Principles of cooperation between EMA and APME

Introduction

1. The medical community, represented by the Estonian Medical Association (EMA), and pharmaceutical manufacturers, represented by the Association of Pharmaceutical Manufacturers in Estonia (APME), are aware of their direct responsibility to patients and society and consider it important to develop guidelines to avoid potential ethical conflicts in their relationships. The principles of cooperation are based on the similar declaration by the Standing Committee of European Doctors (CPME) and the European Federation of Pharmaceutical Industries and Associations (EFPIA).

2. Collaboration between the medical community and the pharmaceutical industry is necessary for the protection of patients' interests and for the safe and effective treatment in the context of both the development and use of medicines.

3. It is important that cooperation between the medical community and the pharmaceutical industry is based on ethical standards and considers societal expectations, thus ensuring the independence of both parties.

4. The transparency of cooperative relations is the basis for ensuring the necessary independence and credibility for both parties. It is therefore necessary to ensure public access to any situation in which agreements between a doctor or a medical association and a pharmaceutical manufacturer may give rise to doubts in regard to undue influence or conflict of interest.

5. The members of the APME shall comply with the APME Code of Ethics[1] in cooperation with doctors, which lays down, among other things, rules for disclosure of information regarding such collaboration. Members of the EMA shall comply with the Estonian Code of Medical Ethics in their activities and conduct. With the principles of cooperation, the EMA and the APME confirm that the cooperation between doctors and pharmaceutical manufacturers is based on the Medicinal Products Act and the general ethical principles and that they take into account the provisions of each other's codes of ethics.

6. This joint declaration covers the following areas:
   1) mutual obligations between pharmaceutical manufacturers and doctors,
   2) events organised and sponsored by pharmaceutical manufacturers,
   3) clinical trials,
   4) consultancy services,
   5) a doctor's employment at a pharmaceutical manufacturer.

Mutual obligations between pharmaceutical manufacturers and doctors

Pharmaceutical manufacturers make a commitment to:

a) provide honest, up-to-date, and research-based information about their products;
b) ensure that sales representatives are adequately trained and competent;
c) share data about their products which is unbiased and based on clinical trials;
d) monitor scientific and clinical information about the product, even when it is already available on the market and to bring important discoveries and information on the safety of the medicine to doctors;
e) not advertise the medicine before obtaining a marketing authorisation;
f) not offer any gifts or unlawful benefits to doctors.

Doctors make a commitment to:

[1] Code of the APME about the promotion of over-the-counter medicines and prescription drugs and collaboration with healthcare professionals

a) inform the pharmaceutical company prior to cooperating with them of any potential conflicts of interest, including the fact that the doctor is performing any public duties at the same time;
b) cooperate with pharmaceutical manufacturers in reporting adverse drug reactions in accordance with applicable requirements;
c) not demand or accept gifts or unlawful benefits from pharmaceutical manufacturers.

Events organised and sponsored by pharmaceutical manufacturers

7. Pharmaceutical manufacturers may organise or support events for doctors. In organising or sponsoring an event, pharmaceutical manufacturers follow the rules set forth in the APME Code of Ethics.

8. Events must be of an educational or scientific nature and the information provided must rely on research-based data.

9. The event to be organised or sponsored must take place in a suitable venue that supports the main purpose of the event. A venue is not appropriate if it is extravagant – i.e. if the venue itself, by its very nature, can be an incentive to attend the event.

10. Event-related hospitality must be limited to travel, catering, accommodation, and registration fees. The provision or sponsorship of entertainment (e.g., sporting, cultural, and recreational activities), either individually or as part of any event, is not permitted.

11. Hospitality associated with the event must not extend to anyone other than the doctor invited to the event.

12. The above principles also apply to events organised outside of Estonia.

Clinical trials

13. The availability of specific knowledge and experience is a prerequisite for conducting clinical trials, therefore, the medical community and pharmaceutical manufacturers collaborate. The aim of the cooperation is to improve the environment of clinical trials in Estonia and to promote cooperation with international partners.

14. The preferred areas of co-operation are the training of doctors and other health care professionals all over Estonia, but also the expansion of research-based thinking in society. Clinical trials are conducted in collaboration to develop products, medicines, and services used in the medical area. Collaborative research and development work also promotes effective and safe treatment in different patient populations.

15. The introduction of new technology used in the clinical trials of pharmaceutical manufacturers helps to increase the motivation and experience of the Estonian medical community to also conduct academic research and scientific projects. As a result, Estonia's international capabilities and attractiveness will improve, both in clinical trials and academic research.

16. Clinical trials are conducted in accordance with good clinical practice of clinical trials, good scientific practice, and ethical principles.

Consulting service for pharmaceutical manufacturers

17. Pharmaceutical manufacturers and doctors may cooperate in the provision of consulting or other services by a doctor as an expert of the field to a pharmaceutical manufacturer. In carrying out this

cooperation, the pharmaceutical manufacturers shall comply with the rules set out in the APME Code of Ethics.

18. Collaboration with the pharmaceutical manufacturer must not compromise the doctor's independence in making clinical decisions regarding the treatment of the patient; it is the primary duty of the doctor to act in the best interests of the patient.

19. There must be a justified need for the service provided by a doctor to the pharmaceutical manufacturer and the fee paid to the doctor for the service must be reasonable and in line with the fair market price for the services rendered.

20. Prior to the provision of the service by a doctor, a written agreement shall be concluded between the doctor and the pharmaceutical manufacturer, specifying the nature of the services to be provided and the fees to be paid for them.

21. It is a good practice that the doctor would allow the pharmaceutical manufacturer to disclose the payments received from them.

22. When providing a service to a pharmaceutical manufacturer, the doctor must declare that they are a consultant to the pharmaceutical manufacturer whenever they write or speak publicly on the subject matter of the contract or any other matter concerning the pharmaceutical manufacturer.

A doctor's employment at a pharmaceutical company

23. A doctor practicing in their specialty being simultaneously employed by a pharmaceutical manufacturer is not recommended. Working simultaneously as a doctor and as a sales representative of a pharmaceutical manufacturer is not allowed.

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Signed digitally

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