

# DOCTOR v SANOFI-AVENTIS

## Special report in journal

A doctor complained about a four page 'special report' on atrial fibrillation which appeared on pages 17-20 of the Health Service Journal (HSJ), 25 November 2010. The top right hand corner of the first page of the report (page 17 of the HSJ) featured a prominent Sanofi-Aventis company logo and, in smaller type, the statement 'This special report is paid for and sponsored by Sanofi-Aventis. Sanofi-Aventis have had no editorial input'.

The complainant noted that the supplementary information to the Code stated that, 'When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial material'. The complainant alleged that the material was promotional because Sanofi-Aventis' new medicine dronedarone [Multaq] was favourably mentioned several times. The editorial style of the special report was extremely similar or identical to that of the HSJ with regard to, *inter alia*, page layout, typeface, font size, colour scheme and number of columns. The complainant submitted that a reader flicking through the journal, especially from back to front, could read pages 18-20 and not know that Sanofi-Aventis had secured publication.

The detailed response from Sanofi-Aventis is given below.

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided, in relation to material aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes.

The special report in question had been paid for and sponsored by Sanofi-Aventis; it had been initiated as a result of a discussion between the HSJ and Sanofi-Aventis' communications agency. The agency had facilitated contact between the HSJ and the clinical and non-clinical experts who provided their input. An email from the agency to the HSJ referred to working with the HSJ to produce a special report and with one of the expert contributors quoted in the special report and listed the key topics that would be covered. The author of

the email thanked the HSJ for its patience in '... getting this off the ground'. Sanofi-Aventis stated that it could check the final text for factual inaccuracies. The Panel noted Sanofi-Aventis' submission that the layout of the piece was chosen by the HSJ to maintain continuity with the rest of the journal.

The top right hand corner of the front cover of the HSJ at issue listed three articles within, one of which was 'Improving cardiac care special report: 17'. The way in which the special report was listed was indistinguishable from the other two articles. There was no reference on the front cover to Sanofi-Aventis' involvement in the special report. The special report contained several positive mentions of dronedarone. In the Panel's view, although other medicines were mentioned, the balance of the piece was in favour of dronedarone.

The Panel considered that Sanofi-Aventis had, through its communications agency, influenced the scope and content of the special report and facilitated contact with clinical and non-clinical experts. In that regard the Panel considered that there was no strictly arm's length arrangement between the provision of sponsorship and the generation of the special report. In the Panel's view, Sanofi-Aventis was inextricably linked to the production of the report and given its content and presentation the report was, in effect, disguised promotional material for dronedarone. The report was not easily distinguished from the editorial content of the HSJ and its content appeared to be wholly independent of Sanofi-Aventis which was not so. A breach of the Code was ruled.

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## COMPLAINT

The complainant noted that the supplementary information to Clause 12.1 of the Code stated that, 'When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial material'. The complainant further noted that Sanofi-Aventis acknowledged that it 'paid for and sponsored' the material. The complainant alleged a breach of Clause 12.1. The material was promotional because Sanofi-Aventis'

new medicine dronedarone [Multaq] was favourably mentioned at least seven times, with no reference to side-effects or safety concerns. The editorial style of the special report was extremely similar or identical to the standard editorial text of the HSJ with regard to page layout, typeface, font, font size, colour scheme, number of columns, text boxes, call-outs etc. The complainant submitted that a reader flicking through the journal, especially from back to front, could read pages 18-20 and not know that Sanofi-Aventis had secured publication.

## RESPONSE

Sanofi-Aventis explained that the 'special report' was a regular feature of the HSJ and appeared in the body of the journal itself rather than as a separate supplement. It was not a promotional piece but rather an independent, educational piece written by the HSJ.

The declaration and sponsorship statement was clearly visible at the outset of the article (page 17) and Sanofi-Aventis had had no editorial input into the report.

The article was written by an HSJ employee and included comments from clinicians and non-clinicians. Atrial fibrillation was of interest to the NHS due to its impact on patients and the NHS as a whole. Given the heritage, current interest and breadth of research that Sanofi-Aventis had carried out in this disease area, it seemed appropriate for the company to support the special report at issue.

Sanofi-Aventis submitted that although the article initially focussed on the cost impact of atrial fibrillation on the NHS it also discussed the overall management of the disease. Many different treatments, both pharmacological and non-pharmacological (such as ablation) were referred to and of the pharmacological treatments mentioned, many classes (eg beta-blockers, calcium channel blockers) and individual medicines (eg aspirin, warfarin, digoxin, amiodarone, dabigatran) other than dronedarone were named. Given that dronedarone was a new treatment option in this disease area, it seemed only logical that it was referred to in the article, either in the author's text or in the comments from the contributing experts. While the side-effects of dronedarone were not mentioned, this was also the case for all the other medicines and classes of medicines that were named.

The layout of the article was not within the control of Sanofi-Aventis. While the company had paid for and sponsored the article, its involvement in the content went no further, other than the opportunity to check the text for factual inaccuracies which it was permitted to point out to the author. The layout of the piece, such as the typeface or font size, was chosen by the HSJ so as to maintain continuity with the rest of the journal.

Sanofi-Aventis noted that the complainant had alleged a breach of Clause 12.1 and referred to

supplementary information in the Code which stated that 'When a company pays for, or otherwise secures or arranges the publication of promotional material in journals, such material must not resemble independent editorial matter'. The article did not promote the prescription, supply, sale or administration of a medicine, and was therefore, by definition, not promotional. The article was authored by an HSJ employee and Sanofi-Aventis did not, as stated clearly at the outset of the special report, have any editorial input. As such, this was not disguised promotional material as it was independent editorial matter. Sanofi-Aventis denied a breach of Clause 12.1.

In response to a request for further information, Sanofi-Aventis stated that the article in question was initiated as a result of discussion between the HSJ and Sanofi-Aventis' communications agency at the time. As such, there was no formal agreement in place between Sanofi-Aventis and the HSJ as limited involvement in the article was anticipated.

Sanofi-Aventis had made no use of the article in promotional activities.

In response to a further request for more information, Sanofi-Aventis explained that communication with the HSJ regarding the article was carried out by its communications agency and not by Sanofi-Aventis itself. There was no formal agreement in place between the communications agency and the HSJ as the article was to be written by an HSJ employee. The article was written following her discussions with the experts who were quoted in the piece. The communications agency helped by facilitating contact between the HSJ and clinical and non-clinical experts who provided their input.

Most of the communication between the HSJ and the communications agency was by telephone or in person, which limited the documentation. Sanofi-Aventis provided an email trail between the HSJ and the communications agency in which, it submitted, the key themes were the logistics of facilitating contact between the HSJ and the contributing experts. The emails demonstrated that the article was never intended to be promotional, hence the lack of briefing material.

## PANEL RULING

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided, in relation to material aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company

and no use by the company of the material for promotional purposes.

The special report in question had been paid for and sponsored by Sanofi-Aventis. The report had been initiated as a result of a discussion between the HSJ and Sanofi-Aventis' then communications agency. The communications agency had helped by facilitating contact between the HSJ and the clinical and non-clinical experts who provided their input. An email from the agency to the HSJ referred to working with the HSJ to produce a special report and with one of the expert contributors quoted in the special report. This email also listed the key topics that would be covered in the article. The author of the email thanked the HSJ for its patience in '... getting this off the ground'. Sanofi-Aventis stated that it could check the final text for factual inaccuracies which it could point out to the author. The Panel noted Sanofi-Aventis' submission that the layout of the piece was chosen by the HSJ to maintain continuity with the rest of the journal.

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special report contained several positive mentions of dronedarone. In the Panel's view, although other medicines were mentioned, the balance of the piece was in favour of dronedarone.

The Panel considered that Sanofi-Aventis had, through its communications agency, influenced the scope and content of the special report and facilitated contact with clinical and non-clinical experts. In that regard the Panel considered that there was no strictly arm's length arrangement between the provision of sponsorship and the generation of the special report. In the Panel's view, Sanofi-Aventis was inextricably linked to the production of the report and given its content the report was, in effect, promotional material for dronedarone. The Panel considered that it was disguised promotion; the presentation of the report was such that it was not easily distinguished from the editorial content of the HSJ and the content of the report itself appeared to be wholly independent of Sanofi-Aventis which was not so. A breach of Clause 12.1 was ruled.

**Complaint received**                      **29 November 2010**

**Case completed**                              **8 March 2011**

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