

PHARMACOSMOS v VIFOR

Ferinject video

Pharmacosmos A/S complained about a video issued by Vifor Pharma UK which referred to Ferinject (ferric carboxymaltose) solution for injection/infusion. Ferinject was indicated for the treatment of iron deficiency when oral iron preparations were ineffective or could not be used.

Pharmacosmos understood that Vifor agreed with the NHS Alliance to contribute to NHS Alliance TV news, an hour-long video which was to be shown at the NHS Alliance conference and posted on the NHS Alliance website. The theme of the conference was to focus on the Quality, Innovation, Productivity and Prevention (QIPP) initiative. The title of the video was 'Delivering QIPP by redesigning iron services'. Vifor provided speakers and allowed filming at its premises. The script was reviewed internally and the video was signed off according to Vifor's procedures.

Pharmacosmos stated that Vifor did not regard its involvement in the video or its content as being promotional and this was at the crux of this case.

Pharmacosmos stated that its complaint was about the video being made available to health professionals in the first place as part of the NHS Alliance conference. Pharmacosmos alleged that it was not clear to the intended audience that the video constituted a promotional presentation from Vifor, in breach of the Code.

The claim 'for patients it would mean a speedier recovery' appeared immediately following a statement that 'Iron treatment protocols are placing a burden on the NHS'. Taken in context with later comments in the video about Ferinject, the clear inference was that Ferinject could speed recovery by allowing the iron services to be redesigned, which was misleading, in breach of the Code.

The first time the brand name was used meant that the generic name and an indication that the product was under intensive monitoring from the Committee on the Safety of Medicine (CSM) was needed. In the absence of a visual indication on screen, this should be stated in the commentary. In addition, the failure to provide prescribing information was in breach of the Code.

Pharmacosmos alleged that the claim 'Ferinject provides ... all the iron they need in just one 30 minute visit' was misleading as not all patients treated with Ferinject could be given all the iron they needed in a single infusion. The maximum dose of Ferinject per treatment was 1000mg and 15mg/kg.

Pharmacosmos stated that it had serious concerns about Vifor's approach to the project as exhibited in the inter-company dialogue. The combined effect of disguised promotion, misleading claims and missing

obligatory information constituted a considerable failure to maintain controls and standards. The detailed response from Vifor is given below.

The Panel noted that the video opened with a sequence which featured the Vifor company name and logo in the centre of the screen together with the title 'Delivering QIPP by redesigning iron services'. In this regard the Panel considered that there was no doubt that the video had been sponsored by Vifor; the company's involvement was clear from the outset. No breach of the Code was ruled.

The Panel considered that although the title of the video was not product related its content was such that most viewers would consider that it promoted Ferinject. The first two minutes of the 3:44 minute video were about general issues but then the information was specifically about Ferinject. The Panel considered that the video was clearly promotional and in that regard its nature was not disguised. No breach of the Code was ruled.

The Panel noted that the video had been filmed at Vifor's offices, Vifor had suggested speakers; its general manager had spoken on the video. The draft script had been reviewed internally and signed off according to company procedure. Vifor had submitted that its input into the video stopped at this stage. The Panel noted that a document provided by Vifor, entitled 'Story Outline', appeared to be a written agreement between the NHS Alliance, the film company and Vifor. The document listed three key messages: 'Vifor Pharma want to raise awareness of their product, Ferinject'; 'Vifor Pharma want to raise awareness of iron deficiency, its symptoms, how anaemia could be better treated now and for patients in the future' and 'Vifor Pharma want to start a conversation among doctors about how this illness is best treated and help them discuss the best funding options with the NHS'. In the Panel's view there was thus no doubt that, at the outset and contrary to the company's response, Vifor knew that the video would promote Ferinject; to consider otherwise demonstrated a fundamental lack of understanding of the Code and its requirements. In this regard the Panel noted the definition of promotion was any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines. The Panel considered that Vifor's submission that its intention was simply to help the debate around the practicality of QIPP by giving a practical example was disingenuous. The Panel considered that the video should have contained prescribing information and other obligatory information for Ferinject which it did not. A breach of the Code was ruled.

In relation to the claim 'for patients it would mean a speedier recovery' the Panel noted that this appeared in a section referring to changes to intravenous (IV) iron services design which would deliver valuable QIPP outcomes. For patients it would mean a speedier recovery and fewer visits to hospital. The previous section referred to Ferinject as the perfect solution to the usual treatment which involved numerous trips to hospital for iron injections over a long period of time. Where Ferinject could be administered as a single dose infusion, the treatment course was shorter than that for products that needed multiple visits. However there was another medicine, Cosmofer (iron (III)-hydroxide dextran complex) which could be administered as a single dose albeit over a longer time period compared to Ferinject. Contrary to Vifor's submission the Panel considered that the claim implied that Ferinject would speed recovery. This was not always so. The Panel did not consider that redesigning the service to use Ferinject would mean a speedier recovery. The Panel considered that the claim was misleading and a breach of the Code was ruled.

In relation to the allegation about the claim 'Ferinject provides ... all the iron they need in just one 30 minute visit', the Panel noted that the claim in the video was not the same. The video stated 'Iron deficiency is currently treated either by a long day in hospital, or multiple visits. But ... Ferinject is different. The patient can receive all the IV iron they need in just one thirty minute visit'. Although the Panel had concerns that, in effect, the claim in the video implied that Ferinject provided all the iron needed in just one visit (as noted above) and that was not so, there was no actual claim that Ferinject provided all the iron needed in just one 30 minute visit as alleged. Nevertheless, the Panel ruled that the implication of the claim in the video was misleading in breach of the Code.

Overall, the Panel found it difficult to understand how the video could be seen as anything other than promotional. The Panel considered that Vifor's conduct in relation to the Code warranted consideration by the Code of Practice Appeal Board and it decided to report the company to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider whether further sanctions were warranted.

The Appeal Board was extremely concerned that Vifor had considered the video non-promotional and in that regard it referred in particular to the key message in 'Story Outline', 'Vifor Pharma want to raise awareness of their product, Ferinject'. The Appeal Board noted Vifor's submission that it had not intended to promote its product. Promotion was defined in the Code as 'any activity undertaken by a pharmaceutical company which promotes the prescription, supply, sale or administration of its medicines'. The Appeal Board noted that a company's intention was not relevant when considering whether its materials or activities were promotional. In the Appeal Board's view the video and the story outline were clearly promotional in nature. The Appeal Board was also extremely

concerned about some of the claims made in the video and queried whether they complied with the Code. In the Appeal Board's view, the fact that the video had been certified through the copy approval system compounded the errors within.

The Appeal Board considered that Vifor's actions demonstrated a fundamental lack of understanding of the Code and its requirements. This case raised very serious concerns regarding the expertise of Vifor's signatories and the role of senior management in compliance matters.

The Appeal Board noted that Vifor had accepted that it had made serious errors and in that regard had already started a review of its policies and procedures. Nonetheless, the Appeal Board decided that Vifor's procedures in relation to the Code should be audited as soon as possible by the Authority. On receipt of the audit report the Appeal Board would consider whether further sanctions were necessary.

The Appeal Board was also extremely concerned that the video might still be in use by some third parties and so it decided to require Vifor to take immediate steps to recover the video by writing to each recipient to ask them, where practical, to return it. The letter should explain why such action was necessary.

Upon receipt of a letter from Vifor regarding the recovery of the video the Appeal Board noted that the NHS Alliance had sent 990 DVDs, which included the Vifor film, to staff in primary care trusts, foundation trusts, acute trusts, local authorities and central government departmental bodies and agencies. The Appeal Board decided that in the circumstances Vifor should work with the NHS Alliance to ensure that those who had been sent copies of the DVD be informed that Vifor's contribution, following a complaint under the Code, had been ruled in breach of the Code and that full details could be found on the PMCPA website.

Vifor was first audited in November 2011 and upon receipt of that audit report the Appeal Board was concerned that the audit report indicated that Vifor had much work to do. It noted from Vifor's response that a preliminary corrective and preventative actions programme had been drawn up. It requested that Vifor be asked to provide timescales. It also decided that Vifor should be asked to provide copies of the correspondence between the company and its head office about the audit report and details about the role of an external consultant.

The Appeal Board was concerned to note that since deciding that Vifor should be audited, another case, which involved a breach of undertaking (Case AUTH/2442/10/11), had been considered by the Panel. On the day of the audit that case was still on going and so was not discussed. The Appeal Board noted, however, that the case had now completed.

The Appeal Board decided that Vifor should be re-audited in March 2012. On receipt of the report for that audit, the Appeal Board would consider if further sanctions were necessary.

Upon receipt of the March 2012 audit report the Appeal Board was disappointed at the lack of progress since the November 2011 audit particularly with regard to the revision of standard operating procedures (SOPs). The Appeal Board noted that new staff were due to be appointed. The Appeal Board considered that Vifor should be re-audited in six months time at which point it expected there to be significant improvement. In the meantime Vifor should provide by the end of June a detailed interim response to the recommendations of the March 2012 audit to include an update on recruitment and SOPs. If the Appeal Board was not satisfied then the re-audit would be brought forward.

Upon receipt of the next audit report, the Appeal Board would decide whether further sanctions were necessary.

On consideration of the interim response from Vifor, the Appeal Board decided that there was no need to reaudit sooner than the currently arranged date, in October 2012.

Upon receipt of the October audit report, the Appeal Board noted that good progress had been made since the last audit. New staff had been appointed who would have key roles in compliance. New standard operating procedures had been written and resources had been committed to Code compliance. The Appeal Board considered that on the basis that Vifor's current commitment to compliance was maintained, no further action was required.

Pharmacosmos A/S complained about a video issued by Vifor Pharma UK Limited which referred to Ferinject (ferric carboxymaltose) solution for injection/infusion. Ferinject was indicated for the treatment of iron deficiency when oral iron preparations were ineffective or could not be used.

COMPLAINT

Pharmacosmos understood from inter-company dialogue that Vifor agreed with the NHS Alliance to contribute to NHS Alliance TV news, an hour-long video which was to be shown at the NHS Alliance conference and posted on the NHS Alliance website. The theme of the conference was to focus on the Quality, Innovation, Productivity and Prevention (QIPP) initiative. The title of the video was 'Delivering QIPP by redesigning iron services'. Pharmacosmos stated that as Vifor entered into this video as partners with the NHS Alliance it was responsible for the content under Clauses 1.2 and 1.8 of the Code. Vifor's view was that perceived benefits of Ferinject aligned with the principles of QIPP and explained these in the video. However, Vifor did not regard its involvement in the video or its content as being promotional. This difference in opinion was at the crux of this case.

Vifor provided speakers and allowed filming at its premises. Vifor stated that the script was reviewed internally and the video was signed off according to Vifor's internal procedures (Pharmacosmos was not sure if it was certified).

Subsequently, Vifor was approached by a third party media company to host the video on its website and gave its permission. The third party media company subsequently emailed registered users of the website (whom Pharmacosmos believed to be both health professionals and members of the public) about new information on the website. As such, the company had acted on behalf of Vifor (and the NHS Alliance) and so Vifor was responsible for the actions of the agency. In inter-company dialogue Vifor had categorically denied responsibility for this email. Pharmacosmos understood that the email had been sent to a wide group of UK health professionals. Pharmacosmos alleged that the content and nature of the email was promotional and within the scope of the Code. It was clear that Vifor did not conduct any meaningful checks on the nature of the third party media company or control the availability of the video and after Pharmacosmos brought the matter to Vifor's attention, Vifor realised that the media company was not part of the NHS Alliance and arranged for the video to be removed from the website. The email was sent in April.

Pharmacosmos stated that it was not at this time raising specific concerns in relation to the email's content or its distribution. Nor was it currently raising any formal complaint in respect of the placement of the video on the website. However it wished to consider the email and the interactions with the third party media company as part of Vifor's overall approach to this project.

Vifor had clearly stated that the video was shown at the NHS Alliance conference and that it gave permission for the video to be displayed on a freely accessible website and that attention was drawn to the video by an email. The video was thus clearly distributed and viewed by a number of different audiences. Pharmacosmos did not believe that withdrawing the video from the third party website was an appropriate response as this action was only in relation to the perceived risk of promoting to the general public, a matter about which it was not complaining.

Pharmacosmos stated that its complaint was about the video being made available to health professionals in the first place as part of the NHS Alliance conference.

As clearly stated in inter-company correspondence, Vifor appeared to believe that its actions were both compliant and responsible. It had completely misunderstood the Code in respect of the fundamental activity, which was that it knowingly participated in creating and distributing a promotional video without sufficient controls or declarations. This raised serious concerns about Vifor's understanding of the Code.

Transparency: Pharmacosmos alleged that it was not clear to the intended audience that the video constituted a promotional presentation from Vifor (as partners in the production), in breach of Clauses 12.1 and 9.10. The video was created in the form of a news report, which added to the impression that it was non-promotional.

However the video clearly promoted the virtues of Ferinject.

Claim, 'for patients it would mean a speedier recovery': This claim appeared immediately following a statement that: 'Iron treatment protocols are placing a burden on the NHS'. Taken in context with the comments that followed later in the video regarding Ferinject specifically, the clear inference was that Ferinject could speed recovery by allowing the iron services to be redesigned, which was misleading, in breach of Clause 7.2.

Obligatory information: The first time the brand name was used meant that the generic name and an indication that the product was under intensive monitoring from the Committee on the Safety of Medicine (CSM) was needed. In the absence of a visual indication on screen, this should be stated in the commentary. A breach of Clause 4.3 was alleged.

In addition, Pharmacosmos alleged that the failure to provide prescribing information was in breach of Clause 4.1.

Claim, 'Ferinject provides....all the iron they need in just one 30 minute visit': Not all patients treated with Ferinject could be given all the iron they needed in a single infusion. The maximum dose of Ferinject per treatment was 1000mg and 15mg/kg. Pharmacosmos alleged that the claim was misleading in breach of Clause 7.2. Pharmacosmos submitted that it was for Vifor to prove why Ferinject provided 'all the iron they needed', not for Pharmacosmos to disprove it.

Overall, Pharmacosmos stated that it had serious concerns about Vifor's approach to the project as exhibited in the inter-company dialogue. The combined effect of disguised promotion, misleading claims and missing obligatory information constituted a considerable failure to maintain controls and standards.

RESPONSE

Vifor stated that the QIPP initiative was driven at a national, regional and local level to support clinical teams and NHS organisations to improve the quality of care they delivered while making efficiency savings that could be reinvested in the service to deliver year on year quality improvements.

The NHS Alliance, organisers of the November 2010 NHS Alliance Annual Conference, asked Vifor to contribute to the 'NHS Alliance TV News', an hour long video, which was to be shown at the meeting. The conference theme was to focus on QIPP and the NHS Alliance proposed that redesigning iron services would be an appropriate example to highlight the financial and patient benefits of QIPP initiatives. The topics were agreed and a contract signed with the story title of 'Delivering QIPP by redesigning iron services'. A copy of the transcript was provided.

Vifor stated that the NHS Alliance considered Vifor might be able to help with this project, as for the vast

majority of patients currently needing intravenous (IV) iron five hospital visits were required to administer 1g of Venofer (a Vifor Pharma product) in the form of 200mg per visit. With Ferinject, these patients could be given 1g in one 30 minute visit, bringing about benefits consistent with the QIPP programme.

At the request of the NHS Alliance, Vifor suggested speakers and allowed filming at its premises and production was carried out by a film company on behalf of the NHS Alliance. The draft script was reviewed internally and signed off according to Vifor's internal procedures. The company's input into the video stopped at this stage.

As the video concentrated not on the product but on the QIPP service delivery benefits, the video was regarded as non-promotional. There was no intention to promote Ferinject and so Vifor did not include the prescribing information.

The video featured two independent speakers each with a broad experience in IV iron management; a clinician with expertise in clinical research with IV iron and a nurse who ran an anaemia clinic in a teaching hospital. The content was controlled entirely by the NHS Alliance and it had the final say over its content.

Vifor explained that the NHS Alliance brought together GP consortia, primary care trusts, clinicians and managers in primary care. Over 850 clinicians and managers attended the 2010 NHS Alliance Annual Conference to debate the implications of the Government's reforms and to learn from leading innovators in commissioning and the provision of integrated care. The video was over 2 minutes long and was played along with other videos, each loop lasting over an hour. Vifor had no stand; it was a specialist company which concentrated on secondary care products and did not promote in primary care.

There was no intention to promote and under the circumstances it could be clearly seen that there was no intention for disguised promotion and so no breach of Clause 12.1. Sponsorship was very clear in the video so this was not a breach of Clause 9.10.

Taken in context, one visit for 1g of iron vs five visits each of 200mg of iron given over several weeks clearly was a treatment given in a shorter time for the condition in question. This was therefore not in breach of Clause 7.2 as the statement did not imply that Ferinject could speed recovery.

The video was over 2 minutes in an hour long video presentation to highlight QIPP benefits. Vifor entered into an agreement with the NHS Alliance which had complete control over the video and Vifor's intention was simply to help the debate around the practicality of QIPP by giving a practical example. As this was service-focused and non-promotional the prescribing information was not added.

In line with its summary of product characteristics (SPC), Ferinject could be given in 15 minutes for 1g

of IV iron; the statement in the video was intended to reflect current clinical practice and had included the set up time as well in the 30 minutes quoted. This obviously compared favourably to five visits for Vifor thus achieving the required iron replenishment in 30 minutes. This was not misleading and thus not in breach of Clause 7.2.

Vifor submitted that when, in late April 2011, it realised that the third party media company was not affiliated to the NHS Alliance, it asked for the video to be removed from the website immediately. Vifor stated that it had been ruled in breach of this already [Case AUTH/2399/4/11] and it had fully acknowledged its mistake in this respect.

In response to a request for further information Vifor stated that it paid for the production of its item on the video along with other organisations that took part in the video. The payment was 50% of the actual cost for the partnership.

PANEL RULING

The Panel noted that although Pharmacosmos had raised a number of concerns about the video and its distribution to various audiences, the complaint was limited to the video being made available to health professionals at the 2010 NHS Alliance Annual Conference.

The Panel noted that the video opened with a sequence which featured the Vifor company name and logo in the centre of the screen together with the title 'Delivering QIPP by redesigning iron services'. In this regard the Panel considered that there was no doubt that the video had been sponsored by Vifor; the company's involvement was clear from the outset. No breach of Clause 9.10 was ruled.

The Panel considered that although the title of the video was not product related ('Delivering QIPP by redesigning iron services') its content was such that most viewers would consider that it promoted Ferinject. The first two minutes of the 3:44 minute video were about general issues but between the second and third minutes all of the information was specifically about Ferinject. The Panel considered that the video was clearly promotional and in that regard its nature was not disguised. No breach of Clause 12.1 was ruled.

The Panel noted that the video had been filmed at Vifor's offices, Vifor had suggested speakers; its general manager had spoken on the video. The draft script had been reviewed internally and signed off according to company procedure. Vifor had submitted that its input into the video stopped at this stage. The Panel noted that a document provided by Vifor, entitled 'Story Outline', appeared to be a written agreement between the NHS Alliance, the film company and Vifor. The document listed three key messages one of which was 'Vifor Pharma want to raise awareness of their product, Ferinject'. The others being 'Vifor Pharma want to raise awareness of iron deficiency, its symptoms, how anaemia could be better treated now and for patients in the future' and 'Vifor Pharma want to start a conversation

among doctors about how this illness is best treated and help them discuss the best funding options with the NHS'. In the Panel's view there was thus no doubt that, at the outset and contrary to the company's response, Vifor knew that the video would promote Ferinject; to consider otherwise demonstrated a fundamental lack of understanding of the Code and its requirements. In this regard the Panel noted the definition of promotion in Clause 1.2 was any activity undertaken by a pharmaceutical company or with its authority which promoted the prescription, supply, sale or administration of its medicines. The Panel considered that Vifor's submission that its intention was simply to help the debate around the practicality of QIPP by giving a practical example was disingenuous. The Panel considered that the video should have contained prescribing information and other obligatory information for Ferinject which it did not. A breach of Clauses 4.1 and 4.3 was ruled.

In relation to the claim 'for patients it would mean a speedier recovery' the Panel noted that this appeared in a section referring to changes to IV iron services design which would deliver highly valuable QIPP outcomes. For patients it would mean a speedier recovery and fewer visits to hospital. The previous section referred to Ferinject as the perfect solution to the usual treatment which involved numerous trips to hospital for iron injections over a long period of time. Where Ferinject could be administered as a single dose infusion, the treatment course was shorter than that for products that needed multiple visits. However there was another medicine, Cosmofer (iron (III)-hydroxide dextran complex) which could be administered as a single dose albeit over a longer time period (4-6 hours) compared to Ferinject (30 minutes including the set up time). Contrary to Vifor's submission the Panel considered that the claim implied that Ferinject would speed recovery. This was not always so. According to its SPC the IV infusion was up to a maximum single dose of 20ml of Ferinject (1000mg of iron) but not exceeding 0.3ml of Ferinject (15mg of iron) per kg body weight. Ferinject 20ml was not to be administered as an infusion more than once a week. The Panel did not consider that redesigning the service to use Ferinject would mean a speedier recovery. The Panel considered that the claim was misleading and a breach of Clause 7.2 was ruled.

In relation to the allegation about the claim 'Ferinject provides ... all the iron they need in just one 30 minute visit', the Panel noted that the claim in the video was not the same. The video stated 'Iron deficiency is currently treated either by a long day in hospital, or multiple visits. But ... Ferinject is different. The patient can receive all the IV iron they need in just one thirty minute visit'. Although the Panel had concerns that, in effect, the claim in the video implied that Ferinject provided all the iron needed in just one visit (as noted above) and that was not so, there was no actual claim that Ferinject provided all the iron needed in just one 30 minute visit as alleged. Nevertheless, the Panel considered that the implication of the claim in the video was misleading and thus the Panel ruled a breach of Clause 7.2.

Taking all the circumstances into account the Panel found it difficult to understand how the video could be seen as anything other than promotional material. The Panel considered that Vifor's conduct in relation to the Code warranted consideration by the Code of Practice Appeal Board and it decided to report the company to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure for it to consider whether further sanctions were warranted.

COMMENTS FROM VIFOR ON THE REPORT

Vifor's presentation during the consideration of the report also covered the report in Case AUTH/2422/7/11.

Vifor submitted that it fully accepted the gravity of the report to the Appeal Board. The company noted that the video in question was withdrawn as soon as it received the first letter of complaint from Pharmacosmos on 26 April and it had not been used since. Vifor stated that its intention was simply to support the QIPP conference but it accepted that it had not fully understood the scope of the video and it took full responsibility for its actions. Vifor submitted that it was an ethical company, committed to abiding to the letter and spirit of the Code and had started a complete review of its internal processes in order to ensure that it fully complied with the Code.

Vifor apologised and accepted that the company had made significant errors which had led to the Panel's rulings of breaches of the Code. Vifor had considered that the video was non-promotional, as the intention was not to promote the product, and it had mistakenly signed it off as such. During the consideration of the report the Vifor representatives mentioned that third parties including the ABPI had used either the video or the information. Vifor submitted that as part of its internal review of processes it had increased support for medical sign-off. Vifor noted that it had recently been inspected by the Medicines and Healthcare products Regulatory Agency (MHRA). Vifor was confident that it had robust procedures in place to ensure that previous errors were not repeated.

APPEAL BOARD CONSIDERATION

The Appeal Board was extremely concerned that Vifor had considered that the video was non-promotional and in that regard it referred in particular to the 'Story Outline' which stated that one of the key messages was 'Vifor Pharma want to raise awareness of their product, Ferinject'. The Appeal Board noted Vifor's submission that it had not intended to promote its product. Promotion was defined in Clause 1.2 of the Code as 'any activity undertaken by a pharmaceutical company which promotes the prescription, supply, sale or administration of its medicines'. The Appeal Board noted that a company's intention was not relevant when considering whether its materials or activities were promotional. In the Appeal Board's view the video and the story outline were clearly promotional in nature. The Appeal Board was also extremely concerned about some of the claims made in the video and queried whether they complied with the Code. In the Appeal Board's view, the fact that the

video had been certified through the copy approval system compounded the errors within.

The Appeal Board considered that Vifor's actions demonstrated a fundamental lack of understanding of the Code and its requirements. This case raised very serious concerns regarding the expertise of Vifor's signatories and the role of senior management in compliance matters.

The Appeal Board noted that Vifor had accepted that it had made serious errors and in that regard had already started a review of its policies and procedures. Nonetheless, the Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require an audit of Vifor's procedures in relation to the Code to be carried out by the Authority. The audit should be conducted as soon as possible. On receipt of the audit report the Appeal Board would consider whether further sanctions were necessary.

The Appeal Board was also extremely concerned that the video might still be in use by some third parties and so it decided, in accordance with Paragraph 11.3, to require Vifor to take immediate steps to recover the video by writing to each recipient to ask them, where practical, to return it. The letter should explain why such action was necessary.

FURTHER CONSIDERATION BY THE APPEAL BOARD

Upon receipt of a letter from Vifor regarding the recovery of the video the Appeal Board noted that the NHS Alliance had sent 990 DVDs, which included the Vifor film, to staff in primary care trusts, foundation trusts, acute trusts, local authorities and central government departmental bodies and agencies. The Appeal Board decided that in the circumstances Vifor should work with the NHS Alliance to ensure that those who had been sent copies of the DVD be informed that Vifor's contribution, following a complaint under the Code, had been ruled in breach of the Code and that full details could be found on the PMCPA website.

Vifor was first audited in November 2011 and upon receipt of that audit report the Appeal Board was concerned that the report indicated that Vifor had much work to do. It noted from Vifor's response that a preliminary corrective and preventative actions programme had been drawn up. It requested that Vifor be asked to provide timescales for the actions. It also decided that Vifor should be asked to provide copies of the correspondence between the company and its head office about the audit report and details about the role of an external consultant.

The Appeal Board was concerned to note that since deciding that Vifor should be audited, another case which involved a breach of undertaking, Case AUTH/2442/10/11, had been considered by the Panel. On the day of the audit that case was still ongoing and so was not discussed. The Appeal Board noted, however, that the case had now completed.

The Appeal Board decided that Vifor should be re-audited in March 2012. On receipt of the report for

that audit, the Appeal Board would consider if further sanctions were necessary.

Upon receipt of the March 2012 audit report the Appeal Board was disappointed at the lack of progress since the November 2011 audit particularly with regard to the revision of standard operating procedures (SOPs). The Appeal Board noted that new staff were due to be appointed. The Appeal Board considered that Vifor should be re-audited in six months time at which point it expected there to be significant improvement. In the meantime Vifor should provide a detailed interim response to the recommendations of the March 2012 audit to include an update on recruitment and SOPs. This interim response should be provided by the end of June 2012 and Vifor advised that if the Appeal Board was not satisfied then the re-audit would be brought forward.

Upon receipt of the next audit report, the Appeal Board would decide whether further sanctions were necessary.

On consideration of the interim response from Vifor, the Appeal Board decided that there was no need to reaudit sooner than the currently arranged date, in October 2012.

Upon receipt of the October audit report, the Appeal Board noted that good progress had been made since the last audit. New staff had been appointed who would have key roles in compliance. New standard operating procedures had been written and resources had been committed to Code compliance. The Appeal Board considered that on the basis that Vifor's current commitment to compliance was maintained, no further action was required.

Complaint received	22 June 2011
Undertaking received	17 August 2011
Appeal Board consideration	12 October 2011 16 November 2011 7 December 2011 19 April 2012 26 July 2012 15 November 2012
Interim case report first published	23 January 2012
Case completed	15 November 2012