

Fees for Services

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Preamble

The *Ethos* of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) is centered on trust to “act with integrity and honesty to improve patient care and build trust with those we serve and to respect the independence of healthcare providers, patients, and other stakeholders.” The purpose of this document is to provide additional interpretation and further guidance toward the relevant provisions of the Code of Practice. This Note for Guidance is not binding by itself. It must be read with the spirit of the Code in mind and always in accordance with applicable laws and regulations and other applicable industry codes. IFPMA member companies and member associations and anyone acting on their behalf are encouraged to take into account the considerations given in this Note for Guidance when implementing the IFPMA Code of Practice in their daily practice. The overall intention of this Note for Guidance is that the cooperation between companies, healthcare professionals (HCPs), and other stakeholders is always based on high ethical standards and clearly aims to benefit patients.

Introduction

Pharmaceutical companies can remunerate HCPs and others (called together “consultants” for the purpose of this Note for Guidance) for advice on subjects relevant to their products or business. Payment of fees for services is covered in Article 7.4 of the IFPMA Code of Practice including the requirement for a legitimate need for the service and that a written contract is agreed in advance. Fees for services can include many activities such as speaking at and/or chairing meetings and events, involvement in medical/scientific studies, clinical trials or training services, participation in advisory board meetings, participation in market research. If a fee for service is offered it should be made clear that it is a payment for such work and advice. Fees for services must be commensurate with the time and effort involved the knowledge, expertise, and the professional status of the recipients. Article 7.4 of the IFPMA Code requires that remuneration must be reasonable and reflect the fair market value of the services provided. Account should be taken of the country of practice of each participant.

Practical guidance – points to consider

The IFPMA considers that the following points are helpful to ensure that fee for service

arrangements meet the required standards and that the relevant information is available to those assessing proposals. The points to consider reflect what information might be pertinent in the event that a company has to respond to a complaint.

The answers to the following questions should be ‘yes’:

1. Are all those involved with the fee for service activity (company staff, third parties, consultants) clear on the need for it and expected output?
2. Has the company evaluated the selection criteria of consultant(s), to ensure suitability and relevant qualifications?
3. Are the consultants being paid no more than ‘fair market value’ for the services provided?
4. If the service relates to an unlicensed/unapproved medicine/indication, is the company confident that there is no promotion of that medicine/indication?
5. Has it been checked that this is a service provided to the company? (For example, a department head training his/her own team is part of the consultant employment/usual duties and is not considered a service to the company).
6. Are the arrangements (such as venue, refreshments, travel, and contract) appropriate?
7. Are there arrangements to manage any conflicts of interest and ensuring transparency of relationship?
 - a. Does the agreement with the consultant require the participant to obtain authorization from his/her regular employer or other consents as applicable (e.g. authorization to perform the service during the working time dedicated to his/her employer entity)?
 - b. Does the agreement with the engaged consultant specify his/her obligation to declare that he/she is a consultant to the company when he/she writes or speaks about a subject matter covered by this agreement?
 - c. Does the presentation from the speaker or publication by the consultant include the disclosure of the name of the company(ies) he/she has been engaged by for providing the service?
8. Are the number of engagements and total remuneration paid to an individual in one year reasonable?
 - a. Did the company introduce measures to ensure acceptable frequency of engagement of HCPs and total HCP payments, to ensure reasonableness and avoid risk of perceived undue influence? As an example, those measures may be: i) internal procedures that include limits or CAPS; ii) including in the agreements a statement of responsibility that the amount received from the

company during the year does not exceed a certain percentage of his/her annual income.

- b. Are the same consultants being hired/used excessively when there are others with the same expertise and availability?

Practical Guidance – additional points to consider for advisory boards

One example of a fee for service activity is advisory boards, which are used by the pharmaceutical industry when necessary to answer legitimate business questions to which the company does not already know the answer.

Advisory board meetings must meet the requirements for meetings in Article 7 of the IFPMA Code including that the meeting is held in an appropriate venue conducive to the business purpose of the meeting and that hospitality is moderate and reasonable as judged by local standards.

To be considered a legitimate advisory board the choice and number of consultants should stand up to independent scrutiny; each consultant should be chosen according to their expertise only, such that they will be able to contribute meaningfully to the purpose and expected outcomes of the meeting. The number of consultants should be limited so as to allow active participation by all and should not be driven by the invitees' willingness to attend. The agenda should allow adequate time for discussion and must focus on gaining advice. The number of meetings and the number of consultants at each meeting should be dictated by need i.e. both should be strictly limited to no more than the number required to achieve the stated objective. Multiple advisory boards on the same topic should be avoided unless a clear need can be demonstrated. Companies should determine if and when advisory board meetings are required. Invitations to participate in an advisory board meeting should state the purpose of the meeting, the expected advisory role, and the amount of work to be undertaken.

The content of advisory board meetings should relate solely to the matter in hand. Discussion of clinical data about a particular medicine should only take place at an advisory board if such discussion is essential to meet the stated objective. To do otherwise might risk the meeting being viewed as disguised promotion for that medicine or promotion of an unlicensed medicine or indication.

A record of the meeting should be prepared, to include the meeting's objectives, attendees, and outcomes. The meeting report and conclusions should only be shared with those who have a legitimate interest in the outcomes of the advisory board.

In addition to the points above, IFPMA considers that the following points are helpful to ensure that advisory boards meet the required standards.

The answers to the following questions should be 'yes':

1. Does the company have a legitimate unanswered business question?
2. Is an advisory board the most appropriate way of obtaining the information?
3. Has the company wholly and solely determined its need for the advisory board?
4. Is the number of delegates/meetings strictly limited to that required to answer the question?
5. Does every consultant have the relevant expertise to contribute meaningfully to the purpose and expected output of the meeting?
6. Is the number of consultants limited so as to allow active participation by all?
7. Does the agenda allow adequate time for discussion? Is a significant majority of the time spent on feedback from the consultants?
8. Does the invitation to consultant clearly state the purpose of the meeting, the expected advisory role, and the amount of work to be undertaken?
9. Are intended presentations to consultants relevant to their role in answering the business question?

Companies should ensure that the following questions are also considered:

1. Could the information be obtained any other way?
2. Are the consultants expected to do any preparatory work?
3. How were the consultants selected?
4. Who from, or on behalf of, the company is attending? Can their attendance be justified? Do they have a defined role and is the ratio of company employees/others to consultants reasonable?
5. How are the outcomes documented? What use will be made of the conclusions/recommendations report?
6. When advisory boards for the same medicine/therapy area have already taken place are there clear reasons for another one?
7. What follow-up, if any, is to be undertaken with consultants? If so, is this appropriate given the non-promotional nature of advisory boards?