



Pharmaceutical advisory boards

— a guide to organising successful
and compliant advisory boards

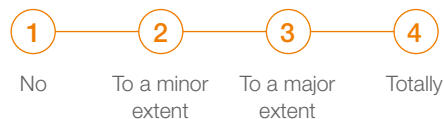
How compliant are
your advisory boards?



Compliant or complaint?

Rate your approach to running advisory boards

Ask yourself these questions to determine whether your next advisory board is likely to be code-compliant, or whether you risk finding yourself in breach.

☐

Was the need for an advisory board identified internally, without any direction from potential attendees?

☐

Is this the only advisory board you are holding to address this specific business question?

☐

Have you recorded your objectives and the questions you want answered?

☐

Can you demonstrate that your selection of delegates is based not just on their expertise but on their ability to answer the specific questions you wish to ask?

☐

Does your correspondence with potential attendees explain their proposed role and the amount of work expected of them, both before and during the event? Do you have contracts in place?

☐

Are all clinical data you plan to share with attendees essential to their remit of answering your specific business questions?

☐

Have you set aside at least 80% of the available time for discussion?

☐

Total

Turn to the inside back cover to see whether you're a **king of compliance or at risk of a breach**

01

Introduction

Advisory boards are an enormously useful means of answering a wide range of legitimate business questions. They can offer valuable insights at all stages of the product life cycle, from the very people who dispense, prescribe, use or pay for it.

Advisory board meetings must comply with all national codes, laws and regulations in the country in which they take place, as well as those relating to the country in which the hosting pharmaceutical company is located. In addition, advisory boards involving any UK healthcare professionals must comply with the Association of the British Pharmaceutical Industry (ABPI) Code of Practice.

In recent years, pharmaceutical advisory boards have come under the media spotlight for all the wrong reasons. Although some breaches of the relevant codes of practice represent a blatant disregard for the rules, many are the result of miscalculations by those involved in organising and running the meeting. In other cases, details relating to the organisation and conduct of perfectly legitimate advisory boards have not been properly documented, casting a dubious shadow over the whole meeting.



In response to this, and to frequent requests for informal advice around advisory boards, the UK's Prescription Medicines Code of Practice Authority (PMCPA) – the organisation that operates the ABPI Code – has issued detailed advice on running Code-compliant advisory boards. Because the ABPI Code is considered by many in the industry to be one of the most stringent in the world, the guidance sets an excellent compliance standard for pharmaceutical advisory boards the world over.

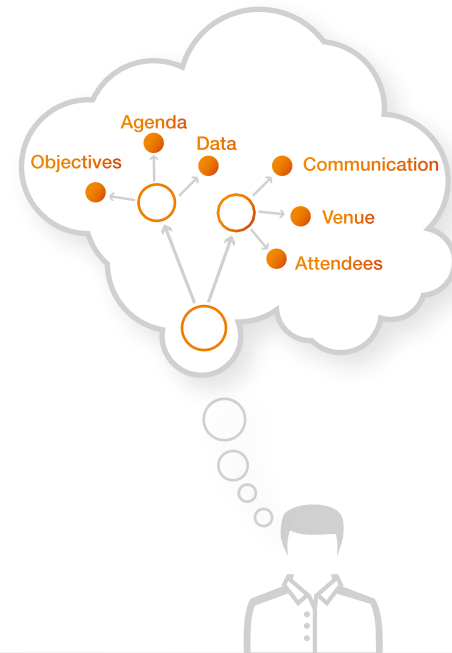
This guide has been written to show how taking the time to follow the PMCPA guidance – and viewing it as a mindset rather than a box-ticking exercise – can streamline the organisation of advisory boards and ultimately help you to get the information you need.

02

So you want to run an advisory board?

The key to running a successful advisory board is to define a clear set of objectives at the outset and keep those in mind throughout the entire process. What exactly do you want to know? How will this information help you to fulfil your business needs?

If you approach an agency to help you plan your advisory board, you should be prepared to answer these questions, and a few more besides. You may find these initial discussions frustrating when you just want to get on with planning your meeting, but experienced agency staff will have been involved in running countless advisory boards, and are likely to have valuable advice to offer in the early planning stages. A good agency will ask about the background and context to your decision to hold an advisory board; they will help you to crystallise your objectives and **consider whether an advisory board really is the best approach**. They will also identify and voice any possible compliance issues at this stage, so that these can be resolved at the earliest opportunity.



One way of avoiding late compliance pitfalls is to produce a concept document spelling out the objectives of the advisory board, along with other plans, such as the number of attendees, their desired expertise and, of course, the proposed venue and subsistence arrangements. Most agencies will do this for you. This document should be shared with your signatories early on, before you act on any of your plans.



03

Find the best people for the job

Once you've identified your business question(s), you'll need to consider who is best placed to provide the answers. It's very easy to fall back on the same group of advisors for every advisory board. Your 'usual' key opinion leaders may be experts in their field, familiar with your brand, and have a solid track record of providing sound advice. But invitees to an advisory board should be chosen according to their expertise and **their ability to answer the specific business question(s)**. So it follows that advisors should only be chosen once the objectives of the advisory board are clear. And the right group of people for the job is unlikely to be the same in each case.

The same principles apply when choosing a chair for the meeting. But here it's also necessary to consider facilitation skills and the candidate's professional standing among their peers. An effective chair can be the difference between a hugely successful advisory board and one that's simply a waste of everyone's time.





Most agencies will offer key opinion leader profiling, to produce a list of potential attendees ranked by their expertise and relevance to the objectives of the advisory board. Besides being a completely transparent way of selecting advisory board attendees, key opinion leader profiling is also a good way to identify rising stars or those who have previously fallen under the radar.

To ensure active participation by all, you should select a maximum of 10 invitees in the first instance. It's always best that the signatories review the list of proposed advisors, and the justification for each one, before any potential advisors are approached. This document should be retained in the approvals folder; you may need to justify your choice of attendees at a later date.



04

Set a clear role for everyone at the meeting

Wherever you are in the world, the vast majority of your communications with healthcare professionals will be subject to national or regional codes of practice. This is likely to include the letters or emails you or your agency send to invite or brief your advisors, so it's important to consider the content of each carefully.

In the era of increased transparency, **many healthcare professionals will exercise caution when deciding whether they should attend an advisory board**. At best, attending an advisory board that is later found to be in breach of the relevant codes is a waste of an advisor's time. At worst, it could compromise their professional standing and, in some cases, lead to disciplinary action by their institution.



As a rule of thumb, **the initial invitation should list the objectives of the advisory board and contain enough information for the advisor to determine whether they would be able to make a meaningful contribution.** It should also detail the proposed advisory role and the amount of work to be undertaken, including preparatory work or development of slides to be presented on the day. Your advisors should sign role-appropriate contracts as soon as possible after accepting the invitation, and certainly before they undertake any work associated with the meeting. In most cases, an honorarium will be offered. The sum must reflect the time and effort taken to participate in the meeting as well as the professional standing of the advisor, and it must be made clear that this is offered in exchange for help and advice.

At this stage, you should also decide which of your colleagues should attend the meeting. There are no hard and fast rules, but this is an area where impressions really count. The number of company staff – particularly marketers – should be kept to a minimum, and those attending should each have a defined role at the meeting. A member of the medical team should normally attend.



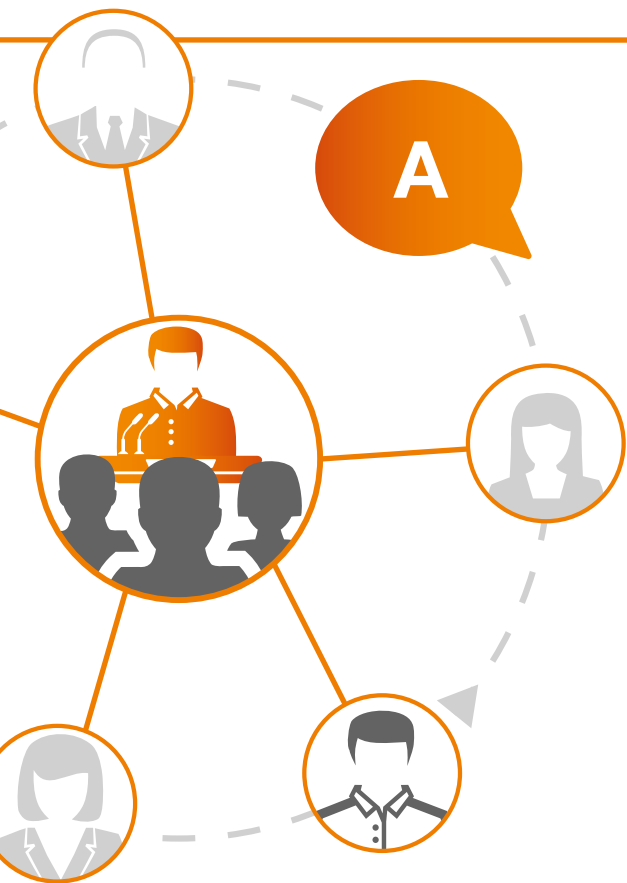
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Get your money's worth

It's very difficult to justify more than one advisory board on the same topic, so it's imperative that you get the answers you need first time. For this to happen, your agenda needs to be carefully designed around your objectives. Although you will inevitably need to provide some context in the form of short presentations, there needs to be adequate time for discussion – **as a rule of thumb, discussion time should make up around 80% of the agenda.**

To maximise time for discussion, you should send your advisors pre-approved preparatory work well in advance of the meeting. This might take the form of a questionnaire asking about practice habits at their centre, the results of which could be used to direct discussion on the day, or some background reading, so that your advisors arrive at the meeting armed with the context they need for a meaningful discussion.





It's a good idea to provide your chair with a pre-approved discussion guide that has a series of clear, direct questions to be answered, so that can they ensure the discussion stays on track. **Your carefully selected advisors should all contribute to the discussion** – after all, you're paying for their expertise – and a good chair will ensure this happens.

06

Keep talking

Good communication is essential when planning an advisory board. If you're using an agency, you should introduce them to your core team members and signatories at the earliest opportunity, so that they can contact these colleagues directly to resolve any issues that arise during the process.

In the run-up to your advisory board, you and your agency should hold briefing calls with your chair and each speaker, to ensure that each person understands their role and how it fits with the objectives of the meeting. Don't be tempted to do this over email; **speakers who have been invited to discuss their presentation are usually more engaged with the meeting**, and are far more likely to produce a suitable presentation by the slide deadline.





You should work with your approvals team to set a realistic slide deadline; **whether tweaks or wholesale changes, slide amendments are nearly always needed, and should be planned for in the approval timelines.** When the final slide set for the meeting is available, it's worth holding an alignment meeting with your agency, core team members and signatories, to ensure that all the key questions to be put to the advisors have been covered.

07

Keep compliance in mind

It's essential that advisory boards are run to high standards, and that the whole process, from conception to the meeting itself, stands up to independent scrutiny. An auditor looking back at the materials at a later date should be able to understand the objectives of the meeting and quickly decide that it was not a promotional activity.

Always keep in mind that the purpose of an advisory board is to seek advice from attendees, not provide them with information or otherwise influence them. **Any information presented at the meeting – particularly clinical data relating to your product – must be with the sole purpose of seeking advice based on it.** The presentation of information that is not essential to meet the advisory board objective is likely to be perceived as disguised promotion, or the promotion of an unlicensed medicine or indication. Clinical data can easily appear promotional out of context, so to avoid doubt, you should include specific questions relating to the clinical data both in the slide set and in the agenda.



Compliance

Agenda

Venue

Attendees

Objectives

Data

A report detailing discussions and outputs of the advisory board should be produced after the meeting, and if you're using an agency, they will usually offer a medical writer to do this for you. **This shouldn't be an unwieldy transcript of the meeting, but a clear, well thought-out document that sets out the feedback received in response to the original business questions,** alongside action points for the company. This report represents the final confirmation that everything was done right, so ensure that a copy is included in the approvals folder before archiving.

The porterhouse approach

By their very nature, advisory boards are so diverse that each one seems to throw up new compliance questions. There's no doubt that a sound knowledge of the relevant codes is essential, and that perceptions of the meeting – held by the people you invite and regulators alike – are as important as the reality.

At Porterhouse, we have organised hundreds of advisory boards, and we can help you navigate compliance with confidence. We firmly believe that as long as you are using advisory boards for their proper purpose – that is, gaining advice – following the PMCPA guidance to the letter can actually help you to get the answers you need.

Let us show you how we do it. We'd love to help.



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Did you know?

- You can legitimately request feedback on promotional materials at an advisory board
- You should never ask participants at an advisory board to complete feedback forms on hospitality or logistics
- Meetings with outputs for external use, such publications or consensus statements, are not genuine advisory boards
- The need for an advisory board must always originate from the pharmaceutical company, not from KOLs keen to discuss particular issues
- Inviting too many advisors and/or company staff can make an advisory board appear promotional



Who we are

Porterhouse provides medical and scientific communications services to the pharmaceutical industry across the globe, with a focus on programmes that can make a significant and measurable impact on both healthcare professionals' and patients' lives.

Our people are our greatest asset and our core values – which emphasise **passion, ambition, family and humour** – inform our approach to the recruitment, training and well-being of our talented, in-house teams of medical writers, account managers, designers, programmers and event planners. This is reflected in the high quality of our work and sets us apart from other agencies.





Established in 2002
in Reading, UK



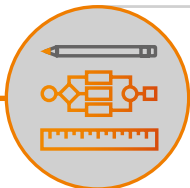
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that are tailored
to our clients' needs



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and intelligent solutions
for a growing number of
pharmaceutical companies



Rapidly growing team
recruiting top talent
in med comms



Invest heavily in
the training and
development of
our staff



Our open and honest
culture is central to
our success

Compliant or complaint?

King of compliance or
at risk of a breach?



<9

There's a lot of room for improvement in how you conceive and implement your advisory board strategy. Perhaps you're starting the whole planning process too late and cutting corners to get things done. You risk upsetting your attendees and missing out on the valuable information you're hoping to get out of the event. What's more, the risk of a code breach is very high. You really need this guide!

9–16

You're doing some of the things you need to do to ensure that your advisory board is money well spent rather than a waste of time and resource. However, you really need to focus on some of the time-consuming and disagreeable tasks, such as getting all the paperwork in place (for example, objectives, contracts and discussion guides). The risk of a code breach is moderate.

17–24

The thought and planning put into your advisory boards is considerable and more than likely they run well and you get answers to the questions you are posing. However, there are some areas that need improvement. Perhaps it's something that's easily fixed, like ensuring you're putting enough discussion time in the agenda. Nevertheless, the overall risk of a code breach is low.

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Well done. Your advisory boards are well planned and executed, and you have all the paperwork in place to ensure that any independent inspection would give you a clean bill of health.



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