

UNIVERSITY PROFESSOR v AGERION

Promotional emails disguised as educational material

A university professor complained about two emails he received on 16 and 23 December from Aegerion Pharmaceuticals. The first had the subject heading 'New guidance for clinicians on homozygous familial hypercholesterolaemia [HoFH]' and drew attention to, and provided a link to, Cuchel *et al* (2014). The second email was the same text with 'Reminder' added to the subject line and had been sent to those who had not clicked through on the link in the first email. Prescribing information for Lojuxta (lomitapide) was included. Lojuxta was indicated as an adjunct treatment in adults with HoFH.

The complainant stated that both promotional emails were mailed directly to his email address and addressed to him personally. The complainant was uncertain why he needed to be reminded of the information, and queried how Aegerion would know whether he had acted upon the original message. The complainant was concerned because the message was sent with clear promotional intent, masquerading as educational material and also because the Code clearly stated that recipients should have opted-in to such direct mailings and that the nature of the material should align with the recipient's clinical interest. The complainant alleged that neither condition was true in this case. The complainant had not opted-in to such mail, nor did he treat patients with HoFH.

The detailed response from Aegerion is given below.

The Panel noted that the emails discussed HoFH and introduced the consensus paper Cuchel *et al*, which was available via a link, and summarised its key points. The Panel noted that Cuchel *et al* discussed new insights and guidance for clinicians to improve detection and clinical management of HoFH. It discussed treatments and included lomitapide on a suggested algorithm for the management of HoFH. The main text of the email did not refer to a specific product but made a general reference to lipid lowering therapy and a subsequent reference to newer treatments offering the possibility of further LDL-C reduction. The two emails were identical other than the prefix 'Reminder' in the subject heading to the second email. The Panel agreed with the company's submission that the emails were promotional. Cuchel *et al*, *inter alia*, discussed a product in which the company had a commercial interest and the emails bore prescribing information.

The Panel noted Aegerion's admission that due to an error on its part, the mailing house had wrongly followed the process for emailing educational materials instead of the process for sending promotional materials. This was why the emails had been sent to the complainant without the requisite prior consent. A breach of the Code was ruled.

The Panel noted Aegerion's submission that the email was targeted at health professionals interested in cardiovascular disease and lipid disorders as they might potentially encounter diagnosed and undiagnosed cases of HoFH in their practice. The Panel noted that, according to Aegerion, when the complainant verified his details with the mailing house in April 2014 he indicated that he was a specialist in cardiovascular disease. The Panel also noted the company's submission about his academic profile and research into atherosclerotic plaques of the carotid. Whilst the Panel noted the complainant's submission that he did not treat patients with this condition, it nonetheless considered that given his speciality his need for or interest in the subject matter of the emails could reasonably have been assumed. No breach of the Code was ruled.

The complainant had alleged that the emails were sent with promotional intent but masqueraded as educational material. In that regard the Panel considered that the recipient's initial impression of the emails was important. In the recipient's inbox the emails appeared as from '[name]<information@hofh-management.co.uk'. The subject heading was 'New guidance for clinicians on homozygous familial hypercholesterolaemia'. On opening the email the text of the email did not bear a separate heading and in the Panel's view some recipients might have been left with the initial impression that the emails contained non-promotional information about HoFH as per their subject headings. This impression was compounded by the sender's address which bore no apparent link to a pharmaceutical company or otherwise indicated the emails' promotional content. The corporate logo did not appear at the outset on the hard copy versions of the email provided by the complainant. Those provided by the company bore the corporate logo on the top left hand corner. The Panel noted that the logo might only have appeared when the email was viewed in the web browser. If this was so, the complainant would not even have been aware at the outset that the email was from a pharmaceutical company. The emails were signed by a senior manager. In the Panel's view the length of the email was such that the pharmaceutical company's involvement and that the emails contained prescribing information would not be apparent until the recipient had scrolled down to the bottom of the emails. In such circumstances the Panel considered that despite the presence of prescribing information their primary characterisation at the outset was as a piece of educational material and the emails were disguised in this regard. A breach of the Code was ruled.

The Panel noted its rulings of breaches of the Code above and considered that high standards had not been maintained. A breach of the Code was ruled.

A university professor complained about two emails sent by Aegerion Pharmaceuticals Limited.

The emails (ref HoFK/UK/001) were identical and were sent on 16 and 23 December. The first email was sent with the subject heading 'New guidance for clinicians on homozygous familial hypercholesterolaemia [HoFH]' and drew the reader's attention to, and provided a link to, Cuchel *et al* (2014). The email was resent on 23 December with the subject heading 'Reminder: New guidance for clinicians on homozygous familial hypercholesterolaemia'. Prescribing information for Lojuxta (lomitapide) was included. The second email was only sent to those original recipients who had not clicked through on the link in the first email.

Lojuxta was indicated as an adjunct to a low-fat diet and other lipid lowering medicines with or without low density lipoprotein (LDL) apheresis in adult patients with HoFH. Genetic confirmation of HoFH should be obtained whenever possible. Other forms of primary hyperlipoproteinaemia and secondary causes of hypercholesterolaemia (eg nephrotic syndrome, hypothyroidism) must be excluded.

COMPLAINT

The complainant stated that both promotional emails were mailed directly to his email address and addressed to him in person. The second email was the same text, but with the word 'Reminder' added to the subject line. The complainant was uncertain why he needed to be reminded of the information, and did not know how Aegerion would know if he had acted upon the original message or not. The complainant was concerned firstly because the message was sent with clear promotional intent, masquerading as educational material and secondly, because the Code clearly stated that recipients should have opted-in to such direct mailings and that the nature of the material should align with the recipient's clinical interest. Neither condition was true in this case. The complainant had not opted-in to such mail, nor did he treat patients with this condition.

The Authority asked Aegerion to respond in relation to Clauses 9.1, 9.9, 11.1 and 12.1 of the Code.

RESPONSE

Aegerion submitted that the email was clearly promotional and in that regard it was not disguised as educational material. The recipients were in appropriate categories of health professionals whose need for the information could be assumed.

Aegerion regretfully acknowledged, however, that due to an error recipients, including the complainant, received the email inadvertently without their prior consent as required by Clause 9.9. The email was sent to health professionals with an interest in cardiology, cardiovascular disease, coronary care and paediatric cardiology or those specialties involved in the management of lipid disorders (chemical pathology, pathology, clinical chemistry and biochemistry), whom Aegerion reasonably

assumed had an interest in receiving information about Lojuxta which was used to lower low density lipoprotein cholesterol (LDL-C) in patients with HoFH. Based on Aegerion's experience, health professionals with an interest in these specialties were among those who treated HoFH patients. However, the company never intended to email promotional information without obtaining prior consent to do so.

Reflecting common practice, Aegerion exercised diligence and care to ensure that the email distribution complied with the Code and the company's standard operating procedures (SOPs). However, given the error described above, the company had reviewed and updated its SOPs and internal training procedures to help ensure that this type of error did not occur again.

Aegerion submitted that it aspired at all times to uphold high standards and that, other than Clause 9.9, it had not breached Clauses 9.1, 11.1 or 12.1.

1 The email distribution

The email concerned a recent clinical update (Cuchel *et al*) published in the European Heart Journal entitled 'Homozygous familial hypercholesterolaemia: new insights and guidance for clinicians to improve detection and clinical management. A position paper from the Consensus Panel on Familial Hypercholesterolaemia of the European Atherosclerosis Society'. Lojuxta was approved as an adjunct treatment for adults with HoFH.

HoFH was caused by genetic defects inherited from both parents that affected the function of the LDL receptor, the receptor responsible for removing LDL-C from the body. It typically presented as highly elevated cholesterol levels, severe and progressive atherosclerosis and premature cardiovascular disease. Aegerion considered Cuchel *et al* was a key cardiology publication as it was the first time that a consensus, European or otherwise, had been published on the diagnosis and management of HoFH. All previous publications discussed diagnosis and management guidance either for general dyslipidaemia or familial hypercholesterolaemia rather than its most severe form, HoFH. The publication included a short discussion on a number of potential treatment options for adults with HoFH, including Lojuxta.

The first email was sent to 2,097 health professionals in the UK and the Republic of Ireland with the reminder email being sent to 2,009 who had not clicked through on the first email – a standard approach by the mailing house used. The mailing house recorded health professionals' specialty based on the elections of health professionals. These records were updated on a regular basis. As noted above, the mailing list was comprised of specialties interested in the diagnosis and management of lipid disorders (chemical pathology, pathology, clinical chemistry and biochemistry), and cardiology, cardiovascular disease, coronary care and paediatric cardiology. A full breakdown of the specialties and

numbers was provided. The final number differed as the list of clinicians within the specialties was continuously being updated.

As noted above, due to an error on Aegerion's part, the mailing house incorrectly followed the process for emailing educational materials to physicians rather than the process for emailing promotional materials, which would have involved the mailing house sending a non-promotional email inviting recipients to click on a link to a landing page with an opt-in to view the promotional message. This error resulted in the email being sent without the consent required under Clause 9.9.

2 The email was not disguised promotion (Clause 12.1)

Aegerion submitted that it did not disguise the email as educational material, nor did it intend to do so.

The justification for sending the email to interested recipients was to provide information on HoFH and to invite the recipient to contact Aegerion if they were interested in receiving information about Lojuxta as a potential treatment for adults with HoFH. The email was purposely targeted to health professionals with an interest in cardiovascular disease and lipid disorders as they could potentially encounter diagnosed or undiagnosed cases of HoFH in their practice.

The email thus had a promotional purpose. Nowhere in the email or the subject matter was it mentioned that it was intended to be educational material. Nor could it be inferred that the email was intended to be promotional material disguised as educational.

It was clear from the information in the email, which included Aegerion's name and the signature of a senior manager that the promotional communication came from Aegerion. The statements at the end of the email made clear that Aegerion marketed Lojuxta as a treatment for HoFH. The email stated:

'If you would like to be contacted to discuss options for the management of HoFH, please contact [name] on [name]@aegerion.com.

Please see the end of this mail for prescribing information on Lojuxta (lomitapide) hard capsules.'

The inclusion of both statements in the email clearly drew attention to the use of Lojuxta as a treatment for HoFH. Further, the email also included a summarised version of the information in the journal and stated that:

'Newer treatments offer the possibility of further LDL-C reduction on top of current standard of care.'

The promotional intent of the email was underlined by the fact that, in accordance with the requirement in the supplementary information to Clause 10.1, it

was certified as promotional material and included the prescribing information for Lojuxta.

Aegerion had the utmost respect for the knowledge and experience of all health professionals with whom it might, from time to time, contact in accordance with applicable rules. Aegerion never intended to deliberately disguise the nature of any promotional material provided to health professionals. Aegerion regretted that the promotional email was sent to recipients who did not opt-in to receiving such information.

3 The complainant's assumed interest in the email

Aegerion understood that Clause 11.1 meant that a reasonable assumption must be evidenced to demonstrate that a recipient of promotional information required, or was interested in, receiving such material. Such a presumption was, arguably, subjective in nature and should be considered in light of the particular facts of each case.

Given the area of their expertise, Aegerion concluded that it was reasonable to assume that the complainant and other recipients of the email would have an interest in receiving emails of this nature. The recipients were listed in the database of the mailing house as having an interest in, among other things, cardiovascular disease and the management of lipid disorders. The mailing house made the categorisation of specialties based on the self-selection of the health professionals. Aegerion submitted that the complainant last verified his contact information with the mailing house in April 2014 as part of its annual cycle of revalidation. Following this revalidation, the complainant indicated that he was a specialist in cardiovascular disease.

As noted above, since the publication concerned HoFH, which typically presented as highly elevated cholesterol levels, severe and progressive atherosclerosis and premature cardiovascular disease, the email was purposely targeted to health professionals with an interest in these topics as they could potentially encounter diagnosed or undiagnosed cases of HoFH in their practice. In particular, the complainant's profile on a university website stated that he was a member of the Institute of Cardiovascular and Medical Sciences and had a particular interest in clinical trials relating to strokes. Aegerion also understood that one of his areas of research was atherosclerotic plaques of the carotid. The complainant had also co-authored a number of articles concerning cardiovascular diseases. Aegerion further understood that the complainant was involved with a national policy making group and was present during an advisory discussion about the use of Lojuxta within one of the UK regions.

Based on the above, Aegerion submitted that the complainant possessed knowledge of, and, presumably an interest in, HoFH and that there was a reasonable assumption that he would be interested in emails of this nature.

4 High standards

The email was promotional and not disguised as educational material. Aegerion regretfully acknowledged that the company's error resulted in the mailing house using its email distribution process for educational materials rather than for promotional materials. This meant that the email was sent to the complainant and the others in breach of Clause 9.9.

Aegerion was committed to maintaining the high standards for which the Code provided at all times during the course of its operations, including in relation to interactions with health professionals. As noted above, Aegerion was also committed to ensuring that this type of error did not occur again.

PANEL RULING

The Panel noted that the emails discussed HoFH and introduced the consensus paper Cuchel *et al*, which was available via a link, and summarised its key points. The Panel noted that Cuchel *et al* discussed new insights and guidance for clinicians to improve detection and clinical management of HoFH. It discussed a range of treatments including lomitapide which it included on a suggested algorithm for the management of HoFH. The main text of the email did not refer to a specific product but made a general reference to lipid lowering therapy and a subsequent reference to newer treatments offering the possibility of further LDL-C reduction. The two emails were identical other than the prefix 'Reminder' in the subject heading to the second email. The Panel agreed with the company's submission that the emails were promotional. Cuchel *et al*, *inter alia*, discussed a product in which the company had a commercial interest and the emails bore prescribing information.

The Panel noted that the Code prohibited the use of emails to promote medicines, except with the prior permission of the recipient. Previous cases had established that text or dialogue requesting permission to send promotional material had to make it abundantly clear that the intention was to send promotional material from pharmaceutical companies about medicines. The Panel noted Aegerion's admission that due to an error on its part, the mailing house had acted incorrectly in that it followed the process for emailing educational materials to physicians instead of the process for sending promotional materials. This error had resulted in the promotional emails being sent, *inter alia*, to the complainant without his requisite prior consent. A breach of Clause 9.9 was ruled.

The Panel noted Aegerion's submission that the email was purposely targeted at health professionals with an interest in cardiovascular disease and lipid disorders as they might potentially encounter

diagnosed and undiagnosed cases of HoFH in their practice. The Panel noted that, according to Aegerion, when the complainant verified his details with the mailing house in April 2014 he indicated that he was a specialist in cardiovascular disease. The Panel also noted the company's submission about his academic profile and research into atherosclerotic plaques of the carotid. Whilst the Panel noted the complainant's submission that he did not treat patients with this condition, it nonetheless considered that given his speciality his need for or interest in the subject matter of the emails could reasonably have been assumed. No breach of Clause 11.1 was ruled.

The complainant had alleged that the emails were sent with promotional intent but masqueraded as educational material. In that regard the Panel considered that the recipient's initial impression of the emails was important. In the recipient's inbox the emails appeared as from '[name]<information@hofh-management.co.uk'. The subject heading was 'New guidance for clinicians on homozygous familial hypercholesterolaemia'. On opening the email the text of the email did not bear a separate heading and in the Panel's view some recipients might have been left with the initial impression that the emails contained non-promotional information about HoFH as per the subject heading of the emails. This impression was compounded by the sender's address which bore no apparent link to a pharmaceutical company or otherwise indicated the emails' promotional content. The corporate logo did not appear at the outset on the hard copy versions of the email provided by the complainant. Those provided by the company bore the corporate logo on the top left hand corner. The Panel noted that the logo might only have appeared when the email was viewed in the web browser. If this was so, the complainant would not even have been aware at the outset that the email was from a pharmaceutical company. The emails were signed by a senior manager. In the Panel's view the length of the email was such that the pharmaceutical company's involvement and that the emails contained prescribing information would not be apparent until the recipient had scrolled down to the bottom of the emails. In such circumstances the Panel considered that despite the presence of prescribing information their primary characterisation at the outset was as a piece of educational material and the emails were disguised in this regard. A breach of Clause 12.1 was ruled.

The Panel noted its rulings of breaches of the Code above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

Complaint received 23 December 2014

Case completed 13 February 2015