



EUROPEAN FEDERATION
OF PHARMACEUTICAL
INDUSTRIES AND ASSOCIATIONS
Today's research, tomorrow's cures

Joint Declaration of CPME and EFPIA on the

COOPERATION BETWEEN THE MEDICAL PROFESSION AND THE PHARMACEUTICAL INDUSTRY

Introduction

1. The medical profession represented by the *Standing Committee of European Doctors (CPME)*, and the pharmaceutical industry represented by the *European Federation of Pharmaceutical Industries and Associations (EFPIA)*, aware of their responsibilities vis-à-vis patients and society, consider it essential to establish a framework that can serve as guidelines at a European level as well as at a national level for the relationship between the medical profession and the pharmaceutical industry.
2. Cooperation between the medical profession and the pharmaceutical industry is important and necessary at all stages of the development and use of medicines to secure safety of patients and efficacy of therapy.
3. It is of vital importance that the collaboration between the medical profession and the pharmaceutical industry is based on general principles, to guarantee high ethical standards and the rights of patients and to respect the expectations of society, whilst ensuring both parties' independence in the conduct of their activities.
4. To ensure both parties' independence and credibility, total transparency is required; therefore any relationship that entails – or might be perceived to entail – conflicts of interest must be publicly disclosed.

5. Competent authorities have set a legal framework within which collaboration in some areas is regulated. In addition to legal provisions, CPME and EFPIA consider it necessary to strengthen the adherence of both parties to their respective ethical principles.

Principles in this joint declaration are without prejudice to provisions in EU and national regulations and guidelines. For instance, national regulations may require, that physicians who are employed should, when applicable, inform and/or seek approval from the employer before entering into any agreements with a company or accepting company sponsorship.

The medical profession and the pharmaceutical industry have each adopted ethical principles applying to the conduct of their activities. This joint declaration identifies for both parties common principles on the most important aspects to be implemented in any cooperation.

6. The areas covered by this declaration are:

- 1) Product information and promotion of approved medicines,
- 2) Meetings organized or sponsored by industry,
- 3) Clinical research, and
- 4) Consultancy and affiliations.

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PRODUCT INFORMATION AND PROMOTION OF APPROVED MEDICINES

7. Information given to physicians by the industry is essential for good pharmaceutical management of patients. The physician's clinical independence when making medical decisions must be guaranteed. The content of information and promotional materials should be truthful and accurate.

Therefore, both parties have to respect the following principles:

8. Industry must:

- a) provide honest and up-to-date information regarding their products, that accurately describes their advantages and disadvantages based on current scientific evidence;
- b) make sure that sales representatives and other industry personnel providing information are adequately qualified and trained;
- c) disclose clinically relevant scientific data about their products at request of physicians;

- d) follow scientific and clinical reports concerning their products after the medicine is available on the market and disclose important observations to doctors without delay;
- e) abstain from advertising medicines before they have been granted a marketing authorisation;
- f) not offer unjustified hospitality, gifts/benefits should be inexpensive and must be relevant to the practice of medicine.

Physicians must:

- a) not ask for gifts/benefits from the industry;
- b) not accept unjustified hospitality; gifts/benefits should be inexpensive and must be relevant to the practice of medicine
- c) report on adverse reactions of medicines.

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MEETINGS ORGANIZED OR SPONSORED BY INDUSTRY

9. Pharmaceutical companies may arrange or sponsor meetings for doctors. Such events must have a clear educational content. The information rendered at any meeting should be based on scientific and medically relevant data.

10. Activities, which form part of systematic continuing professional development (CPD) should be reviewed and certified by relevant bodies.

11. In the announcement the purpose of the event should be clearly stated. Where appropriate, it will also be indicated whether the event is reviewed and certified.

12. The venue of the meeting should be appropriate for the scientific purpose of the meeting, and should not involve travelling beyond what is needed.

13. Industry may pay for lecturers, study material and facilities that are needed for the meeting. It can also pay for travelling and lodging for participants but not for any accompanying persons.

14. Hospitality during the meetings should be generally acceptable, reasonable and strictly limited to the purpose of the event. Sponsoring or organising of sporting or entertainment events is prohibited.

15. The principles of this declaration shall apply also for activities taking place outside EU, EFTA and EEA countries when EU, EFTA or EEA doctors are involved.

CLINICAL RESEARCH

16. The cooperation between the pharmaceutical industry and the medical profession in conducting clinical trials, pharmaco-epidemiological and pharmaco-genomic studies is essential to the development of medicinal products, for an in-depth knowledge of them and for their optimal use in the patient's interest.

17. The following principles must be adhered to in all clinical trials:

- a) All partners in a clinical trial must follow ethical and professional principles and guidelines, such as the Declaration of Helsinki¹ and ICH Good Clinical Practice² guidelines;
- b) Each trial must pursue a scientific and therapeutically relevant aim. No trial should be performed primarily for promotional purposes. The aim of the trial must always be the improvement of therapy, diagnostic methods and/or medical knowledge for the best of the patients;
- c) The aim of the trial must be stated beforehand. Research protocols must be drafted in such a way as to ensure that this aim is achieved and that the conclusions of the study are valid;
- d) The sponsor has to be disclosed to the patients recruited to the study;
- e) A physician must not receive payment or other benefits for only referring patients to clinical trials;
- f) A physician may receive compensation for his/her work in the trial. The compensation of whatever kind must be related to the work done, and must be disclosed to the ethical committee reviewing the study protocol. The compensation must not be linked to any expected result of the study;
- g) All efficacy and safety results on marketed products should be honestly published irrespective of the outcome, at least in summary form on the Internet, within one year after the product received its marketing authorisation. Also, other results of clinical importance should be similarly published;
- h) In publications, lectures and other presentations the sponsor has to be disclosed;
- i) The physician may receive compensation for lecturing about the trial and its results;
- j) When giving presentations on trials the doctor has to disclose his/her connections with all companies in the therapeutic field covered.

¹ The World Medical Association's "Declaration of Helsinki"

² The International Conference on Harmonisation of Regulatory Requirements (ICH) "Good Clinical Practice guidelines"

CONSULTANCY AND AFFILIATIONS

18. Industry may ask medical professionals to act as consultants. In this capacity they can give service or expert advice to industry.

19. Connections to the pharmaceutical industry of this kind must not compromise the clinical autonomy of the consulting or affiliated doctor, who always has to abide by the ethical duty to make medical decisions independently and practise medicine for the benefit of patients.

20. The payment for the consultancy assignment should relate directly to the work performed.

21. When consulting physicians are presenting views or results to other parties, which concern the medico-pharmacological field of the consultancy assignment, a declaration of interest should be presented to ensure transparency to all parties.