**Expert Advisory Committees and supporting groups**

**Declaration of Interests and Confidentiality Undertakings**

**This declaration covers the period between\_\_\_\_\_\_\_\_\_\_\_\_ and \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**Information on the Code of Practice**

The Code of Practice (Code) [[link](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1103036/2022.09.07_The_Code.pdf)] sets out the rules 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. These rules must be adhered to by all chairs and members of Advisory Committees and their supporting groups. The reference to members here includes lay members and co-opted members.

In line with established practice, 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, advised to read these guidance notes on what interests need to be declared and when, and how declared interests should be recorded, before they complete the declaration form. They are also able to seek further guidance from the Committee Secretariat or the Conflict of Interest Group (where conflicts of interest are novel or complex, see section 7 of the Code).

**Summary of the types of interests that need to be declared**

Chairs and members are required to make a full declaration of interests on appointment, before each meeting and annually. The annual declaration of interests must include:

* their own 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 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’.

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| **Note 1:** 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 Committee Secretariat as soon as possible. Participation in meetings and discussions may be restricted as a result. |

The annual declaration of interests made by all chairs and members are published on [Gov.UK.](https://www.gov.uk/government/publications/human-medicines-regulations-2012-advisory-bodies-annual-report-2021) Declaration of interests made by the Chair and members of the British Pharmacopoeia Commission are also published on [Pharmacopoeia.com](https://www.pharmacopoeia.com/the-bp-Commission).

Chairs and members must also inform the Committee Secretariat promptly of any changes or updates to the terms of their declaration during the year. Following the end of an appointment, chairs and members are required to complete the declaration of interest form for that calendar year.

**Personal Interests**

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. Personal interests must be declared as either:

⦁ **specific**: any payment relating to a product under consideration, or

⦁ as **non-specific**: any payment not related to the product under discussion.

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 of the Code and in the declaration form below (see *Conferences, scientific meetings, and other events organised or sponsored by a relevant industry*).

**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.

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| **Note 2:** All chairs and members of Advisory Committees, except members of the British Pharmacopoeia Commission (BPC), are prohibited from holding personal interests in an industry whose business may be directly affected by the advice of the committee (sections 3.5 to 3.12 of the Code).  Chairs and members of supporting groups (for example, Expert Advisory Groups (EAG) and Expert Working Groups (EWG) are permitted to hold personal interests in an industry whose business may be directly affected by the advice of the committee, provided they are not also members of an Advisory Committee to which those rules apply, such as Commission on Human Medicines, Herbal Medicines Advisory Committee, Advisory Board for Registration of Homeopathic Products or the Devices Expert Advisory Committee (and its successors). However, these personal interests must be declared and may still affect participation in discussions (see section 7 of the Code).  Newly appointed chairs and members of Advisory Committees 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 the Code. During this period, they are required to declare any current relevant personal interests (section 6.8 of the Code). |

**Non-Personal Interests**

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.

Non-personal interests must be declared as:

⦁ **specific:** any payment relating to a particular product under consideration, or

⦁as **non-specific:** any payment not relating to the particular product under discussion.

The following are examples of personal interests:

**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 of the Code.*

**Other Relevant Interests**

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.

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 of ‘other relevant interests’ are set out in the Code (see sections 3.16, 3.17 and Annex 1).

**Nil Interests**

Where the Chair or member does not hold any interests, they are still required to complete the form. They can declare nil personal and/or nil non-personal interests by checking the boxes provided.

**Political Interests**

In their public roles, chairs and members of Advisory Committees should be, and seen to be, politically impartial. They should not occupy a paid party-political post or hold a particularly sensitive or high-profile role in a political party. They should also abstain from all controversial political activity and comply with Cabinet Office rules on attendance at Party Conferences. Subject to the above, they may engage in political activity but should, at all times, remain conscious of their responsibilities as members of Advisory Committees and exercise proper discretion. They should inform the Chair of the appropriate Advisory Committee and the Committee Secretariat before undertaking any significant political activity.

**Any Further Questions or Queries?**

Further assistance on declaring interests is available from the Committees Secretariat:

**Phone:** 0203 080 6060

**Email:** [CommitteeServicesTeam@mhra.gov.uk](mailto:CommitteeServicesTeam@mhra.gov.uk) or [CSTrecruitment@mhra.gov.uk](mailto:CSTrecruitment@mhra.gov.uk) when submitting an application.

**Declaration of Interests**

**Name of Member:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Name of Committee(s) or supporting group(s): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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**Date of declaration: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

***Under the guidance of the Code of Practice on Declarations of Interests, I wish to declare to the MHRA that my only interests in the relevant industry are as shown on the following pages***

**CURRENT PERSONAL INTERESTS**

**PLEASE COMPLETE IN UPPER CASE**

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| **Nil Personal Interests:** Please confirm you have nil interests by checking the adjacent box |  |

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| **Name of company** | **Period interest held or date held (month/year)** | **Name of product(s)\*** | **Nature of interest**  **(e.g. shares, fees, consultancy, salary, grants, etc.)** |
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**\****Please state if your interest is limited to a particular product or group of products.*

**CONFERENCES, SCIENTIFIC MEETINGS AND SIMILAR EVENTS ORGANISED OR SPONSORED BY A RELEVANT INDUSTRY**

**PLEASE COMPLETE IN UPPER CASE**

Expenses/Hospitality/Gifts from attendance at conferences, scientific meetings, and other events organised or sponsored by a relevant industry over the previous twelve months must be declared below. Attendance at future events 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.

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| **Note 3:** As set out in section 4 of the Code, in some cases it will be possible for chairs and members of Advisory Committees who are otherwise prohibited from holding personal interests (see Note 2 above) to attend events sponsored by a relevant industry (and accept the payment of their expenses).  **Members are able to seek further guidance on these special rules from the Secretariat.** |

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| **Nil Personal Interests (conferences, scientific meetings and similar events organised or sponsored by a relevant industry):** Please confirm you have nil interests by checking the adjacent box |  |

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| **Conference or event attended** | **Date** | **Name of**  **sponsor(s)\*** | **Nature of Benefit**  **(e.g. expenses, fees, gifts, etc.)** |
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**\****Please state if your interest is limited to a particular product or group of products.*

**CURRENT NON-PERSONAL INTERESTS**

**PLEASE COMPLETE IN UPPER CASE**

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| **Nil Non-Personal Interests:** Please confirm you have nil interests by marking the adjacent box |  |

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| **Name of company** | **Period interest held or date held (month/year)** | **Name of product(s)\*** | **Nature of interest**  **(e.g. shares, fees, consultancy, salary, grants, etc.)** |
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\* *Please state if your interest is limited to a particular product or group of products.*

**ADDITIONAL INFORMATION**

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| **Note 4**: 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.  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 of ‘other relevant interests’ are set out in the Code (see sections 3.16, 3.17 and Annex 1). |

* Please include here any information which, whilst not strictly a personal or non-personal interest within the definitions of the Code, may nevertheless be perceived to cause a conflict of interest.
* Please also include details of any personal interests in the relevant industry held by partners or any adult members of your immediate household.

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| **Nil Additional Information:** Please confirm you have nil additional information by marking the adjacent box |  |

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| **Additional Information** |
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**Confidentiality undertaking**

The chairs and members are bound by the normal rules of confidentiality in respect of any information they acquire as a result of their participation in the work of the Advisory Committees and their supporting groups. By this we mean that the proceedings of the Advisory Committees and their supporting groups are confidential, and individuals must not disclose information they obtain as a result of their participation in such meetings. Advisory Committees and supporting groups’ papers are confidential to protect commercially sensitive information supplied by companies. Regulation 332 of the Human Medicines Regulations 2012 makes it a criminal offence for you to disclose information which you receive in the course of your duties as member of an Advisory Committee or a supporting group, unless you are acting on behalf the Advisory Committee or the supporting group.

**Signature Page**

After completion of the above, please read through the below statement, then sign and date your declaration:

***I declare that the information provided is correct to the best of my knowledge and belief.***

***I will advise the MHRA of any changes to the information during my period of appointment. At the end of my appointment, I will complete the declaration of interest form for the period up to the date my appointment ended.***

***I understand that failure to disclose such information could result in my appointment being terminated.***

***I agree to inform the Chair and the MHRA before undertaking any significant political activity and to comply with the confidentiality undertaking above.***

***I confirm continued acceptance of the terms and conditions of appointment.***

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| **Signature** | **Print name** | **Date** |
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**Please return this document electronically by email to:** [**CommitteeServicesTeam@mhra.gov.uk**](mailto:CommitteeServicesTeam@mhra.gov.uk) **or** [**CSTRecruitment@mhra.gov.uk**](mailto:CSTRecruitment@mhra.gov.uk) **when submitting an application**