

# DOCTOR IN PUBLIC HEALTH v BAYER HEALTHCARE

## Sponsored Journal Supplement

A doctor in public health, complained about an eight page sponsored supplement 'Venous Thromboembolism – Unblock the System, How to treat DVT [deep vein thrombosis] in the Community', sponsored by Bayer HealthCare.

The supplement was distributed as a bound insert in the Health Service Journal (HSJ), 5 September 2014. The Bayer HealthCare company logo appeared in the top right hand corner on the first page of the supplement; running along the bottom edge of the first page was the statement 'Bayer HealthCare sponsored this report. The company has reviewed the data solely to ensure the factual accuracy in relation to Bayer products and compliance with industry guidelines. The views expressed in these articles are not necessarily those of the sponsoring company. Rivaroxaban▼ prescribing information available on page 8'. The Bayer HealthCare logo also appeared at the top of the contents list on page 2. The supplement consisted of four articles, one on service redesign, two GP case studies and one on a charity's perspective.

The complainant alleged that a reader who opened the supplement on the double-page spread, pages 4-5 or pages 6-7 would have no indication the material was sponsored by Bayer since it used the same font, layout and general design as the rest of the HSJ and nowhere on those four pages did it state it was a sponsored supplement (this was only stated on pages 1, 2 and 8).

The detailed response from Bayer is given below.

The Panel noted that the supplement was stapled into the centre of the HSJ. That a sponsored supplement was bound in rather than loose did not necessarily mean that its nature was disguised. The overall impression given to readers was the most relevant factor. The Panel considered that binding a supplement into a journal influenced the way readers would access it; they were not guaranteed to see the first page first and were likely to flick through the journal, often from back to front, and might read an inside page without first seeing the declaration of sponsorship on what would have been the front cover and front inside cover if the supplement were a loose insert. Further, the label 'Health Service Journal supplement' on the bottom of each page in itself was not sufficient to inform the reader that the article was sponsored promotional material produced for a pharmaceutical company.

Although the paper quality of the supplement was slightly thicker and glossier than that of the HSJ, in the Panel's view overall the pages of the supplement were not sufficiently dissimilar to the standard editorial pages of the journal. The Panel noted and considered that as a bound in supplement, given

the way it would be accessed, some readers would not know from the outset that it was a sponsored promotional piece for Xarelto. Its promotional nature was disguised. A breach of the Code was ruled.

The Panel noted its comments above about how readers would access a bound in supplement and considered that the declaration of sponsorship was not adequate. A breach was ruled.

The Panel, although noting its rulings above, did not consider that Bayer HealthCare had failed to maintain high standards and ruled no breach.

A doctor in public health, complained about an eight page sponsored supplement 'Venous Thromboembolism – Unblock the System, How to treat DVT [deep vein thrombosis] in the Community', (ref L.GB.04.2014.6167b) sponsored by Bayer HealthCare.

The supplement was distributed as a bound insert in the Health Service Journal (HSJ), 5 September 2014. Prescribing information for Xarelto (rivaroxaban) appeared on page 8 of the supplement. The Bayer HealthCare company logo appeared in the top right hand corner on the first page of the supplement; running along the bottom edge of the first page was the statement 'Bayer HealthCare sponsored this report. The company has reviewed the data solely to ensure the factual accuracy in relation to Bayer products and compliance with industry guidelines. The views expressed in these articles are not necessarily those of the sponsoring company. Rivaroxaban▼ prescribing information available on page 8'. The Bayer HealthCare logo also appeared at the top of the contents list on page 2. The supplement consisted of four articles, one on service redesign, two GP case studies and one on a charity's perspective.

Xarelto was an anticoagulant indicated, *inter alia*, for the treatment and prevention of DVT.

### COMPLAINT

The complainant alleged that a reader who opened the supplement on the double-page spread, pages 4-5 or pages 6-7 would have no indication the material was sponsored by Bayer since it used the same font, layout and general design as the rest of the HSJ and nowhere on those four pages did it state it was a sponsored supplement (this information was confined to pages 1, 2 and 8).

When writing to Bayer the Authority asked it to respond in relation to the requirements of Clauses 9.1, 9.10 and 12.1 of the Code.

## RESPONSE

Bayer noted the complainant's comments and referred to Clause 9.10 of the Code which stated that material sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. Bayer noted that on the first page of the supplement there was the prominent and clear statement that 'Bayer HealthCare sponsored this report. The company has reviewed the data solely to ensure the factual accuracy in relation to Bayer products and compliance with industry guidelines. The views expressed in these articles are not necessarily those of the sponsoring company. Rivaroxaban ▼ prescribing information available on page 8'.

Bayer submitted that Clause 12.1 stipulated that promotional material must not be disguised. In this regard Bayer noted the last sentence of the sponsorship declaration together with the fact that the Bayer HealthCare logo was also on the front cover immediately below the title of the supplement as well as on page 2 under contents. There was also a job code number (L.GB.2014.6167b) and date of preparation. Prescribing information was printed on the last page of the supplement where there was also an adverse event reporting statement directing reporters to Bayer plc.

The company submitted that there was no requirement to declare sponsorship on each and every page of sponsored material. Consequently the supplement was clearly not in breach of Clauses 9.10 and 12.1 and Bayer had thus not failed to maintain high standards (Clause 9.1).

In response to a request for further information, Bayer stated that it approached an agency to discuss opportunities to highlight examples of best practice where the pathway for treating DVT had been moved from the hospital into primary care. The agency recommended the HSJ to write a supplement. Bayer informed the journal about centres where this had happened and recommended some of the individuals to interview. The journal independently interviewed some of the health professionals in the supplement. In addition, the journal proposed that another individual be interviewed. Two of the individuals recommended for interview by Bayer had participated in a Bayer advisory board. Bayer submitted that although it had nominated some of the interviewees, it was not present during the interviews and had no influence over what the interviewees said. The journal wrote the supplement after the interviews.

Bayer reviewed the earlier editions of the supplement to ensure accuracy and readability and compliance with the Code. Upon final approval of the supplement (28 August 2014) the supplement was distributed as a bound insert in the HJS (5 September 2014), 1,000 copies were printed and distributed to the sales force and an email was sent to the sales force with a link to the HSJ supplement.

Bayer provided a copy of the HSJ at issue, the approved concept document with the agency, the

contract between the agency and the journal and correspondence and emails regarding the article.

Bayer stated that it strongly believed that there was no breach in this supplement. The supplement was clearly distinct from the rest of the HSJ. The paper quality was different. The pagination was separate from the journal. There was a clear declaration of Bayer's contribution to the journal supplement in page 1, a Bayer logo on pages 1 and 2 and prescribing information on page 8. Most importantly, there was a distinct label 'Health Service Journal supplement' at the bottom of pages 2 to 7.

## PANEL RULING

The Panel noted it was acceptable for companies to sponsor material. It had previously been decided, in relation to materials 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.

The Panel noted the requirements of Clause 12.1 and its supplementary information that when a company paid for, or otherwise secured or arranged the publication of promotional material in journals such material must not resemble independent editorial matter.

The Panel noted that the supplement was stapled into the centre of the HSJ. That a sponsored supplement was bound in rather than loose did not necessarily mean that its nature was disguised. The overall impression given to readers was the most relevant factor. The Panel considered that the provision of a supplement, bound into a journal, influenced the way readers would access it; readers were not guaranteed to see the first page first and were likely to flick through the journal, often from back to front, and might thus read one of the inside pages of the supplement without first seeing the declaration of sponsorship on what would have been the front cover and front inside cover if the supplement were a loose insert. Further, the label 'Health Service Journal supplement' appearing at the bottom of each page in itself was not sufficient to inform the reader that the article was sponsored promotional material produced for a pharmaceutical company.

The text of the HSJ itself was written in four columns with a thin black line framing each page, the left hand page was colour coded in the top left hand corner to denote the section of the journal ie news (red), comment (blue) etc. In the news section relevant quotations were reproduced in bold red font within an otherwise normal column of text. The text of the supplement in question was also presented in four columns with a thin black line framing the pages and although the font was identical to that of the HSJ, no colour coding appeared on the left hand pages. Some quotations, however, were reproduced in the same bold red font used in the news section. Although the paper quality of the supplement was slightly thicker and glossier than that of the HSJ itself, in the Panel's view overall the pages of the supplement were not sufficiently dissimilar to the standard editorial pages of the journal. The

Panel noted and considered that as a bound in supplement, given the way it would be accessed, some readers would not know from the outset that it was a sponsored promotional piece for Xarelto. Its promotional nature was disguised. A breach of Clause 12.1 was ruled.

The Panel noted Bayer's submission there was no requirement within the Code for sponsorship to be declared on every page of sponsored material. The supplementary information to Clause 9.10 required the declaration of sponsorship to be sufficiently prominent to ensure that readers of sponsored materials are aware of it at the outset. The Panel noted its comments above about how readers would access a bound in supplement and considered that the declaration of sponsorship was not adequate. A breach of Clause 9.10 was ruled.

The Panel, although noting its rulings above, did not consider that Bayer HealthCare had failed to maintain high standards. Thus no breach of Clause 9.1 was ruled.

During the consideration of this case the Panel noted the supplementary information to Clause 9.10 required the wording of a declaration of sponsorship to be '... unambiguous so that the readers will immediately understand the extent of the company's involvement and influence over the material'. Bayer had suggested many of the individuals who should be approached by the HSJ in the production of the supplement including some health professionals who had previously attended Bayer advisory board meetings. The Panel was concerned to note that the declaration of sponsorship, which appeared on the front cover of the supplement, did not make the extent of Bayer's involvement clear in this regard. The Panel requested that Bayer be advised of its concern.

**Complaint received** **28 September 2014**

**Case completed** **27 November 2014**