**Expert Advisory Committees and supporting groups**

**Declaration of Interests and Confidentiality/Media Undertaking of**

**Invited Experts, Patient Experts and Observers**

 **INSTRUCTIONS**

This form consists of three parts:

* **Personal Details**
* **Public Declaration of Interests**
* **Confidentiality/Media Undertaking of Committee Proceedings**

All parts must be duly completed.

**1. Personal Details**

Enter your full name, telephone number and the e-mail address on which you would like to be contacted regarding this declaration. All personal information provided will be kept confidential and will not be published.

**2. Public Declaration of Interests**

This section asks you to declare any personal and non-personal interests that you currently have or have had within the past 12 months which are potentially relevant to the matter(s) on which you have been invited to provide advice or observe. **See pages 8-9 for examples of what constitute personal and non-personal interests**.

|  |
| --- |
| **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 individual 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. |

Interests declared will be published with your name and affiliation on the [Gov.uk.](https://www.gov.uk/government/publications/human-medicines-regulations-2012-advisory-bodies-annual-report-2020) website and in the website minutes of the meeting. Interests declared by individuals invited to provide advice/observe the British Pharmacopoeia Commission, and its supporting groups, will also be published on Pharmacopoeia.com

**3. Confidentiality & Media Undertaking**

Read carefully the confidentiality undertaking agreement and confirm the information declared on this form by entering your full name.

**SECTION 1: PERSONAL DETAILS**

**First Name:**

**Last Name:**

**Telephone:**

**Contact e-mail address:**

**SECTION 2: PUBLIC DECLARATION OF INTERESTS**

**I hereby declare that, to the best of my knowledge, the only personal or non- personal interests I currently hold (at the time of completion of the form) or have had within the past \*twelve months which are potentially relevant to the matter(s) on which I have been invited to provide advice/observe are those listed below:**

|  |
| --- |
| \*In some circumstances it may be appropriate to continue to declare the interest for longer than the past 12 months (see **Note 1**, page 2). |

**CURRENT PERSONAL INTERESTS**

**PLEASE COMPLETE IN UPPER CASE**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **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.)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**\****Please state if your interest is limited to a particular product or group of products.*

**CONFERENCES, SCIENTIFIC MEETINGS AND SIMILAR EVENTS**

**PLEASE COMPLETE IN UPPER CASE**

Expenses/Hospitality/Gifts from attendance at conferences, scientific meetings, and other events in the past twelve months organised or sponsored by a firm in a relevant industry which has an interest in the matter(s) on which you are invited to provide advice/observe must be declared below.

|  |  |
| --- | --- |
| **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 |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Conference or event attended** | **Date** | **Name of** **sponsor(s)\*** | **Nature of Benefit****(e.g. expenses, fees, gifts, etc.)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

**\****Please state if your interest is limited to a particular product or group of products.*

**CURRENT NON-PERSONAL INTERESTS**

**PLEASE COMPLETE IN UPPER CASE**

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

|  |  |  |  |
| --- | --- | --- | --- |
| **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.)** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

*\* Please state if your interest is limited to a particular product or group of products.*

**ADDITIONAL INFORMATION**

* 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 an industry which is relevant to the work of the committee held by partners or any adult members of your immediate household.

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

|  |
| --- |
| **Additional Information** |
|  |

**This information is correct to the best of my knowledge and belief. I will advise the Medicines and Healthcare products Regulatory Agency of any changes to this information.**

**SECTION 3: CONFIDENTIALITY & MEDIA UNDERTAKING**

Any data placed before the committees is of a highly confidential and commercially sensitive nature. The Medicines and Healthcare products Regulatory Agency is under an obligation to prevent any unauthorised disclosure of such information.

**I acknowledge the statement above and confirm that I will abide by the rule that the proceedings of the committee are confidential and will not be disclosed outside of the meeting.**

The work of committees often has a high media profile and enquiries are common. Unless a committee is in session, standing arrangements are for the Chair to decide the "line to take" in consultation with the secretariat and press advisor. **Individuals present at the meeting must not discuss committee business with the media but should refer enquiries to the Chair or Secretariat.**

**I have noted the statement above and confirm that I will channel all media enquiries to the committees’ Secretariat.**

**I confirm the information declared at sections 1, 2 and 3 is accurate to the best of my knowledge and I consent to my information being stored electronically and my name and interests being published on the Gov.com website (and on the Pharmacopoeia.com website for the British Pharmacopoeia Commission, and its supporting groups) as part of summary minutes and annual report of the relevant committee (normally published in July).**

**FULL NAME:**

**DATE:**

**SIGNATURE:**

**Information on the Code of Practice for individuals involved with Advisory Committees**

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 individuals involved with the Advisory Committees and their supporting groups.

|  |
| --- |
| **Note 2:** Invited Experts and Patient Experts are required to declare any interests in the matter(s) on which they have been invited to provide advice.  |

|  |
| --- |
| **Note 3:** Observers are required to declare any interests in the matter(s) under consideration at the committee discussion that they have been invited to observe. |

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. Individuals 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 Secretariat (see section 7 of the Code).

**SUMMARY OF TYPES OF INTERESTS TO BE DECLARED BY INVITED EXPERTS, PATIENT EXPERTS AND OBSERVERS**

 **Personal Interests**

These are financial interests that involve a payment, in any form, to an individual personally, from afirm in a relevant industry that has an interest in the matter(s) on which the individual is invited by the committee to provide advice or observe. Personal interests must be declared as:

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

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

|  |
| --- |
| **Note 4:** Relevant Industry is defined as an industry, or industries, whose business may be directly affected by the advice of the committee, such as the pharmaceutical industry for the Commission on Human Medicines, British Pharmacopoeia Commission, the Herbal Medicines Advisory Committee and the Advisory Board for Registration of Homeopathic Products; the medical device industry for Devices Expert Advisory Committee; the biotechnology industry for United Kingdom Stem Cell Bank Steering Committee. |

Examples include:

**Consultancies:** any consultancy, directorship, position in or work for a firm in a relevant industry that has an interest in the matter(s) on which the individual is invited to provide advice/observe which attracts regular or occasional payments in cash or kind;

**Fee-paid work:**  any work commissioned by a firm in a relevant industry that has an interest in the matter(s) on which the individual is invited to provide advice/observe for which the individual is paid in cash or kind;

**Shareholdings:** any shareholding in or other beneficial interest in a firm in a relevant industry that has an interest in the matter(s) on which the individual is invited to provide advice/observe. 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 afirm in a relevant industry that has an interest in the matter(s) on which the individual is invited to provide advice/observe.

**Unit trusts and similar:** 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. However, 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.

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

**Non-Personal Interests**

A non-personal interest involves payment that benefits a department for which an individual is responsible. This payment is not received by the member personally. 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.

Examples include:

***Fellowships:*** the holding of a fellowship endowed by a firm in a relevant industry that has an interest in the matter(s) on which the individual is invited to provide advice/observe;

***Support by a firm*** in a relevant industry ***that has an interest in the matter(s) on which the individual is invited to provide advice/observe:*** any payment, other support or sponsorship that does not convey any pecuniary or material benefit to the individual personally but that benefits his/her position or department;

***Grants from a firm*** in a relevant industry ***that has an interest in the matter(s)*** ***on which the individual is invited to provide advice/observe:*** for example, for the running of a unit or department for which an individual is responsible;

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

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

**Other Relevant Interests**

It is not only financial interests in a firm in a relevant industry with an interest in the matter(s)on which the individual is invited to provide advice/observe 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 individual invited by the Advisory Committee to provide advice/observe 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.

**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 or CSTrecruitment@mhra.gov.uk when submitting an application.