

Medicines and
Healthcare products
Regulatory Agency

Committee on the
Safety of Devices



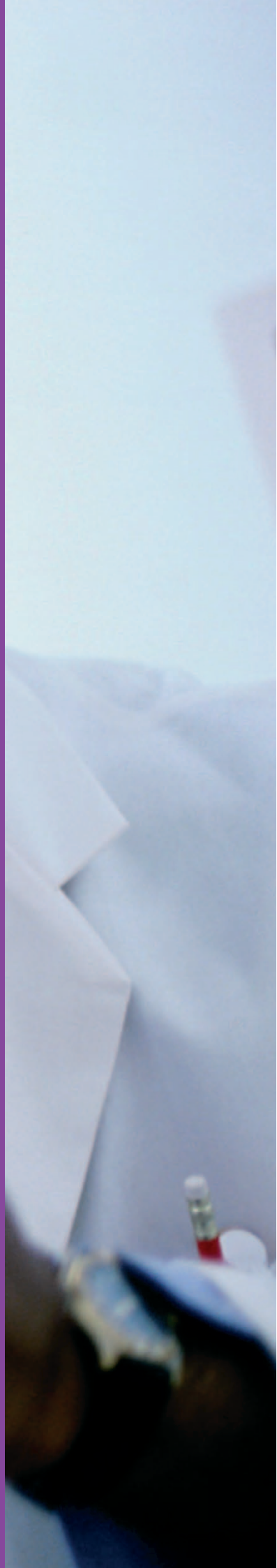
Code of Practice for Members

Committee on the Safety of Devices

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Introduction

1. This code of practice guides the chairman and members of the committee as to the standards expected of them in public life and the circumstances in which they should declare an interest in the medical devices (or other) industries. The **Seven Principles of Public Life** are set out in Annex A and a definition of a medical device in Annex B.

2. In this code, *the medical devices industry* means
 - a. companies, partnerships or individuals who are involved with the manufacture, sale or supply of medical devices
 - b. trade associations representing companies involved with such products
 - c. companies, partnerships or individuals who are directly concerned with research, development or marketing of a medical device which is being considered by the committee.

References to 'the medical devices industry' include cases involving a single company.

Different types of interest

3. The following is intended as a guide to the kinds of interests which should be declared. Where a member is uncertain as to whether an interest should be declared they should seek guidance from the chairman or the secretariat or, where it may concern a particular product which is to be considered at a meeting, from the chairman at that meeting. If members have interests not specified in this Code but which they believe could be regarded as influencing their advice they should declare them. However, members are not under an obligation to search out links between one company or another, for example where a company with which a member is connected has an interest in a medical devices company of which the member is not aware and could not reasonably be expected to be aware.

Personal interests

4. A personal interest involves payment to a member personally. The main examples are:
- a. consultancies – any consultancy, directorship, position in or work for the industry which attracts regular or occasional payments in cash or kind
 - b. fee-paid work – any work commissioned by the industry for which the member is paid in cash or kind
 - c. shareholdings – any shareholding in or beneficial interest in shares of the industry. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management
 - d. gifts and payment in kind
 - e. a non-pecuniary interest in a charity or pressure group whose activities relate closely to the committee's activities giving rise to a perceived or actual conflict.

Non-personal interests

5. A non-personal interest involves payment which benefits a department for which a member is responsible, but is not received by the member personally. The main examples are:
- a. fellowships – the holding of a fellowship endowed by the industry
 - b. support by the industry – any payment, or other support or sponsorship by the industry which does not convey any pecuniary or material benefit to the member personally but which does benefit their position or department: for example:
 - 1. a grant from a company for the running of a unit or department for which the member is responsible

2. a grant or fellowship or other payment to a sponsor, a post or a member of staff in the unit for which the member is responsible. This does not include financial assistance for students
3. the commissioning of research or other work by, or advice from, staff who work in a unit for which the member is responsible.

Members are under no obligation to seek out knowledge of work done for or on behalf of the industry within departments for which they are responsible if they would not normally expect to be informed.

Declaration of interests to the Medicines and Healthcare products Regulatory Agency

6. Members of the committee should inform the Medicines and Healthcare products Regulatory Agency in writing when they are appointed of their current personal and non-personal interests. This should also include such interests of close family members and of people living in the same household. Only the name of the company and the nature of the interest are required; the amount of any salary, fee, shareholding, grant etc. need not be disclosed to the Agency. An interest is current if the member has an on-going financial involvement with the industry, for example if they hold shares in a relevant company, if they have a consultancy contract with the industry or if the department for which they are responsible is in the process of carrying out work for the industry. Members are asked to inform the Agency, through the secretariat, at the time of any change in their personal interests. Changes in non-personal interests can be reported annually. (Non-personal interests involving less than £1000 from a particular company in the previous year need not be declared.)

Declaration of interests at meetings

7. Members are required to declare relevant interests at committee meetings and to state whether they are personal or non-personal interests and whether they are specific or non-specific to the matter or product under consideration.
 - a. A member must declare a personal specific interest if they have at any time worked on a matter or product under consideration and have personally received payment for that work, in any form, from the industry.
 - b. A member must declare a personal non-specific interest if they have a current personal interest in the company concerned, which does not relate specifically to the matter or product under discussion.
 - c. A member must declare a non-specific interest if they are aware that the department for which they are responsible has at any time worked on the matter or product but the member has not personally received payment in any form from the industry for the work done.

- d.** A member must declare a non-personal non-specific interest if they are aware that the department for which they are responsible is currently receiving payment from the company concerned, which does not relate specifically to the matter or product under discussion.

- 8.** The examples of 'personal', 'non-personal', and 'current' interests given in the previous paragraph should be read in the context of paragraphs 3, 4 and 5. A member who is in any doubt as to whether they have an interest which should be declared or whether they should take part in the proceedings, should ask the chairman for guidance. The Secretary of State and/or the committee has the power to determine whether or not a member with an interest should take part in the proceedings.

- 9.** If a member is aware that a product under consideration is or may become a competitor of a product manufactured, sold or supplied by a company in which the member has a current personal interest, they should declare their interests in the company marketing the rival product.

Record of interests

- 10.** A record is kept in the Agency of the names of members who have declared interests to it, and the nature of those interests. The Record of Interests will also state whether or not the member participated in proceedings. The information held on the Record will be available to the public on request.

Standards of public life

- 11.** Committee members are expected to:
 - a.** follow the Seven Principles of Public Life (see Annex A) set out by the Committee on Standards in Public Life, as they apply to their service on the committee
 - b.** comply with this Code, and ensure they understand their duties, rights and responsibilities, and that they are familiar with the function and role of the committee and any relevant statements of government policy
 - c.** not misuse information gained in the course of their public service for personal gain or for political purpose, nor seek to use the opportunity of public service to promote their private interests or those of connected persons, firms, businesses or other organisation, and
 - d.** not hold any paid or high profile posts in a political party, and not engage in specific political activities on matters directly affecting the work of the committee or of the Agency. When engaging in other political activities, members should be conscious of their public role and exercise proper discretion.



Role of members

12. Members have collective responsibility for the operation of the committee. They should engage fully in collective consideration of the issues, taking account of the full range of relevant factors, including any guidance issued by the Agency, agree summaries of committee meetings and ensure that the committee does not exceed its remit.

Terms of appointment of the committee members

13. Appointments to the committee are made by Department of Health Ministers on behalf of UK Health Ministers. Terms of appointment are for four years. Members are not usually invited to serve more than two terms. Appointments may be terminated at a member's request; in the event of unsatisfactory attendance or conduct out of keeping with this Code; or at Ministers' direction. Appointment to the committee is on a voluntary basis and fees are not payable. However members may claim reasonable travel expenses and subsistence at standard Department of Health rates.

The role of the chair

14. The chair has particular responsibility for providing effective leadership on the issues above. In addition, the chair is responsible for:
 - a. ensuring that the committee meets at appropriate intervals, and that the minutes of the meetings and any report to the Medicines and Healthcare products Regulatory Agency accurately record the decisions taken and, where appropriate, the views of individual committee members
 - b. representing the views of the committee to the general public, if necessary
 - c. dealing with media enquiries (via the Agency's Press Officer, when appropriate), and
 - d. briefing new members on appointment, as appropriate; and providing an assessment of their performance, on request, when they are being considered for re-appointment to the committee or some other public body.

It is not appropriate for the chair of the Committee on the Safety of Devices to have any current personal interests in the medical devices industry.

Personal liability of committee members

- 15.** Legal proceedings by a third party against individual members of advisory committees are very exceptional. A committee member may be personally liable, for example, if it is alleged that he/she is liable for some physical harm or injury, which had befallen a person. However, the government has indicated that individual advisory committee members who have acted honestly, reasonably, in good faith and without negligence will not have to meet, out of their own personal resources, any personal civil liability which is incurred in execution or purported execution of their committee functions.

Secretariat

- 16.** The Medicines and Healthcare products Regulatory Agency provides the secretariat.



The Seven Principles of Public Life

Selflessness

Holders of public office should take decisions solely in terms of the public interest. They should not do so in order to gain financial or other material benefits for themselves, their family, or their friends.

Integrity

Holders of public office should not place themselves under any financial or other obligation to outside individuals or organisations that might influence them in the performance of their duties.

Objectivity

In carrying out public business, including making public appointments, awarding contracts, or recommending individuals for rewards and benefits, holders of public office should make choices on merit.

Accountability

Holders of public office are accountable for their decisions and actions to the public and must submit themselves to whatever scrutiny is appropriate to their office.

Openness

Holders of public office should be as open as possible about all the decisions and actions that they take. They should give reasons for their decisions and restrict information only when the wider public interest clearly demands.

Honesty

Holders of public office have a duty to declare any private interests relating to their public duties and to take steps to resolve any conflicts arising in a way that protects the public interest.

Leadership

Holders of public office should promote and support these principles by leadership and example.

Definition of a medical device

A medical device is defined as any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or a physiological process
- control of conception

and which does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means.



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