

5th November 2020

Guidance from the HPRA in relation to Advisory Boards

Advisory Board meetings can serve a legitimate purpose in the development of medicinal products and related areas, and it is acceptable for companies to arrange Advisory Board meetings and to pay healthcare professionals and others for advice on subjects relevant to their products and activities.

The HPRA supports the role of self-regulation in relation to the conduct of such meetings. Notwithstanding this, the HPRA also intends to monitor the conduct of such meetings on an occasional basis to check that the provisions of the Medicinal Products (Control of Advertising) Regulations, 2007, are complied with. This will likely involve HPRA staff attending such meetings, in an observational / regulatory capacity.

The HPRA considers that the following should be ensured before any Advisory Board meeting takes place:

In relation to the Nature and Purpose of the meeting:

- Advisory Boards should only be held to enable companies to answer legitimate questions to which they do not already know the answer. The meeting should have a clear and documented purpose, and the nature of the advice that is being sought by the sponsor of the meeting should be clearly documented and made known to the attendees in advance.
- The agenda should allow adequate time for discussion.
- The meeting should not in any way be promotional in content or promotional in its design or in its arrangements.
- During such meetings, the sponsor of the meeting should take action in situations where an advisor has made verbal statements at the meeting about a medicinal product which contradict, or are not in line with, the authorised Summary of Product Characteristics for the product, if one is in place. The sponsor should use their professional judgement when deciding how to react to such statements, but the goal of their action should be that the other attendees are not misled (intentionally or unintentionally) about the benefits or risks associated with a medicinal product.
- Invitations to participate in an Advisory Board meeting should state the purpose of the meeting, the expected advisory role for the attendees and the expected amount of work to be undertaken by them. The persons at the sponsor company who determine whom should be invited to attend such meetings should have the necessary expertise to do that task, taking into account the purpose of the meeting.

- The content of such meetings should relate solely to the matter at hand. Discussions of clinical data about a particular medicine should only take place at an Advisory Board if such discussion is essential to meet the stated objectives of the meeting. To do otherwise might risk the meeting being viewed as a disguised promotion for that medicine or as the promotion of an unlicensed medicine or indication.
- The choice and number of participants should stand up to independent scrutiny; participants should be chosen according to their expertise such that they will be able to contribute meaningfully to the purpose and expected outcomes of the meeting.
- The number of Advisory Board meetings on a particular topic and the number of participants at each should be limited to no more than the number required to achieve the stated objectives. Multiple Advisory Boards on the same topic should be avoided unless a clear need can be demonstrated. (The number of participants should also be limited so as to allow active participation by all and should not be driven by the invitees' willingness to attend.)

In relation to Inducements and Hospitality:

- The arrangements for such meetings should comply with the inducements and hospitality provisions of Regulation 21 of the Medicinal Products (Control of Advertising) Regulations, 2007. This regulation states the following:

21. (1) A person shall not, in the course of promoting medicinal products to persons qualified to prescribe or supply such products, supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy.

(2) Notwithstanding the provisions of paragraph (1), a person may offer hospitality at sales promotion events or at other events for purely professional and scientific purposes, provided such hospitality—

(a) is reasonable in level,

(b) is strictly limited to the main purpose or scientific objective of the event, and

(c) is not extended to persons other than health professionals.

(3) A person qualified to prescribe or supply medicinal products shall not solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality, sponsorship, or any other inducement, where the provision of such is prohibited by paragraphs (1) and (2) of this Regulation.

- The hospitality should be limited to refreshments/subsistence (meals and drinks), accommodation (if warranted), genuine registration fees and the payment of reasonable travel costs.

- The venue should be appropriate and conducive to the purpose of the meeting - lavish, extravagant venues should be avoided.
- The subsistence associated with the meeting should be secondary to the nature of the meeting, and it should be appropriate and not out of proportion to the occasion.
- Spouses and other accompanying persons, unless qualified as above, may not attend the actual meeting and may not receive any associated hospitality at the company's expense; the entire costs which their presence involves should be the responsibility of those they accompany.

In relation to Expenses and Fees:

- The payment of fees and expenses, including travel, to those attending advisory board meetings is permitted. Honoraria should relate to the services or advice sought from the attendees and should not be offered or provided to compensate merely for the time in attending such meetings.
- If an honorarium is offered, it should be made clear that it is a payment for such work and/or advice. It should be commensurate with the time and effort involved and with the professional status of the recipient. The compensation provided for the services should be reasonable and reflective of the fair market value of such services.
- Where medical consultants are used to help organise or run Advisory Board meetings, there should be a written contract or agreement in place with them, specifying the services the consultant is expected to provide, and the fees and other arrangements for same.
- The use of a medical consultant to provide the relevant service should not be an inducement to them to prescribe, supply, administer, recommend, buy or sell any medicinal product.
- For meetings held in person, the payment of travel expenses and the like for persons accompanying an advisor but not attending the meeting should not be permitted.
