

HPRA Patient Forum Consideration of potential conflicts of interests

1 INTRODUCTION

Given the nature of the HPRA's regulatory functions and responsibilities, particular care is taken to ensure the impartiality, objectivity, integrity and transparency of our activities. Managing potential conflicts of interest is an important part of this process to ensure that the public can have confidence in our work.

With this in mind, members of the patient forum are requested to give due consideration to any potential conflicts of interests and declare any relevant interests prior to each meeting.

2 EMPLOYMENT BY AN ENTITY REGULATED BY THE HPRA

As per the terms of reference for the patient forum, members of the patient forum must not be currently employed by an entity regulated by the HPRA. This is considered to be part of the eligibility criteria for membership of the patient forum. If a member of the patient forum intends to take up such employment, this should be declared and the member will no longer be part of the patient forum.

3 INTERESTS TO BE DECLARED

Prior to each meeting, members of the patient forum should consider whether they have any interests to declare that are relevant to any of the items on the agenda. Interests to be considered would include:

- Financial interests (e.g. stocks, shareholdings) in a company or organisation regulated by the HPRA currently held by the member themselves or a close family member (i.e. their spouse, partner, children or parents)

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- Employment or payment received for work done on behalf of a company/organisation regulated by the HPRA within the past three years for the member themselves or current employment for a close family member
- Involvement in the development of a product (e.g. a medicinal product or medical device) that is regulated by the HPRA
- Funding provided within the past three years by a company/organisation regulated by the HPRA to an organisation in which the member is involved (e.g. patient representative organisation) to support the work/activities of that organisation*
- Other interests, matters or connections that could be reasonably perceived by others as potentially affecting the individual's impartiality
- * All patient organisations who are represented in the patient forum will also be requested to make an annual declaration of funding received from companies/organisations regulated by the HPRA.

The agenda for each meeting will be circulated one week in advance of each meeting to enable members to consider whether they have any interests that are relevant to the agenda items. If a member has any interests to declare relating to any of the agenda items, a description of the interests with details of the relevant companies/organisations or products should be forwarded to the HPRA (scientificaffairs@hpra.ie) and the chair of the patient forum for consideration as soon as possible and in any event at least two working days in advance of the patient forum meeting.

Alternatively if preferred, the member may choose to simply exclude themselves from the relevant agenda item by stating that they have an interest at the start of the meeting and leaving the meeting for the duration of the relevant agenda item; this will then be recorded in the meeting minutes. If intending to follow this approach, members are requested to advise the chair of the patient forum in advance of the meeting.

4 CONSIDERATION OF ANY DECLARED INTERESTS

On receipt of any declaration of interests, the chair of the patient forum in conjunction with the HPRA and the patient forum member will consider any potential for a conflict of interest to arise taking into account:

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- a) the nature of the interest,
- b) the terms of reference of the patient forum and the nature of the agenda item,
- c) the relevance of the interest to the agenda items, and
- d) the principles outlined in the HPRA's conflicts of interest policy.

In the event that there is considered to be a potential conflict of interest, the member will be asked in advance of the meeting not to take part in the discussion relating to the relevant agenda item(s). This will be noted at the start of the meeting and recorded in the meeting minutes.

Alternatively, if it is considered that no action is required based on the declared interest, the rationale for this will be documented and saved with the record of that meeting.

5 QUERIES

If any members of the patient forum have queries in relation to declarations of interests, these may be sent to scientificaffairs@hpra.ie.

HPRA

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