CASE AUTH/2153/8/08

PRESCRIBING SUPPORT PHARMACIST v PROCTER & GAMBLE

Actonel leavepiece

A prescribing support pharmacist complained about an Actonel (risedronate) leavepiece issued by Procter & Gamble. Procter & Gamble also marketed Didronel PMO (etidronate). Both Actonel and Didronel were for use in the treatment or prevention of postmenopausal osteoporosis.

The leavepiece entitled 'Latest NICE [National Institute for Health and Clinical Excellence] information included (July 2008) for Primary and Secondary Prevention of Osteoporotic Fragility Fractures in Postmenopausal Women' was referenced to the relevant NICE final appraisal determinations, July 2008. The complainant telephoned NICE and was told that the guidelines were still in draft form and had not been finalised. Quotations from the guidelines were included in the leavepiece. The complainant alleged that the first quotation was misleading as it appeared to recommend risedronate above etidronate when this was not the case. The second quotation, under the heading 'Should patients be switched?' appeared to be taken out of context to suit the purpose of the company. The complainant could not actually find this quotation in the draft document.

The detailed response from Procter & Gamble is given below.

The Panel noted that running along the bottom edge of the front page of the leavepiece was a dark blue band with the following text in white 'Prescribing information appears on the back page' and then, in slightly less bold print, 'The recommendations made are preliminary and may change after consultation. Readers should consult the [final appraisal document] for full details'. The Panel noted Procter & Gamble's reliance on this statement to set the information given in the leavepiece in context. There was, however, nothing to link the title of the leavepiece to the footnote, although in general claims should not be qualified by the use of footnotes and the like. The Panel considered that the title of the leavepiece was misleading as readers would be unaware, at the outset, that the information was from recommendations that were yet to be finalised. A breach of the Code was ruled.

The Panel noted that page 2 of the leavepiece was headed 'NICE Final Appraisal Determination for Primary and Secondary Prevention of Osteoporotic Fragility Fractures in Postmenopausal Women'. In boxed text the first bullet point read 'Risedronate is recommended as the first alternative treatment option alongside etidronate'. This claim stemmed from a discussion in the NICE document as to what therapy patients should be offered if they were unable to take alendronate – it was concluded that risedronate could be recommended for such women. With regard to etidronate, it was decided that even though it had a better cost effectiveness profile than risedronate there were concerns surrounding the clinical evidence base for the medicine and so it should not be recommended in preference to risedronate. However, etidronate could be offered to women unable to take alendronate and in deciding between risedronate and etidronate, clinicians and patients needed to balance the overall effectiveness profile of the medicines against their tolerability and adverse effects in individual patients.

The Panel did not consider that the first bullet point was a fair and balanced reflection of the NICE final appraisal document. Use of the word 'the' and the underlining of first alternative treatment option implied that risedronate should be chosen first and it was the only second line treatment for patients unable to take alendronate. There was a greater emphasis on risedronate than etidronate and an implication that NICE recommended risedronate in preference to etidronate. The Panel considered that the claim was misleading. A breach of the Code was ruled.

A second box of text contained the bullet point 'Should patients be switched?' followed by the statement 'NICE says "Women who are currently receiving treatment with one of the drugs covered by this guidance should have the option to continue treatment until they and their clinicians consider it appropriate to stop"'. The Panel noted Procter & Gamble's submission that this quotation had been taken from section 1.9 of the NICE final appraisal document. Section 1.9 of the document, however, did not include any underlining and stated 'Women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment should not have been recommended according to sections 1.1 to 1.4, should have the option to continue treatment until they and their clinicians consider it appropriate to stop'. The Panel thus noted that the statement in the NICE document was about patients, who according to the guidance should not have started therapy, being allowed to continue with therapy. The statement was not about switching patients from one therapy to another as implied in the leavepiece. The Panel considered that the quotation as it appeared in the leavepiece under a heading of 'Should patients be switched' was not in its correct context. The quotation was misleading in this regard; a breach of the Code was ruled. The Panel considered that the quotation, as it appeared

in the leavepiece, was not an accurate quotation nor did it reflect the meaning of the relevant sections of the NICE final appraisal document. A further breach of the Code was ruled.

A prescribing support pharmacist complained about an Actonel (risedronate) leavepiece (ref ACT3987) issued by Procter & Gamble Pharmaceuticals UK, Limited. Procter & Gamble also marketed Didronel PMO (etidronate). Both Actonel and Didronel were for use in the treatment or prevention of postmenopausal osteoporosis.

The complainant sent the Authority a copy of the complaint she had sent to the Medicines and Healthcare products Regulatory Agency (MHRA).

COMPLAINT

The complainant noted that the leavepiece stated 'Latest NICE [National Institute for Health and Clinical Excellence] information included (July 2008) for Primary and Secondary Prevention of Osteoporotic Fragility Fractures in Postmenopausal Women'. The reference for this was the relevant NICE final appraisal determinations, July 2008. When the complainant telephoned NICE about this she was told that the guidelines were still in draft form and had not been finalised. Quotations from the guidelines were included in the leavepiece. The complainant alleged that the first quotation was misleading as it appeared to recommend risedronate above etidronate when this was not the case. The second quotation was under the heading 'Should patients be switched?' and appeared to be taken out of context to suit the purpose of the company. The complainant could not actually find this quotation in the draft document.

When writing to Procter & Gamble, the Authority asked it to respond in relation to Clauses 7.2 and 10.2 of the 2008 Code which were the same as under the 2006 Code apart from the numbering (Clause 11 in the 2006 Code was Clause 10 in the 2008 Code).

RESPONSE

Procter & Gamble did not consider that the leavepiece was in breach of the Code, in particular Clauses 7.2 or 10.2.

Procter & Gamble explained that as guidance for osteoporosis had been in development by NICE for over 6 years, during which time there had been an evolution in the NICE position, the company believed it was important to keep health professionals aware of the current thinking. Specifically, guidance on the secondary prevention of osteoporotic fractures in postmenopausal women was published in January 2005; however a new consultation was started in August 2004 and was still ongoing. Guidance for the primary prevention of osteoporotic fractures in postmenopausal women was started in March 2002 and was still ongoing.

NICE had published appraisal consultation documents and lately final appraisal determinations. These were readily available public documents. In the leavepiece at issue, Procter & Gamble endeavoured to make it abundantly clear that these guidelines were preliminary. The heading of the first page of the leavepiece stated, 'Latest NICE information…' which did not imply a final recommendation.

Additionally, a bold banner at the bottom of the first page stated, 'The recommendations made are preliminary and may change after consultation. Readers should consult the [final appraisal document] for full details'. Finally, page 2 was headed 'NICE Final Appraisal Determination…'.

It was only to be expected that health professionals would want to be informed of the latest NICE position on a particular topic. As a company with an interest in osteoporosis, Procter & Gamble developed this leavepiece to provide information on the latest NICE position.

Procter & Gamble considered that the leavepiece made it very clear that it was based on the final appraisal determination and that this might change after consultation and thus did not consider that this was a breach of Clause 7.2 .

As noted above, health professionals were interested in how Procter & Gamble's products were assessed in the latest final appraisal documents from NICE. Thus, the leavepiece stated, 'Risedronate is recommended as the first alternative treatment option alongside etidronate'. The text of the whole statement was in the same typeface and size that gave equal emphasis to etidronate.

This was consistent with the draft NICE guidelines and deliberately used the word 'option' that by definition implied there was more than one. It was well known, however, that clinically etidronate was a less preferred option when treating osteoporosis. The statement in the leavepiece was not misleading and as Procter & Gamble marketed both products it considered that the statement showed equal emphasis to both and it thus did not consider it to be in breach of Clause 7.2.

With regard to the claim on whether patients should be switched, Procter & Gamble submitted that as shown in the NICE final appraisal documents, the majority of patients eligible for osteoporosis treatment would be prescribed generic alendronate, based mainly on its acquisition cost. It followed, therefore, that health professionals questioned whether patients should be switched from their existing treatment to generic alendronate. The leavepiece shared NICE's latest thinking on this.

The guidance given in the final appraisal documents was shown on page 2 of the leavepiece. This statement was made in section 1.9 of both documents for the primary or secondary prevention of osteoporotic fractures. NICE clearly considered it

necessary to make this statement to guide health professionals in the appropriate management of patients. The text had been accurately reflected in the leavepiece and, therefore, Procter & Gamble did not consider this to be a breach of Clause 10.2.

In summary Procter & Gamble considered that it was clear that the leavepiece was based on the final appraisal documents from NICE and that these '…are preliminary and may change after consultation'. As stated above, these were publicly available documents.

The statement made on risedronate and etidronate was consistent with the latest NICE positioning and did not place undue emphasis on risedronate.

Finally, the text that the complainant was unable to find in the final appraisal documents was shown in section 1.9.

Procter & Gamble was convinced that the leavepiece conveyed information of relevance and interest to health professionals in a manner clearly reflective of the source documents and that was not in breach of Clauses 7.2 or 10.2.

PANEL RULING

The Panel noted that the leavepiece was entitled 'Latest NICE information included (July 2008) for Primary and Secondary Prevention of Osteoporotic Fragility Fractures in Postmenopausal Women'. Running along the bottom edge of the front page was a dark blue band with the following text in white 'Prescribing information appears on the back page' and then, in slightly less bold print, 'The recommendations made are preliminary and may change after consultation. Readers should consult the [final appraisal document] for full details'. The Panel noted Procter & Gamble's reliance on this statement to set the information given in the leavepiece in context. There was, however, nothing to link the title of the leavepiece to the footnote. In any event the supplementary information to Clause 7.2 stated 'It should be borne in mind that claims in promotional material must be capable of standing alone as regards accuracy etc. In general claims should not be qualified by the use of footnotes and the like'. The Panel considered that the title of the leavepiece was misleading as readers would be unaware, at the outset, that the information contained within came from recommendations that were yet to be finalised. A breach of Clause 7.2 was ruled.

The Panel noted that page 2 of the leavepiece was headed 'NICE Final Appraisal Determination for Primary and Secondary Prevention of Osteoporotic Fragility Fractures in Postmenopausal Women'. In boxed text the first bullet point read 'Risedronate is recommended as the first alternative treatment option alongside etidronate'. This claim stemmed from a discussion in the NICE document as to what therapy patients should be offered if they were unable to take alendronate – it was concluded that risedronate could be recommended for such women. With regard to etidronate, it was decided that even though it had a better cost effectiveness profile than risedronate there were concerns surrounding the clinical evidence base for the medicine and so it should not be recommended in preference to risedronate. However, etidronate could be offered to women unable to take alendronate and in deciding between risedronate and etidronate, clinicians and patients needed to balance the overall effectiveness profile of the medicines against their tolerability and adverse effects in individual patients.

The Panel did not consider that the first bullet point was a fair and balanced reflection of the NICE final appraisal document. Use of the word 'the' and the underlining of first alternative treatment option implied that risedronate should be chosen first and it was the only second line treatment for patients unable to take alendronate. There was a greater emphasis on risedronate than etidronate and an implication that NICE recommended risedronate in preference to etidronate. The Panel considered that the claim was misleading. A breach of Clause 7.2 was ruled.

A second box of text contained the bullet point 'Should patients be switched?' followed by the statement 'NICE says "Women who are currently receiving treatment with one of the drugs covered by this guidance should have the option to continue treatment until they and their clinicians consider it appropriate to stop"'. The Panel noted Procter & Gamble's submission that this quotation had been taken from section 1.9 of the NICE final appraisal document. Section 1.9 of the document, however, did not include any underlining and stated 'Women who are currently receiving treatment with one of the drugs covered by this guidance, but for whom treatment should not have been recommended according to sections 1.1 to 1.4, should have the option to continue treatment until they and their clinicians consider it appropriate to stop'. The Panel thus noted that the statement in the NICE document was about patients who, according to the guidance should not have started therapy, being allowed to continue with therapy. The statement was not about switching patients from one therapy to another as implied in the leavepiece. The Panel considered that the quotation as it appeared in the leavepiece under a heading of 'Should patients be switched' was not in its correct context. The quotation was misleading in this regard; a breach of Clause 7.2 was ruled. The Panel considered that the quotation, as it appeared in the leavepiece, was not an accurate quotation nor did it reflect the meaning of the relevant sections of the NICE final appraisal document. A breach of Clause 10.2 was ruled.

Complaint received **5 August 2008**

Case completed **15 September 2008**