

JOURNALIST v NOVARTIS

Daily Mail article

A journalist alleged that an article entitled 'Don't scrap asthma jab that saved my son's life', published in the Daily Mail online, promoted Xolair (omalizumab), marketed by Novartis. The complainant noted that no-one from Novartis was mentioned in the article but that others who were quoted were connected to the company. The complainant assumed that Novartis had had a hand in the article which was a one-sided account of Xolair.

The detailed response from Novartis is given below.

The Panel noted that when complaints were received about what an independent journalist had published in the press, its rulings were made upon the material released by the company that might have prompted the article, not the article itself.

The Panel noted the time delay between the relevant press release being issued (9, November 2012) and the publication of the article at issue (11, February 2013). Although the press release was about a draft decision by the National Institute for health and Clinical Excellence (NICE) to revoke existing positive guidance on the use of Xolair in patients aged 12 and above, it did not otherwise appear to have influenced the content of the article in the Daily Mail. The article was principally one mother's story about her 14 year old son and concluded with a general discussion about the potential negative impact of the draft NICE recommendation on patient care. The article quoted a spokesperson from Asthma UK, a hospital consultant in respiratory medicine and included a pack shot of Xolair which Novartis submitted was not a UK pack. The Panel noted that the press release did not refer to the 14 year old boy and although it quoted two hospital physicians, neither were the consultant quoted in the article. The press release did not refer to Asthma UK. The Panel noted Novartis's submission that neither it nor its PR agency had engaged with the author over the story nor did it know about the case study presented.

The Panel noted that the article was quite different to the press release; the press release had been issued three months before the article was published. The Panel noted the content of the press release and did not consider that it promoted Xolair to the public. No breach of the Code was ruled.

The Panel noted that the article described Xolair in very positive terms but that the tone of the press release was quite different and did not appear to have led to the strong, unequivocal claims in the article. The Panel thus ruled no breach of the Code.

The Panel considered that high standards had been maintained. No breach of the Code was ruled including no breach of Clause 2.

A journalist alleged that an article entitled 'Don't scrap asthma jab that saved my son's life' and published 11 February 2013 in the Daily Mail online, promoted Xolair (omalizumab), marketed by Novartis Pharmaceuticals UK Ltd. Xolair was indicated only for the treatment of patients with convincing IgE (immunoglobulin E) mediated asthma.

The relevant press release issued by Novartis was entitled 'NICE [National Institute for health and Clinical Excellence] draft decision on omalizumab (Xolair) could leave people with the most severe form of asthma without an effective and innovative treatment option' and detailed a draft decision by NICE not to recommend the use of Xolair for the treatment of severe persistent allergic asthma which revoked existing positive guidance. The efficacy of Xolair vs alternative treatment options was discussed as was the burden of severe asthma. The press release included quotations from senior health professionals.

COMPLAINT

The complainant alleged that the Daily Mail article was thinly veiled promotion for Xolair. No-one from Novartis was explicitly mentioned in the article but a quick Google search found that a consultant in respiratory medicine who the paper spoke to, had attended advisory boards for, *inter alia*, Novartis as he declared in a recent BMJ article. The complainant also noted that Asthma UK, who's chief executive was interviewed in the piece, was also funded by Novartis to the tune of around £45,000 in 2011.

The complainant submitted that the article stated that other medicines were bad and Xolair was better and implied heavily that NICE should not reject its use on the NHS – all points Novartis emphatically agreed with – and this was not surprising given that two of those interviewed for the article had direct relations with the company.

The complainant assumed that Novartis had had a hand in the story being made known to Asthma UK and the Daily Mail, and the story was very one-sided in its blatant promotion of a prescription only medicine – the article also included a pack shot of Xolair, which the complainant knew from experience could only be obtained from a pharmaceutical company as it needed to be signed off for use.

The complainant stated that Novartis had probably done enough to escape censure under the Code, but he asked that the Authority investigate whether this was so. The complainant also asked that this type of behaviour be reviewed when the Code was next updated, as it made a mockery of policing pharmaceutical companies when they could find way to promote medicines on the world's biggest online news site.

When writing to Novartis, the Authority asked it to consider the requirements of Clauses 2, 9.1, 22.1 and 22.2 of the Code.

RESPONSE

Novartis submitted that it was not involved in the generation of the article.

Novartis stated that it issued a press release in November 2012 (copy provided) shortly after the draft decision from NICE to revoke its current positive guidance for Xolair use in patients aged 12 years and older.

Novartis also confirmed that neither it nor its PR agency had engaged with the author of the article at any point over this story. Nor did it have any interaction or knowledge of the case studies used in the article.

Novartis had, in line with the Code, complied with all requirements on transparency of its relationships with patient groups and listed all the groups supported on its website and thus any funding provided to Asthma UK was openly declared. Members of Asthma UK, including the named representatives, had participated in educational events for Novartis employees to highlight the importance of the company's medicines on the lives of patients with severe persistent allergic asthma. One of the named representatives of Asthma UK had also provided unpaid expertise at a Novartis advisory board.

Novartis stated that it routinely held educational events for a variety of conditions to educate and inform its employees on the importance of the work it did in developing medicines and the impact they could have for people with these conditions.

Novartis confirmed that it had a consultancy agreement as outlined in Clause 20 of the Code with the health professional quoted in the article. These included activities such as Novartis-sponsored medical educational events, symposia and advisory boards on severe asthma and allergy. The health professional was also an investigator on Novartis-sponsored clinical trials.

Novartis submitted that the pack shot shown in the article was not a UK pack for Xolair 150mg. The pack licensed in the UK had an ampoule containing 2ml solvent, whilst the one in the Daily Mail picture showed an ampoule containing 5ml of diluent. An internet search showed that the same pack photograph appeared on an independent website for the pharmaceutical industry. Novartis stated that

this pack shot was not provided to the journalist or Asthma UK by either Novartis UK or by Novartis Switzerland. Furthermore, in 2012 this presentation (powder and solvent) was superseded by a new prefilled syringe. A copy of the current SPC for Xolair (powder formulation) was provided. Unfortunately, Novartis did not have a pack shot for the powder formulation so a copy of the pack artwork image was provided which it believed clearly showed how the pack differed.

For the reasons outlined above, Novartis considered that there was no breach of Clauses 22.1 and 22.2 of the Code in promoting prescription only medicines to the public. Consequently, Novartis did not consider that it had failed to maintain high standards or that it had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The company thus denied breaches of Clauses 9.1 and 2.

Novartis hoped this information had assuaged concerns and provided the reassurance that Novartis continued to uphold high standards in its activities and actions.

PANEL RULING

The Panel noted that when complaints were received about what an independent journalist had published in the press, its rulings were made upon the material released by the company that might have prompted the article, not the article itself.

The Panel noted the time delay between the press release being issued (9, November 2012) and the publication of the article at issue (11, February 2013). The Panel further noted that although the press release was about a draft decision by NICE to revoke existing positive guidance on the use of Xolair in patients aged 12 and above, it did not otherwise appear to have influenced the content of the article in the Daily Mail. The article in the Daily Mail was principally one mother's story about her 14 year old son and how he might be affected by NICE's impending decision. The article concluded with a general discussion about the potential negative impact of the draft NICE recommendation on patient care. The article quoted a spokesperson from Asthma UK and also a hospital consultant in respiratory medicine. The article included a pack shot of Xolair which Novartis submitted was not a UK pack. The Panel noted that the press release did not refer to the 14 year old boy or provide any other case studies and although it quoted two hospital physicians, neither were the consultant quoted in the Daily Mail article. The press release did not refer to Asthma UK. The Panel noted Novartis's submission that neither it nor its PR agency had engaged with the author at any point over the story nor did it have any knowledge of the case study presented.

The Panel noted that the article was quite different to the press release; the press release had been issued three months before the article was published. The Panel noted the content of the press release and did not consider that it promoted Xolair to the public. No breach of Clause 22.1 was ruled.

The Panel noted that article stated that the effects of Xolair were 'unbelievable' and that it 'didn't cause terrible side-effects like other treatments'. In that regard the Panel noted that the tone of the press release was quite different and did not appear to have led to the strong, unequivocal claims in the article. The Panel thus ruled no breach of Clause 22.2.

The Panel considered that high standards had been maintained. No breach of Clause 9.1 was ruled.

The Panel noted its rulings above and consequently ruled no breach of Clause 2.

Complaint received **14 February 2013**

Case completed **26 March 2013**
