CASE AUTH/2008/6/07

MEMBER OF THE PUBLIC/DIRECTOR v PROSTRAKAN

Breach of undertaking and promotion of Rectogesic

A member of the public complained about the promotion of Rectogesic (glyceryl trinitrate (GTN) rectal ointment) by ProStrakan. As the complaint involved three allegations of a breach of the undertaking given in Case AUTH/1892/9/06, these were taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings.

The complainant noted that four months after being told of the outcome of Case AUTH/1892/9/06, he had found a number of Internet sites containing ProStrakan press releases dated 23 March 2006 and 27 September 2006 and two sites containing the ProStrakan Annual Report. All of the documents contained the misleading statement regarding the properties and licensed indication for Rectogesic which was the subject of the ruling in Case AUTH/1892/9/06 namely 'Rectogesic works by relaxing the vascular smooth muscle around the anal canal leading to the dilation of peripheral arteries and veins, aiding the healing of the fissure'. Bearing in mind how easy it was to find these sites, had the company attempted to identify and withdraw these pieces? If not, why not?

The complainant had also found, on ProStrakan's website, a press release which was attached to the company's preliminary financial results for the year ended 31 December 2005 and the company's annual report and accounts 2005. Both of these contained the offending misleading statement regarding the non-existent healing properties of Rectogesic. There was no reason why the company could not have easily identified these and removed them from its website; not to have done so demonstrated a disregard for the Authority which bordered on contempt.

The Panel noted that the Rectogesic summary of product characteristics (SPC) stated that the therapeutic indication was 'relief of pain associated with chronic anal fissure'. The SPC gave a pharmacodynamic explanation as to the effect of GTN ointment via the release of nitric oxide and how this might heal anal fissures but nonetheless clearly stated that in three studies the healing of anal fissures in patients treated with Rectogesic was not statistically different from placebo. Further that Rectogesic was not indicated for healing of chronic anal fissure. Rectogesic was only licensed for the relief of pain associated with chronic anal fissure. In Case AUTH/1892/9/06 the Panel had considered that the claim that Rectogesic aided 'the healing of fissures' was inconsistent with the SPC and thus inaccurate. Breaches of the Code were ruled and on 9 November 2006 the company gave its undertaking in acceptance of those rulings.

The complainant had now found a number of Internet sites containing press releases, or an annual report, which pre-dated Case AUTH/1892/9/06. The Panel considered that it was unreasonable to expect a company to be responsible for every independent site on the Internet which contained information about its activities or products as reported by third parties. This was historical recording of data in electronic form and was beyond the company's control. In that regard the Panel considered that ProStrakan had not breached its undertaking. No breach was ruled which was appealed by the complainant. The Panel considered that material posted on a company's own website was different to that above and that, where possible, it should be amended, or withdrawn, in the light of adverse rulings under the Code. The company had amended the 27 September 2006 press release as this was not an official reporting requirement. It was most unfortunate that the information in the annual report was inconsistent with the SPC but the Panel accepted ProStrakan's explanation that some official documents, once published, could not be changed. The 2005 annual report and accounts and the company's 2006 financial results for the year ended 31 December 2005 had to stay on ProStrakan's site in their original form. In that regard the Panel considered that ProStrakan had not breached its undertaking. No breach of the Code was ruled together with no breach of Clause 2. These rulings were appealed by the complainant.

The Appeal Board was concerned that claims ruled in breach of the Code remained published on independent third party sites on the Internet. Nonetheless the Appeal Board considered that it was unreasonable to expect a company to be responsible for independent sites on the Internet which contained information about its activities or products as reported by third parties. The Internet was a dynamic ever changing medium and third party, independent sites with which a company had had no direct contact, were beyond a company's control. The Appeal Board upheld the Panel's ruling of no breach of the undertaking. The appeal on this point was unsuccessful.

The Appeal Board considered that material posted on a company's own website was different to that above and that, where ever possible, it should be amended, or withdrawn, pursuant to the provision of an undertaking. The company had amended the 27 September 2006 press release as this was not an

official reporting requirement. It was most unfortunate that the information in the annual report was inconsistent with the SPC however the Appeal Board accepted ProStrakan's explanation that some official documents, once published, could not be changed. The 2005 annual report and accounts and the company's 2006 financial results for the year ended 31 December 2005 had to stay on the ProStrakan site in their original form; in any event, to have amended them by way of a note of explanation, as suggested by the complainant, would have amounted to a corrective statement which was not a sanction imposed upon ProStrakan in Case AUTH/1892/9/06. The Appeal Board considered that ProStrakan had not breached its undertaking. The Appeal Board upheld the Panel's ruling of no breach of the Code including Clause 2. The appeal on these points were unsuccessful.

The complainant further noted that his search had identified an 'Advertisement Feature' on the electronic version of Pulse which the complainant alleged promoted Rectogesic. The article dealt with the treatment of anal fissures using 'Licensed topical GTN 4mg/g' which, to the complainant's knowledge, could only be Rectogesic. The article was sponsored by ProStrakan and bore the company logo. It was a two-sided piece and included another advertisement for Rectogesic.

The first treatment algorithm recommended a further 6-8 weeks treatment with Rectogesic if the first course of treatment was not completely successful. This was contrary to the licensed indication that 'Treatment may be continued until the pain abates, up to a maximum of 8 weeks'. The algorithm also suggested that, if after an initial course the patient was unhealed and asymptomatic then the treatment should be continued for a further 6-8 weeks. Asymptomatic patients did not suffer pain. Rectogesic was only licensed for the treatment of pain, not healing, and therefore this too represented another breach of the Code.

The Rectogesic advertisement also did not have any prescribing information. The date of preparation was January 2007. This meant that when this advertisement feature was prepared, the company was aware of the decision regarding the misleading nature of its statement about the non-existent healing properties of Rectogesic, yet it still went ahead with it. Did this not represent yet another breach of the undertaking given in Case AUTH/1892/9/06?

The Panel noted that the complainant had referred to a Quick Guide article which had been developed for publication in The Practitioner journal (December 2006) but had also, unbeknown to ProStrakan, appeared on the online Pulse site. The Quick Guide, headed 'Advertisement Feature', was entitled 'Management of chronic anal fissure' and had been sponsored by ProStrakan.

The Panel noted that one of the objectives in developing the Quick Guide was to maintain Rectogesic's position as the number one treatment for anal fissures. The Quick Guide did not refer to Rectogesic per se but two treatment algorithms noted that topical glyceryl trinitrate 4mg/g was the only licensed medicine. A half page abbreviated advertisement for Rectogesic appeared at the end of the Quick Guide. The Quick Guide was headed 'Advertisement Feature'. It had been developed in association with ProStrakan which had paid for it to be produced. The Panel considered that the article promoted Rectogesic and that the company's involvement in its development, together with the placement of an advertisement, meant that ProStrakan was responsible for its content.

As prescribing information for Rectogesic was not included a breach of the Code was ruled. The Panel did not consider that the last half page of the Quick Guide was a discreet and wholly separate abbreviated advertisement; the whole of the two pages was a full advertisement which lacked prescribing information. It was not an abbreviated advertisement, and thus no breach was ruled in that regard.

The Quick Guide featured a treatment algorithm. For patients with recurrent uncomplicated anal fissures or those who had first presented with idiopathic anal fissure one of the first-line treatments was stated to be topical GTN 4mg/g (ie Rectogesic) for 6-8 weeks. If patients remained unhealed and asymptomatic or if there was some improvement in their condition, a further treatment course of 6-8 weeks was recommended. The Panel noted, however that the Rectogesic SPC stated that treatment might be continued until the pain abated, up to a maximum of 8 weeks. The SPC further stated that if anal pain persisted, differential diagnosis might be required to exclude other causes of pain. In the Panel's view the recommendation to repeat the 6-8 weeks treatment course was inconsistent with the SPC in breach of the Code.

The Panel further noted that a second treatment period of 6-8 weeks was advocated in patients who were unhealed and asymptomatic. Such patients by definition would not have pain and as such were not suitable to be treated with Rectogesic. The algorithm was thus inconsistent with the SPC. A further breach of the Code was ruled.

The Panel considered that although the treatment algorithm was different to material previously considered in Case AUTH/1892/9/06 it nonetheless advocated the use of Rectogesic in patients with anal fissure but no pain ie for healing. In that regard the Panel considered that the Quick Guide was caught by the previous undertaking and thus the undertaking had been breached. A breach of the Code was ruled.

The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry that companies complied with undertakings. The undertaking in Case AUTH/1892/9/06 was signed on 9

November 2006 ie two weeks before the printer's deadline and four weeks before the last date on which the Quick Guide could have been pulled. The Panel considered that the company's failure to stop the publication of the Quick Guide meant that ProStrakan had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

A member of the public complained about the promotion of Rectogesic (glyceryl trinitrate (GTN) rectal ointment) by ProStrakan Group Plc. As the complaint involved three allegations of a breach of undertaking these were taken up by the Director as it was the responsibility of the Authority itself to ensure compliance with undertakings.

1 Press release and annual report

COMPLAINT

The complainant alleged that ProStrakan had breached its undertaking with regard to Case AUTH/1892/9/06. He was told of the outcome of the case at the beginning of January 2007. Having waited a reasonable time (4 months) in order to allow the company to make arrangements to comply with the decision, the complainant conducted his own, very rudimentary check by typing 'ProStrakan, Rectogesic and "Healing of the fissure"' into a search engine and was directed to the following:

- 6 sites containing a ProStrakan press release dated 23 March 2006 and entitled: 'ProStrakan Group plc, the European specialty pharmaceutical company today announces its preliminary results for the year ended 31 December 2005'.

- 5 sites containing a ProStrakan press release dated 27 September 2006 and entitled: 'ProStrakan announces US$ 9 million (£4.7 Million) outright purchase of worldwide rights to Tostran and Rectogesic'.

- 2 sites containing the ProStrakan Annual Report 2005.

All of these contained the misleading statement regarding the properties and licensed indication for Rectogesic which was the subject of the ruling in Case AUTH/1892/9/06 namely 'Rectogesic works by relaxing the vascular smooth muscle around the anal canal leading to the dilation of peripheral arteries and veins, aiding the healing of the fissure'.

ProStrakan would no doubt claim that this was unfortunate but that the company could have little influence over the content of these sites. This might, or might not, be true. However, bearing in mind how easy it was, to quickly and easily find these sites, had the company no doubt with vastly more IT resources at its disposal, attempted to identify and withdraw these pieces? If not, why not?

The complainant was interested to hear the Authority's decision regarding all of the above but in particular he noted that his simple search which led him to two documents on ProStrakan's website ie: a press release which was attached to the company's preliminary financial results for the year ended 31 December 2005 and the company's annual report and accounts 2005.

Both of these still contained the offending misleading statement regarding the non-existent healing properties of Rectogesic. There was no reason why the company could not have easily identified these and removed them from its website. Indeed, not to have done so demonstrated a disregard for the Authority which bordered on contempt. Therefore, in these instances, the complainant believed that the breaches of undertaking were clear.

When writing to ProStrakan, the Authority asked it to respond in relation to Clauses 2 and 22 of the Code.

RESPONSE

ProStrakan stated that it was very concerned about the nature of this complaint, the anonymity allowed the complainant to repeatedly attack the organisation without any declaration of conflicts of interest. ProStrakan refuted the suggestion that its activities disrespected the Authority, in addition, as an organisation ProStrakan could not be held responsible for the historical recording of material on the Internet, which was an unreasonable expectation of the complainant. ProStrakan included copies of all press related materials since the ruling last year, which clearly showed its compliance with the letter and spirit of the Code. ProStrakan therefore considered that it had not breached its undertaking.

The two electronic communications mentioned by the complainant from March 2006 and the 2005 annual report were indeed posted in ProStrakan's archive as the company was obliged under the Financial Service Authority's Disclosure and Transparency Rules applicable to listed companies. The Annual Report and financial statements had to remain on the website for five years following publication. ProStrakan was unable to amend them as they were official documents. Following the complaint last year ProStrakan amended the 27 September press release, as this was not an official reporting requirement.

PANEL RULING

The Panel noted that the Rectogesic summary of product characteristics (SPC) stated that the therapeutic indication was 'relief of pain associated with chronic anal fissure'. Section 5.1 of the SPC gave a pharmacodynamic explanation as to the effect of GTN ointment via the release of nitric oxide and how this might heal anal fissures but nonetheless clearly stated that in three studies the healing of anal fissures in patients treated with Rectogesic was not statistically different from placebo. Further that Rectogesic was not indicated for healing of chronic anal fissure. Rectogesic was only licensed for the relief of pain associated with chronic anal fissure. In Case AUTH/1892/9/06 the Panel had considered that the claim that Rectogesic aided 'the healing of fissures' was inconsistent with the

particulars listed in the SPC and thus inaccurate in that regard. Breaches of the Code were ruled and on 9 November 2006 the company gave its undertaking in acceptance of those rulings.

The complainant had now found a number of sites on the Internet containing press releases, or an annual report, which pre-dated Case AUTH/1892/9/06. The Panel considered that it was unreasonable to expect a company to be responsible for every independent site on the Internet which contained information about its activities or products as reported by third parties. This was historical recording of data in electronic form and was beyond the company's control. In that regard the Panel considered that ProStrakan had not breached its undertaking. No breach of Clause 22 was ruled. The Panel considered that material posted on a company's own website was different to that above and that, where possible, it should be amended, or withdrawn, in the light of adverse rulings under the Code. The company had amended the 27 September 2006 press release as this was not an official reporting requirement. It was most unfortunate that the information in the annual report was inconsistent with the SPC however the Panel accepted ProStrakan's explanation that some official documents, once published, could not be changed. The 2005 annual report and accounts and the company's 2006 financial results for the year ended 31 December 2005 had to stay on the ProStrakan site in their original form. In that regard the Panel considered that ProStrakan had not breached its undertaking. No breach of Clause 22 was ruled together with no breach of Clause 2. These rulings were appealed by the complainant.

APPEAL BY THE COMPLAINANT

The complainant noted he had first complained about a misleading statement in the press relating to Rectogesic almost two years ago. ProStrakan had stated at the time that it was not responsible for the statement and had not been responsible for misleading the press. The Panel decided that it had to take the company's word for this and found in its favour. However the complainant had subsequently demonstrated that ProStrakan had produced misleading materials for the press; the company was found in breach of the Code and obliged to sign an undertaking that it would, amongst other things, ensure that all possible steps would be taken to avoid a similar breach of the Code in the future. It was not disputed that, despite this ruling, a number of pieces of material containing misleading information about Rectogesic continued to be available, and therefore presumably read, on independent sites on the Internet. ProStrakan had stated that as an organisation it could not be held responsible for the historical recording of material on the Internet, which was an unreasonable expectation of the complainant. The Panel agreed with ProStrakan and ruled that it was unreasonable to expect a company to be responsible for every independent site on the Internet which contained information about its activities or products as reported by third parties. This was historical recording of data in electronic form and was beyond the company's control. In that regard the Panel considered that ProStrakan had not breached its undertaking.

The complainant disagreed very strongly with the decision. Firstly, both the Panel and ProStrakan described this as an historical recording. Well, of course, it was, and it was considerably more historic now than it was at the time of the original ruling last year but this was surely a result of the Panel's and ProStrakan's tardiness in dealing with the matter. Was the Panel implying that the longer a company could get away with disseminating misleading information on the Internet, the less likely it was to be called to account for it?

The complainant noted that the Panel had considered that it was unreasonable to expect a company to be responsible for every independent site on the Internet. This rather overstated how onerous the task would be in this particular case, in that the complainant identified very few sites. It was surely not beyond the wit and resources of an organisation the size of ProStrakan to write to each of these six sites to at least request them to take down the misleading material or at least inform them of the misleading nature of the material and of the decision of the Panel. This principle was covered in the Guidelines on company procedure relating to the Code of Practice, paragraph 11, Breaches of the Code, which stated 'Procedures must be in place to ensure that promotional material found to be in breach of the Code is quickly and entirely withdrawn from use, not forgetting material stored electronically and/or in the hands of others such as printers and agencies'. One might not consider press releases to be promotional material but it was surely not too much to expect that the same principle should apply to them.

However, even if there were more than six sites identified, the complainant alleged that this should not abrogate ProStrakan of its responsibility to do whatever it could to stop continually misleading the public. All of these sites contained information which was derived from material produced by the company specifically for this purpose, and distributed to the press in order to enhance sales of its products or increase its share price or both. Presumably the misleading information would have contributed to such an effect and, as long as it continued to be read, continued to do so. Such information produced by the company would presumably have been sent to various media outlets, agencies and individuals in the first place. Therefore, presumably it should be equally possible for the company to contact all these same organisations and individuals to advise them of the Panel's ruling and request cessation of use of the misleading materials, ie it should be no more or less complicated than disseminating the misleading material in the first place. Also the question of how arduous or otherwise this task was, was surely irrelevant in that a sanction should surely reflect and counteract any benefit which the company had obtained, and continued to obtain, from its offence. The knowledge that it would be required to make efforts to fully rectify the effects of any misleading materials which they produced would surely help to make companies more careful about the information about themselves and their products which they

disseminated to the public through press releases etc. The continued presence of this unqualified misleading ProStrakan material in the public domain might rather cast doubt over the effectiveness and deterrence of the sanctions available to the Panel (the complainant referred to the 2005 House of Commons Health Committee report into the Influence of the Pharmaceutical Industry [paragraphs 360 and recommendation number 23]). One was still prompted to ask whether any company would decide that the convenient availability of widespread and misleading information on the Internet, which could lead to increased use and sales of its products, was worth the relatively minor cost of an administrative charge. The complainant stated that he had asked in his original complaint (five months ago now) if the Panel could also let him know how much ProStrakan previously had to pay as administrative charges for its breaches of Clauses 9.1 and 20.2 (Case AUTH/1892/9/06). The complainant had not received a response to this request and asked to be provided with one.

In summary, the complainant did not think that it was unreasonable to expect ProStrakan to have at least tried to have this material withdrawn and that not to have made any attempts at all to do so represented a breach of undertaking.

The complainant stated that with regard to the alleged breach of undertaking relating to materials on the ProStrakan website his response on this matter was similar to the one above. The main thrust of ProStrakan's defence and the Panel's ruling appeared to be that there was a conflict between its obligations to the financial regulators and those to the Panel. If it was indeed true that financial regulations precluded its removing or amending the misleading materials, then surely there was nothing to prevent it adding new and separate materials to its website warning readers that the offending materials contained misleading statements about its products and explaining the Panel's ruling. Not to do so meant that the financial community which read these documents would be misled as to the nature of ProStrakan's products and therefore possibly the company's value. The financial regulators would surely not be happy with this state of affairs – it might be worth discussing this with them.

The complainant alleged that the statement in ProStrakan's undertaking which obliged it to take all possible steps to avoid a similar breach of the Code in the future had not been fulfilled and he wished to appeal the Panel's ruling of no breach of Clauses 2 and 22.

Finally, the complainant noted that ProStrakan had again objected to his anonymity. Over the past two years the complainant noted that his complaints about ProStrakan had resulted in at least six rulings of breaches of the Code, including bringing the industry into disrepute. These were serious matters about which the Panel would not have been aware had the complainant not brought attention to them. Removal of the right to anonymity might be helpful for companies such as ProStrakan in that it might reduce scrutiny of them, but it certainly would not be helpful to patients, doctors, the financial community or the public and the complainant therefore hoped that the Panel were not considering ProStrakan's request.

COMMENTS FROM PROSTRAKAN

ProStrakan submitted that it had maintained its original position and agreed with the decision of the Panel that as an organisation it could not be held responsible for the historical recording of material on the Internet which was an unreasonable expectation of the complainant. The Panel commented in its ruling that it was unreasonable to expect a company to be responsible for every independent site on the Internet which contained information about its activities or products as reported by third parties. ProStrakan submitted that there were many prescription medicines that could be typed into the Internet which led to independent sites containing unsubstantiable claims for which the parent company could not be held responsible or be expected to remove, eg medicines for erectile dysfunction and weight loss. This was a widespread issue and not specific to ProStrakan.

ProStrakan included a quotation from the PMCPA website below:

'Press releases about a medicine do not require prescribing information, although it is considered good practice to include a summary of product characteristics. Once a press release is issued, however, a company should have no control over the placement of any subsequent article and nor should it, or its agent, make any payment in relation to an article's publication. Where articles appear in the press should be at the publisher's discretion and articles should be printed wholly at the publisher's expense. If a company, or its agent, controls or in any way pays for the placement of an article about a product, then that article will be regarded as an advertisement for the product'.

ProStrakan submitted that as it had no control over the independent websites quoted by the complainant, or paid for placement on them, then surely it could not be held accountable for information posted on them. It was a wholly unreasonable request for ProStrakan, or any company for that matter, to have control over what was posted on the world wide web.

With regard to the alleged breach of undertaking relating to materials on the ProStrakan website, ProStrakan maintained its original position in that it was indeed a legal obligation not to amend any financial statements or annual reports and so it was unreasonable, following the Panel's ruling, for the complainant to expect it to do so.

ProStrakan noted that the two electronic documents cited by the complainant from March 2006 and the 2005 annual report were indeed posted in its archive, as it was obliged under the Financial Service Authority's Disclosure and Transparency Rules applicable to listed companies. The annual report and financial statements had to remain on its website for five years from publication. ProStrakan was unable to amend them as they were official documents.

Following the complaint last year ProStrakan had amended the 27 September press release, as this was not an official reporting requirement.

ProStrakan noted that the complainant again made an extended point of insisting on maintaining his anonymity. ProStrakan did not understand his motivation for remaining anonymous as it had no benefit to his complaints and again did not reveal any potential conflicts of interest. ProStrakan strongly objected to this and insisted the complainant revealed his identity as it was now in a position that looked like a sustained personal attack on ProStrakan which, following the Panel's ruling, could be of no further benefit to doctors or patients. ProStrakan questioned the motivation of this complainant. ProStrakan would also ask how many other organisations had this complainant launched a sustained process of complaints against over their claims or independent website listings?

ProStrakan respected the authority of the Panel and always made every effort to work within the letter and spirit of the Code. ProStrakan had signed the undertaking to the Panel's ruling and complied with the Panel's decisions.

COMMENTS FROM THE COMPLAINANT

The complainant noted that ProStrakan appeared to believe that the presence of misleading information on the Internet was none of its responsibility. The truth was that it was entirely ProStrakan's responsibility as it produced and distributed the press releases which resulted in this widespread misinformation in the first place. It was not unreasonable to expect ProStrakan to expend at least as much effort and resource to correct these misleading statements as it expended in creating and disseminating them in the first place. That ProStrakan appeared to have done nothing at all in this respect was a disgraceful abrogation of responsibility and further brought the industry into disrepute. If the ABPI and the PMCPA were unwilling or powerless to compel pharmaceutical companies to do anything at all to at least try and correct misleading and factually incorrect statements about their products which they managed, by hook or by crook, to get onto the Internet, then the complainant feared that the authority and reputation of both organisations would be seriously undermined. The complainant stated that he had asked about the size of the administrative fees paid by ProStrakan so far so as to contrast these paltry amounts with the potentially enormous profits it stood to gain from increased sales and share prices which could result from the kind of misinformation which it had been repeatedly peddling.

The complainant noted that once again ProStrakan objected to his anonymity and asked why the company was so concerned to know his identity? How could knowing his identity mitigate any of its proven and accepted disgraceful behaviour? ProStrakan was sadly mistaken if it thought that by knowing his identity it could intimidate him into silence. The complainant reminded ProStrakan that he had brought to the attention of the Panel and the public serious matters concerning its track record of continuing disregard for the facts and regulations, such as to result in judgements that it had failed to maintain high standards, breached undertakings to its own regulatory body and brought discredit to, and reduced confidence in, its industry. The complainant was proud of his achievements in this respect and he thought ProStrakan should spend its time looking closely at the way it ran its business and question its own behaviour, ethics and motives rather than his.

APPEAL BOARD RULING

The Appeal Board noted that Rectogesic was indicated for 'relief of pain associated with chronic anal fissure'. The Appeal Board noted the company's submission about the steps it had taken to comply with the undertaking given in Case AUTH/1892/9/06.

The Appeal Board was concerned that claims ruled in breach of the Code remained published on independent third party sites on the Internet. Nonetheless the Appeal Board considered that it was unreasonable to expect a company to be responsible for independent sites on the Internet which contained information about its activities or products as reported by third parties. The Internet was a dynamic ever changing medium and third party, independent sites with which a company had had no direct contact, were beyond a company's control. In that regard the Panel considered that ProStrakan had not breached its undertaking. The Appeal Board upheld the Panel's ruling of no breach of Clause 22. The appeal on this point was unsuccessful.

The Appeal Board considered that material posted on a company's own website was different to that above and that, where ever possible, it should be amended, or withdrawn, pursuant to the provision of an undertaking. The company had amended the 27 September 2006 press release as this was not an official reporting requirement. It was most unfortunate that the information in the annual report was inconsistent with the SPC however the Appeal Board accepted ProStrakan's explanation that some official documents, once published, could not be changed. The 2005 annual report and accounts and the company's 2006 financial results for the year ended 31 December 2005 had to stay on the ProStrakan site in their original form; in any event, to have amended them by way of a note of explanation, as suggested by the complainant, would have amounted to a corrective statement which was not a sanction imposed upon ProStrakan in Case AUTH/1892/9/06. The Appeal Board considered that ProStrakan had not breached its undertaking. The Appeal Board upheld the Panel's ruling of no breach of Clause 22 and consequently Clause 2. The appeal on these points were unsuccessful.

2 Quick Guide 'Advertisement Feature'

COMPLAINT

The complainant further noted that his Internet search had identified an 'Advertisement Feature' on the

electronic version of Pulse which the complainant alleged promoted Rectogesic. The article dealt with the treatment of anal fissures using 'Licensed topical GTN 4mg/g' which, to the complainant's knowledge, could only be Rectogesic. The article was sponsored by ProStrakan and bore the company logo. It was a two-sided piece and the bottom half of the second side contained another advertisement for Rectogesic. The article bore the reference MO11/141 and the Rectogesic advertisement had a 'date of preparation' and the reference MO11/129 included within it. Were these dates and reference numbers inserted by the publishers or by ProStrakan? If ProStrakan was responsible then the complainant concluded that both pieces were prepared and presumably approved by ProStrakan for use in this way.

The complainant alleged that the 'Advertisement Feature' was an advertisement for Rectogesic which did not include prescribing information in breach of Clause 4.1.

The first treatment algorithm contained a recommendation for a further 6-8 weeks treatment with Rectogesic if the first course of treatment was not completely successful. This was contrary to the licensed indication which stated 'Treatment may be continued until the pain abates, up to a maximum of 8 weeks'. A breach of Clause 3.2 was alleged.

This same algorithm also suggested that, if after an initial course of treatment, the patient was unhealed and asymptomatic then the treatment should be continued for a further 6-8 weeks. Asymptomatic patients did not suffer pain. Recotgesic was only licensed for the treatment of pain, not healing; a further breach of Clause 3.2 was alleged.

The Rectogesic advertisement also did not have any prescribing information. The complainant noted that prescribing information was not required on an abbreviated advertisement. He was not clear what an abbreviated advertisement was but noted from Clause 5.2 that such advertisements were not allowed on the Internet. Thus he suspected that this advertisement breached either Clause 4.1 or 5.2 or both. Also he saw that the date of preparation was January 2007. This meant that when this advertisement feature was prepared, the company was aware of the decision regarding the misleading nature of its statement about the non-existent healing properties of Rectogesic, yet it still went ahead with it. Did this not represent yet another breach of undertaking relating to the decision on Case AUTH/1892/9/06?

When writing to ProStrakan, the Authority asked it to respond in relation to Clauses 2 and 22 of the Code in addition to the clauses cited by the complainant.

RESPONSE

ProStrakan explained that the advertisement feature was designed to highlight the steps involved in managing chronic anal fissures. It was not an advertisement for Rectogesic and clearly discussed all of the therapies in this area, in a balanced and informed way. There was clear mention of the spontaneous healing rate of chronic anal fissures independent of therapy. In addition, there was clear mention that topical therapies only aided the management of pain.

ProStrakan noted the allegation of a breach of Clause 4.1 but submitted that as the Quick Guide was not an advertisement there was no requirement for prescribing information and no breach of Clause 4.1.

The complainant had further alleged that the mention in the first algorithm of a second course of topical therapy was a breach of Clause 3.2 and that asymptomatic patients were treated a further breach. As stated above this was not an advertisement for Rectogesic and therefore not in breach.

For clarification topical treatments for chronic anal fissure were used for 6-8 weeks of continuous treatment, this did not preclude a physician prescribing a second separate course of 6-8 weeks. This advertisement was intended for health professionals, presumably as the complainant was not treating patients with this very painful condition he was unaware of this. In addition, the complainant had been selective in his interpretation of the algorithm regarding further treatments. The option referred to actually stated, 'Unhealed and asymptomatic or some improvement' (emphasis added). In such circumstances patients could still be symptomatic and as such health professionals used their judgement to decide appropriate courses of action.

The advertisement was an abbreviated advertisement for the printed version of Pulse, it was not an Internet advertisement and as such was not in breach of the alleged clause.

In response to a request for further information ProStrakan stated that it was shocked to discover that the advertisement feature and the abbreviated advertisement still appeared on the Pulse website and immediately contacted the publishers to re-request that the piece be removed. ProStrakan had never commissioned the item to be placed on the website and did not pay for it to appear there; its contract was exclusively for a bound insert in Practitioner. The company was never told by the publishers that the item was to be placed on the electronic version of Pulse. ProStrakan was extremely concerned this was done entirely without its knowledge and had taken steps to ensure that the publishers never initiated any publishing in any media in future without signed consent.

ProStrakan paid for the generation of the article, (a copy of the proposal from the publishers was provided) to be published as a Quick Guide to be bound in Practitioner. The items at issue were produced to replace the run-on when the product name was changed to comply with European legislation from Rectogesic 0.4% to Rectogesic 4mg/g. The publishing agreement, as enclosed, included placement of the Rectogesic advertisement within the article.

ProStrakan stated that the printer's deadline was 24

November 2006. Printed documents were finally bound on 8 December 2006. If the company had pulled the item the last available date would have been a couple of days before final binding.

ProStrakan stressed that this truly was an exceptional situation and it maintained robust policies and procedures to comply with the Code, which were regularly reviewed and updated. The company was very disappointed that the actions of a publisher, which were completely outside its control, had resulted in this complaint.

PANEL RULING

The Panel noted that the complainant had referred to a Quick Guide article which had been published on the Internet. The Quick Guide had been developed for publication in The Practitioner journal (December 2006) but had also, unbeknown to ProStrakan, appeared on the online Pulse site. The Quick Guide, headed 'Advertisement Feature', was entitled 'Management of chronic anal fissure' and had been sponsored by ProStrakan. The last half page of the two page Quick Guide was taken up with an advertisement for Rectogesic.

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided, in relation to material aimed at health professionals that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes.

The Panel noted that a document from the publishers stated that one of the objectives in developing the Quick Guide was to maintain Rectogesic's position as the number one treatment for anal fissures. The Quick Guide itself did not refer to Rectogesic per se but two treatment algorithms noted that topical glyceryl trinitrate 4mg/g was the only licensed medicine. A half page abbreviated advertisement for Rectogesic appeared at the end of the Quick Guide. The Quick Guide was headed 'advertisement feature'. It had been developed in association with ProStrakan and ProStrakan had paid for it to be produced. The first page and a half included a reference code MO11/141 and the advertisement part of the Quick Guide had a reference code MO11/129. Taking all the circumstances into account the Panel considered that the article was promotional for Rectogesic. The Panel considered that the company's involvement in the development of the article, together with the placement of an advertisement, meant that ProStrakan was responsible for the content of the Quick Guide under the Code.

The Panel noted that the Quick Guide had, unbeknown to ProStrakan, been published on the Internet. Although this was not at the behest of ProStrakan the company was nonetheless responsible for what its agents did on its behalf.

The Panel considered that the Quick Guide was, in effect, promotional material for Rectogesic which should have thus included prescribing information for the product. No prescribing information was included and so the Panel ruled a breach of Clause 4.1 of the Code. This ruling was accepted by ProStrakan. The Panel did not consider that the last half page of the Quick Guide was a discreet and wholly separate abbreviated advertisement; the whole of the two pages was a full advertisement which lacked prescribing information. Thus although the article included a visual which appeared to be an abbreviated advertisement, and it had appeared on the Internet, no breach of Clause 5.2 was ruled.

The Quick Guide featured a treatment algorithm for primary care. For patients with recurrent uncomplicated anal fissures or those who had first presented with idiopathic anal fissure one of the first-line treatments was stated to be topical GTN 4mg/g (ie Rectogesic) for 6-8 weeks. If patients remained unhealed and asymptomatic or if there was some improvement in their condition, a further treatment course of 6-8 weeks was recommended. The Panel noted, however that the Rectogesic SPC stated that treatment might be continued until the pain abated, up to a maximum of 8 weeks. It was further stated in the SPC that if anal pain persisted, differential diagnosis might be required to exclude other causes of pain. In the Panel's view the recommendation to repeat the 6-8 weeks treatment course was inconsistent with the particulars listed in the SPC. A breach of Clause 3.2 was ruled.

The Panel further noted that a second treatment period of 6-8 weeks was advocated in patients who were unhealed and asymptomatic. Such patients by definition would not have pain and as such were not suitable to be treated with Rectogesic which was only indicated for relief of pain associated with chronic anal fissure; Rectogesic was not indicated for healing. The algorithm was thus inconsistent with the particulars listed in the SPC. A further breach of Clause 3.2 was ruled.

The Panel considered that although the treatment algorithm was different to material previously considered in Case AUTH/1892/9/06 it nonetheless advocated the use of Rectogesic in patients with anal fissure but no pain ie for healing. In that regard the Panel considered that the Quick Guide was caught by the previous undertaking and thus that the undertaking had been breached. A breach of Clause 22 was ruled.

The Panel noted that an undertaking was an important document. It included an assurance that all possible steps would be taken to avoid similar breaches of the Code in future. It was very important for the reputation of the industry that companies

complied with undertakings. The undertaking in Case AUTH/1892/9/06 was signed on 9 November 2006 ie two weeks before the deadline for getting the PDFs of the Quick Guide to the printers and four weeks before the last date on which the item could have been pulled. The Panel considered that the company's failure to stop the publication of the Quick Guide meant that ProStrakan had brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

Complaint received **6 June 2007**

Case completed **9 November 2007**