# **COMPLAINANT v ORION PHARMA**

# **Email and website**

A complainant who described him/herself as a concerned UK health professional complained about an email from Orion Pharma UK, sent via a named healthcare publication. The email urged recipients to watch a video on 'Medicines optimisation and the clinical challenges in respiratory care'. It was stated at the top of the email that 'This campaign has been produced by [a named healthcare publisher] with funding from Orion Pharma'.

The complainant stated that the email contained promotional information but no prescribing information. The email linked directly to the respiratory academy website which was sponsored by Orion (amongst others). The complainant alleged that the website thanked its valued sponsors who provided arms-length funding to support running of the academy, although the website was designed according to Orion's products and was clearly being used by Orion as a promotional tool, however, it did not appear to be described as such and had no prescribing information.

The complainant alleged that Orion's email which intentionally pointed to the website demonstrated at least an extremely weak process and oversight and at most an intent to set up supposedly independent websites that could be used for promotional purposes.

The detailed response from Orion is given below.

The Panel did not consider that the email in question promoted any particular Orion medicine and thus no prescribing information or adverse event reporting statement was required. The Panel ruled no breaches of the Code in this regard.

The Panel noted that the email stated that the campaign had been produced by the healthcare publisher with funding from Orion. The Panel queried whether this was an accurate description noting Orion's submission that it had commissioned the healthcare publisher to design, create and market a series of key opinion led educational videos focussing on respiratory management. In the Panel's view, Orion was more involved in the video campaign than the declarations in the email implied. The Panel considered that Orion had failed to maintain high standards in this regard and ruled a breach of the Code in relation to the email.

The Panel noted that the complainant had not provided evidence to show that the respiratory academy website was promotional as alleged and the Panel therefore ruled no breach of the Code in this regard. The Panel noted that the website stated that the video series, of which the video in question was a part of, was produced by the healthcare publisher with funding from Orion Pharma. In the Panel's view, Orion was more involved in the production of the videos, including the video at issue above, than the website implied, and the Panel therefore ruled a breach of the Code in relation to declarations on the website about Orion's involvement in the video campaign. Orion had failed to maintain high standards in this regard and a further breach of the Code was ruled.

Whilst the Panel had some concerns about the video, in its view, the complainant had not established that the video was promotional and thus that prescribing information, the adverse event reporting statement or date on which the material was last drawn up was required. The content of the video was not promotional and therefore it did not constitute disguised promotion. The Panel therefore ruled no breaches of the Code in this regard.

Whilst in the Panel's view the complainant had not established that the email or website were promotional, the Panel noted that both the video and email had been certified and therefore ruled no breach of the Code.

The Panel did not consider that the particular circumstances of this case were such as to warrant a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

A complainant who described him/herself as a concerned UK health professional complained about an email (ORI5285v) from Orion Pharma UK Limited, sent via a named healthcare publication. The email urged recipients to watch a video on 'Medicines optimisation and the clinical challenges in respiratory care'. It was stated at the top of the email that 'This campaign has been produced by [a named healthcare publisher] with funding from Orion Pharma'.

#### COMPLAINT

The complainant stated that the email contained promotional information, although it was not clear what the promotional material was. There was no prescribing information.

The complainant stated that he/she had clicked on the link to see what the videos were. This linked directly to the respiratory academy website which was another asset created by the healthcare publisher; the academy was itself sponsored by Orion (amongst others). On the academy website the healthcare publisher thanked its valued sponsors, who provide arms-length funding to support the running of the academy – although the complainant noted that the relationship was so close that the website was designed according to the products Orion had. This was clearly being used as a promotional tool by Orion – although on the website itself it did not appear to be described as such and had no prescribing information.

If the website was alone this could be a simple oversight but Orion's crafting of an email that intentionally pointed at the website that was supposedly separate, demonstrated at least an extremely weak process and oversight and at most an intent to set up supposedly independent websites that could then be used for promotional purposes.

With regard to the email itself, the complainant alleged breaches of Clauses 4.1, 4.2, 4.4, 4.6, 4.9 and 9.1. With regard to the linked website and contained videos, the complainant alleged breaches of Clauses 4.1, 4.2, 4.3, 4.4, 4.6, 4.8, 4.9, 9.1, 9.10, 12.1 and 14.1. Overall, the complainant alleged a breach of Clause 2.

Orion was asked to respond to the clauses cited by the complainant in relation to the 2016 Code.

## RESPONSE

Orion stated that as part of its commitment to help improve patient care in respiratory management, it commissioned the healthcare publishers to design, create and market a series of key opinion led educational 'conversation-style' videos focussing on respiratory management entitled 'Medicines optimisation and the challenges'. Orion had clearly identified its sponsorship of this educational project and had declared involvement on all materials in line with the requirements of Clause 9.10.

The commissioned videos were designed to support health professional education, in particular for those with roles based in medicines management/practicebased pharmacists, GPs, nurses and commissioners; the videos were tailored to the needs of each group. As the videos were educational, each was associated with 0.5 CPD points.

The educational videos did not endorse the use of any specific product. This content was hosted within the clearly identifiable sponsored content section of the respiratory academy website and each video was clearly labelled as being sponsored by Orion. Orion had not placed any product promotional content on this platform. The educational content of the videos reflected the opinions of those involved, and Orion's only involvement was to fund the project and check that the content of the materials was consistent with the requirements of the Code. As such, the material was reviewed and certified by Orion, in accordance with its standard operating procedures. Accordingly, Orion maintained that the requirements of Clause 4 (and the sub-clauses cited by the complainant) did not apply; there was no requirement to provide prescribing information on educational resources that did not contain promotional content.

Email notifications alerting recipients to the availability of the educational videos were sent

to users who had registered with the healthcare publication website. Registration required users to confirm whether they had read and understood the site privacy policy and whether they wished to opt-in to receiving electronic marketing content, which might contain promotional material including from pharmaceutical companies, and detailed how to unsubscribe.

Third party mailing lists were used to distribute sponsored content, such as the videos in question, within the academy health professional community, and required data subjects to opt-in. When signing up to newsletters or registering to attend an event, users were presented with the opportunity to update their third-party consent.

Orion noted that the email notification that was sent in this instance clearly identified that the campaign had been produced by the healthcare publisher with funding from Orion. Orion had made every effort to be clear and transparent and to alert recipients about the nature of its involvement, in line with Clause 9.10. The email notification went on to offer an explanation of the content of the video material available. Orion did not promote the use of any specific product as part of the email notification; the email offered a clear explanation of the educational content of the video resource, so there was no need to fulfil the requirements of Clause 4 (and associated subsections mentioned by the complainant) of the Code.

The academy website was independent from Orion. Orion was a corporate supporter of the academy commissioning platform, 2018-2019. Orion's involvement in this educational video series had been to sponsor an educational campaign that was hosted within this commissioning platform. In all cases, content sponsored by Orion was clearly identifiable.

Treatment choices were discussed in the videos but only in the broadest sense and no specific products were mentioned or endorsed. Orion had not promoted any particular product in association with this project and as no references were made to specific products in the video, Orion refuted the suggestion that the material was disguised promotion.

All material associated with the funding was reviewed and certified in accordance with company procedures and the requirements of the Code. Therefore, Orion maintained that it had met the requirements of Clause 14.1. Orion provided copies of the certificates for the email content and video mentioned by the complainant.

In summary, Orion submitted that the matters raised by the complainant were not representative of the way that it had sponsored this project. From investigations and knowledge of the organisation Orion was confident that the project it commissioned from the healthcare publisher had not been used as a promotional tool or linked in any way to the promotion or prescription of Orion medicines. Orion submitted that it had been clear and transparent about its involvement with the sponsored educational materials available on the academy website. Users must opt-in to receiving emails that contained sponsored content and might update their consent on a project-by-project basis. Therefore, only those who opted in received the email in question.

The project sponsored the provision of materials with genuine educational content for the healthcare community, which aimed to optimise patient treatment through consideration of medicines optimisation in primary care. Orion was keen to support colleagues working in primary care and offered useful resources to help with medicines optimisation in the NHS, as such, the company considered that it had maintained high standards.

As a consequence, Orion did not consider that the email or sponsored video content in question, or the way they were offered to health professionals, were such as to bring discredit upon, or reduce confidence in, the industry and in that regard it denied a breach of Clause 2.

## PANEL RULING

The Panel noted that the email in guestion sent from the named healthcare publication with the subject line 'Join the discussion: think before you prescribe' included in the body of the email the header 'This email has been sent by [named healthcare publication] and contains third party promotional information' followed in more prominent font by 'This campaign has been produced by [named healthcare publisher] with funding from Orion Pharma'. The email invited readers to watch and included a direct link titled 'Medicines optimisation and the clinical challenge in respiratory care' to a video which was hosted within the sponsored content section of a named respiratory academy website. This video was one of three videos within a series. All three videos had the same initial title 'Medicines optimisation and the challenges in respiratory care' and respectively covered the clinical perspective, commissioning perspective and the pharmacy perspective. The video linked to the email in question covered the clinical perspective. All three videos were hosted within the sponsored content section of the academy website and when one video was being viewed within a window on the website, the remaining two videos were available below the window to be selected and viewed.

The Panel noted Orion's submission that the e-mail notification regarding the availability of the educational video was sent to appropriately registered users of the healthcare publication website and third party mailing lists were used to distribute sponsored content, such as the video in question, within the respiratory academy healthcare professional community and required data subjects to opt-in.

The Panel noted that Clause 4.1 of the Code required prescribing information to be included in promotional material. Clause 4.2 listed the elements of the prescribing information required. Clause 4.4 required

that in the case of digital material such as emails the prescribing information as required by Clause 4.1 might be provided either by inclusion in the digital material itself, or by way of a clear and prominent direct single click link. Clause 4.6 stated that in the case of promotional material included on the Internet, there must be a clear, prominent statement as to where the prescribing information can be found.

The Panel did not consider that the email promoted any particular Orion medicine and thus no prescribing information was required. The complainant had not provided evidence to the contrary. The Panel therefore ruled no breach of Clauses 4.1, 4.4 and 4.6 in relation to the email. The Panel noted that Clause 4.9 required that all promotional material must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [web address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]'. The Panel noted its comments above and ruled no breach of Clause 4.9.

The Panel noted that the email notification identified that the campaign had been produced by the healthcare publisher with funding from Orion. The Panel queried whether this was an accurate description noting Orion's submission that it had commissioned the healthcare publisher to design, create and market a series of key opinion led educational videos focussing on respiratory management. In the Panel's view, Orion was more involved in the video campaign than the declarations in the email implied and the Panel considered that Orion had failed to maintain high standards in this regard and ruled a breach of Clause 9.1 in relation to the email.

The Panel noted that Clause 9.10 required that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company must clearly indicate that it has been sponsored by that company. The supplementary information stated that the declaration of sponsorship must be sufficiently prominent to ensure that readers of sponsored material were aware of it at the outset. The wording of the declaration must be unambiguous so that readers would immediately understand the extent of the company's involvement and influence over the material. This was particularly important when companies were involved in the production of material which was circulated by an otherwise wholly independent party, such as supplements to health professional journals.

The Panel noted that the complainant had not provided evidence to show that the respiratory academy website was promotional as alleged and the Panel therefore ruled no breach of Clauses 12.1,14.1, 4.1, 4.3, 4.4, 4.6, 4.8 and 4.9.

The Panel noted that the complainant referred to the phrase which appeared on the sponsors page of the website 'We thank our valued sponsors, who provide arms-length funding to support the running of the Academy'. The Panel noted that directly below this declaration it stated 'See below for a range of sponsored content that we have developed in collaboration with these organisations'. The sponsors page then listed the logos of four different pharmaceutical companies including Orion and at the bottom the page under the heading Sponsored content appeared links to the three videos described above stating sponsored by Orion and another item listed as being sponsored by another pharmaceutical company.

The Panel noted Orion's submission that it was a corporate sponsor of the academy website commissioning platform for 2018-2019. The Panel did not consider that the complainant had provided evidence to show that the statement 'We thank our valued sponsors, who provide arms-length funding to support the running of the Academy' did not reflect Orion's involvement with regard to the running of the academy. The Panel further noted, however, that a footer in very small print which seemed to appear on every page of the academy website including the sponsors page and the page to which the email was directed stated 'The [named academy] has been developed and is produced by [named healthcare publisher], the publisher of [named healthcare publications] working in partnership with [named academy]. All educational content for the website and roadshows has been initiated and produced by [named academy/named healthcare publisher]'. Three pharmaceutical company's logos including Orion's were included above the footer with the title Sponsors.

The Panel further noted that the website stated that the video series, of which the video in guestion was a part of, was produced by the healthcare publisher with funding from Orion Pharma. The Panel noted Orion's submission that its only involvement was the funding of the project and checking that the content of the materials was consistent with the requirements of the Code. The Panel queried whether this was accurate noting Orion's submission that it had commissioned the healthcare publisher to design, create and market a series of key opinion led educational videos focussing on respiratory management. In the Panel's view, Orion was more involved in the production of the videos, including the video at issue above, than the website implied and the Panel therefore ruled a breach of Clause 9.10 in relation to declarations about Orion's involvement in the video campaign including 'All educational content for the website and roadshows has been initiated and produced by [named academy/named healthcare publisher]' and 'This video series has been produced by [named healthcare publisher] with funding from Orion Pharma'.

The Panel noted that whilst the complainant referred to videos when listing the clauses he/ she considered were in breach, the email provided by the complainant directed readers to one of the videos, 'Medicines optimisation and the challenges in respiratory care: A Clinical Perspective'. It was not for the Panel to make out a complainant's allegation and the Panel therefore considered the complaint in relation to the specific video referred to by the complainant.

Whilst the Panel had some concerns about the video, in its view, the complainant had not established that the video was promotional and thus that prescribing information, the adverse event statement or date on which the material was last drawn up was required. The Panel therefore ruled no breach of Clauses 4.1, 4.3, 4.4, 4.6, 4.8 and 4.9 in relation to the video in question.

In the Panel's view, and noting its comments above, the content of the video was not promotional, and therefore it did not constitute disguised promotion and thus no breach of Clause 12.1 was ruled.

The Panel noted that the complainant raised Clause 14.1 which required that promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause. Whilst in the Panel's view the complainant had not established that the email or website were promotional, the Panel noted that both the video and email had been certified as general promotional material under the product 'Corporate' by Orion. The Panel therefore ruled no breach of Clause 14.1.

The Panel noted its ruling of a breach of Clause 9.10 above and considered that Orion had failed to maintain high standards in that regard and a breach of Clause 9.1 was ruled.

The Panel noted its rulings and comments above but did not consider that the particular circumstances of this case were such as to warrant a breach of Clause 2 which was a sign of particular censure. No breach of Clause 2 was ruled.

Complaint received	26 March 2019
Case completed	2 October 2019