

COMPLAINANT v DR FALK PHARMA

Provision of obligatory information on a website

An individual who described him/herself as a 'concerned UK health professional', complained about the Dr Falk Pharma website for health professionals and links from that website. The complainant referred to information provided for Budenofalk (budesonide, used to treat, *inter alia*, Crohn's disease), Salofalk (mesalazine, used to treat ulcerative colitis), Ursofalk (ursodeoxycholic acid, used to treat, *inter alia*, primary biliary cirrhosis) and Jorveza (budesonide, used to treat eosinophilic esophagitis).

The complainant noted that on the webpages for Budenofalk, Salofalk and Ursofalk, there was only a link to the relevant summary of product characteristics (SPC) and no prescribing information. In a media link there was a first mention of Jorveza but there was no generic name stated nor any link to prescribing information. An article on Jorveza, accessed by a link on the website, similarly had no prescribing information. A link to a different website took the reader to an advertisement for Budenofalk which included out-of-date prescribing information as two updates, which included details of special warnings, had not been included. Finally, a link to another published article had no prescribing information and it was not evident that the article was promotional although it was from a promotional website.

The detailed response from Dr Falk Pharma is given below.

The Panel noted that the complainant had only provided a screen shot of one part of the website and not shots of the other pages. Dr Falk Pharma had not been able to supply full details. In the Panel's view, it was important that complainants provided screen shots at the time of their complaint to ensure that the PMCPA had access to the same material as they did. A website could be updated by a pharmaceutical company immediately after the complainant viewed it and before the PMCPA had been notified.

The Panel noted from Dr Falk Pharma that the health professional section of the website was intended for registered health professionals only and was password protected. The media page and other pages were not password protected. The media page was intended for the press and media agencies. Dr Falk Pharma submitted that the article on Jorveza was available to readers once they clicked on the title of the article and that the link to the SPC including the prescribing information was also available.

The Panel noted that it appeared that the media pages on the website referred to the latest articles, press releases etc, content produced and published by Dr Falk Pharma for the media. In addition the media pages also appeared to include content where

Dr Falk Pharma and/or its products were mentioned. This was described as 'Dr Falk Pharma in the media'. The Panel noted that on the pages for health professionals although there were links to the SPCs for (Budenofalk, Salofalk, and Ursofalk), prescribing information had not been provided. The links to the SPCs were not sufficient to meet the requirements of the Code. The legal classification and the cost were also required. The Panel therefore ruled breaches of the Code in relation to Budenofalk, Salofalk and Ursofalk.

In relation to the media link and the first mention of Jorveza, the Panel did not have access to the relevant material. Such a link should not be advertising and therefore although it might be helpful to give the non-proprietary name, there was no requirement to do so. Nor was there a requirement to include prescribing information. The Panel did not consider that the complainant had shown on the balance of probabilities that this material was promotional. Given the circumstances, the Panel ruled no breach of the Code.

In relation to the Jorveza article and the alleged lack of prescribing information, again the Panel noted that it did not have access as to how this appeared on the website. It appeared that the material was an article published in Pharmacy Magazine. The material provided by Dr Falk Pharma was headed 'New drug for eosinophilic oesophagitis' followed by a photograph of a woman who was clutching her stomach. The text below the photograph referred to Jorveza and its indication. The Panel considered that the material was in effect an advertisement for Jorveza. The prescribing information was not provided as part of the material but according to Dr Falk Pharma, a link to the SPC including the prescribing information was provided on the media page. The Panel noted that the media page link stated 'for more information about Jorveza please click here'. There was no mention that this was the link to the prescribing information and as there was no clear link a breach was ruled.

The Panel noted that the complainant had accessed a link from the Dr Falk Pharma website to an advertisement for Budenofalk which appeared in an online journal. The complainant provided the address for the link. The Panel had no information about the link from Dr Falk Pharma or from its website. Historical advertisements would be available in third party publications. If Dr Falk Pharma had provided a direct link to the historical advertisement then this was in effect the same as the company having that advertisement on its own website. The prescribing information in the advertisement for Budenofalk in Gastroenterology Today, Summer 2017 was not up-to-date at the time such a link was used. Given that the complainant

had provided the direct link and that the Dr Falk Pharma media page included links to Dr Falk Pharma in the media, the Panel decided, on the evidence before it, on the balance of probabilities, that the link was to the actual advertisement. Thus the Panel ruled a breach of the Code.

The Panel noted that the published article referred to by the complainant was a review of ursodeoxycholic acid in primary biliary cholangitis. If Dr Falk Pharma had a role in the production/publication of the article then this was not clear. The final page stated the author's conflict of interest as having served on advisory boards and lectured on behalf of Dr Falk Pharma and another company. The Panel did not consider it had sufficient information to understand the arrangements for the publication of the article. Having a published paper on a pharmaceutical company website was not necessarily promotional. The Panel did not consider that the complainant had shown, on the balance of probabilities, that this material was promotional and thus required prescribing information or that placing the article on the website amounted to disguised promotion as alleged. No breach of the Code was ruled. The Panel noted its rulings set out above and ruled a breach as overall high standards had not been maintained. It did not consider the circumstances warranted a ruling of a breach of Clause 2 of the Code which was used a sign of particular censure.

An individual who described him/herself as a 'concerned UK health professional', complained about the Dr Falk Pharma website for health professionals and links from that website. The complainant referred to information provided for all of Dr Falk Pharma's medicines ie Budenofalk (budesonide, used to treat, *inter alia*, Crohn's disease), Salofalk (mesalazine, used to treat ulcerative colitis), Ursofalk (ursodeoxycholic acid, used to treat, *inter alia*, primary biliary cirrhosis) and Jorveza (budesonide, used to treat eosinophilic esophagitis).

COMPLAINT

The complainant referred to five items. Firstly, the complainant noted that on the separate product pages for Budenofalk, Salofalk and Ursofalk, there was only a link to the relevant summary of product characteristics (SPC) and no prescribing information. Secondly, in a media link there was a first mention of Jorveza but there was no generic name stated nor any link to prescribing information. Thirdly, an article on Jorveza, accessed by a link on the website, similarly had no prescribing information. Fourthly, the complainant noted that a link to a different website (issuu.com) took the reader to an advertisement for Budenofalk which included out-of-date prescribing information as two updates, which included details of special warnings, had not been included. Finally, a link to another published article had no prescribing information and it was not evident that the article was promotional although it was from a promotional website.

When writing to Dr Falk Pharma, the Authority asked it to consider the requirements of Clauses 2, 4.1, 4.3, 9.1 and 12.1 of the 2016 Code.

RESPONSE

Dr Falk Pharma stated that it recognised the accidental omission of the prescribing information from its website and that it was working to remedy the matter; the prescribing information would be on the webpages shortly. The company had also reviewed the website in light of this complaint and was in the process of revising the content.

With regard to the out-of-date prescribing information, (the fourth allegation) Dr Falk Pharma noted that the complainant had referred to an advertisement for Budenofalk that appeared in the online version of Gastroenterology Today, Summer 2017. The prescribing information was dated October 2016 and related to the summaries of product characteristics (SPCs) dated July 2016 (granules) and November 2016 (capsules). The capsules SPC was updated after that of the granules and to come into line with the granules. The prescribing information and SPC were therefore correct when the advertisement was published. The SPC was not updated again until after publication. Dr Falk Pharma submitted that one of its standard operating procedures (SOPs) described the process to ensure the prescribing information was updated following revisions to the SPC. Current advertisements had the current prescribing information.

Dr Falk Pharma provided information on how its website was navigated.

In response to a request for further information, Dr Falk Pharma stated that the company was unable to provide a copy of the relevant media webpage as it had been updated and a copy was not kept. Copies of the article on Jorveza and the published article were provided. These were published on the media page of the website.

PANEL RULING

The Panel noted that the complainant had provided a screen shot of one part of the website. The complainant had not provided screen shots of the other pages. Dr Falk Pharma had not been able to supply full details. In the Panel's view, it was important that complainants provided screen shots at the time of their complaint to ensure that the PMCPA had access to the same material as the complainant. A website could be updated by a pharmaceutical company immediately after the complainant viewed it and before the PMCPA had been notified.

The Panel noted the information from Dr Falk Pharma about its website. The information was a presentation dated February 2019 and stated that the health professional section of the website was intended for registered health professionals only and was password protected. The media page and other pages were not password protected. The media page was intended for the press and media agencies. Dr Falk Pharma submitted that the article on Jorveza was available to readers once they clicked on the title of the article and that the link to the SPC including the prescribing information was also available here.

The Panel noted that it appeared that the media pages on the website referred to the latest articles, press releases etc, content produced and published by Dr Falk Pharma for the media. In addition the media pages also appeared to include content where Dr Falk Pharma and/or its products were mentioned. This was described as 'Dr Falk Pharma in the media'.

In relation to the list of products referred to by the complainant, (Budenofalk, Salofalk, and Ursofalk) the Panel noted that these appeared on the pages for health professionals and although there were links to the relevant SPCs on the Dr Falk Pharma website, prescribing information had not been provided. The links to the SPCs were not sufficient to meet the requirements in Clause 4.2 of the Code. This clause listed a number of elements which made up the prescribing information as required by Clause 4.1 and although many of these would be satisfied by the provision of the SPC, the legal classification and the cost were also required. The Panel therefore ruled breaches of Clause 4.1 of the Code in relation to Budenofalk, Salofalk and Ursofalk.

In relation the media link and the first mention of Jorveza, the Panel did not have access to the relevant material. Such a link should not be advertising and therefore although it might be helpful to give the non-proprietary name, there was no requirement to do so. Nor was there a requirement to include prescribing information. The Panel did not consider that the complainant had shown on the balance of probabilities that this material was promotional. Given the circumstances, the Panel ruled no breach of Clauses 4.1 and 4.3 of the Code.

In relation to the Jorveza article and the alleged lack of prescribing information, again the Panel noted that it did not have access as to how this appeared on the website. The presentation provided by Dr Falk Pharma gave some information. It appeared that the material was an article published in Pharmacy Magazine. The material provided by Dr Falk Pharma was headed 'New drug for eosinophilic oesophagitis' followed by a photograph of a woman who was clutching her stomach. The text below the photograph referred to Jorveza and its indication. The Panel considered that the material was in effect an advertisement for Jorveza. The prescribing information was not provided as part of the material but according to Dr Falk Pharma, a link to the SPC including the prescribing information was provided on the media page. The Panel noted that the media page link stated 'for more information about Jorveza please click here'. There was no mention that this was the link to the prescribing information. The Panel considered that there was no clear link to the prescribing information and a breach of Clause 4.1 was ruled.

The Panel noted that the complainant had accessed a link from the Dr Falk Pharma website to an

advertisement for Budenofalk which appeared in an online journal. The complainant provided the address for the link. The Panel had no information about the link from Dr Falk Pharma or from its website. It was not clear whether it was a link to the actual advertisement or to the journal and then readers came across the advertisement. The Panel accepted that historical advertisements would be available in third party publications. If Dr Falk Pharma had provided a direct link to the historical advertisement then this was in effect the same as the company having that advertisement on its own website. The prescribing information in the advertisement for Budenofalk in Gastroenterology Today, Summer 2017 was not up-to-date at the time such a link was used. This would be a breach of Clause 4.1 of the Code. Given that the complainant had provided the direct link and that the Dr Falk Pharma media page included links to Dr Falk Pharma in the media, the Panel decided, on the evidence before it on the balance of probabilities, that the link was to the actual advertisement. Thus the Panel ruled a breach of Clause 4.1.

The Panel noted that the published article referred to by the complainant was a review of ursodeoxycholic acid in primary biliary cholangitis. If Dr Falk Pharma had a role in the production/publication of the article then this was not clear. The final page stated the author's conflict of interest as having served on advisory boards and lectured on behalf of Dr Falk Pharma and another named company. The Panel did not consider it had sufficient information to understand the arrangements for the publication of the article. Having a published paper on a pharmaceutical company website was not necessarily promotional. For example, the supplementary information to Clause 26.2 referred to reference information made available for medicines with marketing authorisations and that this could include published papers. The Panel did not consider that the complainant had shown, on the balance of probabilities, that this material was promotional and thus required prescribing information. The Panel therefore ruled no breach of Clause 4.1 of the Code. The Panel did not consider that placing the article on the website amounted to disguised promotion as alleged and thus ruled no breach of Clause 12.1 of the Code.

The Panel noted its rulings set out above and considered that overall high standards had not been maintained with the website. The Panel therefore ruled a breach of Clause 9.1 of the Code. It did not consider the circumstances warranted a ruling of a breach of Clause 2 of the Code which was used a sign of particular censure.

Complaint received

4 February 2019

Case completed

24 May 2019