CASE AUTH/2267/9/09

SHIRE v PROCTER & GAMBLE

Promotion of Asacol

Shire complained about two leavepieces and a journal advertisement promoting Asacol (modified release mesalazine) issued by Procter & Gamble. Asacol was indicated for the treatment of mild to moderate acute exacerbation of ulcerative colitis and for the maintenance of remission thereof. Asacol was also indicated for the maintenance of remission in Crohn's ileocolitis. Mesalazine was a 5-aminosalicylate (5-ASA).

The detailed response from Procter & Gamble is given below.

Shire alleged that the strapline 'confidence in colitis' beneath the product logo without an equally prominent reference to Asacol's indication promoted Asacol beyond its indication and also overstated the clinical benefits.

Shire noted that there were a number of different types of colitis ie: amoebic, collagenous, common variable immunodeficiency, drug induced, haemorrhagic, infective, ischemic, lymphocytic, post-radiation, pseudomembranous and ulcerative.

During inter-company dialogue, Procter & Gamble relied on the prominence of the correct indication, ulcerative colitis, on the one-page leavepiece, experience of health professionals with the product and the incidence of ulcerative colitis in the UK compared to other forms of colitis. Shire disagreed with Procter & Gamble's assertion that the leavepiece referred to 'ulcerative colitis' anywhere on its face. The references to ulcerative colitis were in any event too far removed from the strapline and logo cluster as well as insufficiently large to qualify it due to the close proximity of this strapline with the Asacol product logo.

Shire also alleged that the word confidence in 'confidence in colitis' encouraged use outside the terms of the summary of product characteristics (SPC) and licensed indications (as explained above) and implied superlative, special performance of the product which Procter & Gamble had failed to substantiate.

The Panel noted that Asacol was indicated for the treatment of mild to moderate acute exacerbations of ulcerative colitis and for the maintenance of remission thereof. It could also be used for the maintenance of remission in Crohn's ileo-colitis. The Panel noted that the front page of the leavepiece was headed 'Examples of how to write a script for Asacol 800mg MR tablets' beneath which was a table of possible dosing regimens and examples of how the prescription would be written. Three regimens were given 'Maintenance of remission (1.6g/day)', 'Mild acute UC (2.4g/day)' and 'Moderate acute UC (4.8g/day)'. The only time the term 'ulcerative colitis' was used in full was in the indications section of the prescribing information on the reverse.

The Panel considered that promotional material must be clear about the relevant indication for the medicine. The reader's attention would be drawn to the strapline 'confidence in colitis' in the bottom right-hand corner of the page. It appeared that Asacol could be used in all types of colitis which was not so. The Panel considered that the strapline 'confidence in colitis' was inconsistent with the Asacol SPC as alleged. A breach of the Code was zruled.

The Panel did not consider that 'confidence' *per se* implied a special merit that had not been substantiated nor did it imply a superlative. Prescribers should expect to be able to prescribe any licensed medicine with confidence. No breach of the Code was ruled.

A journal advertisement featured the photograph of a commuter reading a broad sheet newspaper. The headline running across the front and back pages was 'Back to normal everyday life …' '… Sooner – Asacol 4.8g/day vs. mesalazine 2.4g/day'. A claim beneath the photograph read 'For moderately active UC Higher dosing 4.8g/day Asacol 800mg MR tablets for fast, effective relief from a flare-up. Great news'.

Shire alleged that the claims that Asacol's performance was 'Great news' and that it could return a patient's life 'back to normal' – ie the pre-ulcerative colitis state – were unsubstantiable.

Shire was concerned about the heading 'Back to normal everyday life … Sooner – Asacol 4.8g/day vs. mesalazine 2.4g/day'. Ulcerative colitis was a chronic condition; patients had cycles of remission and relapse. Many patients in remission still had some symptoms. Procter & Gamble had not quantified what was meant by 'normal'. Shire alleged that 'normal', particularly in the phrase 'back to normal' (emphasis added), implied the patient's life was returned to the pre-ulcerative colitis state which was clearly not so as maintenance medicine was still needed. Shire alleged that the claim '*Back to* normal everyday life …' was not balanced or fair, was ambiguous, could not be substantiated and was exaggerated.

Shire was also concerned that given the cyclical nature of remission and relapse occurring with ulcerative colitis, the claim that patients could be 'normal' again after taking Asacol was of poor taste, and did not maintain high standards.

Shire alleged that the superlative 'Great' in relation to Asacol was inappropriate. The reference to 'Great news' clearly referred to the claim 'Back to normal everyday life…' '…Sooner – Asacol 4.8/day …'. Procter & Gamble had not qualified 'Great' nor had it provided evidence to substantiate it.

The Panel noted that the headline read 'Back to normal everyday life…' '… Sooner …'. The advertisement showed a commuter reading his newspaper on a busy train. The Panel did not consider that the advertisement implied that Asacol would return patients to the pre-ulcerative colitis state. 'Normal' was used to describe 'life' and implied that, despite still having ulcerative colitis, a patient could resume everyday activities. The Panel did not consider that 'normal' would be read as describing the patient's disease state. In the Panel's view the claim was not unbalanced or unfair and it could be substantiated. The claim did not exaggerate the clinical efficacy of Asacol. The Panel did not consider that the claim was in poor taste or failed to maintain high standards. No breach was ruled.

With regard to the claim 'Great news' the Panel noted that it was not a superlative. Fast, effective relief from an ulcerative colitis flare up would be 'Great news'. Beneath this claim was the further claim that Asacol 4.8g/day provided relief from rectal bleeding and increased stool frequency 10 days faster (median time to symptom relief 19 days vs 29 days) than mesalazine 2.4g/day (Marion *et al* 2006). The Panel did not consider that the claim was exaggerated as alleged. No breach was ruled.

The Panel noted that the product logo incorporated the strapline 'confidence in colitis'. The product logo appeared in the bottom right-hand corner of the advertisement where it was most likely to attract the reader's attention. The Panel noted its ruling above. The claim 'confidence in colitis' would become associated with Asacol. 'Colitis', however, was a general term and required qualification for the precise disease state to be described. The Panel noted that the advertisement referred to 'moderately active UC' although again the only reference to 'ulcerative colitis' was in the prescribing information. However, the strapline, which was in larger font than the reference to UC, implied that Asacol could be used in all types of colitis and this was not so. The Panel considered that the strapline 'confidence in colitis' was inconsistent with the Asacol SPC as alleged. A breach of the Code was ruled.

The prescribing leavepiece highlighted the fact that oral mesalazine products were not interchangeable and thus should not be prescribed generically. Shire noted that the leavepiece incorporated the views of a named doctor only and Procter & Gamble had failed to substantiate all the claims made in such opinion by reference to either the opinion of the majority of health professionals or other prescribing guidance.

The doctor's opinion as stated in the leavepiece, read: 'Similar to certain other drugs, for example anti-convulsives, mesalazine should be prescribed by brand name. Until we get hard evidence that two different mesalazine formulations are therapeutically equivalent and have the same benefits and sites of action, I consider that patients should not be switched and are kept on their existing brand name mesalazine preparation'.

Shire alleged that the above was misleading in a promotional context as it was one health professional's opinion and Procter & Gamble had not substantiated all the claims within this quotation, in particular the statement that 'patients should not be switched and are kept on their existing brand name mesalazine preparation'. Procter & Gamble had not quoted a source that showed that this statement either represented all if not the majority of health professionals or provided prescribing guidance to justify the same. Shire noted that the MIMS February 2009 guidelines stated 'Different aminosalicylates and their various forms are not interchangeable and are designed to release active drug at different sites along the colon. They should be prescribed according to their mode and site of action and the brand name should always be specified'. The MIMS guidance did not, however, go on to state that switching from an existing prescription should be avoided. As the named doctor expressly acknowledged in his quotation, there was no data to substantiate this claim (that patients on Asacol should not be switched to other 5-ASAs).

The Panel noted that the quotation from the named doctor 'I consider that patients should not be switched and are kept on their existing brand name mesalazine preparation' was unqualified. It might well be the view of the doctor quoted but promotional material had to reflect the balance of the evidence. The other supporting documentation referred to the differences between the various preparations and the need to avoid unplanned substitution. However it might be necessary to change patients' therapy for clinical reasons. In this regard the Panel noted Procter & Gamble's submission that patients should not be switched between different oral mesalazine products *unless there were specific clinical reasons to do so.* This advice was not given. Thus the Panel considered that the quotation at issue was misleading as alleged. A breach of the Code was ruled.

Shire Pharmaceuticals Ltd complained about the promotion of Asacol (modified release mesalazine) by Procter & Gamble Pharmaceuticals UK, Limited. Asacol was indicated for the treatment of mild to moderate acute exacerbation of ulcerative colitis and for the maintenance of remission thereof. Asacol was also indicated for the maintenance of remission in Crohn's ileocolitis. Mesalazine was a 5-aminosalicylate (5-ASA).

There were three items at issue; an 800mg MR tablets dosing leavepiece (ref AS7709/56655); a

journal advertisement (ref AS7965/58698.02) and a prescribing leavepiece (ref AS7927/58854.04).

1 Dosing leavepiece (ref AS7709/56655)

COMPLAINT

Shire alleged that by using the strapline 'confidence in colitis' beneath the product logo without an equally prominent reference to Asacol's indication on this leavepiece, Procter & Gamble had not only promoted Asacol beyond its indication but had also overstated the clinical benefits by the use of 'confidence' in the logo cluster.

Shire noted that under the heading 'colitis' in the Oxford Textbook of Medicine (3rd edition) the following types were listed: amoebic, collagenous, common variable immunodeficiency, drug induced, haemorrhagic, infective, ischemic, lymphocytic, post-radiation, pseudomembranous and ulcerative.

During inter-company dialogue, Procter & Gamble relied on the prominence of the correct indication, ulcerative colitis, on the one-page leavepiece, experience of health professionals with the product and the incidence of ulcerative colitis in the UK compared to other forms of colitis. Shire disagreed with Procter & Gamble's assertion that the leavepiece referred to 'ulcerative colitis' anywhere on its face. The references to ulcerative colitis were in any event too far removed from the strapline and logo cluster as well as insufficiently large to qualify it due to the close proximity of this strapline with the Asacol product logo. In relation to Procter & Gamble's other points, the Code was clear that the promotion of a product had to be consistent with its summary of product characteristics (SPC), which this leavepiece was not, and it was an inadequate defence to rely on the experience of health professionals and the incidence of ulcerative colitis. It could not be assumed that all newly qualified health professionals would be familiar with the indication for Asacol 800mg MR tablets or the incidence of ulcerative colitis in the UK compared with other forms of colitis.

Shire also alleged that the use of the word confidence in 'confidence in colitis' encouraged use outside the terms of the SPC and licensed indications (as explained above) in a way which would not be rational. Furthermore, 'confidence' in close proximity to the Asacol product name in the logo cluster implied superlative, special performance of the product which Procter & Gamble had failed to substantiate. Shire alleged breaches of Clauses 3.2 and 7.10 of the Code.

RESPONSE

Procter & Gamble noted that the leavepiece was a single double-sided A5 sheet. The front page presented examples of how a clinician could write a prescription for Asacol 800mg MR tablets for various licensed indications within ulcerative colitis. The strapline 'confidence in colitis' appeared in the bottom right-hand corner directly beneath the product logo 'Asacol 800mg MR Tablets (mesalazine)'. Prescribing information was on the reverse.

Procter & Gamble fundamentally disagreed with Shire's alleged breaches of the Code as the strapline was only intended be read in the context of the whole leavepiece where specific licensed indications for Asacol within ulcerative colitis were mentioned and formed an integral part of the material.

Procter & Gamble submitted that the leavepiece clearly illustrated and described examples of possible dosing regimens for Asacol 800mg MR tablets. These were presented in a table which formed the core of the leavepiece. Here the licensed indications for Asacol were described ie maintenance of remission, treatment of mild and moderate acute UC. The strapline 'confidence in colitis', which appeared with much less prominence ie in the bottom right-hand corner of the leavepiece, was intended to be read in the context of all of the information presented.

Procter & Gamble noted that Clause 7.2 stated *inter alia*, that 'Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine'. Procter & Gamble firmly believed this was the case for the leavepiece in question, and in its entirety, any clinician receiving this, whether familiar with ulcerative colitis or newly qualified, would be able to make an informed decision as to whether Asacol was a suitable and appropriate treatment choice.

Procter & Gamble submitted that the leavepiece neither endorsed nor encouraged Asacol 800mg MR tablets to be prescribed outside of the product's licensed indications. The strapline, when read in the context of the leavepiece, could not be misinterpreted nor did it encourage use outside of the licensed indications.

By referring to 'colitis' in the context of the leavepiece and mesalazine, Procter & Gamble had followed a concept used by physicians and patients as evidenced by the term used in names of organisations, journals, etc, clearly referring to ulcerative colitis in their respective context eg National Association of Crohn's and Colitis (NACC), European Federation of Crohn's and Ulcerative Colitis Associations (EFCCA), Journal of Crohn's and Colitis (JCC), European Crohn's and Colitis Organisation (ECCO).

Turning to the word 'confidence', Procter & Gamble submitted that this did not portray any special or superlative quality to Asacol 800mg MR Tablet. The impression given to health professionals was that they could be reasonably assured that the product was appropriate for their patient, within the specific indications, given the level of evidence and patient-years of exposure with the product. Again, this was part of a general statement to be read in the context of the leavepiece.

In summary, Procter & Gamble submitted that the strapline 'confidence in colitis', when read in the context of the leavepiece, which provided information consistent with the SPC for Asacol 800mg MR tablets, and, given the disease area and recognisable nature of the class of medicine (mesalazine), would not mislead and certainly did not promote Asacol outside of its licence.

Procter & Gamble therefore submitted that the leavepiece complied with Clauses 3.2 and 7.10.

PANEL RULING

The Panel noted that Asacol 800mg MR tablets were indicated for the treatment of mild to moderate acute exacerbations of ulcerative colitis and for the maintenance of remission thereof. It could also be used for the maintenance of remission in Crohn's ileo-colitis. The Panel noted that the front page of the leavepiece was headed 'Examples of how to write a script for Asacol 800mg MR tablets' beneath which was a table of possible dosing regimens and examples of how the prescription would be written. Three regimens were given 'Maintenance of remission (1.6g/day)', 'Mild acute UC (2.4g/day)' and 'Moderate acute UC (4.8g/day)'. The only time the term 'ulcerative colitis' was used in full was in the indications section of the prescribing information on the reverse.

The Panel considered that promotional material must be clear about the relevant indication for the medicine. The reader's attention would be drawn to the strapline 'confidence in colitis' in the bottom right-hand corner of the page. It appeared that Asacol could be used in all types of colitis which was not so. The Panel considered that the strapline 'confidence in colitis' was inconsistent with the particulars listed in the Asacol SPC as alleged. A breach of Clause 3.2 was ruled.

The Panel did not consider that use of 'confidence' *per se* implied a special merit that had not been substantiated as alleged nor did it imply a superlative. Prescribers should expect to be able to prescribe any licensed medicine with confidence. In that regard the Panel ruled no breach of Clause 7.10.

2 Journal advertisement (ref AS7965/58698.02)

This advertisement featured the photograph of a commuter reading a broad sheet newspaper. The headline running across the front and back pages of the newspaper was 'Back to normal everyday life …' '… Sooner – Asacol 4.8g/day vs. mesalazine 2.4g/day'. A claim beneath the photograph read 'For moderately active UC Higher dosing 4.8g/day Asacol 800mg MR tablets for fast, effective relief from a flare-up. Great news'.

COMPLAINT

Shire alleged that the claims that Asacol's performance was 'Great news' and that the product could return a patient's life 'back to normal' – ie the pre-ulcerative colitis state – were unsubstantiable. Shire also repeated its concerns raised in Point 1 above in relation to the strapline – 'confidence in colitis' used in close proximity to the product logo.

Shire was concerned about the heading 'Back to normal everyday life … Sooner – Asacol 4.8g/day vs. mesalazine 2.4g/day'. Ulcerative colitis was a chronic condition whereby patients had cycles of remission and relapse. Many patients in remission still exhibited some symptoms. Procter & Gamble had failed to quantify what was meant by 'normal'. Shire alleged that the use of the word 'normal' (in the absence of any qualification such as symptom control) and particularly in the phrase '**back to** normal' (emphasis added) implied the patient's life was returned to the pre-ulcerative colitis state when this was clearly not the case, for example maintenance medicine still needed to be taken. Shire therefore alleged that the claim 'Back to normal everyday life …' was not balanced or fair, was ambiguous, could not be substantiated and exaggerated the clinical properties of Asacol in breach of Clauses 7.2, 7.4 and 7.10.

Shire alleged that Procter & Gamble's response highlighted the exacerbation of troublesome symptoms which disrupted a patient's life and routine. The response stated that a patient with well controlled symptoms could enjoy a reasonably 'normal' everyday life and would be able to perform a 'normal everyday' activity such as commuting to work. Shire did not accept these arguments because Procter & Gamble had not qualified what it meant by a reasonably 'normal' everyday life in the advertisement and the above arguments did not adequately address the use of the term '**back to** normal' which implied the pre-ulcerative colitis state.

Shire was also concerned that given the cyclical nature of remission and relapse occurring with ulcerative colitis, the claim that patients could be 'normal' again after taking Asacol was of poor taste, and did not maintain high standards. Shire therefore alleged a breach of Clause 9.1.

Shire alleged that use of the superlative 'Great' in relation to Asacol was inappropriate. The reference to 'Great news' clearly referred to the claim 'Back to normal everyday life…' '…Sooner – Asacol 4.8/day …'. Therefore the claim 'Great news' was logically to be understood to refer back to Asacol. Procter & Gamble had not qualified what it meant by 'Great', nor had it provided evidence to substantiate 'Great'. Shire alleged a breach of Clause 7.10.

Shire noted that during inter-company dialogue, Procter & Gamble had claimed that it had not ascribed the claim 'Great news' to an aspect of Asacol *per se* and thus it was not a superlative. For the reasons set out above, Shire disagreed with Procter & Gamble's interpretation of 'Great news'. In the context of the advertisement 'Great news'

related to the 'Back to normal' headline. By stating that such a claim was 'Great', Procter & Gamble had implied that Asacol had additional or superlative merits that other mesalazine products were lacking. Therefore, Shire alleged a breach of Clause 7.10.

RESPONSE

Procter & Gamble noted that the advertisement featured a patient travelling on a busy commuter train whilst reading his newspaper. The claims 'Back to normal everyday life …' and '… Sooner – Asacol 4.8/day vs. mesalazine 2.4g/day' appeared as a headline on his newspaper. Directly underneath the visual was the text 'For moderately active UC'. Below this the following claims appeared 'Higher dosing 4.8g/day Asacol 800mg MR tablets for fast, effective relief from a flare up. Great news'. Further details about symptom relief (rectal bleeding and increased stool frequency) were then given. Shire alleged that Procter & Gamble had failed to qualify what was meant by 'normal' and in particular 'Back to normal'. Shire alleged that the claims in which these words/phrases were used could not be substantiated and exaggerated the clinical properties of Asacol 800mg MR.

Procter & Gamble submitted that the claim in question was 'Back to normal everyday life … Sooner …' which was different from just 'Back to normal' as referred by Shire. 'Normal', when read in the context of the entire claim, and the overall theme of the advertisement, was sufficiently qualified both visually and through the inclusion of further text. The overall impression created by the advertisement was of a patient with ulcerative colitis who was able to carry out a normal everyday activity such as commuting to work whilst reading a newspaper. Such an activity, as clinicians would appreciate, would pose great difficulty to a patient experiencing the troublesome symptoms of an ulcerative colitis flare, for example, frequent bowel movements and visits to the toilet. Indeed the concept of health related normality for patients with ulcerative colitis and Crohn's disease, was having the freedom to carry out everyday life activities (family, social and work related) without hassle, etc.

Procter & Gamble submitted that clinicians would not get the impression from the advertisement that Asacol would return patients to the pre-ulcerative colitis state as alleged by Shire. Instead the advertisement represented 'normal' in terms of an ulcerative colitis patient being able to go about their everyday life and participate in regular, normal everyday activities, such as commuting on a train. The advertisement did not imply that patients with moderately active ulcerative colitis would, or could, return to the non-disease state. Furthermore, Procter & Gamble stated that it would be surprised if a clinician would make this wrong assumption as ulcerative colitis was a chronic condition.

Procter & Gamble submitted that the use of the word 'normal' and the headline 'Back to normal everyday life …' '…Sooner …' in the full context of the advertisement did not breach Clauses 7.2, 7.4 and 7.10 as alleged by Shire.

Procter & Gamble also strongly disagreed that the advertisement was in poor taste or that high standards had not been maintained through the use of headline 'Back to normal everyday life …' '… Sooner…'. Procter & Gamble therefore denied a breach of Clause 9.1.

Procter & Gamble submitted that with regard to the strapline 'confidence in colitis', again this was part of a general statement only to be read in the context of the advertisement, where information, consistent with the SPC for Asacol, was presented ie the statement 'For moderately active UC' which appeared directly beneath the visual. Procter & Gamble referred to its response to Point 1 above.

The phrase 'Great news' appeared as part of the claim 'Higher dosing 4.8g/day Asacol 800mg MR tablets for fast, effective relief from a flare up. Great News', which appeared under the visual part of the advertisement. Procter & Gamble submitted that it related to the headline in the newspaper which read 'Back to normal everyday life …' '… Sooner …'. Clinicians and patients would agree that fast and effective relief from the debilitating symptoms associated with a moderately active flare of ulcerative colitis would be considered and welcomed as great news. The claim did not ascribe any special qualities to Asacol itself. Therefore, Procter & Gamble denied a breach of Clause 7.10.

PANEL RULING

The Panel noted that the headline read 'Back to normal everyday life…' '… Sooner …'. The advertisement showed a commuter reading his newspaper on a busy train. The Panel did not consider that the advertisement implied that Asacol would return patients to the pre-ulcerative colitis state. 'Normal' was used to describe 'life' and implied that, despite still having ulcerative colitis, a patient could resume everyday activities. The Panel did not consider that 'normal' would be read as describing the patient's disease state. In the Panel's view the claim was not unbalanced or unfair. No breach of Clause 7.2 was ruled. The Panel considered that the claim could be substantiated. No breach of Clause 7.3 was ruled. The claim did not exaggerate the clinical efficacy of Asacol. No breach of Clause 7.10 was ruled. The Panel did not consider that the claim was in poor taste or failed to maintain high standards. No breach of Clause 9.1 was ruled.

With regard to the claim 'Great news' the Panel noted that it was not a superlative. Fast, effective relief from an ulcerative colitis flare up would be 'Great news'. Beneath this claim was the further claim that Asacol 4.8g/day provided relief from rectal bleeding and increased stool frequency 10 days faster (median time to symptom relief 19 days vs 29 days) than mesalazine 2.4g/day (Marion *et al* 2006). The Panel did not consider that the claim was

exaggerated as alleged. No breach of Clause 7.10 was ruled.

The Panel noted that the product logo incorporated the strapline 'confidence in colitis'. The product logo appeared in the bottom right-hand corner of the advertisement where it was most likely to attract the reader's attention. The Panel noted its ruling in point 1 above. The claim 'confidence in colitis' would become associated with Asacol. 'Colitis', however, was a general term and required qualification for the precise disease state to be described. The Panel noted that the advertisement referred to 'moderately active UC' although again the only reference to 'ulcerative colitis' was in the prescribing information. However, the strapline, which was in larger font than the reference to UC, implied that Asacol could be used in all types of colitis and this was not so. The Panel considered that the strapline 'confidence in colitis' was inconsistent with the particulars listed in the Asacol 800mg MR SPC as alleged. A breach of Clause 3.2 was ruled.

3 Prescribing leavepiece (ref AS7927/58854.04)

The leavepiece highlighted the fact that oral mesalazine products were not interchangeable and thus should not be prescribed generically.

COMPLAINT

Shire noted that the leavepiece incorporated the views of a named doctor only and Procter & Gamble had failed to substantiate all the claims made in such opinion by reference to either the opinion of the majority of health professionals or other prescribing guidance.

Shire noted that the doctor's opinion as stated in the leavepiece, read:

'Similar to certain other drugs, for example anti-convulsives, mesalazine should be prescribed by brand name. Until we get hard evidence that two different mesalazine formulations are therapeutically equivalent and have the same benefits and sites of action, I consider that patients should not be switched and are kept on their existing brand name mesalazine preparation.'

Shire alleged that the above was misleading in a promotional context as it was the opinion of one health professional and Procter & Gamble had not substantiated all the claims within this quotation, in particular the statement that 'patients should not be switched and are kept on their existing brand name mesalazine preparation'. Procter & Gamble had not quoted a source that showed that this statement either represented all if not the majority of health professionals or provided prescribing guidance to justify the same. Shire noted that the MIMS February 2009 guidelines stated 'Different aminosalicylates and their various forms are not interchangeable and are designed to release active drug at different sites along the colon. They should be prescribed according to their mode and site of action and the brand name should always be specified'. The MIMS guidance did not, however, go on to state that switching from an existing prescription should be avoided. As the named doctor expressly acknowledged in his quotation, there was no data to substantiate this claim (that patients on Asacol should not be switched to other 5-ASAs). For the above reasons, Shire alleged a breach of Clause 7.2.

Shire alleged that Procter & Gamble's response during inter-company dialogue was to state that the opinion was current and consistent with the prescribing guidance for mesalazines. However Procter & Gamble's correspondence did not provide details of any prescribing guidance to support the claim. Shire thus did not accept Procter & Gamble's position.

RESPONSE

Procter & Gamble noted that the title of the leavepiece, 'When prescribing oral mesalazine Are you confident that your patients are receiving the therapy that their Gastroenterologist intended?', appeared above a visual of a patient receiving their prescription in the pharmacy. The heading on the second page stated '5-ASAs are not interchangeable'. The subheading stated that 'Oral mesalazine is one of the few therapeutic classes where brand name prescribing is recommended'. Shire had alleged that use of this clinical opinion in the material was misleading in breach of Clause 7.2.

Procter & Gamble submitted that the focus of the leavepiece was the non-interchangeability of all oral mesalazine products and not switching between products, as alleged by Shire. In the context of oral mesalazine products, due to their individual release characteristics, non-interchangeability between different brands was widely agreed, documented and supported. In order to support the non-interchangeability of oral mesalazine products the leavepiece referred to MIMS (February 2009 [when the material was prepared], and was consistent with current MIMS September 2009 and BNF March 2009) and a clinical opinion from a named doctor, and cited two other references, Forbes and Chadwick (1997) and Forbes *et al* (2005).

Procter & Gamble submitted that the leavepiece also stated that 'Asacol 800 mg MR tablets and Asacol 400 mg MR tablets: are not interchangeable (consistent with prescribing other 5-ASAs)'. The quotation and non-interchangeability statements applied to all other oral mesalazine products. Indeed, patients should not be switched between different oral mesalazine products unless there were specific clinical reasons to do so. Therefore, the opinion in its entirety supported the fact that *switching* between oral mesalazine products should not be considered due to the nature of the non-interchangeability between such products. Procter & Gamble denied a breach of Clause 7.2.

PANEL RULING

The Panel noted that the quotation from the named doctor 'I consider that patients should not be switched and are kept on their existing brand name mesalazine preparation' was unqualified. It might well be the view of the doctor quoted but promotional material had to reflect the balance of the evidence. The other supporting documentation referred to the differences between the various preparations and the need to avoid unplanned substitution. However it might be necessary to change patients' therapy for clinical reasons. In this regard the Panel noted Procter & Gamble's submission that patients should not be switched between different oral mesalazine products *unless there were specific clinical reasons to do so*. This advice was not given. Thus the Panel considered that the quotation at issue was misleading as alleged. The Panel ruled a breach of Clause 7.2.

Complaint received **15 September 2009**

Case completed **4 November 2009**