CASE AUTH/2758/5/15

GALEN v STIRLING ANGLIAN

Promotion of CosmoCol

Galen submitted a complaint about the promotion of CosmoCol (Macrogol 3350 plus electrolytes) by Stirling Anglian Pharmaceuticals.

An advertisement in MIMS, March 2015 was headed 'CosmoCol Macrogol 3350. Powder for oral solution' and featured pack shots of the CosmoCol range above details of their pack size and cost.

Galen alleged that the abbreviated advertisement was a breach of the Code as it contained details of pack sizes and cost. In addition, stating 'macrogol 3350. Powder for oral solution' did not meet the requirements for providing the non-proprietary name or the active ingredients of Cosmocol. The full non-proprietary name should read 'macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride'.

Galen alleged a further breach of the Code as a leavepiece did not include the non-proprietary name or the active ingredients.

The detailed response from Stirling Anglian is given below.

The Panel noted Stirling Anglian's submission that the reason for recommending CosmoCol was related to its value proposition in terms of cost and pack size. The Panel considered that the content of the advertisement went beyond that described in the Code for an abbreviated advertisement. In the Panel's view the advertisement should have included prescribing information and a breach of the Code was ruled.

The Panel noted that according to its SPC the name of one of the products in the range was CosmoCol Orange Lemon and Lime flavour powder for oral solution. Its active ingredients were given as Macrogol 3350, sodium chloride, sodium hydrogen carbonate and potassium chloride. The Panel considered that neither the abbreviated advertisement nor the leavepiece listed the active ingredients as reflected in the SPC and breaches of the Code were ruled.

Galen submitted a complaint about an advertisement and a leavepiece for CosmoCol (Macrogol 3350 plus electrolytes) issued by Stirling Anglian Pharmaceuticals. CosmoCol was indicated for the treatment of chronic constipation and faecal impaction.

The advertisement appeared in MIMS March 2015 and had the same date of preparation as the leavepiece February 2015. The 2015 Code applied other than newly introduced requirements which were covered by the transition period which ran until 30 April 2015. In relation to the complaint being considered, there were no relevant newly introduced requirements covered by the transition period for the introduction of the 2015 Code.

A Abbreviated advertisement

This advertisement (ref 00010010005 1.0) appeared in MIMS, March 2015. The advertisement was headed 'CosmoCol Macrogol 3350. Powder for oral solution' and featured pack shots of the CosmoCol range. Below each of the five packs was, *inter alia*, details of pack size and cost.

COMPLAINT

Galen alleged that the advertisement was in breach of Clause 5.2 in that, via copy and visuals, it contained details of pack sizes and cost. Galen noted that the supplementary information to Clauses 5.4, 5.5, 5.6, 5.7 and 5.8, Permitted Information, specifically listed details of pack size and cost as elements which should not be included in abbreviated advertisements. In addition, Galen noted that Clause 5.4 required that abbreviated advertisements must provide, *inter alia*, the non-proprietary name of the medicine or list of active ingredients using approved names where such exist. Galen did not consider that by simply stating 'macrogol 3350. Powder for oral solution' qualified as listing the non-proprietary name or the active ingredients of Cosmocol. The full non-proprietary name should read 'macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride'.

RESPONSE

Stirling Anglian denied any breach of the Code on the basis that the details of pack size and cost stated in the advertisement met the exemption cited in the supplementary information to Clause 5. Stirling Anglian stated that in its view the reason for recommending CosmoCol in the advertisement was directly related to the value proposition in terms of cost and pack size. On that basis the company refuted Galen's alleged breaches of the Code.

In relation to the non-proprietary name, Stirling Anglian stated that it had elected to use the form of words approved by the Medicines and Healthcare Products Regulatory Agency (MHRA) as a description of CosmoCol when a licence authorization was granted which was 'Macrogol 3350 powder for oral solution'. The company thus denied a breach of the Code. However, it had taken the opportunity, following a recent price reduction for CosmoCol to review and modify its promotional material such that CosmoCol was described as follows: 'CosmoCol – Macrogol 3350, sodium chloride, potassium chloride, sodium hydrogen carbonate'. Copies of the revised materials were provided.

In response to a request for further information including confirmation of the non-proprietary name

of CosmoCol, Stirling Anglian provided copies of correspondence from the MHRA regarding the grant of the marketing authorisation for CosmoCol.

The company stated that in each case the name of the medicine was listed as CosmoCol (flavour) powder for oral solution. The name of the medicine was specified in Section 1 of the summary of product characteristics (SPC) and the active ingredients in Section 2.

PANEL RULING

The Panel noted the requirements of Clause 5 and in particular Clause 5.8 which stated that abbreviated advertisements may contain a concise statement consistent with the summary of product characteristics (SPC) giving the reason why the medicine was recommended for the indication or indications given. The Panel noted that the supplementary information to Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9, Permitted Information, stated that the contents of abbreviated advertisements were restricted as set out in the aforementioned clauses and the following information should therefore not be included in abbreviated advertisements: dosage particulars, details of pack sizes and cost. There might be exceptions to the above if the information provided, for example the cost of the medicine or the frequency of its dosage or its availability as a patient pack, was given as the reason why the medicine was recommended for the indication or indications referred to in the advertisement. Artwork used in abbreviated advertisements must not convey any information about a medicine additional to that permitted under Clauses 5.4, 5.5, 5.6, 5.7, 5.8 and 5.9.

The Panel noted that the advertisement headed 'Family Values' depicted five patient packs beneath each of which was a description of the number of sachets per pack and their cost. Also included were cost claims such as 'lowest cost' and claims about taste and a claim about dosage –'highly versatile half-dose'. The lower half of the advertisement discussed the benefits of the breadth of the CosmoCol range and included comments about the company's qualities under the headings 'Reliable', 'Honest', 'Hardworking', and 'Nurturing'.

The Panel noted the company's explanation that the reason for recommending CosmoCol was related to its value proposition in terms of cost and pack size. The Panel noted the content of the advertisement and considered that the detailed information provided went beyond that described in the relevant supplementary information to Clause 5, set out above and in addition went beyond the provision of a concise statement giving the reason why the medicine was recommended for the indication/ indications given as set out in Clause 5.8. In the Panel's view the detail provided was such that the material could not take the benefit of the exemption for abbreviated advertisements and the need for prescribing information as set out in Clause 5.1. In the Panel's view the advertisement should have included prescribing information as required by Clause 4.1. A breach of Clause 5.2 was ruled.

The Panel noted that Clause 5.4 required abbreviated advertisements to contain, *inter alia*, the non-proprietary name of the medicine or a list of active ingredients using approved names where such existed. The Panel noted that according to its SPC the name of one of the products in the range was CosmoCol Orange Lemon and Lime flavour powder for oral solution. Its active ingredients were given as Macrogol 3350, sodium chloride, sodium hydrogen carbonate and potassium chloride. The correspondence from the MHRA provided by Stirling Anglian referred to the name of the product as CosmoCol Orange Lemon and Lime flavour powder for oral solution. The Panel considered that as the abbreviated advertisement did not list the active ingredients as reflected in the SPC it did not satisfy the relevant requirement in Clause 5.4 and a breach of that clause was ruled.

B Leavepiece

The leavepiece (ref 00010010006 1.0) at issue was similar in design to the abbreviated advertisement at point A above and had the same heading 'CosmoCol Macrogol 3350. Powder for oral solution'. The date of preparation was February 2015.

COMPLAINT

Galen alleged a breach of Clause 4.3 in that it did not consider Macrogol 3350. Powder for oral solution' listed the non-proprietary name or the active ingredients for CosmoCol. In its view the full non-proprietary name should read 'Macrogol 3350, sodium chloride, sodium hydrogen carbonate, potassium chloride'.

RESPONSE

Stirling Anglian noted that it had elected to use the form of words approved by the MHRA as a description of CosmoCol when a licence authorization was granted which was 'Macrogol 3350 powder for oral solution'. The company thus denied a breach of the Code. However, it had taken the opportunity, following a recent price reduction for CosmoCol to review and modify its promotional material such that CosmoCol was described as follows: 'CosmoCol – Macrogol 3350, sodium chloride, potassium chloride, sodium hydrogen carbonate'. Copies of the revised materials were provided.

In response to a request for further information including confirmation of the non-proprietary name of CosmoCol, Stirling Anglian provided copies of correspondence from the MHRA regarding the grant of the marketing authorisation for CosmoCol.

The company stated that in each case the name of the medicine was listed as CosmoCol (flavour) powder for oral solution. The name of the medicine was specified in Section 1 of the summary of product characteristics (SPC) and the active ingredients in Section 2.

PANEL RULING

The Panel noted that the content of the one page leavepiece was closely similar to the advertisement. It was headed 'CosmoCol Macrogol 3350. Powder for oral solution'. The Panel noted that Clause 4.3 required the non-proprietary name or the list of active ingredients using approved names where such existed to appear immediately adjacent to the most prominent display of the brand name.

The Panel noted that according to its SPC the name of one of the products in the range was CosmoCol Orange Lemon and Lime flavour powder for oral solution. Its active ingredients were given as Macrogol 3350, sodium chloride, sodium hydrogen carbonate and potassium chloride. The correspondence from the MHRA referred to the name of the product as CosmoCol Orange Lemon and Lime flavour powder for oral solution.

The Panel considered that as the leavepiece did not list the active ingredients as reflected in the SPC, the material did not satisfy the relevant requirement in Clause 4.3 and thus a breach of that clause was ruled.

Complaint received **12 May 2015**

Case completed **12 August 2015**