers should be aware of material and non-material interests in medicine.

Material interests include being:

- an employee of a private firm
- a stockholder
- a member of a company board of directors
- a regular consultant of a private firm
- an occasional consultant of a private firm
- an official speaker of a private firm
- an occasional speaker of a private firm
- getting refunds from a private firm
- recipient of honoraria
- a clinical investigator in a sponsored trial
- recipient of research support from a private firm
- owning a patent (Fava 2007)

Non-material interest in medicine include:

- personal recognition
- career advancement
- visibility in the media
- favouring a relative, friend, or colleague
- exclusive commitment to a school of thought or ideology (adapted from Maj 2008)

This framework was developed with the use of the following policy documents:

1. American Psychiatric Association – Report of the APA Workgroup on Relationships between Psychiatrists and the Pharmaceutical and Medical Device Industries (2009?)
2. Federation of the Swedish County Councils and the Swedish Association of the Pharmaceutical Industry – Agreement on forms of cooperation between pharmaceutical companies and medical professionals in the public healthcare sector (2007)
3. Royal College of Psychiatrists – Good Psychiatric Practice. Relationships with pharmaceutical and other commercial organisations (CR148)
4. World Psychiatric Association – Recommendations for relationships of psychiatrists, healthcare organizations working in the psychiatric field and psychiatric associations with the pharmaceutical industry (2009?)

FRAMEWORK FOR GUIDELINE DEVELOPMENT

1. Disclosure of contacts with and benefits from sponsorship

Healthcare professionals and organisations working in the psychiatric field and psychiatric associations may have relationships with sponsors that affect objectivity. These relationships may include lecture fees, consultancy, service on advisory boards, equity interests in companies, industry gifts, licensure of patents, industry funding for clinical, research, or educational activities. This also involves financial interests that the organisation's leaders may have in commercial organisations, e.g. stock ownership, receipt of honoraria, etc.

General

Level 1

Healthcare professionals and organisations should disclose all material benefits received from sponsorship. They should also be aware of non-material benefits as defined above.

Level 2

Any contacts between individual practitioners or organisations and a commercial sponsor should be documented in a written statement setting out the purpose of the relationship and the rights and obligations of both parties. There is a clear correlation between professional behaviour and material benefits.

Level 3

There should be a register of disclosures of material benefits, open to the general public. Non-disclosure by individual healthcare professionals and organisations should have consequences in line with national regulations.

Publications and presentations

Level 1, 2 and 3

Declaration of material benefits should always be included in publications and presentations in line with ICMJE[1] guidance.

2. Training and sponsorship

Healthcare professionals and medical organisations are involved in the education, specialist training and professional development. Sponsorship influences educational programmes. Sponsored educational activities have been shown to affect the delivery of care.

Undergraduate education

Level 1, 2 and 3

Undergraduate education should not be sponsored. Recognition of the potential influence of sponsorship on the delivery of healthcare should be an integral part of undergraduate curricula.

Specialist training

Level 1 and 2

National specialist training programmes should provide:

- information on the potential influence of sponsorship on the delivery of healthcare and the existence of guidelines relating to this issue
- skills in managing the relationships with representatives of sponsors
- skills in critical evaluation of scientific literature in relation to potential bias introduced by sponsorship

Level 3

- Training institutions should ensure that psychiatrists in training have no individual contact with representatives of sponsors with commercial interests
- Topics specified in level 1 and 2 should be an integral part of specialist training curricula

[1] International Committee of Medical Journal Editors

Continuing Medical Education

Level 1 and 2

- The extent of sponsors' involvement must be fully disclosed in any CME event
- CME can only be accredited when there is no sponsors' influence on the selection of speakers and the programme

Level 3

CME events must be free from any commercial sponsorship (funding, management, selecting of speakers and programme, etc.) to obtain accreditation.

3. Guidelines and other consensus statements

Clinical practice guidelines (CPGs) are a set of recommendations based on current evidence and expert consensus to improve the quality and effectiveness of patient care. Any influence that the authors of CPGs experience from their interactions with sponsors affects the objectivity of the guidelines. The same applies to other consensus statements such as diagnostic or classifications manuals.

Level 1 and 2

There should be a formal process for discussing conflict of interest, including disclosure of material interests, for authors prior to the development of the clinical practice guidelines.

Level 3

CPGs and other consensus statements should only be developed by authors not benefitting from sponsorship.

4. Formularies

Healthcare organisations and associations can maintain formularies (a catalogue of medications used for prescribing). Decisions about which medications to include should be made only on the basis of clinical utility, taking into account limitations on resources.

Level 1 and 2

There should be a framework for discussing conflict of interest, including disclosure of material interests, for members of formulary committees.

Level 3

Healthcare professionals receiving material benefits from sponsors cannot serve on formulary committees.

5. Research in relation to external sponsorship

The involvement of any external organisations in sponsoring research leads to conflict of interest. This includes, but is not limited to, equity ownership in the company, receipt of royalty payments from the company, membership on company advisory boards, consultation to the company, and participation in speaking engagements funded by the company. Financial conflict of interest in research leads to biased results which affects the quality of health care. Biased study results arise from interventions by the sponsor in the planning, design, subject selection, methodology, data analysis or publishing.

Disclosure

Level 1 and 2

- Healthcare professionals who engage in research should disclose all material benefits received from sponsorship.
- Persons who are subjects of research should be informed of the institutions' or researchers' conflict of interest

Level 3

Healthcare professionals who participate in clinical research should not receive payment from the sponsor unrelated to actual cost of research.

Study protocol

Level 1

There should be appropriate research ethics committee approval.

Level 2

Healthcare professionals and persons participating in research as subjects should be fully informed of the protocol.

Level 3

Sponsors should have no influence on study protocol development.

Publications and presentations

Level 1, 2 and 3

- In line with ICMJE guidance authors should declare:
  - their contribution to the study
  - they had access to all data
- Sponsors should not be allowed to restrict publication of research findings in any way or have the right to control how findings are presented.

6. Psychiatric associations, scientific psychiatric journals and sponsorship

Psychiatric associations are involved in activities such as organising congresses and scientific meetings, training, examinations, developing curricula and guidelines, publishing journals, public education, etc. These activities are affected by sponsorship.

Level 1

- Public disclosure should be made of all sponsorship. Association officers and editorial boards of their scientific journals should disclose sponsorship at least annually.
- Psychiatric associations should develop and implement guidelines regulating the organisation's and members' relationships with sponsoring bodies.
- When organising scientific congresses associations should make reasonable efforts to seek sponsorship from multiple sources.

Level 2

Psychiatric associations and scientific journals should seek to minimise sponsorship.

Level 3

Scientific activities should be free from all sponsorship, including scientific congresses and journals.

7. Marketing activities aimed at general public

The last decade has seen a tendency to market products directly to healthcare professionals, patient organisations and the general public. Advertising drugs to patients is not allowed in most countries, so companies try to inform patients in other ways to influence clinical practice.

Level 1, 2 and 3

- Doctors should be aware of marketing strategies used by sponsors with commercial interests to inform the general public of their products.
- Doctors should not cooperate in disseminating information provided by sponsors with commercial interests.

8. Contacts with sponsors

Sponsors with commercial interests employ representatives to establish personal relationships with healthcare professionals, offer gifts and samples and provide information intended to promote their companies' products. Even if gifts are not accepted clinical practice is influenced by the tendencies toward reciprocity. As a result, decisions may be based on something other than patients' best interests. Accepting material benefits, even if small, has been shown to correlate with the belief that representatives have no impact on clinical practice and with a positive attitude towards the sponsors with commercial interests.
Doctors should be aware of the reasons why pharmaceutical companies distribute samples. Distribution of samples has been shown to have an effect on clinical practice.

Level 1 and 2

- Doctors and organisations should disclose all material benefits received from sponsors with commercial interests.
- Doctors should ensure that items carrying companies' logos do not appear in patient care areas.
- Samples should only be used for patients who would otherwise be unable to have access to medications.
- Doctors in public healthcare should not meet representatives of sponsors during working hours.

Level 3

- Doctors should not accept any benefits from sponsors with commercial interests.
- Doctors should not have individual contacts with representatives of sponsors with commercial interests.

Working group membership

1. Joanna Carroll (UK), Secretary
2. Roelof ten Doesschate (The Netherlands), Chair
3. Manuel Gomez-Beneyto (Spain), Vice-Chair
4. Sameer Jauhar (EFPT)
5. Nils Lindefors (Sweden)
6. Halis Ulas (Turkey)
7. Roland Urban (Germany)

Declarations of interest

Members of the working group represent their national psychiatric associations that may have received benefits from sponsors. They declare the following interests in the last five years:

1. Joanna Carroll – employee of the Royal College of Psychiatrists, administrative secretary of the UEMS Section of Psychiatry
2. Roelof ten Doesschate – holds shares in a fund that has interests in non-specified pharmaceutical industries
3. Manuel Gomez-Beneyto – chairs an independent research and teaching association (ADISAM) which has received unrestricted grants for research not involving drugs. Member of the executive committee of the Spanish Association of Neuropsychiatry whose congresses are sponsored by the industry.
4. Sameer Jauhar – selected to attend Lundbeck Institute for an educational seminar in 2007
5. Nils Lindefors – country coordinator of a European RCT with antipsychotic drugs (EUFEST) with academic investigative leadership, partly funded by non-restricted grants from a group of pharmaceutical industries. Principal investigator of a Swedish RCT with oros-metylphenidate with total funding from the National Board of Health and Welfare and the County Council of Stockholm.
6. Halis Ulas – executive committee member of the Psychiatric Association of Turkey which receives grants from pharmaceutical industry for organising its congresses (2007 – to date)

References

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Maj, M (2008) Non-financial conflicts of interests in psychiatric research and practice. British Journal of Psychiatry, 193, 91-92

Royal College of Psychiatrists (2008) Good Psychiatric Practice – Relationships with pharmaceutical and other commercial organisations

UK Department of Health (2000) Commercial Sponsorship – Ethical Standards for the NHS