

Managing Conflicts of interest

Consultation document

Code of Practice for the Commission on Human Medicines, the British Pharmacopoeia Commission, the Committee on Medical Devices, the United Kingdom Stem Cell Bank Steering Committee, and other expert advisory committees

April 2022

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1. Introduction

1.1 The Medicines and Healthcare products Regulatory Agency (MHRA), operating as the Licensing Authority on behalf of the Secretary of State, regulates medicines, medical devices and blood components for transfusion in the United Kingdom. Our purpose is to protect and improve patient health by enabling the earliest access to, and high-quality supply of, safe, effective and innovative medical products through proportionate, data-driven assessment of risks and benefits.

1.2 We aspire to be a leading global example of delivering excellence in public health and patient safety, enabled through regulation and at the forefront of innovation. Delivering our vision relies on our ability to quickly realise the benefits that new therapies and innovative healthcare products can bring to patients, while still ensuring the right levels of safety, quality and efficacy.

1.3 In delivering our vision, we utilise expert and impartial advice from a number of advisory committees, including:

- The Commission on Human Medicines (CHM), which advises MHRA on the safety, efficacy and quality of medicinal products,
- Committee on Medical Devices (CMD)¹ which provides MHRA with advice on a wide range of aspects relating to the introduction and safe use of medical devices,
- The British Pharmacopoeia Commission (BPC), which provides official standards for pharmaceutical substances and medicinal products,
- Herbal Medicines Advisory Committee (HMAC), which advises MHRA on the safety and quality of herbal medicinal products for human use,
- Advisory Board for Registration of Homeopathic Products (ABRHP), which advises MHRA on safety and quality in relation to any homeopathic medicinal product for human use,
- UK Stem Cell Bank Steering Committee (UKSCBSC), which oversees the activities of the UK Stem Cell Bank and UK research involving established human embryonic stem cell lines, whether obtained from the bank or from elsewhere.
- The Review Panel, which carries out statutory and non-statutory reviews of proposals, decisions and provisional decisions taken by MHRA.

1.4 The role and purpose of some of the advisory committees are set out in legislation, for instance, the CHM and the BPC to which members are appointed by ministers. The CMD is also moving onto a statutory footing.

1.5 Certain advisory committees such as the CHM are able, with the approval of MHRA, to appoint sub-groups in the form of expert advisory groups that have a specific clinical or scientific focus, as well as expert working groups which are usually single-issue in nature, focusing on a specific safety issue for example. Taking into account all the advisory and working groups, there are around 50 committees and groups in operation at the moment, both statutory and non-statutory, and more than 200 members.

1.6 A summary of the function and purpose of all the advisory committees, along with a list of their expert advisory and/or working groups, is included at Annex 2.

¹ Previously the Devices Expert Advisory Committee (DEAC)

The Importance of Impartiality

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 advisory committees but may also have an impact on their impartiality. For example, they may have shareholdings from previous industry employment or have been involved in conducting clinical trials.

1.8 As an organisation that aims to protect and improve public health, it is paramount that Ministers, the public and healthcare professionals are able to have confidence that the advice and information provided by the advisory committees is impartial and that the processes in place to identify and manage conflicts of interest are robust, proportionate and underpinned with transparency. The MHRA recognises that conflicts of interest are complex, that clear guidance materials are needed to proactively support members to report interests accurately and that interests must be managed correctly.

1.9 This is why we have reviewed the rules governing the identification and handling of conflicts of interest for the MHRA advisory committees, which are currently contained in the [CHM Code of Practice](#), the [BPC Code of Practice](#) and the CMD Code of Practice. These Codes have been reviewed and brought together for the first time with the aim of identifying particular pressure points and inconsistencies between the different committees, refreshing the rules and processes so as to ensure they meet expectations of the public we serve and to ensure enhanced transparency across all advisory committees. In particular, the review considered the following essential stages of a conflict of interest process:

1. Definition and Scope
2. Identification and management of interests
3. Managing breaches and sanctions

1.10 Over the course of the review we have been developing proposals around conflicts of interest management that would strengthen public confidence and ensure that the MHRA can:

- Actively manage conflicts of interest and associated issues of gifts, hospitality, other payments and influence
- Proactively support individuals to ensure that they know what is and is not acceptable – to prevent wrongdoing from occurring
- Provide the public with accessible information so that they can see what is happening and, where appropriate, ask questions
- Take firm and decisive action when individual wrongdoing is discovered – including where appropriate, disciplinary action

Structure of this consultation and how to respond

1.11 In this consultation we will present our proposals for changes to the current Codes of Practice of the advisory committees. Please submit your views and comments on our proposal by 24 May 2022 via [our online template](#). It is our intention to use the outputs of this consultation to develop guidance on management of conflicts of interest, which would apply across the MHRA advisory committees.

Confidentiality

1.12 We will publish a summary of the responses we receive to this consultation on the Gov.uk website in due course.

1.13 You can request to keep your name and/or organisation confidential and excluded from the published summary of responses. If you would like any part of the content of your response (instead of or as well as your identity) to be kept confidential, please let us know and make it obvious by marking in your response which parts we should keep confidential.

1.14 We will do our best to meet your request and will process your personal data in accordance with the Data Protection Act 2018 and the UK Data General Data Protection Regulation 2016/279 ("GDPR"). In most circumstances this will mean that your personal data will not be disclosed to third parties. However, because we are a public body subject to Freedom of Information legislation, we cannot guarantee that we will not be obliged to release your response even if you say it is confidential. We collect and handle your data in accordance with the public task lawful basis set out in article 6(1)(e) GDPR. Further details on how we handle your personal data, including on your right to object to processing, is set out [in MHRA's privacy notice](#).

2. Policy governing conflicts of interest

2.1 The current Codes of Practice for the advisory committees are based on the UK public sector's principles-based approach to managing conflicts (see [National Audit Office: Conflicts of Interest, 2015](#)). This approach sets out high level requirements and frameworks from which public bodies make their own informed decisions on the best processes to implement. Best practice is drawn from ethical standards and behaviours contained in codes of practice and policy documents such as the Nolan Principles [7-principles-of-public-life](#) and the Cabinet Office guidance on standards of conduct for members of public bodies [Code of Conduct](#).

Definition of Conflict of interest

2.2 The National Audit Office defined a conflict of interest as:

'a set of circumstances that creates a risk that an individual's ability to apply judgement or act in one role is, or could be, impaired or influenced by a secondary interest. It can occur in any situation where an individual or organisation (private or government) can exploit a professional, or official role for personal or other benefit'.

2.3 The definition of a conflict of interest adopted across the current Codes of the advisory committees is based on the NAO definition.

'A conflict arises when a reasonable person would consider that an individual's ability to apply judgement or act in the work of an advisory 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.'

Recognising the risk of conflicts of interest

2.4 A conflict of interest is not an actual occurrence of bias or a corrupt decision but, rather, a set of circumstances that past experience and other evidence have shown poses a risk that an individual's impartiality may become compromised by some other interest(s). To avoid these risks manifesting in actual bias or corrupt decisions, and to provide guidance for formulating and applying such policies, the NAO suggests that a framework is desirable for analysing a multitude of different interests which could lead to a conflict so that:

'Departments and other bodies design a proportionate approach that reflects the nature and scale of conflicts that they are exposed to and their risk appetite'.

2.5 Our review has helped the MHRA advisory committees to map out the range of circumstances in which conflicts of interest can commonly occur and develop appropriate principles and rules on their management. These circumstances (or more accurately, classification of interests), are summarised in Table 1 at page 7.

Responsibility to declare interests

2.6 The responsibility for identifying and declaring interests in compliance with the Code of Practice rests with individuals. The Cabinet Office guidance for Board Members of Public Bodies [Code-of-Conduct-](#) (pp 4) places on individuals the following responsibility:

"You must ensure that no conflict arises, or could reasonably be perceived to arise, between your public duties and your private interests, financial or otherwise. You must comply with the rules of the body on handling conflicts of interests. As a minimum, these will require you to declare publicly, usually in the body's register of interests, any private financial or non-financial interests of your own, or of close family members, which may, or may be perceived to, conflict with your public duties."

Finding the balance between interests and the best expertise

2.7 The MHRA and Ministers need the highest quality scientific and clinical advice from a wide range of experts to ensure the best possible public health outcomes, but this comes with challenges. Many experts have, or may have had, connections with the pharmaceutical, medical device or biotechnology industries and other commercial organisations whose business is considered relevant to their work on advisory committees and may have an impact on their impartiality. The recent [Report of the Independent Medicines and Medical Devices Safety Review – "First Do No Harm"](#) commented:

"An ideal expert would be an individual who is knowledgeable and respected in their field, but who has no personal, professional or financial links which might influence their position. We recognise that it may not be possible, or even desirable, for an expert to have no interest in a matter being reviewed."

2.8 This recognition builds on the approach set out in 2015 by the National Audit Office, who stated that: conflicts of interest are ... 'common and unavoidable' and it is:

“not reasonable or desirable to completely eliminate the risk of conflicts of interest. It is better to recognise the associated risks and put measures in place to identify and manage conflicts when they do arise.”

Our proposal

2.9 Our Review found that the approach to utilising the MHRA advisory committees and their supporting groups has grown organically over time, with a resulting variance in the supporting frameworks, such as the management of any conflicts of interest. This inconsistency in approaches to managing conflicts of interest makes it harder for members of the advisory committees and the Secretariat staff (who provide administrative support to the advisory committees) to understand the rules and to ensure that members comply with them. This can also be confusing for the public and can lead to a loss of trust in the independence of the advisory committees, which is critical to safeguarding future advice which supports MHRA to act rapidly to ensure the safe use of drugs and devices.

2.10 To address this, and to ensure that that all members of the advisory committees are subject to consistent and comparable high standards, we propose a single Code for managing conflicts of interests across all advisory committees. There are, of course, some differences in the role and remit of the different advisory committees, and this may be reflected in the interests members are able to hold. Such distinctions will be addressed and explained in the new Code of Practice and highlighted in this document as they arise.

Recommendation 1:

Introduce **a single Code of Practice for all the advisory committees**. This will ensure that all expert advisory committee members are subject to consistent and comparable high standards. There are, of course, some differences in the role and remit of the different advisory committees, and this may be reflected in the interests members are able to hold. Such distinctions will be addressed and explained in the new Code where they arise.

3. Definitions and scope of conflicts of interest: Current Codes of Practice

3.1 The current Codes of Practice of the advisory committees aim to provide confidence to Ministers, patients, the public and healthcare professionals that the advice on which decisions about medicines are based is impartial and promotes transparency by publishing annual declarations of interests in [the advisory committees’ annual reports](#).

Types and Categories of interests

3.2 The Codes of Practice categorise types of interest which must be declared into the following areas:

- **Member’s own financial interests**
- **Financial interests held by immediate family or payments to a department for which the individual is responsible**
- **other interests that might affect, or be considered to have the potential to affect, the member’s impartiality**

When declaring financial interests, members use the categories shown in Table 1.

Table 1

Personal interests	Personal interests involve the payment, in any form, to an individual personally, by a pharmaceutical company whose business may be directly affected by the advice of the advisory body. Personal interests may be • Specific – related to the medicinal product under discussion • Non-specific – not related to the medicinal product under discussion
Non-Personal interests	A non-personal interest involves payments which are not received by the member personally but that benefit a department for which the individual is responsible. As with personal interests, non-personal interests may be specific or non-specific.
Other relevant interests	Interests that fall under this heading cover a range of circumstances which could reasonably be perceived as affecting the individual's impartiality. Examples are given in paragraph 4.7 of the Code (reproduced in Annex 3). These include intellectual interests, for example, research and authoring papers relating to a specific product or range of products; making public statements about a product/range of products; and involvement with competitor products. Although examples are given in the Code these are not exhaustive and these interests present challenges for the Chair and members in determining whether a specific circumstance can be construed as falling under this heading. In considering "other" interests that need to be declared, consideration should be given to meeting the standards reasonably expected by the public. The guiding principle is to declare if the matter might reasonably be perceived as affecting a member's impartiality.

Personal interests

3.3 In Table 1 above, we have mapped out the circumstances in which potential conflicts can occur and have adopted principles and rules across the advisory committees which promote greater consistency. In applying our principles and rules we recognise that there are some differences in the role and remit of the different advisory committees, and this has an impact on the personal interests Commissioners and members can hold.

3.4 Under the current Codes, the Chair and members of CHM are not permitted to hold personal interests in the pharmaceutical industry. However, in the case of the other advisory committees, the prohibition to hold personal interests in the pharmaceutical, medical devices and/or biotechnology industry apply only to the chairs and not the members. The review considered that the rationale for the different treatment of advisory committees was not clear.

Our proposal

3.5 Applying a risk-based approach to our assessment of interests, we propose that members of advisory committees be prohibited from holding personal interests in industries such as the pharmaceutical, medical device and/or biotechnology industry (depending on which are relevant to the particular work of that committee) since a perceived conflict of a member can undermine the advice provided to Ministers and the MHRA and subsequent decisions on the basis of that advice.

Chairs

3.6 The **chairs of advisory committees are prohibited from holding any current personal interests in industries relevant to the work of their committee, such as the pharmaceutical, medical device and/or biotechnology 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 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

CHM

3.7 The CHM performs several statutory functions advising MHRA (who operate as the Licensing Authority on behalf of the Secretary of State) 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 and marketing authorisation 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, we recommend that members of CHM should continue to be prohibited from holding personal interests in the pharmaceutical industry.**

ABRHP and HMAc

3.8 The ABRHP and HMAc provide MHRA with advice on 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 would be specifically defined in the Code to include the homeopathic and/or herbal medicine industry) to be a member of these committees. 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 the MHRA, and subsequent decisions on the basis of that advice. **Therefore, we recommend that members of ABRHP and HMAc should be prohibited from holding personal interests in the pharmaceutical industry.**

CMD

3.9 CMD is responsible for providing MHRA with independent, 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 CMD. 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, we recommend that members of CMD should be prohibited from holding personal interests in the medical devices 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 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, we recommend that members of the UKSCBSC be prohibited from holding personal interests in the biotechnology industry.**

BPC

3.11 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, that is, 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 and marketing authorisation of medicines. For this reason, we recommend that **members of the BPC should continue to be permitted to hold personal interests in the pharmaceutical industry, but they must comply with the Code of Practice 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 of the new Code.

Recommendation 2:

Members of the advisory committees, except the BPC, **to be prohibited** from holding personal interests in industries relevant to the work of that committee, such as the pharmaceutical, medical device and/or biotechnology industry depending on the work of the committee. The principle here is, taking into account that members of these advisory committees are exposed to sensitive and confidential discussions, for example, on licencing and marketing authorisation of medicines or aspects relating to the introduction and safe use of medical devices, a perception that an interest might have the potential to influence member can undermine the advice provided to Ministers and the MHRA and subsequent decisions on the basis of that advice.

Members of BPC **should continue to be permitted** to hold personal interests. BPC standards are an important component in the overall control of medicines, however, members of the BPC do not themselves take part in the sensitive and confidential discussions on licencing and marketing authorisation of medicines.

The chairs of advisory committees, including the BPC, **are not permitted** to hold any current personal interests in industries relevant to the work of their committee, such as the pharmaceutical, medical device and/or biotechnology industry depending on the work of the committee. 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 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 of expert advisory and working groups

3.12 The rule prohibiting the holding of personal interests in industries such as the pharmaceutical, medical device and/or the biotechnology 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 CMD. But these personal interests must be declared and may still affect or prevent participation in expert discussions, as outlined in section 7 of the new Code.

Co-opted members (Experts for the Day) and Patient Expert

3.13 The CHM, BPC and CMD have powers to co-opt members if a regular member is unable to attend or to provide advice where additional specialist advice and/or experience is required. These co-opted members are known as 'Experts for the Day' (see paragraph 5.1 of the current [Codes of Practice of these advisory committees](#)). Experts for the Day are not permitted by the Code to hold interests in the issue under discussion.

Our proposals

3.14 As the topics under discussion are often specialist with a small pool of experts available to choose from, sometimes an expert will have interests which prevent them from attending or offering advice/views on the matter under discussion. As it is in the interests of patients that Ministers and the MHRA have access to the best advice whilst protecting the impartiality of the committee we propose that the definitions in paragraph 5 of the current Codes are replaced. Similarly, expert patient contributors may be invited to contribute, give evidence and/or answer questions from the advisory committees. In the new Code, new categories of attendees are defined making a clear distinction between 'members' with full rights including voting rights and those experts that are invited to contribute their expertise but not participate in the discussion or vote. This distinction allows invited experts to hold interests in the matter under discussion whilst ensuring the impartiality of the decisions made by the committees, and for the committees to benefit from the insight of patient experts who may have a clear interest in the outcome of the discussions.

Recommendation 3:

Replace 'Expert for the Day' with 'Co-opted Member' and introduce new categories of 'Invited Expert', 'Patient Expert' and 'observer' to cover circumstances where specific expertise or experience is required. This may include specialists and expert patient contributors, invited to contribute, give

evidence and/or answer questions from the advisory committees and EAG/EWGs. Invited experts and Patient Experts are permitted to have interests in the item under discussion as their participation is limited and they will not participate in the discussion or vote. These interests will be captured and recorded in the minutes of the meeting, published on gov.uk.

Replace 'Expert for the Day' with 'Co-opted Member' and introduce new categories of 'Invited Expert', 'Patient Expert' and 'observer' defined as:

1. **Co-opted member:** Members appointed under Regulation 13 and Regulation 14 (Expert Advisory Groups) of the Human Medicines Regulations 2012 as amended, and equivalent. 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 in the same way as Members and Commissioners and will be subject to the same restrictions on interests they may hold while serving as a member of the relevant committee.
2. **Invited Expert** - 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 expert from providing advice or answering questions as their participation is limited. This enables the committee to have access to the best expertise whilst preserving impartiality of the decisions/recommendations.

3. **Patient Experts** - Patients or their representatives may be invited to meetings to bring their individual expertise or experience to specific topics/items and may also be invited to forward comments to contribute their lived experience as users of medicines and medical devices.

The perspectives that patients provide are very valuable and complement the scientific information considered. As with invited experts, they will be asked to declare any interests in the matter under consideration. Having interests will not prevent them from contributing their advice and experience as they do not have full rights to participate in the discussion or to vote.

4. **Observer** – representative or individual observing an item or the entire meeting. 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.

Non-Personal interests

3.15 The current definition of non-personal interests in the Codes of Practice of the advisory committees (for example, [paragraph 4.6 of the current CHM Code](#)) present challenges particularly in

light of the changed size and structure of university and hospital units and departments. It is often unrealistic to expect the head of a large department to be aware of all the projects and activities undertaken by its staff. We recommend that the definition is amended to require members to declare those interests which they 'could reasonably be expected to be aware of' as 'reasonableness' is an established test in law.

Recommendation 4:

The scope of **non-personal interests** should be amended to define the scope more clearly. Since the Codes of Practice were originally developed the organisation and size of university and hospital departments and units has increased significantly making it unrealistic for a member who is in charge of a unit/department to know of all the activities and projects that members of the unit could be involved with, and thus to have an impact on the members impartiality.

It is recommended that the scope of non-personal interests is clarified to make it clear that members in charge of large departments or units are only responsible for declaring interests they could **reasonably be expected to be aware of**.

Guidance on identifying and recording interests

3.16 Most interests (for both members and immediate family) are time-limited to those held currently or held within the preceding 12 months. However, certain interests will not be restricted to the last 12 months and must be declared each year and at relevant meetings.

3.17 Whilst the broad classifications and categories of interests defined in the current Codes of Practice of the advisory committees are still appropriate, experience has shown that conflicts of interest are complex. To promote good governance, supporting guidance and examples are needed to assist members, chairs and MHRA Secretariat staff to identify, report and manage interests accurately. **We recommend that more specific guidance is included on managing non-personal and other relevant interests.**

Recommendation 5:

Whilst broadly the classification and categories of interests are still appropriate experience has shown that the conflicts of interest are complex and to promote good governance, we recommend **further guidance is published** refining the categories within 'other relevant interests', to assist members and staff to identify, report and manage conflicts accurately.

It is recommended that the current categories of personal/non-personal/specific/non-specific and other relevant interests are retained but that further guidance is published to assist with interpretation for members, Chairs and MHRA Secretariat staff.

4. Identification and management of interests

Identifying interests

4.1 Currently individuals complete an annual Declaration of Interests form and the information is published in [the advisory committees' annual reports](#). The current practice and processes for identifying and reporting interests are detailed below.

Chair and members (except members of BPC):

- **During the appointment process:** any conflicts are discussed with candidates at interview and may prevent the appointment process continuing unless the candidate is willing to dispose of the interest within three months of appointment
- **Annually following appointment:** Annual Declaration of interests are made. These are published in [the Annual Reports](#).
- **Prior to the meeting:** interests in the matters to be discussed are invited before the meeting
- **At the meeting:** the Chair reminds members prior to the meeting start of the importance of declaring interests in the matters under discussion and again before each item is discussed

Invited experts (including patient experts and observers)

- **Prior to sending any papers and/or participation in a meeting; request to send written comments**
- **At the meeting:** The Chair reminds members and attendees prior to the meeting start and before each item of the importance of declaring interests in the matters under discussion.

Our proposal

4.2 We recognise the importance of providing patients and the public with timely and accessible information. To improve ease of access and timeliness compared to current practice, it is recommended that members' declarations of interest are made available on the advisory committees' websites in a new Public Register of Interests from appointment and as they are updated by members throughout the year as needed.

Recommendation 6:

To improve public access and timeliness of publication it is recommended that members' declarations of interest are published in a new **Public Register of Interests** available on the advisory committees' websites from appointment and as they are updated by members throughout the year as needed.

Managing Interests

4.3 The Codes of Practice make it clear that members must declare any interest prior to the meeting if possible and, in any case, before the item is discussed. Declaring an interest might mean that the member will not be able to participate or may have to withdraw from certain parts of the meeting.

Whether the member will be permitted to take part in the discussion will depend upon the circumstances. The Chair is ultimately responsible for taking the decision, advised as needed by the Secretariat. If it is not appropriate for the member to take part in the proceedings, at the Chair's discretion, they may be asked questions by members and then leave the meeting. Any interests declared are recorded in the minutes, including if the member was asked to leave the meeting for that item and/or was asked to answer questions before leaving.

4.4 If members or the Chair need advice prior to the meeting about a potential interest, they may contact the Secretariat provided by the MHRA.

Our proposal

4.5 We realise that determining whether or not an interest should be declared can sometimes be challenging for the chairs and members of the advisory committees, and also the Secretariat staff. To address this, we propose to set up a Code of Interest Advisory Panel, made up of senior managers from the MHRA, the committees' secretariat, and the chairs and deputy chairs of advisory committees, to provide advice to members uncertain about declaring interests or unclear about the interpretation of this Code.

4.6 To ensure consistency in the advice it provides to members of the advisory committees, we consider that the Conflict of Interest Advisory Panel would benefit from having access to a record of how conflict of interests have been managed. Therefore, we propose that a database of decisions is maintained recording how any conflict of interests have been managed and for transparency decisions should be published in the annual reports of the advisory committees.

Recommendation 7:

Set up a **Code of Practice Conflict of Interest Advisory Panel**, made up of senior managers from the MHRA, the committees secretariat, and the chairs and deputy chairs of advisory committees, to provide advice to members uncertain about declaring interests or unclear about the interpretation of this Code.

A **database of decisions** will be maintained to promote consistency and transparency. Decisions should be published in the Annual Report of the Advisory Committee.

Managing breaches and sanctions

4.7 There may also be situations when interests will not be identified, declared or managed appropriately and effectively. This may happen innocently, accidentally or because of deliberate actions. These situations are referred to as 'breaches'.

4.8 The current Codes of Practice of the advisory committees do not provide for dealing with potential breaches of the conflict of interest policy, leading to uncertainty about how such a scenario should be dealt with and what type of disciplinary action may be warranted.

4.9 To avoid such uncertainty in the future, we propose that the new single Code of Practice for the advisory committees should include a consistent process for addressing breaches of the Code on conflict of interests.

Our Proposal

Recommendation 8:

The new Code of Practice for the advisory committees will establish a consistent process for **addressing breaches of the conflict of interest policy**. It will provide details of:

- a conflict of interest panel process, overseen by an independent Chair, for establishing whether the action/omission amounted to a breach
- what actions or omissions will result in disciplinary proceedings being initiated against a member
- the potential sanctions for breaches of the conflict of interest Code, and
- the process for appealing against the decision to impose sanctions.

Full details of the recommended process for dealing with breaches of conflict of interest policy are provided at Annex 3 of the new Code of Practice.

4.10 The appointment of an independent Chair to oversee the panel process will ensure that there is an impartial voice to assist the Panel in coming to fair and evidence-based judgements.

5. Conclusion

5.1 In this document we have shown that the decisions of the MHRA, taken on behalf of Ministers on the safety, quality and efficacy of medicines and medical devices, benefit greatly from the involvement of experts in the advisory committees. We have also shown that these experts may have interests which have the potential to have an impact, or be perceived to have an impact on their impartiality, for example, a previous affiliation with an organisation that might be impacted by decisions taken.

5.2 Conflicts of interest are a common challenge that can arise in a range of discussions and deliberations of these advisory committees. The central issue for us is the proper management of potential conflicts of interest; to recognise the associated risks and put measures in place to identify and manage conflicts when they do arise.

5.3 That is why we have reviewed the current arrangements for managing conflicts of interest across the independent advisory committees, and proposed improvements. We believe the proposals we have developed, which are presented in this document for consultation, will drive forward in practice our commitment to operating as a more transparent and inclusive regulator.

5.4 We look forward to receiving views on these proposals from all interested parties – organisations, healthcare professionals, patients and the general public - to allow us to review them further and refine them so that they reflect best practice.

5.5 The public consultation will run for six weeks from 12 April 2022. Have your say by visiting [our online template](#).

LIST OF RECOMMENDATIONS
Recommendation 1: Introduce a single Code of Practice for all the advisory committees. This will ensure that all expert advisory committee members are subject to consistent and comparable high standards. There are, of course, some differences in the role and remit of the different advisory committees, and this may be reflected in the interests members are able to hold. Such distinctions will be addressed and explained in the new Code where they arise.
Recommendation 2: Members of the advisory committees, except the BPC, to be prohibited from holding personal interests in industries relevant to the work of that committee, such as the pharmaceutical, medical device and/or biotechnology industry depending on the work of the committee. The principle here is, taking into account that members of these advisory committees are exposed to sensitive and confidential discussions, for example, on licencing and marketing authorisation of medicines or aspects relating to the introduction and safe use of medical devices, a perception that an interest might have the potential to influence member can undermine the advice provided to Ministers and the MHRA and subsequent decisions on the basis of that advice. Members of BPC should continue to be permitted to hold personal interests. BPC standards are an important component in the overall control of medicines, however, members of the BPC do not themselves take part in the sensitive and confidential discussions on licencing and marketing authorisation of medicines. The chairs of advisory committees, including the BPC, are not permitted to hold any current personal interests in industries relevant to the work of their committee, such as the pharmaceutical, medical device and/or biotechnology industry depending on the work of the committee. 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 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.
Recommendation 3: Replace 'Expert for the Day' with 'Co-opted Member' and introduce new categories of 'Invited Expert', 'Patient Expert' and 'observer' to cover circumstances where specific expertise or experience is required. This may include specialists and expert patient contributors, invited to contribute, give evidence and/or answer questions from the advisory committees and EAG/EWGs. Invited experts and Patient Experts are permitted to have interests in the item under discussion as their participation is limited and they will not participate in the discussion or vote. These interests will be captured and recorded in the minutes of the meeting, published on gov.uk. Replace 'Expert for the Day' with 'Co-opted Member' and introduce new categories of 'Invited Expert', 'Patient Expert' and 'observer' defined as: 1. Co-opted member: Members appointed under Regulation 13 and Regulation 14 (Expert Advisory Groups) of the Human Medicines Regulations 2012 as amended, and equivalent. 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 in the same way as Members and Commissioners and will be subject to the same restrictions on interests they may hold while serving as a member of the relevant committee.

2. **Invited Expert** - 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 expert from providing advice or answering questions as their participation is limited. This enables the committee to have access to the best expertise whilst preserving impartiality of the decisions/recommendations.

3. **Patient Experts** - Patients or their representatives may be invited to meetings to bring their individual expertise or experience to specific topics/items and may also be invited to forward comments to contribute their lived experience as users of medicines and medical devices.

The perspectives that patients provide are very valuable and complement the scientific information considered. As with invited experts, they will be asked to declare any interests in the matter under consideration. Having interests will not prevent them from contributing their advice and experience as they do not have full rights to participate in the discussion or to vote.

4. **Observer** – representative or individual observing an item or the entire meeting. 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.

Recommendation 4:

The scope of **non-personal interests** should be amended to define the scope more clearly. Since the Codes of Practice were originally developed the organisation and size of university and hospital departments and units has increased significantly making it unrealistic for a member who is in charge of a unit/department to know of all the activities and projects that members of the unit could be involved with, and thus to have an impact on the members impartiality.

It is recommended that the scope of non-personal interests is clarified to make it clear that members in charge of large departments or units are only responsible for declaring interests they could **reasonably be expected to be aware of**.

Recommendation 5:

Whilst broadly the classification and categories of interests are still appropriate experience has shown that the conflicts of interest are complex and to promote good governance, we recommend **further**

guidance is published refining the categories within ‘other relevant interests’, to assist members and staff to identify, report and manage conflicts accurately.

It is recommended that the current categories of personal/non-personal/specific/non-specific and other relevant interests are retained but that further guidance is published to assist with interpretation for members, Chairs and MHRA Secretariat staff.

Recommendation 6:

To improve public access and timeliness of publication it is recommended that members’ declarations of interest are published in a new **Public Register of Interests** available on the advisory committees’ websites from appointment and as they are updated by members throughout the year as needed.

Recommendation 7:

Set up a **Code of Practice Conflict of Interest Advisory Panel**, made up of senior managers from the MHRA, the committees secretariat, and the chairs and deputy chairs of advisory committees, to provide advice to members uncertain about declaring interests or unclear about the interpretation of this Code.

A **database of decisions** will be maintained to promote consistency and transparency. Decisions should be published in the Annual Report of the Advisory Committee.

Recommendation 8:

The new Code of Practice for the advisory committees will establish a consistent process for **addressing breaches of the conflict of interest policy**. It will provide details of:

- a conflict of interest panel process, overseen by an independent Chair, for establishing whether the action/omission amounted to a breach
- what actions or omissions will result in disciplinary proceedings being initiated against a member
- the potential sanctions for breaches of the conflict of interest Code, and
- the process for appealing against the decision to impose sanctions.

Full details of the recommended process for dealing with breaches of conflict of interest policy are provided at Annex 3 of the new Code of Practice.

The function and purpose of MHRA advisory committees

The Commission on Human Medicines (CHM)

The functions of the CHM are set out in regulation 10 of the Human Medicines Regulations 2012 (as amended):

- to advise Ministers and the Licensing Authority on matters relating to human medicinal products including giving advice in relation to the safety, quality and efficacy of human medicinal products where either the Commission thinks it appropriate or where it is asked to do so;
- to consider those applications that lead to Licensing Authority action as appropriate (i.e., where the Licensing Authority has a statutory duty to refer or chooses to do so);
- to consider representations made (either in writing or at a hearing) by an applicant or by a licence or marketing authorisation holder in certain circumstances; and
- to promote the collection and investigation of information relating to adverse reactions to human medicines for the purposes of enabling such advice to be given.

The CHM has 18 Commissioners, 11 EAGs, 5 EWGs with over 200 members in total involved in the Commission's work. EWGs are set up, as required, by the CHM to address specific topic areas. These are normally set up for a relatively short period.

- Infection Expert Advisory Group
- Cardiovascular, Diabetes, Renal, Respiratory and Allergy Expert Advisory Group
- Chemistry, Pharmacy and Standards Expert Advisory Group
- Clinical Trials, Biologicals and Vaccines Expert Advisory Group
- Gastroenterology, Rheumatology, Immunology and Dermatology Expert Advisory Group
- Medicines for Women's health Expert Advisory Group
- Neurology, Pain and Psychiatry Expert Advisory Group
- Oncology and Haematology Expert Advisory Group
- Paediatric Medicines Expert Advisory Group
- Pharmacovigilance Expert Advisory Group
- Sodium Valproate Expert Working Group
- Isotretinoin Expert Working Group
- Covid-19 Therapeutics Expert Working Group
- Covid-19 Vaccines Benefit Risk Expert Working Group
- Real World Data Expert Working Group
- Reclassification Stakeholder Group – high strength toothpaste

Herbal Medicines Advisory Committee (HMAC)

The HMAC and its functions were established by the Herbal Medicines Advisory Committee Order 2005 (SI 2005/2791) pursuant to the powers contained in section 4 of the Medicines Act 1968. HMAC advises on the safety, quality and efficacy in relation to human use, of:

- herbal medicinal products eligible for registration under the simplified traditional use registration procedure established under European Directive 2004/24/EC, and
- unlicensed herbal medicinal products (unless it is subject to an application for a marketing authorisation, product licence or a homeopathic certificate of registration).

The primary role of the Committee will be issues relating to safety and quality, since there is not a requirement for efficacy to be separately demonstrated in relation to registered traditional herbal medicines or unlicensed products sold under section 241 of the Human Medicines Regulations 2012. However, efficacy is still relevant - under the traditional herbal registration scheme, the pharmacological effects or efficacy of the medicinal product must be plausible on the basis of long-standing use and experience.

Committee changed on the 1st November 2012 from being an Advisory Non-Departmental Public Body (ANDPB) to an MHRA Expert Committee.

There are currently 13 members appointed by the MHRA.

Advisory Board for Registration of Homeopathic Products (ABRHP)

ABRHP was established in 1994 by the Medicines (Advisory Board on the Registration of Homeopathic Products) Order 1994 (as Amended) pursuant to the powers contained in section 4 of the Medicines Act 1968 (as amended) to:

- give advice on safety and quality in relation to any homeopathic medicinal product for human use, in respect of which a certificate of registration has been granted or applied for.
- give advice on safety, quality and indications for use within the UK homeopathic tradition in relation to any homeopathic medicinal product for human use,
 - in respect of which a marketing authorisation has been granted or has been applied for, or
 - in respect of which a licence of right has been granted.

The Board changed on the 1st November 2012 from being an Advisory Non-Department Public Body (ANDPB) to an MHRA expert Committee

The ABRHP has 9 members appointed by the MHRA.

The British Pharmacopoeia Commission (BPC)

The functions of the BPC are set out in Regulation 11 of the Human Medicines Regulations 2012 (as amended):

- preparing new editions of the British Pharmacopoeia (BP) and British Pharmacopoeia (Veterinary) (BP (Vet))
- providing advice to the United Kingdom delegation to the European Pharmacopoeia Commission
- the selection and publication of British Approved Names (BAN)

The BPC has 11 members appointed by Ministers. The BPC EAGs and Panels of Experts are generally focussed on the production of monographs for medicines and are split into specific areas. Working parties are established for specialised areas and may be for a specified time period. These include

Expert Advisory Groups

- Antibiotics
- Biological and Biotechnological Products
- Herbal and Complementary Medicines
- Medicinal Chemicals 1
- Medicinal Chemicals 2

- Medicinal Chemicals 3
- Pharmacy and Nomenclature
- Unlicensed Medicines

Panel of Experts

- Blood Products
- Excipients
- Inorganic and General Chemicals
- Microbiology
- Radioactive Materials
- Veterinary Medicines
- Veterinary Immunological Products

Working Parties

- Advanced Therapy Medicinal Products
- Analytical Quality by Design
- Alternative Approaches for Documentary and Physical Standards for Biotechnological Products

The Committee on Medical Devices (CMD)

CMD has replaced the Devices Expert Advisory Committee (DEAC). DEAC was formed following an independent review on the Medicines and Healthcare products Regulatory Agency's (MHRA) access to clinical advice and engagement with the clinical community. 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.

The Medicines and Medical Devices Act 2021 introduces a power to allow the government to establish a statutory expert advisory committee on medical devices.

UK Stem Cell Bank Steering Committee (UKSCBSC)

UKSCBSC was established in December 2002 as an independent national committee overseeing the activities of the UK Stem Cell Bank and UK research involving established human embryonic stem cell (hESC) lines, whether obtained from the bank or from elsewhere.

The role of the steering committee is to support stem cell research and to ensure that this is conducted within an ethical framework that is transparent to the public.

The Review Panel

The Review Panel is a departmental expert committee which carries out statutory and non-statutory reviews of proposals, decisions and provisional decisions taken by Medicines and Healthcare Products Regulatory Agency.

The terms of reference for the Review Panel (MHRA) are to:

- review the provisional determinations made by the Medicines and Healthcare Products Regulatory Agency (MHRA) concerning the classification of a product as a medicine

- perform the role of the 'reviewers' in relation to decisions or proposals made by the MHRA related to the grant, renewal, revocation, suspension, refusal or variation of manufacturer's or wholesale dealing licences, and UK marketing authorisations (the 'persons appointed' role)
- consider representations about decisions made in relation to advertising

Other relevant interests

4.7 It is not only financial interests in the pharmaceutical industry that are relevant. A wide range of other matters may also be considered to be relevant, depending on the circumstances and matters under consideration by a committee on which an individual serves, and could include non-financial interests. There are no hard and fast rules concerning “other” interests that need to be declared. In considering whether an interest is relevant and therefore should be declared, the guiding principle must be whether the matter might reasonably be perceived as affecting a member’s impartiality. Some examples of matters that might fall under this heading 7 are set out below. These are not exhaustive, and individuals should always seek advice from the MHRA Secretariat if they are in any doubt about whether or not a matter is relevant:

- An individual, or his department, has done research work relating to a particular product, or class of products. Although the research has not been funded by any particular pharmaceutical company, the research has taken a particular line e.g., in relation to the safety of the products, or their efficacy;
- An individual has made public statements (either favourable or unfavourable) about a particular company, or product, or class of products or about a competitor’s product or class of product;
- The relevant 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 he is a retail pharmacist and he 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, adult child no longer living in the same household, or non-family member whose work or other interests are closely associated with the pharmaceutical industry and which could reasonably be perceived as affecting the individual’s impartiality. An example might be where a committee is giving advice in relation to a product and a close family member or friend has had a major development responsibility for that product;
- Interests in a company manufacturing the delivery system (for example, syringes or other medical equipment) for a particular medicinal product;