



Healthcare
Improvement
Scotland

SMC
Advice on new
medicines

Code of practice on declarations of interest

For chair and members of the Scottish Medicines
Consortium Committee, New Drugs Committee and
SMC expert advisers

March 2018

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Published March 2018

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1. Introduction

Purpose of the code

This code of practice sets out the rules to be followed in relation to holding and declaring interests in the pharmaceutical industry. The code applies to the chair, members of SMC, members of NDC, clinical expert advisers and expert advisers representing the patient and carer voice. The advice of the SMC concerns matters that are connected with the pharmaceutical industry and it is therefore desirable that members should have a good understanding of the work of the 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.

Importance of impartiality

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 SMC/NDC or its advisory groups 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.

In order to provide reassurance 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 chairs, members of the various committees and expert advisers, and the actions taken to manage potential conflicts of interest are made public.

2. Scope

Committees and groups to which this code applies

The code of practice applies to the chairs and members of the following committees and groups:

- Scottish Medicines Consortium
- New Drugs Committee
- Clinical expert advisers consulted by SMC
- Expert advisers representing the patient and carer voice

3. Definitions

For the purposes of this code of practice, the following definitions apply:

Pharmaceutical industry

“Pharmaceutical industry” means:

- a. companies, partnerships or individuals who are involved with the manufacture, sale or supply of medicinal products, including herbal medicinal products and homoeopathic products
- b. trade associations representing companies involved with such products, and
- c. companies, partnerships or individuals who are directly concerned with research, development or marketing of a medicinal product that is being considered by SMC or its sub-committees and advisory groups.

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

It is recognised and acknowledged that those who are members of or advisors to SMC from an industry background could be deemed to have a personal non-specific interest in every item discussed. SMC welcomes the participation of industry members, and also recognises such general interests. For the avoidance of doubt it is noted that such general interest is deemed to have been declared by virtue of "industry" membership of SMC. It is still the responsibility of each individual to declare any personal or non-personal specific interests.

Immediate family

“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 that need to be declared

Summary of interests that need to be declared

It is the responsibility of each individual to identify and to declare all relevant interests. The following types of interest must be declared by chairs, members of all committees and expert advisers:

- 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, and
- 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 the section entitled “other relevant interests”.

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

A personal interest in the context of this code, involves the payment, in any form, to an individual, 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 SMC secretariat to each committee will advise if a chair, committee member or expert adviser 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 the section entitled “Attendance at conferences, scientific meetings and similar” (page 6);

Unit trusts and similar: Assets over which chairs, committee members and expert advisers 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 chairs, committee members and expert advisers 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.

Non-personal interests

A non-personal interest involves payment that benefits a department for which an individual is responsible (e.g. through position of clinical lead or head of department), but is not received by the member personally. As with personal interests, non-personal interests at a meeting may be declared as specific or non-specific. The main examples that follow should not be regarded as a definitive list, and advice should be sought through the secretariat if a chair, committee member or expert adviser 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.

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

Other relevant interests

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 or advises, 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 the 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 should 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 SMC 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 participates in, or is connected with, a voluntary organisation, Patient Group or pressure group that would have an interest in the outcome of the advice being given
- An individual has a family member who suffers from an illness who would benefit from treatment if a product under discussion were to be authorised
- 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 member or expert adviser 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 member or expert adviser is giving advice in relation to a product and a close family member or friend has had a major development responsibility for that product, and
- Interests in a company manufacturing the delivery system (e.g. syringes or other

medical equipment) for a particular medicinal product.

Attendance at conferences, scientific meetings and similar

SMC recognise 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. SMC also recognise 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 individuals' impartiality in any way.

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.

Expenses or hospitality provided by a pharmaceutical company should be declared. Expenses or hospitality beyond that reasonably required for accommodation, meals and travel to attend meetings and conferences might reasonably be perceived as affecting an individual's impartiality and would constitute a personal interest.

Benefits of this nature paid to an immediate family member that also benefit the committee chair, committee member or expert adviser (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.

Participation on an advisory board in relation to a specific product might reasonably be perceived as affecting an individual's impartiality and would constitute a personal specific interest.

The situations described are not exhaustive and individuals should always seek advice from the SMC Secretariat if in doubt about whether or not they should attend, or whether, having attended, they need to declare attendance as an interest.

5. Position of expert advisers called to advise the committees on specific issues, e.g. independent review panel or Patient and Clinician Engagement meeting.

Clinicians or representatives from patient groups may be invited to advise a committee on particular issues, without being co-opted as members, for example an independent review panel or a Patient and Clinician Engagement meeting. Experts invited to attend such committees or groups may participate fully in all discussions and may vote as required. They are therefore required to make a full declaration of interests.

Clinicians advising SMC or its sub-committees should in general not hold personal interests in the issue under discussion. It is expected that experts invited to participate in Patient and Clinician Engagement meetings that relate to specific medicines may hold personal interests but these must be declared according to standard process. Details of interests declared by these advisors will be included in the output from the Patient and Clinician Engagement meetings considered at SMC.

Chairs and vice-chairs of SMC and NDC should refrain from commenting on submissions outwith the SMC process.

6. Declarations of interests

Chairs and members of SMC and its sub-committees are required to make a full declaration of interests on appointment and annually. Clinical expert advisers are required to make a declaration of interests each time they are consulted in relation to a specific medicine. If an individual is uncertain as to whether or not an interest should be declared, he or she must seek guidance from the SMC secretariat.

Annual declaration

The annual declaration must include all the financial (personal and non-personal) interests in the pharmaceutical industry of the chair and committee 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. Committee members and chairs are also required to include in the annual declaration details of any other matter that could reasonably be regarded as affecting their impartiality.

The declaration of certain interests will not be restricted to the last 12 months. For example, an individual's significant involvement in the development of a particular product will need to be

declared each year as well as at relevant meetings and may restrict that individual's participation in some discussions.

The chair and committee 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.

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 committee member, although we recognise that in very exceptional circumstances it may be possible for that individual to be identified.

The annual declaration made by all chairs and members of all SMC and its sub-committees will be retained by the secretariat.

Declarations at meetings

Chairs, committee members and expert advisers are required to declare relevant interests at meetings, whether or not those interests have previously been declared to SMC. The type of interest must be declared, that is, whether it is personal or non-personal, specific or non-specific or other.

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 SMC secretariat in advance of the meeting if possible. This will enable the secretariat to ensure that a member's involvement in proceedings is appropriate. Where it has not been possible to identify such issues in advance, the individual must raise the issue with the SMC secretariat or the chair as early as possible before the meeting takes place, and in any event before discussion of the relevant agenda item. The chair 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

"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 withdraw from the meeting table to a designated area

within the meeting room before the discussion commences and return to the meeting table only when that agenda item is complete.

The following paragraphs describe, for each category of interests declared, the actions to be taken.

Personal interests

A committee member or expert adviser must declare a *personal specific interest* if he or she 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 chair exercises their 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. In the case of less significant involvement, or less specific work with or on a product, the individual may be permitted to take part in discussions once a period of three years has elapsed, 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. A personal specific interest will not prohibit expert advisers from participating in a Patient and Clinician Engagement group.

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 chair's discretion to answer questions from other members¹. 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 have 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.

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 chair'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. Such an interest will not prohibit expert advisers from participating in a Patient and Clinician Engagement group.

Non-personal interests

A committee member or expert adviser 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 (except to answer questions) if he or she has personal knowledge of the product under discussion through his or her own work or through direct supervision of other people's work. Such an interest will not prohibit expert advisers participating in a Patient and Clinician Engagement group. Non-personal interests normally lapse after a period of 12 months.

A committee member or expert adviser must declare a *non-personal, non-specific interest* if their department is currently receiving payment that 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 that it is not appropriate for them to do so.

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

If an individual has declared an interest that 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 or not 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. It may not be appropriate for an individual to take any part in discussions, except at the chair's discretion to answer questions from other members. The chair and/or the SMC secretariat will advise on these matters. The chair of the committee is responsible for taking the decision on how declared interests should be handled.

¹ A chair with a personal non-specific interest should not chair the part of the meeting where the product is discussed.

Competitor products

It is important to remember that not only the company whose application is being considered will be affected by the advice that is given – companies who make competitor products may also be affected.

If a product is being discussed and an individual is aware that he or she has an interest in a company that 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 where an application for a new active substance is under consideration that will directly affect the market of another company for a similar product in which an individual has an interest. 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. The final decision on whether a member may take part is for the chair.

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

A record is kept by the SMC secretariat of:

- names of chairs and committee members who have declared interests on appointment or through the annual declaration, and the nature of the interest
- names of clinical expert advisers who have declared interests each time consulted in relation to a specific medicine, and the nature of the interest, and
- names of chairs and committee members who have declared interests at meetings of the SMC, NDC and Patient and Clinician Engagement groups, giving dates, names of relevant products and companies, details of the interest declared and whether the individual took part in the proceedings.

9. Publication of interests

Interests declared to the SMC by chairs and members of all committees are retained by the secretariat and made available on request.

Published March 2018

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