

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.

