Clause 18 – Sponsorship and Arm's Length Arrangements

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Summary

The aim of the session was to better understand clause 18 of the ABPI Code of Practice. How should we look at the detail, but not forget the overall perception of materials, in order to ensure the correct compliance procedures are undertaken? We covered sponsorship, arm's length criteria and discussed a number of relevant case studies. This was followed by a round table discussion on a variety of examples of the clause in practice.

Sponsorship

Rina started the session by gaining a consensus regarding the definition of sponsorship, highlighting the frequency of the term in the ABPI yet the lack of definition. Demonstrating the importance of sponsorship and the caution that should be undertaken, Rina drew our attention to a sponsorship agreement between Viking Rivers and the TV show "Broadchurch". At the end of a programme an advertisement for the next episode showed a scene involving a burning boat; this had obvious negative (repercussions and) associations with the sponsors, which resulted in the cancellation of sponsorship and huge financial and brand ramifications.

Rina then described clause 18:

Clause 18: Items for Patients, Promotional Aids, MEGS, Joint Working, Outcome Agreements and Patient Access Schemes

- **18.1 No inducements to prescribe**
- **18.2 Patient support items**
- **18.3 Promotional aids**
- **18.4 MEGS criteria**
- **18.5 Joint working**
- **18.6 Criteria for and disclosure of donations and grants**
- **18.7 Contracts for service provision**

Then explaining that MEGS are; medical and educational goods and grants and the categories they encompass; goods, services, grants, donations and benefits-in-kind Rina talked us through the MEGS checklist:

MEGS must:

- **Have a direct and obvious link to patient care**
- **Be non-promotional in every way including the intention, tone, impression and content**
- **Be publically disclosed (grants and donations only)**

MEGS must not:

- **Be linked to bribery or promotion i.e. not be an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.**
- **Be provided to individuals for their personal benefit**
- **Contain the name of any medicine as this gives the impression of promotion. A company name is fine.**

Returning to the **definition of sponsorship** Rina defines it as the "reactive provision of funding or benefit-in kind to an, organisation, institution, association comprised of HCPs…"

Highlighting that sponsorship is "***provided under an arm's length arrangement*** *so that a company may not be liable for content, use etc. of the item"*

Demonstrating the importance of sponsorship and the caution that should be undertaken, Rina drew our attention to a sponsorship agreement between Viking Rivers and the TV show "Broadchurch"

Rina went on to explain the criteria of an arm's length arrangement according to the PMCPA's advice issued in November 2007.

Arm's Length Arrangements Criteria

1. **Company / agency has NOT originated / initiated**
2. **Company / agency has not chosen author**
3. **Company / agency has no control / influence over material / activity**

N.B Factual accuracy check cannot be seen as editorial input.

1. **Company / agency has handed over money ONLY**
2. **A written agreement is in place**
3. **Company's declaration of involvement is explicit**
4. **The Company is not planning on using the activity / material in a promotional manner**

N.B. Factual accuracy check cannot be seen as editorial input. An arm's length arrangement should not be implied when a company is inextricably linked to the production of a piece.

Case Studies

Rina then highlighted a number of case studies that applied to sponsorship and the arm's length arrangement. She helped put them into context and allowed us the opportunity to gain insights into the PMCPA's rulings and thought processes. I have highlighted a couple of the cases but have a full list can be found at the end of this article.

One of the cases reviewed was GSK / Director v Chiesi, AUTH/2435/6/12. The case was related to Fostair, licensed to treat asthma in the UK, not COPD. GSK alleged Chiesi promoted Fostair for use in COPD in an article published in Respiratory Disease in Practice, in an edition sponsored by Chiesi. There was an alleged breach of clause 9.1 and 25.

The panel wanted to establish, 'was as there an arm's length arrangement? If not was Chiesi reliable for the article about Fostair in COPD?

The following proceedings involved toing and froing between the PMCPA and Chiesi. Whilst Chiesi's initial response appeared excellent, and to adhere to the arm's length arrangement criteria, they still did not disclose a copy of the contract between Chiesi and the publishers.

Chiesi continued to reiterate its lack of input into the journal, highlighting the fact they had not reviewed the materials or had involvement in distribution and not purchased reprints or used the journal in promotion. What eventually transpired through direct questioning from the PMCPA was that Chiesi had suggested the author of the article in question.

The panel ruled that it is possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its content. Factors indicating that there had not been an arm's length arrangement would include the selection of an author by the pharmaceutical industry. This meant that Chiesi was liable for the article in which promoted Fostair in COPD. A breach of 9.1 and 2 was given.

With a note of concern due to the number of times the panel needed to question Chiesi and the fact that Chiesi's initial submission had been incorrect, Chiesi were reported to the Appeal Board and received a public reprimand and 2 audits.

Learning - Rina helped use this case to show how important it is to demonstrate understanding of the code; even when under investigation or when in error. It can and has reduced the severity of ruling. Had Chiesi disclosed their selection of the author, would they have had such severe repercussions? Had Chiesi consciously thought through the perception that author identification created? As experts in their field with insights into HCPs' opinions and mindsets should they have it under a different MEGS and therefore put the article through the right approval process?

There were a couple of cases discussed relating to meetings, hospitality and sponsorship. In the case Anonymous Health Professionals v Astellas, Allergan, Baxter, Ferring, Ipsen, Janseen, Orion, Pfizer, Recordati and Takeda, Case AUTH/2546-48, 52, 54, 56, 59-61, 63/11/12 ten companies supported the Irish Society of Urology (ISU) meeting, which apparently had 'excessive hospitality'. The venue was the 5* Colloden Estate and Spa, Belfast; advertised as a luxurious hotel, golf club, spa etc.

On the agenda for the meeting were scientific / educational sessions from 9am Friday with a conference dinner at 7pm. Scientific / educational sessions were then planned from 9am Saturday until the AGM at 12.10pm when the meeting closed with lunch. This was then followed by an invitation to play golf at 12.50pm. Although none of the companies were involved in the selection of the venue, the organisation of the golf or gala dinner, or considered the golf to be part of the event, all were found in breach of clause 9.1.

The panel commented that the impression that was created was that all companies had supported the entire meeting (including the golf and gala dinner). The agenda merely listed the companies who had supported the meeting rather than detailing who exactly had supported which elements.

Some key areas of learning were discussed and emphasised including the importance of 'intention'. Ways to clearly demonstrate your intentions were provided, including the importance of ensuring a thorough written agreement is in place. This will ensure that you see the final materials. It is also important to provide upfront information on your involvement – a pro-claimer on your exhibitors stand to show involvement to better manage expectations and therefore perception was also advised.

Workshop

For the workshop we had a number of round table discussions on activities governed by clause 18 and its various complications. We were tasked with coming up with a list of pitfalls and proposals on the subjects two of which I have covered below:

Social Media

Pitfalls:

- **PVG repercussions**
- **Data removal and approval of information**
- **Aligning policies i.e. facebook vs. company vs. industry regulations**
- **Drug access and demographics**
- **Freedom of information act**

- **Damage evidence**
- **Incorrect / inaccurate responses and information**

Proposals:

- **Centralised reporting of AEs**
- **SOPs defining what will and won't be reported**
- **Implement quality systems**
- **Are you; or are you not going to vet every piece of information**

Learning's from discussion - don't do it unless you really are ready – think about how you will monitor and govern activities before you start.

Joint Working

Pitfalls:

- **Variation of SOPs**
- **Can slow down speed of working**
- **Different risk averse attitudes can exist**
- **Agency choice and relationships vary**
- **Master responsibilities**
- **Organisational structure and set up**
- **IT and system compatibility**
- **Complexity of contracts**

Proposals

- **Communication – set specific days and times to hold TC's etc.**
- **Detailed working practices and expectation management**
- **Common goal / framework**
- **Implement service level agreements**
- **Transparency and direct points of contacts – take accountability**
- **Use facilities i.e. technology**
- **Audit and quality steps and actions**

Learnings from discussion - If a breach occurs – ensure someone is taking personal accountability. If you demonstrate actions such as retraining you are able to demonstrate the issue is not systematic. It can help avoid an audit. Ensure the project has to have a start and a finish i.e. has to be project based and can be assessed to an end point.

Conclusion

The session was a great way to share best practice and talk through the similarities and differences in activities and remits. It provided us with a good understanding of sponsorship, code requirements and the arm's length arrangement. It became evident that no set up is the same, with SOPs varying from company to company and involvement in factual accuracy checks differing between organisations. It was made clear that it is easier to reduce risk in promotional activities that and how complex non-promotional activities can be. It is certainly important to look at the bigger picture; how activities are being perceived and the balance of social and educational activities. It was certainly evident that Rina has an impressive understanding and memory of PMCPA cases, if you asked a question you would be guaranteed to be provided with a case number and key learning!

For further information please contact Julia Day on **julia.day@axess.co.uk**

Appendix:

Case AUTH / 1951-5/2/07

Case AUTH / 2333/7/10

Case AUTH / 2435/6/12

Case AUTH / 1644

Case AUTH / 1897/10/06

Case AUTH/2546-48, 52, 54, 56, 59-61, 63/11/12