

CODE OF PRACTICE ON INTERESTS
FOR CHAIRMEN AND MEMBERS OF
THE BRITISH PHARMACOPOEIA COMMISSION

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CODE OF PRACTICE FOR CHAIRMEN AND MEMBERS OF THE BRITISH PHARMACOPOEIA COMMISSION

1. INTRODUCTION

Purpose of the Code

1.1 This Code of Practice sets out the rules to be followed by chairmen and members of the British Pharmacopoeia Commission (BPC) holding and declaring interests in the pharmaceutical industry. The Code of Practice also provides guidance on holding and declaring other relevant interests, and on how interests that have been declared will be managed. Separate rules apply to chairmen and members of all the statutory committees and Expert Advisory Groups (EAGs) established to give advice to the Licensing Authority and Ministers on the regulation of medicines available on the UK market.

Importance of impartiality

1.2 Ministers expect the advice they receive on matters relating to the regulation of medicines to be impartial. Ministers also expect to be able to seek such advice from a wide range of highly skilled professionals who are senior and well regarded in their respective fields. Many experts in the field of medicines have, or have had, connections with the pharmaceutical industry and other commercial organisations whose business may be considered relevant to their work on the advisory bodies but may have an impact on their impartiality. For example, the University department for which an individual is responsible may have received a research grant from industry, or the individual may have shareholdings from previous industry employment.

1.3 To reassure Ministers and the public that the advice on which decisions about medicines is based is impartial, it is important to have in place a robust policy governing the declaration and management of relevant interests. In the interests of transparency and accountability, this Code of Practice, the declarations made by chairmen and members of the BPC, and the actions taken to manage potential conflicts of interest are made public. In addition, where an individual has declared in advance of a meeting an interest that would disqualify him or her from the relevant discussions, this information will be used by the secretariat to ensure that, wherever possible, the relevant committee papers are not sent to that individual.

2. SCOPE

Committees to which the Codes apply

2.1 This Code of Practice applies to the chairman and members of the BPC, and takes account of the fact that their role and remit differs from the other committees. There is a separate Code of Practice that applies to the following committees and groups:

- Commission on Human Medicines (CHM)
- The following Section 4 committees:
Herbal Medicinal Products Committee (HMAC);
The Advisory Board on the Registration of Homoeopathic Products (ABRH);
- The Expert Advisory Groups (EAGs) established by the CHM and/or the Section 4 committees.

3. DEFINITIONS

3.1 For the purposes of this Code of Practice, the following definitions apply:

Pharmaceutical Industry

3.2 “Pharmaceutical industry” means:

- Companies, partnerships or individuals who are involved with the manufacture, sale or supply of medicinal products, including herbal medicinal products and homoeopathic products;
- Trade associations representing companies involved with such products;
- Companies, partnerships or individuals who are directly concerned with research, development or marketing of a medicinal product, including herbal medicinal products and homoeopathic products which is being considered by the CHM or by one of the Section 4 committees or Expert Advisory Groups.

References to “the pharmaceutical industry” include cases involving a single company.

Immediate family

3.3 “Immediate family” means:

Spouse or partner and members of the family living in the same household. Members of the family include dependent children, any adult children or other relative (such as parent) living in the same household.

4. INTERESTS WHICH NEED TO BE DECLARED

Summary of interests that need to be declared

4.1 It is the responsibility of each individual to identify and to declare all relevant interests. The following types of interest must be declared by chairmen and members of the BPC:

- Their own financial interests in the pharmaceutical industry (financial interests are either personal or non-personal, and, where a product is under discussion at a meeting, either specific to that product, or non-specific);
 - Financial interests in the pharmaceutical industry held by members of their immediate family;
 - Any other matter that could affect their impartiality, or that could reasonably be perceived as affecting their impartiality. Some examples of interests that are relevant in the context of this Code of Practice, not all associated with the pharmaceutical industry, are set out in section 4.7 below.
- 4.2 The following paragraphs describe in more detail the types of interests that must be declared. The procedures for handling interests that have been declared are described in Section 7.

Personal interests

- 4.3 A personal interest in the context of this Code, involves the payment, in any form, to an individual personally, by a pharmaceutical company whose business may be directly affected by the advice of the advisory body. At a meeting, personal interests must be declared as *specific* (that is, payment relates to a particular product under consideration), or as *non-specific* (that is, not related to the particular product under discussion). The following main examples of interests to be declared should not be regarded as a definitive list, and the Medicines and Healthcare products Regulatory Agency (MHRA) secretariat to each committee will advise if a chairman or member is in any doubt.

Consultancies: any consultancy, directorship, position in or work for the pharmaceutical industry which attracts regular or occasional payments in cash or kind;

Fee-paid work: any work commissioned by the pharmaceutical industry for which the individual is paid in cash or kind;

Shareholdings: any shareholding in or other beneficial interest in the pharmaceutical industry. This does not include shareholdings through unit trusts or similar arrangements where the individual has no influence on financial management;

Expenses/hospitality provided by a pharmaceutical company: special rules apply to attendance at conferences or similar events. These are covered in paragraphs 4.8 et seq. below;

Unit trusts and similar: Assets over which chairmen and members and/or their immediate family have no financial control (such as holdings in a wide share portfolio - Unit Trust or similar - where the Fund Manager has full discretion over the composition of the portfolio) do not need to be declared. However, funds held in a portfolio in which chairmen and members and/or their immediate

family have the ability to instruct the Fund Manager as to the composition of the fund must be declared.

Pension entitlement Accrued pension rights from earlier employment in the pharmaceutical industry do not need to be declared.

Personal interests - special rules applicable to the BPC

- 4.4 The BPC does not advise on licensing matters but advises on the publication of the British Pharmacopoeia and on British Approved Names. Its members are not prohibited from holding personal interests in the pharmaceutical industry, but they must comply with this Code of Practice in respect of declaring personal interests. Where such an interest is declared, members will be permitted to take part in discussions at the chairman's discretion and following advice from the MHRA secretariat where appropriate.
- 4.5 The chairman of the BPC is not permitted to hold any current personal interests in the pharmaceutical industry. He or she is required to make a declaration on appointment that he/she is disposing /have disposed of any such current personal interests.
- 4.6 The chairman has three months from the date of appointment to dispose of any current personal interests in the pharmaceutical industry. During this period, he/she is required to declare any relevant current personal interests at meetings and should not take part in any consideration or discussion of the relevant product(s) or any vote in relation to the product(s).

Non-personal interests

- 4.7 A non-personal interest in the context of this Code, involves payment that benefits a department for which an individual is responsible, but is not received by the member personally. As with personal interests, non-personal interests at a meeting must be *specific* or *non-specific*. The main examples that follow should not be regarded as a definitive list, and the advice of the committee secretariat provided by the MHRA should be sought if a chairman or member is in any doubt.

Fellowships: the holding of a fellowship endowed by the pharmaceutical industry or any other relevant industry;

Support by the pharmaceutical industry or any other relevant industry: any payment, other support or sponsorship by the pharmaceutical or other industry that does not convey any pecuniary or material benefit to the individual personally but that benefits his/her position or department;

Grants from a company: for example, for the running of a unit or department for which an individual is responsible;

Grants or fellowships to sponsor a post or staff member in the unit for which the individual is responsible: this does not include financial assistance given to individual students;

Commissioning of research or other work or advice from staff who work in a unit for which the individual is responsible.

Other relevant interests

4.8 It is not only financial interests in the pharmaceutical industry that are relevant. A wide range of other matters may also be considered to be relevant, depending on the circumstances and matters under consideration by a committee on which an individual serves, and could include non-financial interests. There are no hard and fast rules concerning “other” interests that need to be declared. The legal rule against bias in the decisions and proceedings of public bodies can be stated as follows: if a fair-minded and informed observer would conclude, in all the circumstances, that there is a real possibility of bias, the member should not take part in proceedings. It is therefore not relevant that the member himself believes that he is unbiased, impartial or has an open mind. In considering whether an interest is relevant and should be declared, the guiding principle must be whether the matter might reasonably be perceived as possibly affecting a member’s impartiality. Some examples of matters that might fall under this heading are set out below. These are not exhaustive and individuals should always seek advice from the MHRA Secretariat if they are in any doubt about whether or not a matter is relevant:

- An individual, or his department, has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular pharmaceutical company, the research has taken a particular line e.g. in relation to the safety of the products, or their efficacy;
- An individual has made public statements (either favourable or unfavourable) about a particular company, or product, or class of products or about a competitor’s product or class of product;
- An individual can knowingly make a financial gain from the use of information received as a member of the BPC and its Advisory Groups;
- An individual participates in, or is connected with, a charity or pressure group that would have an interest in the outcome of the advice being given;
- An individual has a family member who has suffered a severe reaction or other problem as a result of treatment with a product under discussion;
- Matters relating to persons who are not immediately family members, but are closely connected with the committee expert e.g. adult child no longer living in the same household, or non-family member whose work or other interests are closely associated with the pharmaceutical industry and which could reasonably be perceived as affecting the individual’s impartiality. An example might be where a committee is giving advice in relation to a product and a

close family member or friend has had a major development responsibility for that product;

Attendance at conferences, scientific meetings and similar

- 4.9 Government recognises that it is usual for conferences, scientific meetings and other events associated with healthcare, medicines or related matters to receive some form of sponsorship either directly, or indirectly via a special fund, from the pharmaceutical industry. Government also recognises the importance of being able to receive advice from leading experts who are able to keep themselves up to date with developments at the cutting edge of science, and that this is mainly done through attendance at educational and scientific events and meetings. It is therefore essential to set out rules for attendance at these and similar events as questions may be legitimately raised as to whether participation in the event, or even mere attendance, will compromise their impartiality in any way.
- 4.10 The nature of the events that fall within the scope of this Code of Practice and the industry sponsorship received can vary widely from, at one extreme, a conference sponsored by a single company to launch a product to, at the other extreme, a scientific meeting organised by a learned society that has received some financial support from a number of companies paid into a dedicated meeting fund. Between these extremes there are many variations in events and funding that may occur.
- 4.11 Ministers have established a discretionary fund to meet the reasonable expenses (e.g. travel and accommodation costs) incurred in the attendance by committee chairmen and members who are not permitted to hold personal interests in the pharmaceutical industry. It is therefore also available to the chairman of the BPC. The MHRA committee secretariat will administer the fund, and the chairman must make an application in good time to enable appropriate travel and other arrangements to be made. The fund will cover educational events that are relevant to maintaining his/her expertise, where acceptance of financial support from industry (for example a single pharmaceutical company) would not be appropriate. Separate guidance on the allocation of resources from the fund has been developed for use by the MHRA secretariat.
- 4.12 In some cases it will be permissible for the BPC chairman to attend events sponsored by the pharmaceutical industry (and accept the payment of expenses) without recourse to the MHRA discretionary fund. For example, where a learned society holds an international conference that is funded by a number of different pharmaceutical companies, it will generally be acceptable for the chairman to accept such an invitation and to receive payment of expenses, although in such instances declaration of attendance and receipt of funding must be declared in the normal way. On the other hand, it would not be acceptable for him to receive payment in relation to a conference wholly funded by the pharmaceutical industry and where its primary purpose was to promote a product or a particular class of products.

- 4.13 If funding and/or expenses are paid specifically for his/her attendance but nevertheless paid to his/her department rather than the individual himself, it will not normally be acceptable for the individual to attend.
- 4.14 Benefits of this nature paid to an immediate family member that also benefit the BPC chairman (e.g. a company pays his or her flight costs so that he or she can attend a conference with a family member) must be declared as the individual's own interest. However, there is no requirement to declare educational conferences and similar events attended by immediate family members.
- 4.15 The rules for holding personal interests in the pharmaceutical industry do not apply to members of the BPC, and for the reasons set out in paragraph 4.4 above. Therefore, these experts may attend meetings sponsored by the pharmaceutical industry and accept funding of expenses, but these must be declared.
- 4.16 Attendance at conferences, scientific meetings and other events relevant to this Code must be declared as soon as practicable and not later than the first meeting of the committee after the event has taken place. This declaration may affect an individual's participation in discussions over the subsequent months. The declarations will be published annually in the report of the work of the committees.
- 4.17 The situations described are not exhaustive and individuals should always seek advice from the MHRA Secretariat if they are in any doubt about whether or not they should attend, or whether, having attended, they need to declare attendance as an interest.

5. SPECIAL POSITION OF EXPERTS ATTENDING FOR THE DAY AND EXPERTS CALLED TO ADVISE THE COMMITTEE ON SPECIFIC ISSUES

- 5.1 Experts who are invited to attend committees for the day, for example if a regular member cannot be available or cannot participate in discussions because of his or her interests, are known as "Experts for the Day". They are co-opted as full members of the committee for that day, may participate fully in all discussions and may vote. They are therefore required to make a full declaration of interests in the same way as is required of a full member of that committee. In addition, experts may be invited to advise the committee on particular issues, without being co-opted as members. Such experts should not hold personal interests in the issue under discussion.

6. DECLARATION OF INTERESTS

- 6.1 Chairmen and members are required to make a full declaration of interests on appointment and annually. They must also inform the MHRA secretariat promptly of any changes or updates to the terms of their declaration during the year. This includes reporting promptly attendance at events described in paragraphs 4.8 – 4.17. If an individual is uncertain as to whether or not an interest should be declared, he or she must seek guidance from the MHRA secretariat. The Chairman and members are also required to make further

declarations of relevant interests at meetings when they will be advised as to the procedure that will apply.

Annual declaration

- 6.2 The annual declaration must include all the financial (personal and non-personal) interests in the pharmaceutical industry of the chairman and members currently held or held in the last 12 months and financial interests in the pharmaceutical industry that they know of that are held by their immediate family. Members and the chairman are also required to include in the annual declaration details of any other matter which could reasonably be regarded as affecting their impartiality.
- 6.3 The declaration of certain interests will not be restricted to the last 12 months.
- 6.4 The chairman and members' declaration of their own interests will identify them with the interests declared, but the interests declared do not need to be quantified. For example, in declaring a grant received by a department for which the individual is responsible, only the company name is required, not the value of the grant.
- 6.5 When the annual declaration includes matters relating to other persons, names are not required, nor do the interests declared need to be quantified. For example, in declaring shareholdings only the company name is required, not the numbers or values of shares held. Family members should be referred to simply as: "immediate family member" and closely connected persons as "other person". In nearly all circumstances this will protect the anonymity of those whose interests must be declared by the serving committee member, although we recognise that in very exceptional circumstances it may be possible for that individual to be identified.
- 6.6 The annual declaration made by the chairman and members of the BPC will be published each year in the Annual Report of the Advisory Bodies.

Declarations at meetings

- 6.7 The chairman and members are required to declare relevant interests at meetings, whether or not those interests have previously been declared to MHRA. The type of interest must be declared, that is, whether it is personal or non-personal, specific or non-specific or other.
- 6.8 If an issue arises for discussion and an individual is concerned about a matter that could be regarded as affecting his or her impartiality and this matter has not already been declared, he or she must raise this with the MHRA secretariat in advance of the meeting if possible. This will enable the secretariat, wherever possible, to ensure that a member is not sent any papers concerning matters in which he or she has an interest that would disqualify them from proceedings. Where it has not been possible to identify such issues in advance, the individual must raise the issue with the MHRA secretariat or the chairman as early as possible before the meeting takes place, and in any event before discussion of

the relevant agenda item. The chairman of the committee is responsible for taking the decision on how declared interests should be handled.

7. PARTICIPATION IN DISCUSSIONS WHEN AN INTEREST HAS BEEN DECLARED

- 7.1 “Taking part in discussions” means speaking at meetings or voting. Where an individual is not to take part in a discussion, he or she should leave the room before the discussion commences, and return only when that agenda item is complete.
- 7.2 The following paragraphs describe, for each category of interests declared, the actions to be taken.

Personal Interests

- 7.3 A member must declare a *personal specific interest* if an individual has worked on the product under consideration and is receiving or has received payment for that work. As a general rule, the individual will normally not be allowed to take part in discussions as they relate to that product, except where the Chairman exercises his discretion (which will be rarely exercised) to answer questions from other members. A significant involvement in the development of a product will usually debar an individual from ever participating in discussion on that product. A less significant involvement, or less specific work with or on a product, may not permanently debar an individual, but such decisions will need to be taken on a case by case basis, taking account of the nature of the involvement, its specificity and when the work was undertaken.
- 7.4 If an individual has declared a *personal non-specific interest* the individual must take no part in discussions on that agenda item, except at the Chairman’s discretion to answer questions from other members. If the personal non-specific interest relates to shares that have been disposed of, the individual will generally be permitted to take part in discussions once three months have elapsed from the date of the disposal of them. If the personal non-specific interest relates to other matters, such as a payment received from a pharmaceutical company, the individual will generally be permitted to take part in discussions once 12 months has elapsed from the date of receipt of payment. However, in some cases it will not be appropriate for the individual to take part even though 12 months have elapsed – for example, where he has an ongoing consultancy or other financial relationship with the pharmaceutical company.
- 7.5 If the individual has declared a personal interest in relation to a member of his or her immediate family, he or she should similarly take no part in discussions except at the Chairman’s discretion to answer questions from other members. Such interests may range from a family member’s major role in the development of a product under consideration to a family member’s shareholdings.

Non-Personal Interests

- 7.6 A member must declare a *non-personal specific interest* if the department for which the individual is responsible is currently receiving payment in respect of work done on the product. The individual will generally not be able to take part in proceedings where a department for which he has responsibility has carried out specific work on the product under discussion.
- 7.7 A member must declare a *non-personal, non-specific interest* if their department is currently receiving payment which does not relate to the product under discussion. Such an interest will not normally debar an individual from taking part in discussions, unless exceptional circumstances arise in which it is not appropriate for them to do so.
- 7.8 If an individual declares non-personal interests of an immediate family member, this will not generally prevent him or her from taking part in discussions.

Other Interests

- 7.9 If an individual has declared an interest which does not fall within one of the categories described, but which he or she considers could be perceived as affecting his or her impartiality, whether that individual will be permitted to take part in discussions will depend upon the circumstances. In some cases, it will be sufficient for the individual to declare the interest, so that others taking part in the discussion are aware of his or her interests and can view his or her contribution in that light. In other circumstances it may not be appropriate for an individual to take any part in discussions, except at the chairman's discretion to answer questions from other members. The chairman and/or the MHRA Secretariat will advise on these matters. The chairman of the committee is responsible for taking the decision on how declared interests should be handled.

Rival Products

- 7.10 It is important to remember that not only the company whose product is being considered will be affected by the advice that is given by advisory bodies – companies who make competitor products may also be affected.
- 7.11 If a product is being discussed and an individual is aware that he or she has an interest in a company which markets a rival or competitor product, the business of which will directly benefit or suffer as a result of the advice that is given, the individual must declare that interest at the meeting. An example might be a change to the publication as a result of information provided by another company, or a new monograph that would apply to a number of a company's products. Interests in a competitor company should be declared as personal or non-personal and specific or non-specific, in the usual way. Whether the individual will be permitted to take part in discussions will depend upon the circumstances and the extent to which the business of the competitor is likely to be affected. In relation to personal interests in a competitor, the general guideline is that unless the potential effect of the decision on which the

committee is advising is so small as to be incapable of influencing the member's advice, the member should not take part in proceedings. The final decision on whether a member may take part is for the chairman.

7.12 There is no requirement to carry out specific research to identify issues such as these – individuals need only to declare interests of which they are aware.

8. RECORD OF INTERESTS

8.1 A record is kept in the MHRA of:

- names of chairmen and members who have declared interests on appointment, when an interest first arises or through the annual declaration, and the nature of the interest;
- names of chairmen and members who have declared interests at meetings of the CHM, Section 4 Committees, including the BPC, and EAGs, giving dates, names of relevant products and companies, details of the interest declared and whether the individual took part in the proceedings.

9. PUBLICATION

9.1 Interests declared to the MHRA by chairmen and members of all committees, including EAGs, will be published each year in the Annual Reports of the CHM and Section 4 Committees (normally published in July).

9.2 Interests of immediate family and other closely connected people declared by chairmen and members will be included in the Annual Reports. This information will provide only the name of the committee chairman or member, the source of the interest (e.g. the company name), will not provide any financial information nor numbers (e.g. for shares) nor identify the family member or other holding the interest by name.