



Medicines & Healthcare products Regulatory Agency

Policy on Declaring and Managing Interests for Members of the MHRA Unitary Board

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1. INTRODUCTION / PURPOSE

- 1.1 This policy sets out the rules to be followed by the members of the MHRA Unitary Board (herein known as the Board) holding and declaring interests in the pharmaceutical and medical devices industry. The policy also provides guidance on holding and declaring other relevant interests, and on how interests that have been declared will be managed.
- 1.2 This policy supports a culture in which we are transparent about the interests of Board members, so that the effect of interests is known, understood and managed.

2. SCOPE

- 2.1 This policy applies to all members of the Board: both Non-Executive Directors and Executive Directors, in the latter case, in the context of the Board meetings.
- 2.2 Separate policies apply to Executive Directors and other members of staff, as well as members of expert advisory committees.
- 2.3 The Chair is responsible for taking the final decision on how declared interests should be handled. Where the interest is declared by the Chair, the responsibility lies with the Deputy Chair in consultation with the Board Secretary as appropriate. If it is necessary, legal advice may be sought from DHSC Legal advisers on any interest.

3. INTERESTS WHICH NEED TO BE DECLARED

- 3.1 It is the responsibility of each individual to identify and to declare all relevant interests. The following types of interest must be declared by the Chair and members of the Board:
 - Their own financial interests in or payments from the pharmaceutical and medical devices industry or other relevant industries (financial interests are either personal or non-personal, and either specific to a product being discussed, or non-specific);
 - Financial interests in the pharmaceutical and medical devices industry held by members of their immediate family;
 - Any business interests or positions of authority outside of their role in the MHRA regardless of whether they are linked to the health sector or not

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

3.2 At a meeting, personal interests must be declared as specific (that is, payment relates to a particular product under consideration), or as non-specific (that is, not related to the particular product under discussion).

Definitions

3.3 “Medical Device Industry” and “Pharmaceutical Industry” are defined as:

- Companies, partnerships or individuals who are involved in the manufacturing, supply, selling, offering to supply, storage, importing, or exporting of medical products (encompassing medical devices and medicinal products), active substances, excipients, parts, materials and accessories.
- Trade associations representing companies involved with such products.
- Companies, partnerships or individuals who are directly concerned with research, development or marketing of a medical product and medical devices which is being considered by the Agency.

3.4 “Immediate family” is defined as a spouse or partner and members of the family living in the same household.

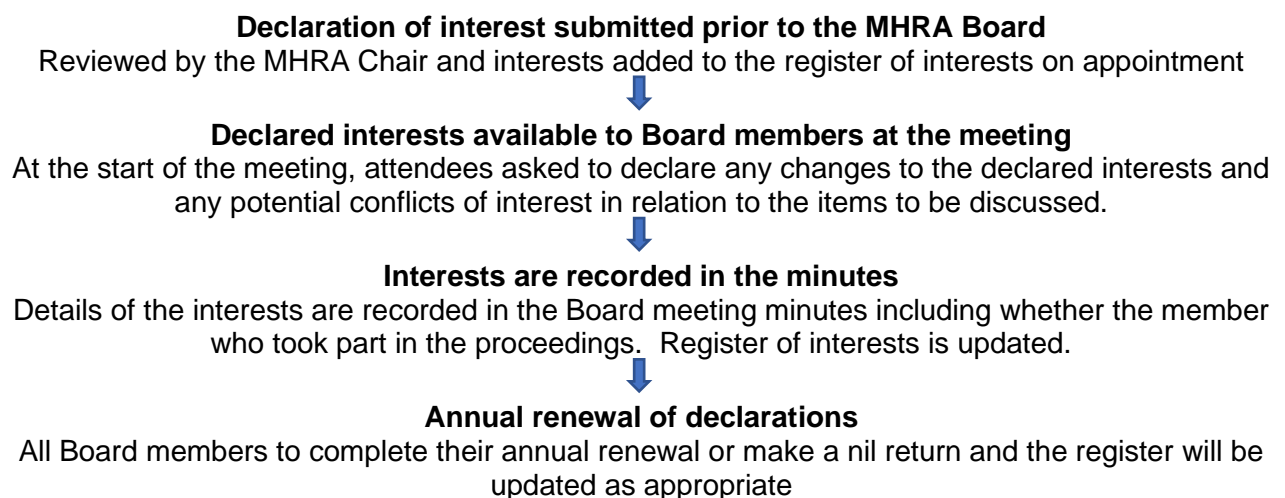
4. DECLARATION OF INTEREST

4.1 The Chair and Board members are required to make a full declaration of interests on appointment and annually. They must also inform the Board Secretary promptly of any changes or updates to the terms of their declaration during the year. If an individual is uncertain as to whether or not an interest should be declared, he or she must seek guidance from the Board Secretary.

4.2 The Chair and members are also required to make further declarations of relevant interests at meetings, where they will be advised as to the procedure that will apply.

4.3 The declaration of interest form is available in **Annex A**.

4.4 The process for declaring interests is as follows:



Annual declaration

- 4.5 Each year every Board member must make an annual declaration. This must cover:
- all the financial (personal and non-personal) interests in the medical devices and/or pharmaceutical industry of the Chair and members currently held or held in the last 12 months;
 - financial interests in the medical device and/or pharmaceutical industry that they know of that are held by their immediate family.
 - any business interests or positions of authority outside of their role in the MHRA regardless of whether they are linked to the health sector or not
- 4.6 Board members and the Chair are also required to include in the annual declaration details of any other matter which could reasonably be regarded as affecting their impartiality.
- 4.7 A member must declare a personal specific interest if an individual has worked on a product under consideration and is receiving or has received payment for that work.

Declarations at meetings

- 4.8 At any time in the year, if the Chair or members become aware of a matter on which any discussion at Board meetings could be regarded as affecting their impartiality, they must alert the Board Secretary. This will ensure that the Board Secretary can withhold any papers on such matters from that member.
- 4.9 On receipt of papers, if the Chair or members realise that there is a matter for discussion which could call into question their impartiality, they must immediately alert the Board Secretary who will note that this member will leave the meeting for this part of the agenda.
- 4.10 At the beginning of each Board meeting, the Chair and members are required to declare relevant interests, whether or not those interests have previously been declared to the Agency.
- 4.11 If an issue arises for discussion during the meeting on which the individual believes could call into question their impartiality, they should immediately speak up, excuse themselves from the discussion and leave the meeting.
- 4.12 The Chair is responsible for taking the decision on how declared interests should be handled (where the interest is declared by the Chair, the responsibility lies with the Deputy Chair in consultation with the Board Secretary as appropriate).

5. PARTICIPATION IN DISCUSSIONS WHEN AN INTEREST HAS BEEN DECLARED

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

Personal Interests

- 5.2 The Chair and Board members' declaration of their own interests will identify them with the interests declared, but the interests declared do not need to be quantified.
- Involvement in the development of a product will usually debar an individual from ever participating in discussion on that product. A less significant involvement, or less specific work with or on a product, may not permanently debar an individual, but such decisions will

need to be taken on a case by case basis, taking account of the nature of the involvement, its specificity and when the work was undertaken.

- If an individual has declared a personal non-specific interest the individual must take no part in discussions on that agenda item, except at the Chair's discretion to answer questions from other members.
- If the individual has declared a personal interest in relation to a member of his or her immediate family, he or she should similarly take no part in discussions except at the Chair's discretion to answer questions from other members. Such interests may range from a family member's major role in the development of a product under consideration to a family member's shareholdings.
- A member must declare a non-personal specific interest if the organisation for which the individual is responsible is currently receiving payment in respect of work done on the device and/or product. The individual will generally not be able to take part in proceedings where an organisation for which they have responsibility, has carried out specific work on the product under discussion.
- A member must declare a non-personal, non-specific interest if their organisation is currently receiving payment which does not relate to the product under discussion. Such an interest will not normally debar an individual from taking part in discussions, unless exceptional circumstances arise in which it is not appropriate for them to do so.
- If an individual declares non-personal interests of an immediate family member, this will not generally prevent him or her from taking part in discussions.

Non-Personal Interests

- 5.3 When the annual declaration includes matters relating to other persons, names are not required, nor do the interests declared need to be quantified. For example, in declaring shareholdings only the company name is required, not the numbers or values of shares held. Family members should be referred to simply as: "immediate family member" and closely connected persons as "other person". In nearly all circumstances this will protect the anonymity of those whose interests must be declared by the serving committee member, although we recognise that in very exceptional circumstances it may be possible for that individual to be identified.

Interests of the Chair

- 5.4 For the purposes of paragraph 6.1 to 6.3, if the interest in question has been declared by the Chair, the discretions referred to in those paragraphs should be exercised by the Deputy Chair in place of the Chair in consultation with the Board Secretary as appropriate. Where the Chair has declared an interest, he should step down as Chair for the agenda item to which the declared interest relates.

6. RECORDS AND PUBLICATION

- 6.1 All declared interests that are relevant or could be perceived to be relevant to MHRA's work will be entered onto the register of interests.
- 6.2 The annual declaration made by the Chair and members of the Board will be published each year in the MHRA Annual Report.
- 6.3 The register of current interests for Board members will also be published on the MHRA page on GOV.UK.

7. REVIEW

7.1 This policy will be reviewed every 3 years unless an earlier review is required.

Board COI Policy – Annex A: Declarations of interest form

2020-21

MHRA Unitary Board member – Register of interest form

Name				
Name of company / organisation	Nature of interest / role	Personal (ie remunerated) or Non-Personal	Specific (ie individual product) or Non-Specific	Current Interest Now or in Last 12 Months

Signed

Date

Board COI Policy – Annex B: Examples of interests to be declared

1. Personal interests

1.1 A personal interest in the context of this policy, involves the payment, in any form, to an individual personally, by a pharmaceutical or medical devices company whose business may be directly affected by decision of the Board.

1.2 At a meeting, personal interests must be declared as **specific** (that is, payment relates to a particular product under consideration), or as **non-specific** (that is, not related to the particular product under discussion).

1.3 The following main examples of interests to be declared should not be regarded as a definitive list, and the Board Secretary will advise (with legal advice if necessary) if the Chair or any Board member is in any doubt.

- **Consultancies:** any consultancy, directorship, position in or work for the pharmaceutical or medical devices industry which attracts regular or occasional payments in cash or kind;
- **Fee-paid work:** any work commissioned by the pharmaceutical and medical devices industry for which the individual is paid in cash or kind;
- **Shareholdings:** any shareholding in or other beneficial interest in the pharmaceutical and medical devices industry. This does not include shareholdings through unit trusts or similar arrangements where the individual has no influence on financial management;

- **Expenses/hospitality provided by a pharmaceutical or medical device company:** special rules apply to attendance at conferences or similar events. These are covered in the last section of this annex.
- **Unit trusts and similar:** Assets over which the Chair 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 Chair and Board 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 pharmaceutical or medical devices industry do not need to be declared.**

2. Non-personal interests

2.1 A non-personal interest in the context of this Policy, involves payment that benefits a department for which an individual is responsible, but is not received by the member personally. As with personal interests, non-personal interests at a meeting must be declared as specific or non-specific. The main examples that follow should not be regarded as a definitive list, and the advice of the Board Secretary should be sought if the Chair or any Board member is in any doubt.

- **Fellowships:** the holding of a fellowship endowed by the pharmaceutical industry or medical device industry;
- **Support by the pharmaceutical industry or medical device industry:** any payment, other support or sponsorship by the pharmaceutical or medical device industry that does not convey any pecuniary or material benefit to the individual personally but that benefits his/her position or department;
- **Grants from a company:** for example, for the running of a unit or department for which an individual is responsible;
- **Grants or fellowships to sponsor a post or staff member in the unit for which the individual is responsible:** this does not include financial assistance given to individual students;
- **Commissioning of research or other work or advice from staff who work in a unit for which the individual is responsible;**
- **Conference, scientific meeting or other meeting attendance funded by the pharmaceutical or medical device industry.**

3. Other relevant interests

3.1 It is not only financial interests in the medical device and/or 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 the Board, and could include any business interests and positions of authority outside of your role in the MHRA.

3.2 There are no hard and fast rules concerning “other” interests that need to be declared. The legal rule against bias in the decisions and proceedings of public bodies can be stated as follows: if a fair-minded and informed observer would conclude, in all the circumstances, that there is a real possibility of bias, the Board member should not take part in proceedings. It is therefore not relevant that the Board member themselves believes that they are unbiased, impartial or has an open mind.

3.3 In considering whether an interest is relevant and should be declared, the guiding principle must be whether the matter might reasonably be perceived as possibly affecting a Board member's impartiality. Members of the Board should always seek advice from the Board Secretary if they are in any doubt about whether or not a matter is relevant. The Board Secretary will seek legal advice if necessary.