Medicines & Healthcare products Regulatory Agency

Code of Practice for the Commission on Human Medicines, the British Pharmacopoeia Commission, the Devices Expert Advisory Committee (and its successors), the United Kingdom Stem Cell Bank Steering Committee, and other expert advisory committees

Identifying, declaring and managing interests

Effective from: 8 September 2022

Next review date: 8 September 2025

1. Introduction

1.1 Operating as the Licensing Authority on behalf of the Secretary of State, the Medicines and Healthcare Products Regulatory Agency (MHRA) has a mission to protect and improve patient and public health through the effective regulation of medicines, medical devices and blood components for transfusion, underpinned by cutting-edge scientific knowledge and research.

1.2 Decisions relating to the safety, quality and efficacy of medicines, medical devices and blood components for transfusion are often taken in the face of significant uncertainties and can be complex in form, scope, and potential consequences. These difficult decisions involve making use of the best available scientific evidence to weigh the respective benefits and risks of medicines, medical devices and blood components for transfusion and making difficult judgements to provide the greatest benefit to the affected populations.

1.3 Consequently, decisions relating to the safety, quality and efficacy of medicines, medical devices and blood components for transfusion can benefit hugely from the involvement of experts; highly skilled professionals who have appropriate expertise and are well regarded in their respective fields.

1.4 MHRA decision making is supported by expert advice from several independent expert advisory committees. These include:

- Commission on Human Medicines (CHM)
- Herbal Medicines Advisory Committee (HMAC)
- Advisory Board for Registration of Homeopathic Products (ABRHP)
- British Pharmacopoeia Commission (BPC)
- The Devices Expert Advisory Committee (DEAC) and its successors
- United Kingdom Stem Cell Bank Steering Committee (UKSCBSC)
- The Review Panel

1.5 These Advisory Committees can also establish working groups to address specific problems.

The importance of a code of practice on conflicts of interest

1.6 In the public interest, MHRA needs the expert advice it receives, to take decisions on behalf of Ministers on matters relating to the safety, quality and efficacy of medicines, medical devices and blood components for transfusion to be impartial. In practice, trust in expert advice can easily be tainted by the presence of real or perceived conflicts of interest.

1.7 Many experts in the field of medicines and medical devices have, or have had, connections with the pharmaceutical, medical device and/or biotechnology industry and other commercial organisations whose business may be considered relevant to their expertise and role in the committee but may also have an impact on perceptions of their impartiality. For example, they may have shareholdings from previous industry employment or have been involved in conducting clinical trials.

1.8 To build and maintain confidence that the advice on which decisions about the regulation of medicines, medical devices and blood components for transfusion are based is impartial and to maintain confidence in the work of the committees, it is essential to have a robust policy to identify and effectively manage any potential conflicts in the interests of transparency and accountability.

2. Purpose and scope of the Code

Purpose of the Code

2.1 This Code of Practice (Code) sets out the rules and process to be followed for identifying and declaring personal and non-personal interests which are potentially relevant to the work of a committee and how those interests will be managed. It also contains guidance on holding and declaring any other relevant interests, including how interests that have been declared will be managed.

2.2 In line with established practice[1], the Code places the responsibility for identifying and declaring all interests on the individuals involved with the Advisory Committees and their supporting groups. Members are, however, able to seek guidance from the Secretariat or the Conflict of Interest Group (where conflicts of interest are novel or complex, see section 7) on what interests need to be declared and when, and how declared interests should be recorded.

2.3 For transparency and accountability all interests declared, and the actions taken to manage potential conflicts of interest, are publicly available on Gov.uk as detailed at paragraph 6.10 below.

Scope of the Code

2.4 The Code applies to chairs, members, co-opted members and invited and patient experts participating in or providing advice to the following Commissions and Expert Advisory Committees (collectively known as the Advisory Committees), and their respective expert advisory groups (EAGs) /expert working groups (EWGs) and other supporting groups:

- Commission on Human Medicines (CHM)
    - CHM Expert Advisory Groups (EAGs)
    - CHM Expert Working Groups (EWGs)
- Herbal Medicines Advisory Committee (HMAC)
- Advisory Board for Registration of Homeopathic Products (ABRHP)
- British Pharmacopoeia Commission (BPC)
    - BPC Expert Advisory Groups (EAGs)
    - BPC Expert Panels (EPs)
    - BPC Working Parties (WPs)
- The Devices Expert Advisory Committee (DEAC) and its successors
    - DEAC Expert Advisory Groups (EAGs)
- United Kingdom Stem Cell Bank Steering Committee (UKSCBSC)
- The Review Panel.

2.5 The principles in this Code also apply to observers and invited experts who are asked to contribute written advice and do not attend committee meetings.

General definitions

2.6 The following definitions apply:

Code	• This document, including subsequent revisions or changes, if any.
Advisory Committee	• CHM, HMAC, ABRHP, BPC, DEAC, UKSCBSC and the Review Panel.

[1] National Audit Office: Conflicts of Interest, 2015

	• The term Advisory Committee does not include their supporting groups such as EAGs/EWGs unless the context indicates otherwise.
Committee	• A catch all term for all Advisory Committees and their supporting groups within the scope of this Code.
Conflict of interest	• A conflict arises when a reasonable person would consider that an individual's ability to apply judgement or participate in the work of a committee is, or could be perceived to be, impaired or influenced by one or more of their interests. • A conflict of interest is most likely to arise when the interest is specific – this means it relates to matters under consideration at a meeting and/or informs a potential recommendation/decision.
Relevant industry	• An industry, or industries, whose business may be directly affected by the advice of the committee, such as the pharmaceutical industry for CHM, BPC, HMAC and ABRHP, the medical device industry for DEAC, the biotechnology industry for UKSCBSC.
Pharmaceutical industry	• "Pharmaceutical industry" means: • Companies, partnerships or individuals who are involved with the manufacture, sale or supply of medicinal products, including herbal medicinal products and homeopathic 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 homeopathic products which are being considered by any of the groups or bodies covered by this Code. • References to "the pharmaceutical industry" include cases involving a single company.
Conflict of interest	• "Biotechnology industry" means: • Companies, partnerships or individuals who are involved in the manufacture, sale or supply of biotechnological products; • Trade associations representing companies involved with such products; • Companies, partnerships or individuals who are directly concerned with research, development or marketing of a biotechnical product which is being considered by any of the groups or bodies covered by this Code.

	• References to "the biotechnology industry" include cases involving a single company.
Medical device industry	• "Medical device industry" means: • Companies, partnerships or individuals who are involved in the manufacturing, supply, selling, offering to supply, storage, importing, or exporting of medical devices, active substances, excipients, parts, materials and accessories; • Trade associations representing companies involved with such products; • Companies, partnerships or individuals who are directly concerned with research, development or marketing of a medical product which is being considered by any of the groups or bodies covered by this Code. • References to "the medical device industry" include cases involving a single company.
Medical device	• A medical device is defined as any instrument, apparatus, appliance, software, 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.
Accessory	• For the purposes of this Code, any reference to "medical product" or "medical device" is intended to include articles which whilst not being a medical device, are designated specifically by their manufacturer to be used together with a medical device to enable it to be used in accordance with the use intended by the manufacturer.
Parts and materials	• For the purposes of this Code, any reference to "medical product" or "medical device" is intended to include the terms "parts" and "materials", which shall mean all parts and materials constructed and designated to be used

	for medical devices and that are essential for the integrity thereof.
Immediate family	• Partner, spouse, and family members living in the same household. Family members include dependent children, any adult children or other relative (such as a parent) living in the same household.
Members and Commissioners	• Members or Commissioners of CHM and BPC are appointed under provisions in the Human Medicines Regulations 2012, as amended, with full rights to participate in discussions and to vote, subject to the limits on participation set out in this Code or subject to the discretion of the Chair. • Members of other committees are generally appointed by the MHRA, on behalf of the Secretary of State, with full rights to participate in discussions and to vote, subject to the limits on participation set out in this Code or subject to the discretion of the Chair.
Lay Members	• Advisory Committees, and their supporting groups, in addition to any members with relevant specialist expertise in the topics to be discussed may also have **one or more lay members.** • A "lay member" describes individuals who sit on our Advisory Committees or groups to provide a non-specialist contribution to discussions about medicines, medical devices and research. • Lay members are typically members of the community who have an interest in the committees' discussion area, for example: members of the public, patients, carers or those from related areas such as a support group within the community. • This contribution gives the committee a different viewpoint from the experts who sit on the committee, thus aiding a fuller understanding of the area being discussed. • Lay members have full rights to participate in the discussion and to vote. • Like other members of advisory committees, lay members are subject to the rules governing the identification and management of conflicts of interest, including those set out for Members in this Code. And, like other members of Advisory Committees lay members, except lay members of the British Pharmacopoeia Commission, are

	prohibited from holding interests in an industry that is relevant to their committee.
Co-opted Members known as 'Members for the Day'	• CHM and BPC co-opted members, and co-opted members of their EAGs, are appointed under Regulations 13 and 14 of the Human Medicines Regulations 2012. They are full members of the committee for that day and may participate fully in all discussions and may vote. They will make full declarations of interest before, or at, a meeting in the same way as Members and Commissioners. • For other committees, co-opted members are appointed by the Chair. They are full members of the committee for that day and may participate fully in all discussions and may vote. They will make full declarations of interest before, or at, a meeting in the same way as Members and Commissioners.
Invited expert	• Invited experts are not members. They may be specialists invited to advise a committee on a specific issue/issues. Invited experts may provide written comments and/or may be invited to attend a meeting. • The role of an invited expert is limited to providing advice and answering questions and they do not have full rights to participate in the discussion or to vote. • They will be asked to declare any interests in the matter under consideration. • Having interests will not prevent an invited expert from providing advice or answering questions as their participation is limited. This enables the committee to have access to the best advice whilst preserving impartiality of the decisions/recommendations.
Patient Experts	• Patients or their representatives may be invited to meetings for specific topics or items and or to forward comments contributing their lived experience as users of medicines and medical devices. • They will be asked to declare any interests in the matter under consideration but having an interest in the topic or medicine will not prevent the patient experts from providing advice or answering questions as they do not have full rights to participate in the discussion or to vote. • The perspectives that patients provide are very valuable and complement the scientific information considered in reaching advice on regulatory options.

Observers	• Observers: typically include staff from the Department for Health and Social Care or other Health Service organisation such as NHS England, NICE or the Devolved Administrations. Observers will sign a confidentiality undertaking and be asked to declare any interests in the matters under consideration. They may be asked to answer specific questions, for example, on matters of fact but will not otherwise participate in the meetings.
Competitor product	• A medicinal and/or medical product that targets a similar patient population with the same clinical purpose (i.e. to treat, prevent or diagnose a condition), and constituting potential commercial competition.

Note: Patient and the public are able to participate in meetings and discussions of the advisory committees and working groups either as 'lay members' (that is, standing members of committees) or as 'patient experts' (that is, giving evidence to the committee on a specific topic).

3. Defining and categorising interests

3.1 For the purposes of the Code of Practice, interests are divided into personal and non-personal interests and 'other relevant' interests. The types of interest that must be declared are:

- an individual's own financial interests in any relevant industry for that committee; these may be:
  - **personal** or **non-personal**; and
  - **specific** or **non-specific** to the product under discussion.

- financial interests of immediate family in the relevant industry.

- any other matter that could affect impartiality, or that could reasonably be perceived as affecting impartiality.

3.2 Examples of each type of interest are set out below.

Note: It is the responsibility of each individual to identify and to declare all relevant interests. If there is any doubt about whether an interest should be declared, individuals should seek guidance from the Secretariat, the Chair or the **Conflict of Interest Group** at the earliest opportunity. The purpose of the Conflict of Interest Group is to provide advice to the Secretariat, MHRA senior managers and the Chairs of the committees where there is doubt regarding the classification and/or management of a conflict of interest. If individuals have interests not specified in the Code, but which they believe could be perceived as influencing their advice, they should in all cases declare them.

Personal interests

3.3 These are financial interests that involve a payment, in any form, to an individual personally, from any relevant industry whose business may be directly affected by the advice of the committee. Interests declared prior to, or at, a meeting will be either:

- **specific**: payment relates to a product under consideration.
- **non-specific**: not related to the product under discussion.

3.4 The following are examples of personal interests:

- **Consultancies**: any consultancy, directorship, position in, or work for a relevant industry which attracts regular or occasional payments in cash or in kind.

- **Fee-paid work**: any work commissioned by a relevant industry for which the individual is paid in cash or in kind.

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

- **Expenses/hospitality/gifts** provided by a relevant industry: special rules apply to attendance at conferences or similar events. These are covered in section 4, below.

- **Unit trusts and similar**: Funds held in a portfolio in which chairs 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. Assets over which chairs 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.

- **Note: Pension entitlements** such as accrued pension rights from earlier employment do not need to be declared.

Personal interests - application of rules

Chairs

3.5 **The chairs of Advisory Committees are prohibited from holding any current personal interests in a relevant industry**. The chairs of Advisory Committees are in a special position in relation to the work of their committee and have greater scope to influence the outcome of discussions. The chairs help the Advisory Committees to work collaboratively, ensure a balanced contribution from all committee members and take decisions about the potential conflicts of interest of their committee members. The chairs can best do this when they are free from any personal interests themselves.

Members

3.6 There are some differences in the role and remit of the different Advisory Committees, and this has an impact on the personal interests members are able to hold. Such a distinction can be made between the CHM, ABRHP, HMAC, DEAC, UKSCBSC, and The Review Panel on the one hand and the BPC on the other.

CHM

3.7 The CHM performs a number of statutory functions supporting Ministers and MHRA (as the Licensing Authority) in relation to the safety, quality and efficacy of human medicinal products in the UK. Taking into account that members of CHM are exposed to sensitive and confidential discussions on licencing, marketing authorisation and safe use of medicines, we consider that it would be imprudent for a person who has personal interests in the pharmaceutical industry to join those discussions. Even though a member is expected to remain entirely impartial at all times, a perception that an interest might have the potential to influence the member can undermine the advice provided to Ministers and the MHRA, and subsequent decisions on the basis of that advice. **Therefore, the Code prohibits members of the CHM from holding personal interests in the pharmaceutical industry.**

ABRHP and HMAC

3.8 The ABRHP and HMAC provide MHRA advice on the safety, quality and efficacy in relation to human use of homeopathic and herbal products, respectively. As such, we consider that it would be imprudent for a person who has personal interests in the pharmaceutical industry (which by the table in paragraph 2.6 is defined to include the homeopathic and/or herbal medicine industry) to be a member of these bodies. Even though a member is expected to remain entirely impartial at all times, a perception that an interest might have the potential to influence the member can undermine the advice provided to MHRA, and subsequent decisions on the basis of that advice. **Therefore, the Code prohibits members of ABRHP and HMAC from holding personal interests in the pharmaceutical industry**.

DEAC

3.9 DEAC is responsible for providing MHRA with independent, external, expert clinical and scientific input and advice on a wide range of aspects relating to the introduction and safe use of medical devices. As such, we consider that it would be imprudent for a person who has personal interests in the medical devices industry to be a member of DEAC. Even though a member is expected to remain entirely impartial at all times, a perception that an interest might have the potential to influence the member can undermine the advice provided to Ministers and the MHRA, and subsequent decisions on the basis of that advice. **Therefore, the Code prohibits members of DEAC from holding personal interests in the medical device industry.**

UKSCBSC

3.10 The role of the UKSCBSC is to support stem cell research and to ensure that this is conducted within an ethical framework that is transparent to the public. Taking into account that members of UKSCBSC are engaged in drawing up a code of practice for the operation of the Stem Cell Bank and for the use of stem cell lines, we consider that it would be imprudent for a person who has personal interests in the biotechnology industry to be a member of UKSCBSC. Even though a member is expected to remain entirely impartial at all times, a perception that an interest might have the potential to influence the member can undermine the advice provided to Ministers and the MHRA and subsequent decisions on the basis of that advice. **Therefore, the Code prohibits members of the UKSCBSC from holding personal interests in the biotechnology industry.**

The Review Panel

3.11 The Review Panel performs statutory and non-statutory reviews of the provisional determinations made by the MHRA concerning the classification of a product as a medicine, and

decisions or proposals made by the MHRA relating to the grant, renewal, revocation, suspension, refusal or variation of manufacturer's or wholesale dealing licences. As such, we consider that it would be imprudent for a person who has personal interests in the pharmaceutical industry to be a member of The Review Panel. Even though a member is expected to remain entirely impartial at all times, a perception that an interest might have the potential to influence the member can undermine the advice provided to Ministers and the MHRA and subsequent decisions on the basis of that advice. **Therefore, the Code prohibits members of the Review Panel from holding personal interests in the pharmaceutical industry.**

BPC

3.12 The BPC is responsible for providing global independent standards which underpin the quality testing of medicines, and therefore their safety and efficacy. BPC standards are an important component in the overall control of medicines, in that they provide the means for an independent judgement as to the quality of a drug substance or medicinal product which complements and assists the licensing and inspection processes of the MHRA. However, members of the BPC do not themselves take part in the sensitive and confidential discussions on licencing, marketing authorisation or other regulatory action relating to medicines or devices. For this reason, **the Code permits members of the BPC to hold personal interests, but they must comply with the Code in respect of declaring personal interests**. The Chair of the BPC may decide on the need for any exclusion of members from meetings or discussions in light of those declarations, as set out in section 7.

Expert Advisory Groups and Expert Working Groups

3.13 The rule prohibiting the holding of personal interests in a relevant industry does not apply to chairs and members of supporting groups, such as EAGs or EWGs, unless they are also members of an Advisory Committee to which those rules apply, such as CHM, ABRHP, HMAC or DEAC. In keeping with the Code however, these personal interests must be declared and may still affect participation in discussions (see section 7 below).

Non-personal interests

3.14 Non-personal interests are financial interests which involve payment that benefits a third party with whom the member is closely associated. For example, a grant from a company towards the running of a unit or department for which a member is responsible but is not received by the member personally would be a non-personal interest. Members are not under an obligation to seek out knowledge of work done for, or on behalf of, industry and other relevant bodies by departments or units for which they are responsible but must declare all of those interests which they could reasonably be expected to be aware of.

> **Note**: Where regular audits of departments or units are undertaken, it would be reasonable to expect members to make themselves aware of the projects and activities being undertaken by their staff to satisfy themselves that these interests do not have the potential to turn into conflicts.

3.15 Non-personal interests declared prior to/at a meeting will be either **specific** or **non-specific to the item being considered.** The following are examples:

- **Fellowships**: the holding of a fellowship endowed by the pharmaceutical, medical device and/or biotechnology industry or any other relevant industry

- **Support by the pharmaceutical, medical device and/or biotechnology industry** or any other relevant industry: any payment, other support, or sponsorship by the pharmaceutical and/or medical device or other relevant industry that does not convey any pecuniary or material benefit to the individual personally but that benefits his/her position or department or an immediate family member

- **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.

Further examples of these types of interests and the appropriate management of them are given in Annex 1.

Other relevant interests

3.16 It is not only financial interests in the pharmaceutical, medical device, biotechnology or other relevant industry that give rise to potential conflicts. A wide range of other matters may also be relevant, depending on the circumstances and matters under consideration by the committee on which the individual serves.

3.17 In considering "other" interests that need to be declared, this should be done so in view of meeting the standards reasonably expected by the public. The guiding principle is to declare if the matter might reasonably be **perceived** as having the potential to affect a member's impartiality. Some examples are set out below.

- **An individual or their department has done research work** relating to a particular product, or class of products. Although the research has not been funded by a pharmaceutical, medical device and/or biotechnology company, the research has taken a particular view, for example in relation to the safety, quality or efficacy of the products.

- **An individual is actively involved in an ongoing or scheduled trial or research** aimed at determining the effectiveness of the matter under consideration.

- **An individual has authored or co-authored a paper submitted in connection with the matter under consideration.**

- **An individual has made public statements/published a clear opinion about the matter under consideration** (either favourable or unfavourable) and/or about a company, or product, or class of products or about a competitor's product or class of product.

- **The committee is considering whether a product should be reclassified**. For example, from prescription only to a pharmacy medicine, and the individual has a particular interest in the reclassification being made, for example, because they are a retail pharmacist and they will benefit financially.

- **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 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 expert** , for example, an adult child no longer living in the same household, or non-family member whose work or other interests are closely associated with a relevant 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.

- **Interests in a company manufacturing the delivery system** (for example, syringes or other medical equipment) for a medicinal product.

Further examples of these types of interests and the appropriate management of them are given in Annex 1.

4. Conflicts arising from attendance at conferences, scientific meetings and similar

Chairs

4.1 As set out in section 3 above, chairs of Advisory Committees are prohibited from holding personal interests in a relevant industry. However, in some cases it will be possible for them to attend events sponsored by a relevant industry (and accept the payment of their expenses). For example:

- Where a learned society holds an international conference that is sponsored by a number of different pharmaceutical companies, it will generally be acceptable for the individual to accept an invitation and receive payment of expenses, although it should be included in the individual's declaration of interests in the normal way.
- If payment of expenses is paid by the individual's employer rather than the individual directly then a conflict of interest may not arise.
- Benefits of this nature paid to an immediate family member that also benefit the individual (for example, a company pays flight costs so that the individual can attend a conference with a family member) must be declared as the individual's own interest. Educational conferences and similar events attended by immediate family members do not need to be declared.

4.2 The examples described above are not exhaustive and if they are unsure, individuals should always seek advice from the Secretariat about whether they should attend, or whether, having attended, they need to declare attendance as an interest. Any interest should be declared before and at the first meeting of the Advisory Committee following attendance at an event.

Members

4.3 As set out in section 3 above, members of Advisory Committees other than the BPC are prohibited from holding personal interests in a relevant industry. However, in some cases it will be permissible for them to attend events and conferences sponsored by a relevant industry (and accept the payment of expenses). This will be in line with expectations of the chairs' interests set out in paragraph 4.1.

4.4 As set out in paragraph 3.11 above, the rules against holding personal interests in a relevant industry do not apply to members of the BPC. Therefore, members may attend meetings sponsored by the pharmaceutical industry and accept funding of expenses, but these must be declared and may affect participation in discussions.

Members of Expert Advisory and Working Groups

4.5 The rules for holding personal interests in a relevant industry do not apply to chairs and members of EAGs or EWGs, unless they are also members of an Advisory Committee to which those rules apply, such as CHM, ABRHP, HMAC or DEAC. Therefore, members may attend meetings sponsored by the pharmaceutical, medical device, biotechnology or other relevant industry and accept funding of expenses, but these must be declared and may affect participation in discussions.

4.6 When a chair or member attends an educational conference or similar, it must be declared if they attend or participate in, for example, "satellite" meetings sponsored and arranged by specific companies or focusing on specific products where involvement in discussions might reasonably be perceived as having the potential to affect their impartiality.

4.7 Attendance at conferences, scientific meetings, and other events relevant to this Code must be declared before and at the first meeting of the committee after the event has taken place. This declaration may affect participation in discussions.

5. Co-opted Members, Invited Experts and Patient Experts

Co-opted members known as 'Members for the Day'

5.1 Co-opted members, known as Members for the Day, are invited to be part of a committee to provide cover for absent experts or bring specific knowledge. They are treated as full members of the relevant committee and may participate in all discussions and vote. They must submit a declaration of interests and are subject to the same rules regarding the holding of interests in the issue under discussion as the full members of the relevant committee. The co-opted member ceases to be a member at the end of the meeting.

Invited Experts

5.2 Invited experts are invited to advise on a specific issue or issues. They may attend a meeting and/or provide written comments in advance. The role of an invited expert is limited to providing advice and/or answering questions and, where they attend meetings, they do not have full rights to participate in the discussion or to vote.

5.3 Invited experts are required to declare any interests in the matter on which they have been invited to provide advice. Having interests in the item under discussion will not prevent an invited expert from providing advice and/or answering questions as their participation is limited. This enables the committee to have access to the best advice whilst preserving impartiality of members who make decisions on the advice provided.

Patient Experts

5.4 Patient experts are invited to advise on a specific issue or issues. They may attend a meeting and/or provide written comments in advance. The role of a patient expert is limited to providing advice and/or answering questions and, where they attend meetings, they do not have full rights to participate in the discussion or to vote.

5.5 Patient experts are required to declare any interests in the matter on which they have been invited to provide advice but having an interest will not preclude them from providing advice and/or answering questions as their participation is limited. This enables the committee to benefit from their expertise and experience which is very valuable in reaching decisions on the advice provided.

Note: Declarations of members for the day, invited experts and patient experts are published in the same way as permanent members of Advisory Committees and EWGs/EAGs, on Gov.uk and in the committee minutes for transparency reasons.

6. Declaring interests

6.1 **Chairs and members** are required to make a full declaration of interests when applying for an appointment and to update that declaration annually. They must also inform the Secretariat and provide an updated declaration promptly as and when there are any changes or updates to their interests. This includes reporting attendance at events described in section 4 above. Chairs and members are asked to declare any relevant interests before the meeting to the Secretariat and at the beginning of meetings (orally). Decisions will be taken on whether the interest restricts or prevents their participation. It is the responsibility of individuals advising/participating in meetings to identify and declare interests at the earliest opportunity and to ensure that their declaration of interests remains up to date.

6.2 **Invited experts, patient experts** and **co-opted members** (Members for the Day) make a declaration on the item(s) under consideration when invited to contribute advice and/or participate at a meeting.

6.3 **Observers** make a declaration on the items under consideration when invited to attend a meeting.

6.4 The individual's 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 that was received by a department for which they are responsible, only the company (or equivalent) name is required, not the value of the grant.

6.5 When the individual's declaration includes interests that relate to another person, names are not required, and the interests declared do not 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, although we recognise that in very exceptional circumstances it may be possible for that individual to be identified.

During the appointment process

6.6 Candidates submit a declaration of interests when applying for a role. The nature of any potential conflict will determine if it will prevent an individual from being appointed. If an interest does not automatically prevent the individual from appointment, the appointment panel will discuss with the individual how the conflict could be managed prior to reaching a final decision on their appointment.

6.7 Where there is doubt regarding the handling of a conflict of interest, the appointment panel may refer a potential conflict to the 'Conflict of Interest Group'. A candidate may be offered the option to dispose of the interest if appropriate.

6.8 Chairs and members of Advisory Committees (except members of BPC who are permitted to hold personal interests) have three months from the date of appointment to dispose of any current personal interests in a relevant industry which they are not permitted to hold in accordance with the rules on personal interests in section 3.5 to 3.12, above. During this period, they are required to declare any relevant current personal interests at meetings and to exclude themselves from discussion on the relevant product(s) and abstain from any vote.

Annual and continuous declarations of interest

6.9 The annual declaration of interests must include:

- all the financial (personal and non-personal) interests in any relevant industry such as (depending on the work of the committee) the pharmaceutical, medical device and/or biotechnology industry of the chairs and members currently held or held in the last 12 months
- financial interests (that they know of) in any relevant industry that are held by their immediate family
- any other matter which could reasonably be regarded as affecting their impartiality as set out in the section on 'Other relevant interests'.

Note. In some circumstances it may be appropriate to continue to declare the interest for longer than the past 12 months if, for example, the member had a significant involvement in the development of a medicinal product. These potential conflicts are considered on the basis of individual circumstances and advice should be sought from the Secretariat as soon as possible. Participation in meetings and discussions may be restricted as a result.

6.10 The annual declaration of interests made by all chairs and members are published on Gov.uk [Link]. Interests declared by invited experts and observers will be recorded in the minutes for the items/meetings they contributed to and those minutes are also published on Gov.UK. Declaration of interests made by the Chair and members of BPC are also published on Pharmacopoeia.com [Link].

Declarations before and at meetings

6.11 Chairs and members are required to declare relevant interests prior to and 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 relevant interest.

6.12 If an individual considers that an interest may affect their impartiality in relation to any agenda item, or could reasonably be perceived as affecting their impartiality, and that interest has not already been declared in relation to that meeting, they must inform the Secretariat in advance of the meeting if at all possible. This will enable the Secretariat to ensure that the papers relating to that item are not sent to the individual. Where it has not been possible to identify such issues in advance, the individual must raise the issue with the Secretariat and 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 ultimately responsible for taking the decision on how declared interests should be handled.

Note: BPC members are not prohibited from holding interests in the pharmaceutical industry. Although they are required to notify the Secretariat and/or the Chair of an interest they have in an agenda item before the meeting, they are not barred from receiving papers relating to that agenda item.

7. Managing participation at meetings when an interest has been declared

7.1 Depending on the nature of the interest declared members/experts will have their participation in the meeting restricted and may be excluded from the meeting during discussion of the item. Specific interests in the matter under discussion are most likely to give rise to a perception of a conflict. Specific interests include matters relating to the product or issue being considered and competitor products, topic area and research/clinical trials.

7.2 The guidance below outlines circumstances where it may be possible for the individual to remain in the meeting for questions only and leave before the discussion and vote. Where an individual is not taking part in the discussion they should leave the meeting before the discussion commences and return only when that agenda item is complete.

7.3 Where it is necessary to co-opt members every effort will be made to select experts who do not have a conflict of interest that would require a member to withdraw from any part of the discussion and or vote. For invited and patient experts, there is discretion to invite an individual with a conflict when the work of the committee would be impaired without their advice, such as in an area where the pool of experts is small for example. In those circumstances, the invited expert may present information and/or answer questions from the Chair and members but will leave before the discussion and vote. However, the Chair is responsible for balancing the need for input from the expert against the public's expectations of independent, unbiased advice.

7.4 Where there is doubt regarding the interpretation or management of a conflict of interest prior to the meeting it may be referred to the Secretariat.

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

Personal Interests (Chair and members including co-opted members)

Personal Specific interests

7.5 A personal specific interest will have been declared if an individual has worked on the product under consideration and is receiving or has received payment for that work. Generally, the individual will 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.

7.6 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 and balanced with the expectation of independent, impartial and objective advice. Advice may be taken from the Conflict of Interest Group on specific complex or novel situations.

Note: The Chair and members of Advisory Committees (except members of BPC) are not permitted to hold personal interests.

Personal Non-specific interest

7.7 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 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.

7.8 If the personal non-specific interest relates to other matters, such as a payment received from a relevant industry the individual will generally be permitted to take part in discussions once 12 months has elapsed from the date of receipt of payment. In some cases, it will not be appropriate for the individual to take part even though 12 months have elapsed – for example, where the individual has an ongoing consultancy or other financial relationship with a relevant industry.

Personal interests relating to immediate family

7.9 If the individual has declared a personal interest in relation to a member of their immediate family, they 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.

Non-Personal Interests (Chair and members including co-opted members)

Non-personal specific interest

7.10 If a non-personal specific interest is declared such as the department for which the individual is responsible is currently receiving payment for specific work on the product under discussion, the individual will generally not be able to take part in the discussion or vote but may, at the Chair's discretion, answer questions before leaving the meeting for that item.

Non-personal non-specific interests

7.11 A non-personal non-specific interest will not normally affect the individual's participation in the meeting but should be declared in the usual way.

Non-personal interests relating to immediate family

7.12 If an individual declares non-personal interests of an immediate family member, this will not generally prevent them from taking part in discussions.

Further examples of these types of interests and the appropriate management of them are given in Annex 1.

Other relevant interests

7.13 If an individual has declared an interest which does not fall within the personal or non-personal categories described above, but which they consider could be perceived as affecting their impartiality, permission to take part in discussions will depend upon the circumstances. An example might be where a member owns retail pharmacies and the discussion addresses the classification of a product from prescription to non-prescription status. 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 the interest and can view their contribution in that light.

7.14 In other circumstances 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 Secretariat will advise.

Note: The Chair of the committee is ultimately responsible for taking the decision on how declared interests should be handled.

Further examples of these types of interests and the appropriate management of them are given in Annex 2.

Interests in competitor products

7.15 It is not only the company whose application or safe use is being considered that will be affected by the advice that is given by committees, companies who make competitor products may also be affected.

7.16 If a product is being considered and the individual has an interest in a company which markets a 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 generic product is being considered and the individual holds an interest in the current brand-leader, or where 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. 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.

Note: An example relevant to the BPC might be a change to the British Pharmacopoeia 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.

7.17 It is the responsibility of members to declare all interest of which they are aware in a timely and appropriate manner.

Consideration of Classes of Products

7.18 If a committee is considering issues relating to a class of products, the issue of interests remains relevant. Individuals must still declare interests in the usual way. Whether they will be permitted to take part in discussions will depend upon the circumstances, including the class of products being considered and the nature of the advice being given.

Novel or complex conflicts of interest

7.19 Advice and decisions on complex conflicts of interest, should be submitted to the MHRA Conflict of Interest Group.

8. Recording interests and publication of information

8.1 For transparency and accountability all interests declared, and the actions taken to manage potential conflicts of interest, for example, if a member has withdrawn from the discussion and decision of an agenda item, are publicly available on Gov.uk as detailed at paragraph 8.4 below.

1. Declarations of Interest – Public Register of Interests

8.2 The Declarations of Interest for chairs and members received during the appointment process and the annual declarations of interest submitted by members together with any updates during the year as interests arise are published on Gov.UK. Interests of immediate family and other closely connected people (which should be anonymised as set out at paragraph 6.5, above) declared by chairs and members are included in the Public Register. This information includes:

- The name of the committee chair or member
- Source of the interest (for example, the company name), excluding any financial information, numbers (for example, for shares) and classification as family member or other holding the interest.

2. Minutes of meetings

8.3 The minutes of all meetings of the committees are recorded showing:

- names of chairs, members, invited and patient experts and observers who have declared interests at meetings
- dates, names of relevant products and companies (or a general description of the relevant product where representations are made to the committee in confidence), details of the interest declared and whether the individual took part in the proceedings and/or when they left the meeting and returned.

8.4 Minutes are made available on Gov.UK

9. Handling breaches

9.1 If an interest is not correctly declared or identified, there is a conduct process in place to handle these circumstances. Full details of the conduct panel and process are set out at Annex 3.

9.2 Anyone who is aware of breaches of this Code of Practice should report their concerns to the Secretariat, the committee Chair or a senior member of MHRA.

10. Review

10.1 This Code will be reviewed every three years unless an earlier review is needed.

Annex 1

Examples of handling non-personal interests

In the following examples the pharmaceutical industry is taken to be a relevant industry to the committee the individual is involved with.

Example 1:
A member is a Principal Investigator to a Clinical Trial for a similar product (and potential competitor) to the one under consideration. The trial received grant funding from a pharmaceutical company. The company is not the same one as involved with the application being considered.

The interest should be declared, and the member may be permitted to answer questions but will be excluded from both the discussion and decision.

Example 2:
A member's university received a grant from a government led public-private partnership funding health research. The partnership collaborated with a range of stakeholders including the pharmaceutical industry.

The interest should be declared, and the member may participate without restrictions.

Example 3:
A member's university received grant funding from the pharmaceutical company that made the application under consideration. The member does not receive any funding directly from the pharmaceutical company, but their salary is partly covered by the general grant funding paid to the university. The company has no influence over the member's research work.

The interest should be declared, and the member will not be able to take part in the discussion or vote on the application made by the pharmaceutical company but may, at the Chair's discretion, answer questions before leaving the meeting for that item.

Example 4:
The (BPC) member is employed by a pharmaceutical company that manufactures similar/competitor products to that under discussion (for example: (i) the company produces a product that is used for the same indication to the monograph under discussion, but containing a different active ingredient; (ii) the company produces a different formulation (but with the same active ingredient) to that under discussion)

The member should declare an interest. Although unlikely, a member may perceive either an advantage or a disadvantage to their company's product if a particular monograph is published and so try to influence decisions. If this situation occurs it may be appropriate in the first instance to ask the member only to respond to questions directly from the Chair. It may be advisable to ask them to leave the room after the discussion to allow unbiased decisions to be made.

Example 5:
A member was clinical lead during a clinical trial but did not have any responsibility for the trial itself.

The interest should be declared. The member will be allowed to remain for specific questions from the Chair but to leave for the deliberations and decision.

Example 6:
A member is employed by a pharmaceutical company and the product for which a monograph is being developed or revised is currently (or was formerly) manufactured by that company.

The interest should be declared. The members will be able to participate in the discussions.

Annex 2

Examples of other relevant interests

Example 1:
A member has a close family member who has a rare disease and the item/treatment under discussion is for the same condition. There are no or very few other products available to treat the rare disease.

The interest must be declared but would not necessarily exclude the member from the discussion or decision.

Example 2:
Journal or other publications in which the member expresses a clear opinion about the treatment/item being considered.

The interest must be declared, and the member would be excluded from the decision but may be invited at the Chair's discretion to answer questions from the committee.

Example 3:
The member sits on a data safety monitoring committee for a study/trial into the same/similar condition to that under consideration. The study/trial is funded by a government agency for health and care research.

The interest should be declared but is unlikely to exclude the member from the discussion or decision provided no specific companies are funding/involved with the research and the members expertise will be valuable to the discussion.

Example 4:
The member sits on the Board (non-executive member with no salary) of a not for profit organisation sponsored by the government. The organisation is providing advice on re-purposing a site which will eventually produce a medicine of a type under consideration by the committee. The organisation will not make decisions on whether or which pharmaceutical company may use the new site.

The interest should be declared but will not exclude the member from the discussion or the decision.

Example 5:
A member (or immediate family member) is connected to a charity group or patient pressure group that could be affected by the decisions taken.

The member should declare an interest. The Advisory Committee/EAG will benefit from the direct experience/knowledge of the member but will need to ensure that decisions are reached impartially. The member should be able to participate in the discussions, but it may be appropriate to ask the member only to respond to questions directly from the Chair.

Example 6
A member's salary is part-funded by a government-funded research unit which is attached to a hospital or university which is involved in development of a medicinal product. The member is not involved with the development of the medicinal product.

The member should declare the interest but will not be excluded from the discussion or the decision.

Annex 3

Conflict of Interest Conduct Panel and Conduct hearing

1.1 A Conflict of Interest Conduct Panel (Panel) will be arranged where MHRA:

- has knowledge of information that is inconsistent in a material respect with the information included in the individual's Declaration of Interests form, and it appears that the information should have been declared, or
- becomes aware that an individual has previously or is currently engaged in an interest which MHRA has previously advised them would be incompatible with their involvement in the committee or has knowledge of a potential breach in the use of confidential information.

The Panel

1.2 A Non-Executive Director of the MHRA will be appointed to chair the Panel.

1.3 For the CHM (and its working groups), the Panel will also include three senior managers from MHRA (including the Governance Director), Principal Assessors to CHM and Manager with responsibility for the Committee Secretariat.

1.4 For ABRHP and HMAC (and their working groups), the Panel will also include three senior managers from MHRA (including the Governance Director) and the Manager with responsibility for the Committee Secretariat.

1.5 For the BPC (and its working groups), the Panel will also include three senior managers from MHRA (including the Governance Director) and the Secretary and Scientific Director.

1.6 For the DEAC, UKSCBSC and the Review Panel (and their working groups), the Panel will also include three senior managers from MHRA (including the Governance Director) and the relevant Manager with responsibility for Committee Secretariat.

1.7 The Committee Chair or Vice- Chair of the relevant body/committee will be consulted for their views. Where the non-disclosure or non-timely disclosure is by a Chair, a Chair of another committee may be consulted for insight and advice.

Process

1.8 The Secretariat will write to the individual in question to advise them of the creation of a panel in response to the scenarios set out in paragraph 1 above. The individual will be informed of the make-up of the panel. The individual will be invited to clarify within 10 working days:

- the reason for the absence of the information to be declared, and to complete the Declaration of Interest with the missing information, or
- the reason for engaging/retaining the interest, or
- reason for disclosure of confidential information.

1.9 If the information is not provided by the individual within the 10 working days (or any extension mutually agreed), the Panel may decide to restrict the individual's involvement in committee meetings following discussion with the Chair of the committee (a Chair of another committee may be consulted where the non-disclosure or non-timely disclosure is by a Chair). If this decision is taken, the Secretariat will write to inform the individual.

1.10 The response provided by the individual will be assessed by the Panel, taking into account other information from the Secretariat and advice from the Chair, to reach a decision on whether

the omission to declare the interest or the engagement in the interest should result in further action.

1.11 If the decision of the Panel is that:

- the information missing from the Declaration of Interests form is a declarable interest according to this Code or the Cabinet Office Code of Conduct for Members of Public Bodies; or
- the individual did not declare the missing information, or engaged in the interest intentionally or through gross negligence, or
- they failed otherwise to meet their obligations under the Code,

then the Panel will initiate a conduct hearing.

1.12 If it is found, following the clarification/additional information provided by the individual, that:

- the individual's omission to declare the interest, or engagement in the interest was not done intentionally or through gross negligence, or
- the individual did not fail otherwise to meet their obligations under rules governing the identification and handling of conflicts of interest contained in the Code.

no further action will be taken, other than requesting the individual to submit an updated Declaration of Interests form, for the Secretariat to record. The Secretariat will keep a record of the Panel's decision and will report annually on breaches and action taken to the Panel.

Conduct hearing

1.13 Where the Panel finds that a conduct issue has occurred, the Panel will write to the individual in question to invite them to a conduct hearing to present their point of view. The Chair of the relevant committee will also be invited to attend and provide comment at the hearing (a Chair of another committee may be consulted where the non-disclosure or non-timely disclosure is by a Chair). The Panel will take into consideration any comments or documents submitted before the hearing.

1.14 The Panel may decide to recommend suspending the individual's involvement in the committee work until the conduct hearing has been completed. The individual and the relevant Chair will be notified of the suspension.

1.15 If it is found, following the assessment of all the submitted information and comments at the hearing from the individual and relevant Chair, that the

- the individual's omission to declare the interest, or engagement in the interest was not done intentionally or through gross negligence, or
- the individual did not fail otherwise to meet their obligations under rules governing the identification and handling of conflicts of interest contained in the Code.

no further action will be taken, other than requesting the individual to submit an updated Declaration of Interests for the Secretariat to record. The Secretariat will keep a record of the Panel's decision and will report annually on breaches and action taken to the MHRA's Conflicts of Interest Advisory Group.

1.16 If it is found, following the assessment of all the submitted information and comments at the hearing from the individual and relevant Chair, that the individual:

- did not declare the missing information, or
- engaged in the interest intentionally or through gross negligence, or

- failed otherwise to meet their obligations under the Code,

the Panel will make its recommendation to the MHRA Chief Executive Officer. It may recommend that the individual face disciplinary action, including a written or verbal warning; a direction to relinquish the conflicting interests prior to further involvement in participating in committee meetings; restricted involvement in the committee or the termination of their appointment.

1.17 The MHRA Chief Executive Officer will consider the recommendation of the Panel and:

- Where the individual is also a CHM Commissioner, provide a formal recommendation to the Secretary of State who is responsible for the termination of the Commissioner's appointment.
- For all other individuals, provide a formal recommendation to the Chair of MHRA who is responsible for the termination of the individual's appointment.

Notification of the Decision

1.18 Where the individual is also a CHM Commissioner, the Secretary of State will provide a letter to the Commissioner informing them of their decision, in response to the Chief Executive Officer's recommendation and the reasons for the decision. The letter will also provide information on how to appeal.

1.19 For all other individuals, the Chair of the MHRA will provide a letter to the individual informing them of the decision and the reasons for the decision. The letter will also provide information on how to appeal.

Appeal Process

1.20 The appeal must be received within 10 working days, from the date of the letter notifying the individual of the decision, providing any further supporting documents and information.

1.21 The MHRA Chief Executive Officer and the Chair of MHRA, with the assistance of a Chair of a committee not associated with the relevant individual, will assess all the submitted documents and information for a final decision. The Panel will advise the Secretary of State as necessary of their final recommendation.

1.22 Where not appointed by the Secretary of State, the Chair of MHRA will inform the individual of the final decision.

Integrity of the Scientific Review

1.23 Where a conduct issue has occurred the decision may be taken by the MHRA Chief Executive Officer with advice from the Panel to initiate a review of the committee proceedings/decisions at which the individual provided advice to ensure the integrity of the process and to recommend if any re-evaluation is required. If so, the outcome and any action taken will be documented.