

MEMBER OF THE PUBLIC v PROSTRAKAN

Newspaper article about Rectogesic

A member of the public complained about an article in The Herald in which ProStrakan discussed its reaction to the recent rejection of Rectogesic (glyceryl trinitrate (GTN) rectal ointment) by the Scottish Medicines Consortium (SMC).

ProStrakan was quoted as saying that Rectogesic was 'an ointment for the treatment of anal fissures'. The complainant noted that Rectogesic was licensed only to relieve pain associated with chronic anal fissures. It was not licensed to heal chronic anal fissures nor was it licensed for use in acute anal fissures.

Furthermore, a ProStrakan spokesman was quoted as saying that '[Rectogesic] costs much less than surgery'. The complainant alleged that this comparison was not accurate, balanced, fair, objective and unambiguous, or based on an up-to-date evaluation of all the evidence. Rectogesic was not licensed as an alternative to surgery and nor did the summary of product characteristics (SPC) indicate that its use would prevent the need for surgery. Further, the SMC report did not indicate that ProStrakan had submitted any data that Rectogesic was a cost-effective alternative to surgery for the relief of chronic anal fissure pain.

Furthermore, a ProStrakan spokesman stated that Rectogesic was 'currently the only alternative to surgical treatment'. Putting aside the fact that Rectogesic was not licensed for this purpose this statement was still untrue. The SMC report identified three products which were licensed for the relief of anal fissure pain (Anusol, Anacal and Xyloproct) and stated that there were alternative treatments which were of similar effectiveness to Rectogesic and 'somewhat cheaper'. The comparison was misleading.

Surgery was carried out in order to promote healing of fissures, prevent recurrence and relieve pain and Rectogesic was only licensed for the relief of pain associated with chronic anal fissures. Thus the complainant alleged that comparisons of Rectogesic with surgery were not substantiable.

The complainant alleged that the article presented information on a prescription only medicine to the public in a way which was not fair or balanced. Furthermore, the most common side effect of Rectogesic, headache, was not mentioned in the article. Thus a misleading impression was given that Rectogesic was an entirely safe alternative to surgery.

The Panel noted that the article in the Glasgow Herald included quotations from ProStrakan's spokesperson other statements were not in quotation marks.

The statement that Rectogesic was an ointment for the treatment of anal fissures was not in quotation marks in the article but was attributed to ProStrakan. The article was misleading in this regard but the Panel did not consider this was the responsibility of ProStrakan. In the absence of any detail of what ProStrakan said to the journalist no breach of the Code was ruled.

The Panel did not consider that the claim 'costs much less than surgery' implied that Rectogesic was licensed as an alternative to surgery as alleged but nonetheless noted that if

treatment with GTN was unsuccessful surgery might be an option. The Panel did not consider that the statement '... costs much less than surgery' was a comparison that failed to reflect the requirements of the Code and no breach was ruled.

The statement that Rectogesic was the only alternative to surgical treatment was not in quotation marks in the article but was attributed to a ProStrakan spokesman. The article was misleading in this regard but the Panel did not consider this was the responsibility of ProStrakan. In the absence of any detail of what ProStrakan said to the journalist no breach of the Code was ruled.

The Panel did not consider that the fact that the article made no mention of the most common side effect meant that a misleading impression was given that Rectogesic was an entirely safe alternative to surgery. No breach of the Code was ruled.

A member of the public complained about an article in The Herald (a newspaper in Scotland) regarding Rectogesic (glyceryl trinitrate (GTN) rectal ointment), a product of ProStrakan Group plc. Rectogesic was indicated for the relief of pain associated with chronic anal fissure. Treatment was for a maximum of eight weeks.

COMPLAINT

The complaint concerned an article in which ProStrakan discussed its reaction to the recent rejection of Rectogesic by the Scottish Medicines Consortium (SMC). The company was quoted as saying that Rectogesic was 'an ointment for the treatment of anal fissures'. Treatment of anal fissures had two components which were the promotion of healing and the relief of pain. Rectogesic was licensed only for the relief of pain associated with chronic anal fissures. It was not licensed for the healing of chronic anal fissures and it was not licensed for anything at all relating to acute anal fissures. A breach of Clause 3.2 of the Code was alleged.

Furthermore, a ProStrakan spokesman was quoted as saying that '[Rectogesic] costs much less than surgery'. However, Rectogesic was not licensed as an alternative to surgery and nor was there any information in its summary of product characteristics (SPC) indicating that use of Rectogesic would prevent the need for surgery. Neither was there any indication in the report of the SMC that any data was presented to it by ProStrakan indicating that Rectogesic was a cost-effective alternative to surgery for the relief of chronic anal fissure pain. Hence a further breach of Clause 3.2 was alleged.

All claims and comparisons should be accurate, balanced, fair, objective and unambiguous. They should be based on an up-to-date evaluation of all the

evidence and that evidence should be presented clearly. The comparisons of Rectogesic with surgery discussed above did not meet these criteria in breach of Clause 7.2.

Furthermore, a ProStrakan spokesman stated that Rectogesic was 'currently the only alternative to surgical treatment'. If one put to one side for a moment the fact that Rectogesic was not licensed for this purpose and there appeared to be no data or information either in the SMC report or on the SPC to support its use in this way, this statement was still blatantly untrue. The SMC itself, in its report, identified three products which were licensed for the relief of anal fissure pain (Anusol, Anacal and Xyloproct) and stated that there were alternative treatments which were of similar effectiveness to Rectogesic and 'somewhat cheaper'. Hence a further clear breach of Clause 7.2.

A comparison could only be allowed if it was not misleading. The complainant alleged, for reasons stated above, that the comparison with surgery was misleading and hence in breach of Clause 7.3. Furthermore, comparisons should only be made between medicines or services for the same needs or intended for the same purpose. Surgery was carried out in order to promote healing of the fissures, prevent recurrence and relieve pain. Rectogesic was only licensed for the relief of pain associated with chronic anal fissures and hence there was a further breach of Clause 7.3.

Any information, claim or comparison must be capable of substantiation. The comparisons with surgical treatment discussed above were not supported by any information in the article, the SMC report or the SPC and hence one must assume that no substantiation was possible. A breach of Clause 7.4 was alleged.

Information on a prescription only medicine which was made available to the public (either directly or indirectly) must be presented in a fair and balanced way. The complainant did not believe that this article, and ProStrakan's involvement in it, met this criterion and hence Clause 20.2 was breached. Furthermore, particular emphasis was placed in the Code on the fact that information should not be misleading with respect to the safety of the product. The most common side effect of treatment with Rectogesic was apparently headache (SMC report and SPC) but no mention of this was made in the article. Thus a misleading impression was given that Rectogesic was an entirely safe alternative to surgery. A further breach of Clause 20.2.

RESPONSE

ProStrakan provided the press statement from the SMC website which led The Herald newspaper to write the article in question. The publication of the SMC decision was part of its standard operating procedure following a process of review. ProStrakan strongly supported the SMC and actively engaged in a constructive dialogue with it. ProStrakan was surprised at the SMC's decision and had recently been granted an opportunity to resubmit its case for this product in light of new and restructured evidence.

As with all journalists the article's author obtained his information from many sources and, in this case, ProStrakan's discussions with him followed a telephone approach from him precipitated by the public posting of the press statement on the SMC website. In his article the journalist quite clearly differentiated which statements were made by ProStrakan's spokesperson through the use of quotation marks, the rest of his article was his own interpretation and paraphrasing derived from his research. ProStrakan was disappointed that the complainant felt aggrieved by the article; however, ProStrakan believed it had acted within the Code.

ProStrakan provided a copy of the publicly available Prodigy (NHS independent information source) patient information leaflet as well as the SPC, which detailed current treatment practices, and the licensed indication.

ProStrakan addressed each issue in turn:

Clause 3.2 – an ointment for the treatment of anal fissures. The press release quite clearly stated that Rectogesic should be used 'for the relief of pain associated with chronic anal fissures'; the journalist had not quoted ProStrakan directly on this matter and it did not have any editorial control over his work. It was probable that as a lay person he had not understood the differentiation. Therefore, ProStrakan did not believe it was in breach of the Code.

Clauses 3.2 and 7.2 – cost effective, in that it cost much less than surgery. ProStrakan did not believe this was promoting Rectogesic as it was commenting on the press release and the SMC documentation, clarifying the economic statement. This also applied to Clauses 7.3 and 7.4. In ProStrakan's submission to the SMC it pointed out that there were no licensed alternatives to Rectogesic that had proven efficacy in the treatment of chronic anal fissures, which was why no cost effectiveness analysis against medical treatments was conducted. ProStrakan's position had been clarified with the SMC and a broader cost effectiveness case would be included in ProStrakan's resubmission to allow the SMC to re-assess its position.

ProStrakan provided the health economic section that was submitted to the SMC regarding Rectogesic and surgery; this clarified the position of Rectogesic used within the SMC process.

Also provided was a detailed evidence search for the products mentioned in the SMC report ie Anusol, Xyloproct and Anacal, which was submitted as part of the review process detailing that there was no evidence that these products worked in chronic anal fissures and that their broad licence was a historical anomaly rather than a reflection of the evidence. This was reinforced in the current recommendations for the treatment as shown in the Prodigy document.

A study versus surgery was included in ProStrakan's original submission, the pdf on the website did not show these data as it was not part of the SMC process to include all submitted data.

Clause 7.2 – currently the only alternative to surgical treatment. As stated above this was not a direct quote from ProStrakan as the journalist had been consistent

in his use of quotation marks for those statements directly attributed to ProStrakan. ProStrakan had no editorial control over what the journalist had produced; it therefore did not believe this was a breach of the Code.

As a point of clarification on the complaint, Anusol, Anacal and Xyloproct were identified as comparator medications, not alternative treatments of similar effectiveness. As stated above ProStrakan had provided the SMC with a detailed search for evidence, which showed there was no data to show that they were effective in the treatment of chronic anal fissures. Indeed literature was available that showed that lignocaine (the main constituent of these products) could be detrimental. The historical licence for anal fissures was granted prior to the appreciation that chronic anal fissures were not simple tears, rather they had a more complicated pathophysiology as described in the Prodigy document.

Clause 20.2 – ProStrakan believed it had reacted in a considered and appropriate manner to a request for its comments on the SMC press release; it had been clearly quoted in the article and commented on information freely available to the public. ProStrakan believed it had not promoted Rectogesic in this article which had been promoted by a third party. ProStrakan’s comments in the article had been directed at addressing the SMC press release, ProStrakan therefore could not understand the extrapolation of the complainant to the side effects for Rectogesic and did not believe it was in any way misleading.

PANEL RULING

The Panel noted that complaints about articles in the press were considered with regard to the information supplied by the pharmaceutical company to the press and not on the content of the article itself. The conversation with the journalist from a national newspaper had to meet the requirements of Clause 20 of the Code. Rectogesic should not be promoted to the public as it was a prescription only medicine. Clauses 3.2, 7.2 and 7.4 of the 2003 Code related to the promotion of medicines rather than the provision of information to the public. Some changes in this regard had been made to the 2006 Code. This complaint was being considered under the 2003 Code using the Constitution and Procedure set out in the 2006 Code of Practice booklet.

The article in the Glasgow Herald included quotations from ProStrakan’s spokesperson for which ProStrakan took responsibility.

The statement that Rectogesic was an ointment for the treatment of anal fissures was not in quotation marks in the article but was attributed to ProStrakan. The article was misleading in this regard but the Panel did not consider this was the responsibility of ProStrakan. In the absence of any detail of what ProStrakan said to the journalist no breach of Clauses 3.2 and 20.2 of the Code was ruled.

With regard to the quotation that Rectogesic ‘... costs much less than surgery’, the Panel noted that the information from Prodigy, which was described by ProStrakan as an NHS independent information source, stated that about 7 in 10 of patients with a chronic anal fissure were successfully treated with a course of GTN ointment and about 5 in 10 would heal with regular warm baths and use of an anaesthetic cream for pain relief. Surgery was described as an option if GTN treatment did not work and was an option for recurring fissures. Treatment with Rectogesic was limited to a maximum of eight weeks. The Panel did not consider that the claim ‘costs much less than surgery’ implied that Rectogesic was licensed as an alternative to surgery as alleged but nonetheless noted that if treatment with GTN was unsuccessful surgery might be an option. The Panel did not consider that the statement ‘... costs much less than surgery’ was a comparison that failed to reflect the requirements of Clauses 3.2, 7.2 and 20.2 of the Code. Thus no breach was ruled.

The statement that Rectogesic was the only alternative to surgical treatment was not in quotation marks in the article but was attributed to a ProStrakan spokesman. The article was misleading in this regard but the Panel did not consider this was the responsibility of ProStrakan. In the absence of any detail of what ProStrakan said to the journalist no breach of Clauses 7.2, 7.3, 7.4 and 20.2 of the Code was ruled.

The Panel did not consider that the fact that the article made no mention of the most common side effect meant that a misleading impression was given that Rectogesic was an entirely safe alternative to surgery. No breach of Clause 20.2 of the Code was ruled.

Complaint received 17 April 2006

Case completed 19 May 2006