

## Recommendations for Advisory Boards

### A. General Guidelines

- A.1. Advisory Boards, also Consulting Boards, are an essential source of information for pharmaceutical companies, drawing upon the specialized knowledge of experts (such as physicians or other members of the medical profession, etc.) concerning certain diseases and hands-on practical experience with approved therapies. At the same time, further therapeutic inquiries (e.g. a therapy options not yet medically fully established, opportunities for improving therapies, etc.) and issues regarding future therapies can be discussed within the framework of Advisory Boards.
- A.2. To the extent that physicians or other healthcare professionals serve on Advisory Boards, they are subject to the general provisions of the FSA Code of Conduct Healthcare Professionals. The guidelines governing compatible collaboration can be found in Article 18 FSA Code of Conduct Healthcare Professionals. In addition, the FSA Code of Conduct Healthcare Professionals contains specific restrictions with respect to the promotion of non-approved drugs and indications (Article 9 FSA Code of Conduct Healthcare Professionals). For the staging of events, which also includes meetings of Advisory Boards, there are also additional concrete guidelines in Article 20 FSA Code of Conduct Healthcare Professionals.
- A.3. The establishment of Advisory Boards initially requires that there be a clearly-defined and unequivocally comprehensible need for information or advisory in the company, which cannot be adequately covered by the company's in-house expertise alone. The experts involved must be able to contribute to the relevant issues based on their scientific knowledge or other expertise (Article 18 Section 1 FSA Code of Conduct Healthcare Professionals). The selection of the experts enlisted must not exceed the demand to answer the specific question. This demand must be justified on a case-by-case basis and depending on the respective issues. This also applies to the number of such meetings.
- A.4. The experts involved in the Advisory Board are allowed to be adequately remunerated in proportion to their contribution to the Advisory Board (Article 18 Section 1 Item 6 FSA Code of Conduct Healthcare Professionals). The company must document the contractual relationship, the services rendered and document the considerations on adequate remuneration. The company must also utilize the results derived from the Advisory Board in a suitable manner and document this as well (Article 18 Section 1 Item 5 FSA Code of Conduct Healthcare Professionals).
- A.5. In the discussion of drugs or indications that are not, or not yet, approved, the restrictions specified in Section 9 FSA Code of Conduct Healthcare Professionals (and Article 3a Medicinal Products Advertising Act) may continue to apply.
- A.6. Beyond the requirements already mentioned, the selection of a conference hotel for Advisory Boards, for example, should only be based on objective criteria. One such reason, for example, is not the leisure value of the conference venue. In addition, companies should avoid conference hotels that are known for their entertainment value

or are considered extravagant (Article 20 Section 3 FSA Code of Conduct Healthcare Professionals). If hospitality is provided to participants at such meetings, it must be appropriate and is not allowed to exceed the maximum value limit (Article 20 Section 3 FSA Code of Conduct) set by the FSA Board of Management (as of February 2018: EUR 60 including VAT for food and beverages).

## **B. Questions concerning the evaluation of the actual existing need for information and advisory**

The following questions can help to determine whether a planned measure is in line with the above criteria or which specific aspects may require further discussion. In this, the specific guidelines of the respective codes of conduct are always to be taken into consideration as well:

The answer to the following questions should be "Yes". If the answer is "No" to any of the questions, this could indicate a compliance problem and the planned Advisory Board should once again be internally reviewed concerning this aspect/these aspects prior to implementation:

1. Is there an insufficiently-met or not fully met need for information in the company intending to set up an Advisory Board that cannot be sufficiently or fully met solely through available in-house expertise?
2. Is an Advisory Board for addressing the questions raised under Item 1 the most suitable way of covering the existing need for information? Were the objectives of the Advisory Board described by the company in sufficient detail during the planning phase?
3. Does each of the Advisory Board members have adequate expertise, scientific or other knowledge necessary to make a meaningful contribution towards the fundamental issue?
4. Is the number of experts involved selected in such a way that it is not larger than the actual need to answer the specific question?
5. Has the number of Advisory Boards been limited to such an extent that no more meetings are staged than are necessary to address the specific issue?
6. Does the invitation to the Advisory Board clearly raise the issue to be discussed, the requirements of the invited advisor and the anticipated scope of the advisory requirement?
7. Does the agenda of the Advisory Board provide sufficient time for discussion of the issue? Is sufficient time provided for the feedback of the advisors to be discussed?
8. To the extent that advisors are remunerated for their participation on the Advisory Board, is the anticipated remuneration totally reasonable?

In addition to questions 1-8, the following questions may help to further evaluate the admissibility of an Advisory Board. If the answer is "No" to any of the questions, this could indicate a compliance problem and the planned Advisory Board should once again be internally reviewed concerning this aspect/these aspects prior to implementation:

9. Has the question been examined whether any of the Advisory Boards already being planned in the company are overlapping in scope to the extent that there is no longer any necessity to establish an additional Advisory Board?
10. To the extent that the specific advisory topic involves drugs or indications that are not, or not yet, approved, have the rules in Article 9 FSA Code of Conduct Healthcare Professionals (and of Article 3a Therapeutic Products Advertising Act) been sufficiently evaluated?
11. Is there clarity among all persons involved (company employees, agencies and consultants that may have been called in) concerning the concrete need for advisory and the planned outcome of the Advisory Board?

Furthermore, companies should ensure that the following questions have been sufficiently taken into consideration in the planning of Advisory Boards:

12. Are the advisors' reimbursed expenses (e.g. for travel and accommodation costs, etc.) reasonable?
13. What criteria were used for selecting the advisors involved?
14. Which employees of the company extending the invitation participate in the Advisory Board and what were the criteria by which they were selected? Do these employees perform a previously-defined task in the Advisory Board, and is the relationship between company employees and advisors involved reasonable in terms of the specific advisory topic?
15. Will there be a summary/an outcome of the Advisory Board? How will the outcome of the Advisory Board continue to be utilized within the company?
16. Have there been comparable Advisory Boards concerning the specific drug/therapeutic field in the recent past (e.g. within the past twelve months)? If so, what is the objective rationale that requires the formation of another Advisory Board?

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