CASE AUTH/2257/8/09

VOLUNTARY ADMISSION BY FERRING

Information sent to patient group

Ferring voluntarily admitted that its public relations (PR) agency had sent unapproved copy about Firmagon (degarelix) to a patient organisation. The matter had come to light during the investigation of concerns raised by a competitor company. Firmagon was indicated for the treatment of advanced prostate cancer.

The action to be taken by the Authority in relation to a voluntary admission by a company was set out in the Constitution and Procedure which stated, *inter alia*, that the Director should treat the matter as a complaint if it related to a potentially serious breach of the Code. The provision of inappropriate information to the public and/or a patient organisation was a potentially serious matter and the Director decided to treat the matter as a complaint.

Ferring submitted that it was appropriate to provide the patient organisation with information about Firmagon, a new treatment for hormone deprivation therapy of advanced prostate cancer. Ferring gave the PR agency an approved press release about the launch of Firmagon for it to give to outside agencies including the patient organisation. No other briefing materials should have been provided to external agencies, including the patient organisation, without the prior approval of Ferring. However, following discussions with the patient organisation, the PR agency, unbeknown to Ferring emailed an edited version of the approved press release from which the patient organisation developed content for its website.

Ferring did not consider that the information emailed to the patient organisation fully and properly reflected the content of the approved press release. In particular: it omitted background information about prostate cancer; a consultant urologist's clinical opinion about the place of Fimagon; information about side effects and references; it added text that exaggerated the time taken by LHRH agonists to achieve castrate levels of testosterone and the statement 'Ask your doctor for more information about FIRMAGON' and it amended the text '… aimed at patients has been produced by Ferring Pharmaceuticals who hold the marketing authorisation FIRMAGON …' to '… aimed at patients has been produced by Ferring Pharmaceuticals who make FIRMAGON…'.

These changes significantly altered the balance of the information from that presented in the approved press release. The PR agency told Ferring that the patient organisation had requested simplified information with a limited word count and so the two worked together to produce the text that was ultimately provided. Ferring did not consider that it was acceptable for the PR agency to amend and provide copy to the patient organisation without its prior approval.

Following the provision of the non-approved copy, the home page for the patient organisation contained a link entitled 'DEGARELIX (Firmagon). More details about this new drug here – and how to order your free DVD'. Details of the DVD 'Progress for a Healthy Lifestyle: A Guide for Men on Hormone Therapy for Prostate Cancer' were provided. The information contained on the page was essentially the same as the text provided by the PR agency. This was set up by the patient organisation following the provision of the information from the PR agency together with a few samples of the DVD, which the patient organisation had endorsed. Ferring acknowledged that the juxtaposition in a link box on the patient organisation homepage, for details concerning Firmagon and the offer of the DVD was not satisfactory. Ferring emailed the patient organisation to ask it to separate the DVD information from the degarelix information and provide a new link to information on the DVD and how to get it from the patient organisation.

Changes were made to the patient organisation website about a month after the website went live.

Ferring took this situation extremely seriously and had had urgent detailed discussions to establish the circumstances. A review of the PR agency established that there were no other similar occurrences and that this was a one-off event that occurred because it wished to assist a patient organisation with limited resources.

Ferring told all relevant staff about the matter and would review of all agency agreements to ensure that there was no repeat.

The detailed response from Ferring is given below.

The Panel noted that Ferring's PR agency had provided unapproved copy about Firmagon. The Panel noted Ferring's submission that its PR agency had worked independently with the patient organisation. The Panel noted that companies were responsible for information about their products issued by their PR agencies. If this were not so it would be possible for agencies to act beyond the scope of their agreement with the pharmaceutical company, in a way which the company could not do itself and so avoid the

restrictions of the Code. It was important that pharmaceutical companies actively managed their PR agencies in this regard and ensured that they had Code compliant systems in place.

It was not unacceptable to give information about prescription only medicines to patient organisations but its content and provision had to comply with the Code. Transparency was a key requirement.

It appeared from an email dated 22 June from the PR agency to the patient organisation that the agency had in effect provided camera ready copy. Ferring had submitted that the published material was essentially the same as the text provided by its agency. It was unclear whether the original request for copy by the patient organisation was unsolicited. This was thought to be unlikely given the distribution of the DVD was to be from the patient organisation website. The email however was dated 22 June whereas the press release was dated 24 June. Firmagon was launched on 22 June. Irrespective of the status of the original request the material provided still had to comply with the Code.

The Panel was very concerned about the amendments made to the approved press release; Important information had been omitted and text had been amended.

With concern, the Panel noted in addition to those changes to the press release cited by Ferring a sentence in the approved press release which read 'Firmagon doesn't cause these initial hormone surges and so doctors don't prescribe anti-androgen therapy to counteract this, avoiding associated side effects and offering an effective monotherapy' had been changed to read '… avoiding associated side-effects *and ensuring that men with prostate cancer only have to take one medication instead of two*' (emphasis added). The Panel noted Ferring's acknowledgement that the totality of the changes significantly altered the balance of the information presented in the press release.

The text provided to the patient organisation had not been certified as required by the Code and a breach was ruled. The changes made to the press release were such that the information was misleading and not presented in a balanced way; information about side effects had been omitted and the time taken by a class of competitor products to achieve castration levels of testosterone had been exaggerated. Also mention was made of only having to take one medicine instead of two. In the Panel's view the amended press release would encourage members of the public to ask their health professional to prescribe a specific prescription only medicine, Firmagon. The material failed to comply with the Code and a breach was ruled.

The Panel was concerned about the misleading nature of the changes made to the press release. The agency had in effect provided the patient organisation with copy ready for publication although the patient organisation was told it could 'tweak' the copy or simplify the language. The Panel noted that as published on the patient organisation website the material did not refer to Ferring's role in the creation of the material. It appeared to be patient organisation material. The Panel considered that the changes made to the material were such that Ferring via its agency had in effect sought to influence text presented as patient organisation material in a manner favourable to its own interest. A breach of the Code was ruled.

The Panel was very concerned about the misleading content of the material and the relationship with the patient organisation as evidenced by the email correspondence. The email dated 22 June from the agency to the patient organisation gave the overall impression that publication of the Firmagon copy and the offer of the DVD on the patient organisation website were an integral part of the Firmagon launch strategy. Reference was made to measuring the number of website hits to measure impact. Whilst this was not necessarily unacceptable it was important that readers were aware of Ferring's role in relation to the creation of material published on the patient organisation's website. The Panel noted that Ferring had not raised this point specifically in its voluntary admission.

The Panel was concerned that Ferring only discovered this matter when so informed by a competitor company. Whilst it was unfortunate that Ferring had been placed in this position by its agency which appeared to have ignored the agreement between the parties, Ferring was nonetheless responsible for activity undertaken on its behalf. The Panel noted that misleading material had been provided to a patient organisation for publication. Information about side effects had been omitted. The arrangement was not transparent. High standards had not been maintained. A breach of the Code was ruled. On balance the Panel considered that the circumstances brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Ferring Pharmaceuticals Ltd voluntarily admitted that its public relations (PR) agency had sent unapproved copy about Firmagon (degarelix) to a patient organisation. The matter had come to light during the investigation of concerns raised by a competitor company. Firmagon was indicated for the treatment of advanced prostate cancer.

The action to be taken by the Authority in relation to a voluntary admission by a company was set out in Paragraph 5.4 of the Constitution and Procedure which stated, *inter alia*, that the Director should treat the matter as a complaint if it related to a potentially serious breach of the Code. The

provision of inappropriate information to the public and/or a patient organisation was a potentially serious matter and the Director decided to treat the matter as a complaint.

COMPLAINT

Ferring submitted that it was appropriate to provide the patient organisation with information containing basic facts about Firmagon, a new treatment for hormone deprivation therapy of advanced prostate cancer. Ferring provided the PR agency with an approved press release, for communication to outside agencies including the patient organisation. This press release related to the launch of Firmagon on 22 June 2009. No other briefing materials should have been provided to external agencies, including the patient organisation, without the prior approval of Ferring. However, following discussions with the patient organisation, the PR agency emailed an edited version of the approved press release from which the patient organisation developed content for its website. Copies of the approved press release and the information provided to the patient organisation by the PR agency were provided. Ferring noted that the email containing the non-approved copy was blind circulated to a senior brand manager at Ferring at the same time as it was sent to the patient organisation. Unfortunately, the email arrived at a very busy period during the launch week and was viewed on a hand held device rather than a computer and so the attachment was not opened. There was no reason to believe from the contents of the email that the information provided was not the approved press release and so the attachment was not later reviewed.

Ferring noted that Paragraph 12 of the Guidelines on Company Procedures Relating to the Code of Practice, gave information about interaction between pharmaceutical companies and patient organisations: 'Pharmaceutical companies can interact with patient organisations or any user organisation such as disability organisations, carer or relative organisations and consumer organisations to support their work, including assistance in the provision of appropriate information to the public, patient and carers'.

From this guidance, Ferring was unclear whether it was acceptable under the Code for the PR agency to work with the patient organisation in the way that it did, in order to assist the patient organisation to produce the text it wished to place on its website.

Ferring only learnt about this after the event, when it found out that the content on the patient organisation website was not consistent with the information that would have been provided by the approved press release. Ferring did not consider the information provided to the patient organisation by the PR agency fully and properly reflected the content of the approved press release.

In particular, following discussion with the patient organisation, the PR agency made some significant changes to the approved press release:

- The omission of background information about prostate cancer.
- The omission of comments by a consultant urologist, which gave a clinical opinion about the place of Firmagon as a new option for androgen deprivation therapy in patients with advanced hormone-dependent prostate cancer.
- The addition of text that exaggerated the time taken by LHRH agonists to achieve castrate levels of testosterone by adding '(and longer)' in the following text '… unlike existing hormone treatments which take up four weeks (and longer) to reduce testosterone to the required levels'. This was amended by the PR agency with the intention of reflecting the situation in which the use of an anti-androgen preceded the administration of an LHRH agonist, which was not a claim that Ferring supported as sustainable.
- The omission of information regarding side effects.
- The addition of the text 'Ask your doctor for more information about FIRMAGON'.
- Amending the text '… aimed at patients has been produced by Ferring Pharmaceuticals who hold the marketing authorisation FIRMAGON …' to '… aimed at patients has been produced by Ferring Pharmaceuticals who make FIRMAGON …'.
- The omission of references.

Ferring acknowledged that these changes significantly altered the balance of the information from that presented in the approved press release. The PR agency told Ferring that the patient organisation had requested simplified information with a limited word count and so the two organisations worked together to produce the wording that was ultimately provided to the patient organisation by the PR agency. Ferring did not consider that it was acceptable for the PR agency to make amendments and provide any copy to the patient organisation without its prior approval.

Following the provision of the non-approved copy, the home page for the patient organisation contained a link entitled 'DEGARELIX (Firmagon). More details about this new drug here – and how to order your free DVD'. Details of the DVD 'Progress for a Healthy Lifestyle: A Guide for Men on Hormone Therapy for Prostate Cancer' were provided. The information contained on the page was essentially the same as the text provided by the PR agency. This was set up by the patient organisation following the provision of the information from the PR agency together with a small number of samples of the DVD, which the patient organisation had endorsed. Ferring understood that this went live on 24 June. Ferring acknowledged that the juxtaposition in a link box on the patient organisation homepage, for details concerning Firmagon and the offer of the DVD was

not satisfactory. Ferring emailed the patient organisation on 25 June to ask it to separate the DVD information from the degarelix information and provide a new link to information on the DVD and how to get it from the patient organisation. In subsequently telephone calls (26 and 29 June) Ferring was told that the website was managed by a trustee of the charity who would take account of the request but as this was an independent patient organisation, he would decide how and when the relevant changes would be made.

Ferring was then informed by the patient organisation that changes were being made on 3 July. Changes were made to the patient organisation website on 6 July that consisted of the addition of a separate link to details about the DVD, although the reference to the DVD was not removed from the link to degarelix or from the degarelix information page.

On 24 July, Ferring once again asked that the information on the patient organisation website be updated as quickly as possible, and the website was revised later that day, to take account of all Ferring's concerns. Information about the DVD was no longer linked to information about Firmagon and the information provided about Firmagon was acceptable to Ferring. Copies were provided of the relevant pages of the website as they appeared on 7 August.

Ferring took this situation extremely seriously and had had urgent detailed discussions with the PR agency to establish the circumstances surrounding this issue, and to ensure that appropriate procedures were put in place to prevent a repeat of this unacceptable practice. A review of the PR agency established that there were no other similar occurrences and that this was a one-off event that occurred because it wished to assist a patient organisation with limited resources.

Ferring had told all relevant staff about this matter and would review all agency agreements to ensure that their was no repeat.

When writing to Ferring, the Authority asked it to respond in relation to Clauses 2, 9.1, 14.3, 22.2 and 23.6 of the Code.

RESPONSE

Ferring believed that a key aspect of this case was that of how the text given to the patient organisation by the PR agency was decided upon and agreed between those two parties. Under Clause 23.1 pharmaceutical companies were allowed to work with patient organisations.

In an initial meeting to discuss the disease awareness DVD, the patient organisation agreed to endorse the DVD and wished to offer it through its website. No payment to the patient organisation was discussed, offered or paid. No agreement had been entered into between Ferring and the patient organisation, other than that Ferring would supply it with disease awareness DVDs free of charge and it in turn would offer them at no charge to patients who visited its website. Ferring had not provided, nor currently provided any additional financial or other support to the patient organisation.

Whilst Ferring accepted that the text that was provided by the PR agency following a telephone conversation with the patient organisation would not have complied with the Code if it were provided unsolicited, the text was prepared only after a telephone conversation between the PR agency and the chief executive of the patient organisation. The text was intended to help to meet the patient organisation's immediate needs because its staff were extremely busy with other activities at that time. The PR agency did not intend to provide inappropriate material and the changes made to the approved press release reflected the needs and usual style for content on the patient organisation's website eg the patient organisation normally included a recommendation that patients discussed their treatment needs and options with their own doctor.

In this instance, the PR agency worked independently with the patient organisation, with good intentions. However, Ferring acknowledged that this was not appropriate, and the actions of the PR agency resulted in the provision of text that had not been approved by Ferring. In mitigation, however, as soon as Ferring became aware of this action steps were taken to correct the situation, as outlined above.

In addition, the actions of the PR agency contravened its agreement with Ferring, which stated, *inter alia*:
'[The Agency] agrees, in addition, not to make any statement on Ferring's behalf or concerning Ferring to the press, media, investors, brokers, banks, financial analysts and/or any other person unconnected with Ferring without the prior approval of Ferring. This Clause 4 together with Clauses 6, 9 and 10 will survive any expiry or termination of this Agreement.'

Ferring did not believe that there had been a breach of Clause 2, which related to promotional activities or materials that brought discredit upon, or reduced confidence in, the pharmaceutical industry, either by positive action or inadequate action. Ferring believed that the PR agency worked in good faith to try to meet the needs of the patient organisation. The text provided to the patient organisation did not exaggerate the properties of Firmagon, although Ferring acknowledged that it lacked balance, for example, by excluding information relating to side effects. As stated above, the PR agency's actions contravened its agreement with Ferring, and it should be noted that when Ferring became aware of the situation, steps were taken that resulted in the removal of the original copy and subsequent posting of appropriate information on the patient

organisation website as quickly as possible. Ferring noted that a breach of Clause 2 denoted particular censure and it did not consider that the circumstances surrounding this event related in type or scale to the examples of activities which could lead to a breach of this clause.

Ferring did not consider that there had been a breach of Clause 9.1, which related to the maintenance of high standards in promotional activities. As previously noted, the PR agency had tried to assist the patient organisation by providing text for its website in accordance with the patient organisation's needs. In addition, the PR agency contravened the agreement between it and Ferring to seek prior approval for the copy that was provided to the patient organisation.

Ferring accepted that this matter might be in breach of Clause 14.3 since the PR agency essentially provided the patient organisation with uncertified copy, albeit following a telephone conversation with the patient organisation which resulted in the provision of text was intended to meet the needs of the patient organisation.

Ferring accepted that this matter might be in breach of Clause 22.2 since the information provided to the patient organisation lacked balance, for example, by excluding information relating to side effects, and included the statement 'Ask your doctor for more information about Firmagon' albeit following a telephone conversation with the patient organisation, which resulted in the provision of text intended to meet the needs of the patient organisation.

Ferring did not consider that there had been a breach of Clause 23.6, which related to a company attempting to influence patient organisation material in a manner favourable to its own commercial interests. As previously described, the PR agency had tried to assist the patient organisation to prepare text for its website that was in accordance with the patient organisation's needs. Ferring did not believe that the text provided was promotional, or that it would raise unfounded expectations in patients.

Ferring had reviewed all agreements with agencies to ensure that provisions were in place to require that agencies working on its behalf provided only approved communications to approved recipients.

PANEL RULING

The Panel noted that Ferring's PR agency had provided unapproved copy about Firmagon to a patient organisation. The Panel noted Ferring's submission that its PR agency had worked independently with the patient organisation. The Panel noted that companies were responsible for information about their products issued by their PR agencies (Clause 22.5). If this were not so it would be possible for beyond the scope of their agreement with the pharmaceutical company and in a way which the company could not do itself and so avoid the restrictions of the Code. It was important that pharmaceutical companies actively managed their PR agencies in this regard and ensured that they had Code compliant systems in place.

It was not unacceptable to make available information about prescription only medicines to patient organisations but its content and provision had to comply with the Code particularly Clauses 22 and 23 and the relevant supplementary information. Transparency was a key requirement.

It appeared from an email dated 22 June from the PR agency to the patient organisation that the agency had in effect provided camera ready copy. Ferring had submitted that the published material was essentially the same as the text provided by its agency. It was unclear whether the original request for copy by the patient organisation was unsolicited. This was thought to be unlikely given the distribution of the DVD was to be from the patient organisation website. The email however was dated 22 June whereas the press release was dated 24 June. Firmagon was launched on 22 June. Irrespective of the status of the original request the material provided still had to comply with the Code.

The Panel was very concerned about the amendments made to the approved press release. Certain important information had been omitted such as information about side effects. Text had been amended: the phrase 'and longer' had been added to a sentence about onset of action which now read 'This is unlike existing hormone treatment which can take up to four weeks **(and longer)** to reduce testosterone to the required levels' (emphasis added), an amendment which Ferring acknowledged exaggerated the time taken by LHRH agonists to achieve castration levels of testosterone.

With concern, the Panel noted in addition to those changes to the press release cited by Ferring a sentence in the approved press release which read 'Firmagon doesn't cause these initial hormone surges and so doctors don't prescribe anti-androgen therapy to counteract this, avoiding associated side effects and offering an effective monotherapy' had been changed to read '… avoiding associated side-effects **and ensuring that men with prostate cancer only have to take one medication instead of two**' (emphasis added). The Panel noted Ferring's acknowledgement that the totality of the changes significantly altered the balance of the information presented in the press release.

The text provided to the patient organisation had not been certified as required by Clause 14.3; a breach of that clause was ruled. The changes made to the press release were such that the information was misleading and not presented in a balanced way; information about side effects had been

omitted and the time taken by a class of competitor products to achieve castration levels of testosterone had been exaggerated. Also mention was made of only having to take one medicine instead of two. In the Panel's view the amended press release would encourage members of the public to ask their health professional to prescribe a specific prescription only medicine, Firmagon. The material failed to comply with Clause 22.2 and a breach of that clause was ruled.

The Panel was concerned about the misleading nature of the changes made to the press release. The agency had in effect provided the patient organisation with copy ready for publication although the patient organisation was told it could 'tweak' the copy or simplify the language. The Panel noted that as published on the patient organisation website the material did not refer to Ferring's role in the creation of the material. It appeared to be patient organisation material. The Panel considered that the changes made to the material were such that Ferring via its agency had in effect sought to influence text presented as patient organisation material in a manner favourable to its own interest. A breach of Clause 23.6 was ruled.

The Panel was very concerned about the misleading content of the material and the relationship with the patient organisation as evidenced by the email correspondence. The email dated 22 June from the agency to the patient organisation gave the overall impression that publication of the Firmagon copy and the offer of the DVD on the patient organisation website were an integral part of the Firmagon launch strategy. Reference was made to measuring the number of website hits to measure impact. Whilst this was not necessarily unacceptable it was important that readers were aware of Ferring's role in relation to the creation of material published on the patient organisation's website (Clauses 9.10 and 23.8 referred). The Panel noted that Ferring had not raised this point specifically in its voluntary admission.

The Panel was concerned that Ferring only discovered this matter when so informed by a competitor company. Whilst it was unfortunate that Ferring had been placed in this position by its agency which appeared to have ignored the agreement between the parties, Ferring was nonetheless obliged to take responsibility for activity undertaken on its behalf. The Panel noted that misleading material had been provided to a patient organisation for publication. Information about side effects had been omitted. The arrangement was not transparent. High standards had not been maintained. A breach of Clause 9.1 was ruled. On balance the Panel considered that the circumstances brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

During its consideration of this case the Panel noted that the home page of the patient organisation website featured a highlighted box which referred to Firmagon and linked to the Firmagon copy. The agency's role in relation to the placement of the banner was unclear. The Panel was concerned about the banner. The email from the agency to the patient organisation stated 'Thanks so much for offering to put a box on your front page relating to "For more information about Firmagon, click here …"'. Thus, at the very least, the agency had been put on notice that the reference to Firmagon would appear on the front page. The Panel queried whether this, in effect, advertised Firmagon, a prescription only medicine to the public in contravention of Clause 22.1. The Panel noted that Ferring had not raised this point in its voluntary admission.

Complaint received **7 August 2009**

Case completed **17 September 2009**