

VOLUNTARY ADMISSION BY DR FALK PHARMA

Promotion to the public via YouTube

Dr Falk Pharma UK voluntarily admitted breaches of the Code in that a video made by the company, which discussed the use of mesalazine tablets and granules to treat inflammatory bowel disease, appeared on YouTube. Dr Falk Pharma marketed Salofalk (mesalazine) in a number of different forms including tablets and granules.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Dr Falk Pharma.

Dr Falk Pharma explained that the video, made in 2015 in conjunction with a third party, for use for a limited period within the NHS Alliance, was available on YouTube without the knowledge or permission of Dr Falk Pharma.

The video discussed the cost of inflammatory bowel disease to the NHS and used a patient case study. A clinician commented that mesalazine granules could be more effective than tablets in reaching the inflamed areas of the bowel and mentioned a study supported by Dr Falk Pharma that looked at the effectiveness of granules and the savings that might accrue for the NHS. A senior executive at the company was interviewed and further discussed the study and the benefits of mesalazine granules.

Following an investigation into the matter, Dr Falk Pharma recognized that the video posted on the NHS Alliance website did not meet the requirements of the Code. It was not known how many people viewed the video on this website and how many of them were not health professionals. The company therefore accepted breaches of the Code as a prescription only medicine might have been promoted to the public and members of the public might have been encouraged to ask their health professional to prescribe that medicine. These breaches were due to a failure to meet internal requirements relating to document review. The video had not been intended as promotional but in hindsight should have been certified; high standards had not been maintained and further breaches of the Code were acknowledged.

The video had been viewed 131 times on YouTube and was removed on 6 August 2018. The company investigated further and found that an unknown person placed the video on YouTube in December 2015 and the reason for the upload was unknown. Dr Falk Pharma stated that it did not monitor social media outside of its control and so it was entirely unaware that the video in question was on YouTube; it was no longer available on the NHS Alliance website.

The detailed response from Dr Falk Pharma is given below.

The Panel considered that given the content of the film and its focus on the advantages of Salofalk, it was difficult to understand how the company decided that the film was not promotional. It appeared that Dr Falk Pharma now accepted that the film was promotional. The video had not been certified and thus the Panel ruled a breach of the Code.

The Panel noted that Dr Falk Pharma did not place the material on YouTube. The video was to be distributed by the NHS Alliance and to be hosted on its website for 12 months to encourage social sharing and promotion of the programme. It was to be sent to various organisations and promoted via a programme press release to relevant journalists. It was also part of the programme at the NHS Alliance Conference on 9 December 2015.

The company had no documentation which covered the archiving/withdrawal of the film at the end of the one year contract and there was no evidence that Dr Falk had been clear about the access to the film or had limited viewing to those to whom prescription only medicines could be advertised.

If the promotional film had been seen by the public it would have constituted advertising a prescription only medicine to the public. On the narrow ground that the company had not made the film available to the public on YouTube the Panel ruled no breach of the Code.

However, the Panel considered that Dr Falk Pharma's voluntary admission included that the availability of the film on the NHS Alliance website meant that the company had promoted its prescription only medicine to the public. There was no justification from Dr Falk Pharma that the audience for the NHS Alliance, including its website, was an appropriate audience for the advertising of prescription only medicines. The Panel considered that on the available information, Dr Falk Pharma had promoted a prescription only medicine to the public and ruled a breach of the Code. Statements had been made which would encourage members of the public to ask their health professionals to prescribe a prescription only medicine and a further breach was ruled.

The Panel considered that high standards had not been maintained. The failure to recognise the film as promotional material showed poor understanding of the Code as did the failure to certify the film and the lack of due diligence on the particulars in the agreement with the third party. A breach of the

Code was ruled. On balance, the Panel considered that the circumstances did not warrant a ruling of a breach of Clause 2 and ruled accordingly.

Dr Falk Pharma UK Ltd voluntarily admitted breaches of the Code in that a video made by the company, which discussed the use of mesalazine tablets and granules to treat inflammatory bowel disease, appeared on YouTube. Dr Falk Pharma marketed Salofalk (mesalazine) in a number of different forms including tablets and granules.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with Dr Falk Pharma.

VOLUNTARY ADMISSION

Dr Falk Pharma explained that on 2 August 2018, a third party unconnected with the company informed it that an informational video, made in 2015 for use for a limited period within the NHS Alliance, was available on YouTube. The company took immediate steps to have the video removed from YouTube and this was achieved on 6 August. The video had been uploaded to YouTube without the knowledge or permission of Dr Falk Pharma but the company nonetheless recognized the need to take responsibility and to voluntarily admit breaches of the Code.

Dr Falk Pharma submitted that investigation into the placing of the video on YouTube brought to light further breaches of the Code in relation to the placement of the video on the NHS Alliance site.

Dr Falk Pharma explained that it made the video in conjunction with a third party for the NHS Alliance website as information on inflammatory bowel disease and its treatment. The video was to be available on the NHS Alliance site for 12 months. A transcript was provided.

The video discussed the cost of inflammatory bowel disease to the NHS and illustrated the personal impact of the disease using a patient case study. A clinician described the use of mesalazine tablets to treat inflammatory bowel disease and commented that mesalazine granules could be more effective in reaching the inflamed areas of the bowel compared with tablets. The doctor mentioned a study supported by Dr Falk Pharma that looked at the effectiveness of granules and the savings that might accrue for the NHS. The study was adopted by the National Institute for Health and Care Excellence (NICE) as a quality and productivity case study. A senior executive of Dr Falk Pharma was then interviewed and further discussed the study and the benefits of mesalazine granules. The video closed with the patient commenting on the personal benefit to him.

Following the investigation into the matter, Dr Falk Pharma now recognized that the final version of the video posted on the NHS Alliance website did not meet the requirements of the Code. It was not known how many people viewed the video on the NHS Alliance website and how many of them were

not health professionals. The company therefore accepted a breach of Clause 22.1 as a prescription only medicine might have been promoted to the public and a breach of Clause 22.2 as members of the public might have been encouraged to ask their health professional to provide the concerned medicine.

The investigation found that these breaches were due to a failure to meet internal requirements relating to document review. The video had not been intended as promotional but in hindsight should have been certified and therefore a breach of Clause 14.1 had occurred.

The company also accepted a breach of Clause 9.1 as high standards had not been maintained.

Dr Falk Pharma noted that the video had been viewed on YouTube 131 times before it was removed on 6 August 2018. The company could only find that an unknown person placed the video on YouTube in December 2015 and therefore the reason for the upload was unknown. As expected, the video was no longer available on the NHS Alliance site as the contract was for one year.

Dr Falk Pharma stated that it did not monitor social media outside of its control. The company only monitored its own social media accounts in case of any reports of adverse drug reactions due to its products, which was a requirement of the pharmacovigilance guidelines. The company only ran a Twitter account which was monitored twice a week and was entirely unaware that the video in question was on YouTube.

Dr Falk Pharma reiterated that it fully accepted responsibility under the Code, and the breaches outlined above, despite having no knowledge of, nor providing permission for, the video to be on YouTube.

Dr Falk Pharma was asked to consider the requirements of Clause 2 in addition to Clauses 9.1, 14.1, 22.1 and 22.2.

RESPONSE

Dr Falk Pharma reiterated that it made the video in conjunction with a third party for the NHS Alliance website as information on inflammatory bowel disease and its treatment. The video was to be available on the NHS Alliance site for 12 months from December 2015. Dr Falk Pharma provided the web address for the page where the video was posted; access to that page was not limited. It was impossible to determine how many people viewed the video during the year.

Dr Falk Pharma stated that it was contacted by letter of 31 July, received 2 August 2018, detailing the complaint. The letter made several points including that the video was found on YouTube and therefore breached Clauses 22.1 and 22.2 of the Code and as there was no certification reference there was a possible breach of Clause 14.1. Dr Falk Pharma provided its agreement with the third party.

Following correspondence with the case preparation manager who clarified that Clause 14.3 and Clauses 26.1 and 26.2 (instead of Clauses 22.1 and 22.2 referred to by Dr Falk Pharma) were relevant, Dr Falk Pharma confirmed that as the video was made in 2015, Clauses 14.1 and 14.3 of the 2015 Code were breached. The video was made available by NHS Alliance during 2016 and hence Clauses 26.1 and 26.2 of the 2016 Code applied. The video was on YouTube during 2016 until August 2018 and thus Clauses 26.1 and 26.2 of the 2016 Code applied. Dr Falk Pharma submitted that it had provided all of the information and documentation already and it had no further comments.

PANEL RULING

In considering this matter and given that Clauses 14.1 and 14.3 of the 2015 Code were the same in the 2016 Code, the Panel decided to consider the matter under the 2016 Code. The Panel also noted that the voluntary admission incorrectly referred to Clauses 22.1 and 22.2 of the Code rather than Clauses 26.1 and 26.2.

The Panel noted that Clause 1.2 defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

Given the content of the film and its focus on the benefits of using Dr Falk Pharma's product it was difficult to understand how the company decided that the film was not promotional. The focus was on the advantages of Salofalk (mesalazine granules). The Panel noted that it appeared that Dr Falk Pharma now accepted that the film was promotional by its acknowledgement of a breach of Clause 14.1. The promotional material had not been certified and thus the Panel ruled a breach of Clause 14.1. The Panel noted that Clause 14.3 included a requirement that material for the public and patients was certified. The Panel noted its ruling regarding Clause 14.1 and considered that this covered the position and therefore in its view, there was no need to consider Clause 14.3.

The Panel noted that the company did not place the material on YouTube. It appeared from the signed agreement with the third party that Dr Falk Pharma had full editorial control over the film and owned the copyright in the segment. The programme was to be distributed by the NHS Alliance and the third party. It was to be hosted on the NHS Alliance website for 12 months to encourage social sharing and promotion of the programme. It was to be sent to various

organisations and promoted via a programme press release to relevant industry journalists of the care sector press. It was also part of the programme at the NHS Alliance Conference on 9 December 2015.

The company had no documentation which covered the archiving/withdrawal of the film at the end of the one year contract.

There was no evidence that Dr Falk Pharma had been clear about the access to the film or had limited viewing to those to whom prescription only medicines could be advertised.

If the promotional film had been seen by the public it would have constituted advertising a prescription only medicine to the public. On the narrow ground that the company had not made the film available to the public on YouTube the Panel ruled no breach of Clauses 26.1 and 26.2 of the Code.

However, the Panel considered that Dr Falk Pharma's voluntary admission included that the availability of the film on the NHS Alliance website meant that the company had promoted its prescription only medicine to the public. The Panel considered that the agreement with the third party implied that the distribution of the film was wide. There was no justification from Dr Falk Pharma that the audience for the NHS Alliance, including its website, was an appropriate audience for advertising of prescription only medicines. The Panel considered that on the available information, Dr Falk Pharma had promoted a prescription only medicine to the public and ruled a breach of Clause 26.1. Statements had been made which would encourage members of the public to ask their health professionals to prescribe a prescription only medicine and a breach of Clause 26.2 was also ruled.

The Panel considered that high standards had not been maintained by Dr Falk Pharma. The failure to recognise the film as promotional material showed poor understanding of the Code. As did the failure to certify the film and the lack of due diligence on the particulars in the agreement with the third party. Dr Falk Pharma had not maintained high standards and a breach of Clause 9.1 was ruled. On balance, the Panel considered that the circumstances did not warrant a ruling of a breach of Clause 2 and ruled accordingly.

Voluntary admission received **6 September 2018**

Case completed **12 November 2018**