

Arm's length arrangements

Q&A slides from webinar on PMCPA learning portal



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What is the difference in definition between “hands-off” vs “arm’s-length”?

Neither term appears in the Code. They appear in cases, usually because of the complainant’s or company’s reference to them. The Panel would likely treat the terms as synonymous, but much would depend on the particular circumstances of the case and the context in which the complainant or respondent company had used the term.

For the purposes of this webinar, the term arm’s length will be used.

What is the difference between sponsorship, arm's-length sponsorship and a grant?

The definition of sponsorship in the Code (Clause 1.22) is broad. The definition of a grant (Clause 1.5) is narrower. However, there is nothing in the Code that says an activity can *only* be a sponsorship *or* a grant. The terms are not mutually exclusive within the Code. This was reflected in the Appeal Board's ruling in Case AUTH/3845/11/23 and has also been reflected in numerous Panel rulings including Case AUTH/3895/5/24 and Case AUTH/3907/05/24.

The Code definitions leave open a category of funding which could be both sponsorship *and* a grant i.e. a grant is a limited form of sponsorship and has certain criteria as referred to in Clause 23.

The definition of grant specifies that there is no consequent obligation on the recipient organisation to provide goods/services to the benefit of the pharmaceutical company in return. While company definitions may differ, there is nothing in the Code definition of sponsorship that requires a company to receive a benefit in return.

The Code does not specifically use the term 'arm's-length sponsorship'. This term has been defined through case precedent to essentially relate to a limited form of sponsorship where the company is not liable under the Code for the content of material, akin to material produced under a grant.

Can a company have a sponsorship agreement that is not arm's-length?

Yes, sponsorship agreements do not have to be arm's-length. However, if the sponsorship is not arm's-length, the pharmaceutical company is responsible for the content of the material under the Code.

It is important to note that regardless of the arrangement, companies will be held accountable under the Code for ensuring transparency through the requirement for an adequate declaration of involvement statement, as illustrated in [Case/0446/01/25](#).



Does any benefit in return for funding compromise an arm's-length agreement?

If the sponsorship agreement requires the recipient organisation to provide a benefit in return to the pharmaceutical company then the sponsorship is not strictly arm's-length. This follows the same principle as a grant in Clause 23 where there must be no consequent obligation on the recipient organisation to provide goods/services to the benefit of the pharmaceutical company in return.



Does any type of report in return compromise an arm's-length arrangement or just when associated with the company's products?

The determining factor is whether the report is a requirement of the sponsorship agreement and considered a benefit to the pharmaceutical company.

Companies will likely require evidence that the recipient organisation has used the funds for the intended purpose – that is just due diligence and does not affect any arm's-length arrangement. However, detailed reports which contain analytical data may be perceived as a benefit. For example, in Case AUTH/3821/9/23 the reports included the number of patients starting the company's medicine and geographical location. The provision of these reports to the pharmaceutical company was part of the sponsorship agreement.

The analytical data received by the company does not necessarily have to be product related in order to be perceived as a benefit. E.g., in Case AUTH/3629/4/22 the company received quarterly updates on a disease awareness campaign including where in the country people had accessed the campaign, the age/gender profile of people who had engaged on social media and how many had downloaded the voucher/discount code for a cholesterol test. The provision of these reports to the company was part of the sponsorship agreement.

In both these cases, the Panel concluded the arrangement was not arm's-length.

Each case would be assessed on its individual merits.

What about receipt of exhibition space or a symposia slot when sponsoring a conference?

It is common practice for companies to sponsor meetings or events like conferences and get an exhibition booth and/or a symposia slot as a benefit in return. The company would be responsible for the content of its exhibition booth and symposia under the Code but not necessarily for the content of other independently run sessions at that meeting/event.

It is important to note that if a company chooses to fund a specific session run by an independent organisation at an event/meeting, it will be responsible for the content of that particular session under the Code if the arrangement was not strictly arm's-length. See Case/0283/09/24 which relates to a company providing funding to support a symposium run by an independent medical education provider at a conference.

Regardless of the arm's length nature of the arrangement, when a company sponsors any event/meeting, the company should satisfy itself that it is an appropriate event/meeting to sponsor under the Code, including review of the venue, hospitality, agenda and intended audience.

Does the PMCPA arm's-length Q&A only apply to material or activities which mention the company's products?

No. For example, if sponsorship of a patient organisation's disease awareness campaign is not strictly arm's-length the company will be liable for the content under the Code, including certification requirements. See Case AUTH/3629/4/22.





Thank you

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Code of Practice Authority

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