

*The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues.*

## **Guidelines on transparency of relationships between doctors and healthcare industry**

### **Preamble**

In the treatment context, the relationship established between a patient and his/her doctor is based on mutual trust. Doctors are expected to always act for the best interest of their patients. Patients have the right to safety and to the best treatment possible. The physicians' decision in prescribing certain medicines, as well as in using certain devices, materials, equipment, and diagnostic tools in the course of a treatment should in no way be induced by commercial factors. Conflicts of interest can harm the independence of doctors and may limit patients' capacity to take an informed decision.

However, the collaboration between the medical profession and commercial companies involved in the healthcare sector (hereafter 'commercial companies') is important and necessary at all stages of the development and use of medicinal products and health technologies, in order to secure safety of patients and efficacy of therapy. On the one hand, commercial companies involved in the healthcare sector develop new drugs, treatments, therapies, medical devices and even eHealth solutions that are of benefit to patients. On the other hand, doctors provide their experience and knowledge to help these developments. This collaboration is essential to patients and society as a whole.

In order to ensure that this collaboration is conducted in an ethical way, that trust is maintained and that patients' rights are respected and protected, transparency is required and conflicts of interests are to be avoided. As such CPME acknowledges the developments made at European and national levels aiming at the disclosure of relationships between doctors and commercial companies.

We acknowledge that while industry-led regulation is a reality in many European countries, recent trends show a growing shift towards government adoption of policies to regulate relationships between doctors and the healthcare industry<sup>1</sup>.

We also take note of the debate at the European level to enhance transparency and set minimum standards of reporting on transfers of value between doctors and the healthcare industry. We support such initiatives and recommend that transparency registers should include details such as the name of the marketing authorisation holder, the prescriber, the medicinal product concerned, the purpose of transfer, and the monetary value. To ensure accountability and transparency to the public, this information should be accessible and publicly available in a consistent and regular manner.

We also underline that registration of transfers of value between doctors and healthcare industry should not be duplicated at the national or EU level.

In light of the above, CPME considers it necessary to establish a framework that can serve as guidelines for doctors at European level. The present document is without prejudice to national professional codes and laws, notably if they go beyond the provisions outlined below.

- a. Considering the 1949 WMA international code of medical ethics, as amended in 2022 ([WMA London 1949 Code](#));
- b. Considering the 2004 WMA statement concerning the relationship between doctors and commercial enterprises, as amended in 2020 ([WMA Tokyo 2004 Statement](#));
- c. Considering the 2005 CPME-EFPIA Joint declaration on the cooperation between the medical profession and the pharmaceutical industry ([CPME 2005/O69](#));
- d. Considering the 2007 CPME-EUCOMED Joint declaration between the medical profession and the medical technology industry ([CPME 2007/O28](#));
- e. Taking into account that in the European Union, transparency of relationships between doctors and commercial companies is a national competence, and that applicable national regulations shall always prevail;
- f. CPME believes the following principles should always apply:

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<sup>1</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6015505/>, last accessed on 2 August 2024.

## Gifts

Clinical practice and prescribing behaviour of doctors should not be influenced by payments in cash, gifts or promotional material distributed by commercial companies. The following principles should always apply:

1. Doctors may not accept gifts, commission, services or other benefits from commercial companies, unless they are financially insignificant and do not impair their clinical independence.
2. Doctors are strongly advised not to accept free medical samples.

## Meetings and conferences

Medical events and conferences that are partially or fully sponsored by commercial companies are often attended by doctors. The following principles should always apply:

3. These meetings have a scientific and professional purpose only.
4. Hospitality is reasonable and strictly limited to the purpose of the event. Persons accompanying doctors to these meetings do not see their costs reimbursed.
5. All sources of funding for such events are publicly disclosed.
6. The relationships, commercial interests or financial ties that organisers and lecturers might have with the sponsoring entity are also disclosed.

## Continuous Medical Education / Continuous Professional Development (CME/CPD)

Basic and postgraduate training and continuing education for doctors need to constantly adapt to scientific development, as diagnostic, procedures and therapeutic agents rapidly evolve. CME/CPD events are often sponsored by commercial companies. Regardless how CME/CPD activities are organised, their content should be free from any undue influence. The following principles should always apply:

7. Activities and events may only be considered as forming part of CME/CPD after they have been reviewed and certified by a competent authority or other independent body in case there is no such authority.
8. The content and material of CME/CPD activities and events are designed by the organisers and may not be influenced by sponsoring companies.
9. All sources of funding of CME/CPD activities and events are publicly disclosed.

## Medical faculties and students

Interactions between medical students and commercial companies often take place in the context of their basic medical training. The following principle should always apply:

10. Medical faculties must ensure that medical students are not subject to any influence in the course of their medical training by commercial companies.

## Participation in research and scientific publications

Collaboration of doctors with industry in the area of clinical research is key to the development of innovative products and procedures. The following principle should always apply:

11. Research fully or partially funded by a commercial company follows applicable laws and regulations, as well as ethical and professional guidelines, such as the WMA Declaration of Helsinki<sup>2</sup>.
12. The purpose of clinical trials is to advance medical knowledge, diagnostic methods and therapies for the best interest of patients and society as a whole.
13. The compensation of a doctor participating in a clinical trial is based on his/her actual work provided and not on the outcomes of the trial.
14. All results of the clinical trial, whether positive, negative or inconclusive, are disclosed together with the financial and material support received from sponsors. The results should be published in an easily accessible format.
15. In publications, lectures and other presentations involving the investigated product, doctors make a declaration of interest for full transparency.

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<sup>2</sup> World Medical Association's [Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects](#).

## Consultancy activities

Doctors are often solicited by commercial companies to provide specific medical expertise through consultancy services. The following principles should always apply:

16. Doctors acting as consultants can provide medical expertise to commercial companies as long as this activity does not compromise their clinical autonomy and their ethical duty to take medical decisions independently in the best interest of patients.
17. Consultancy activities are conducted on the basis of a contract, which defines the nature, and purpose of the consultancy, as well as the fee to be paid for the services provided. The amount of the fee reflects the services provided.
18. Consultancy activities are publicly disclosed when the concerned doctor publishes an article or a report, gives a lecture or any other kind of presentation.