

NORGINE v MOVETIS

Promotion of Resolor

Norgine complained about the promotion of Resolor (prucalopride) by Movetis (UK) Limited. The material at issue, was a folder, a leavepiece and a drop card each of which contained the claim, 'At last! A new way out of chronic constipation in women'. Resolor was indicated for the symptomatic treatment of chronic constipation in women in whom laxatives failed to provide adequate relief.

Norgine alleged that the claim was not in accordance with the terms of the Resolor marketing authorization and was inconsistent with the summary of product characteristics (SPC). Resolor was not indicated for all women with chronic constipation, only those who failed to respond to laxatives. Norgine further alleged that the claim was misleading as it implied that Resolor was suitable for all women with chronic constipation and that was not so. And finally it exaggerated Resolor's properties by claiming that it was a 'A new way out of chronic constipation in women'. The claim was all embracing as it implied that Resolor was licensed and could be used for all cases of chronic constipation and that was not so.

In inter-company dialogue, Movetis had stated that it would ensure that all future promotional items clearly stated 'in whom laxatives fail to provide adequate relief'. Norgine noted, however that the same claim was made in material produced after the undertaking was given.

The detailed response from Movetis is given below.

The folder, leavepiece and drop card at issue all included the claim 'At last! A new way out of chronic constipation in women' beneath the most prominent mention of the brand name. This was immediately followed by a picture of a woman's stomach beneath which was the claim 'Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief'.

The Panel considered that any qualification necessary to ensure compliance with the Code should be part of the claim itself or appear prominently within the same visual field. The Panel considered each item separately as the context of claims could be a relevant factor.

With regard to the A4 folder, the Panel considered that the qualification that Resolor was to be used when laxatives had not provided adequate relief should have appeared as part of the claim itself or immediately beneath it. The size of the folder was relevant. The visual separation of the claim from its

qualification by the illustration of the woman's stomach meant that the claim at issue was inconsistent with the SPC. The claim was also misleading about Resolor's licensed indication and did not promote its rational use; the claim could not stand alone without reference to another statement. Breaches of the Code were ruled.

With regard to the A5 leavepiece, the Panel noted that the layout was similar to the front of the folder. The qualification on page 1 was physically nearer to the claim at issue due to the smaller size of the item but again the claim and its qualifications were separated by the illustration. The physical separation was compounded by the fact that the qualification was in a smaller font size and less prominent font colour and background contrast than the claim at issue above. Further, page 3 of the leavepiece included the claim, omitting the phrase 'At last...' without any mention that the product could only be used when laxatives had failed to provide adequate relief. The Panel considered that the claim on both pages 1 and 3 was inconsistent with the SPC. Breaches of the Code were also ruled for the same reasons as with the folder.

The drop card consisted of two sides and was the size of a large bookmark. The claim at issue was again separated from its qualification by the illustration of the woman's stomach. In addition the qualification appeared as the first of a series of claims on the front of the drop card which were of identical font size and colour and thus as a group were clearly differentiated from the prominent claim at issue above. The claim at issue was thus inconsistent with the SPC. Breaches of the Code were ruled for the same reasons as with the folder.

Upon appeal by Movetis of all of the Panel's rulings of breaches of the Code, the Appeal Board noted that each item at issue was headed 'Resolor prucalopride. At last! A new way out of chronic constipation in women'. This claim was above a picture of a woman's stomach partially covered by the woman's hands which were angled downwards. Below the photograph was the second claim 'Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief'.

The Appeal Board noted that the cover of the A4 folder featured the claims and picture described above. The only other text was the Movetis corporate logo in the bottom right hand corner. The Appeal Board considered that with virtually no other text to distract a reader, the eye was drawn almost immediately from the headline claim to the

second claim. The Appeal Board thus did not consider that readers would be misled as to the licensed indication for Resolor and in its view the A4 folder promoted the rational use of the medicine. No breaches of the Code were ruled.

The Appeal Board noted that the front cover of the A5 leavepiece was closely similar to that of the A4 folder. The Appeal Board considered that its comments about the folder also applied to the front cover of the leavepiece. No breaches of the Code ruled.

The Appeal Board noted that when the leavepiece was opened out, the double page spread of pages 2 and 3 featured the product name and strapline 'A new way out of chronic constipation in women' at the bottom of page 3. To the right of that claim was the photograph of the woman's stomach and hands and to the right of that was that tagline 'Rx prucalopride 1-2mg od'. The Appeal Board noted that the claim 'A new way out of chronic constipation in women' was not qualified in any way and was followed by a very simple prescribing instruction. The Appeal Board was concerned that this was not sufficiently clear with regard to Resolor's indication that it was only for those women in whom laxatives had failed to provide adequate relief. The claim 'A new way out of chronic constipation' on page 3 was inconsistent with the SPC, misleading and did not promote rational use. The Appeal Board upheld the Panel's rulings of breaches of the Code.

With regard to the drop card, the Appeal Board noted that the top half featured the heading, photograph and second claim as previously described. Although the bottom half of the card featured a number of claims for Resolor the heading and the second claim were only separated by the photograph; there was no intervening text. The Appeal Board noted its comments and rulings above with regard to the A4 folder and considered that they also applied to the drop card. The Appeal Board ruled no breaches of the Code.

Norgine Pharmaceuticals Ltd complained about the promotion of Resolor (prucalopride) by Movetis (UK) Limited. The claim at issue was 'At last! A new way out of chronic constipation in women'. Resolor was indicated for the symptomatic treatment of chronic constipation in women in whom laxatives failed to provide adequate relief.

COMPLAINT

In inter-company dialogue, Norgine had alleged that the unqualified claim 'A new way out of chronic constipation in women' which appeared in a Resolor advertisement published in the BMJ, 28 April 2010, was not in accordance with the terms of the Resolor marketing authorization and was inconsistent with the summary of product characteristics (SPC) in breach of Clause 3.2. Resolor was not indicated for all women with chronic constipation, only those who failed to respond to laxatives. Secondly, the claim was

misleading as it implied that Resolor was suitable for all women with chronic constipation and that was not so, in breach of Clause 7.2. And thirdly, it exaggerated the properties of Resolor by claiming that it was a 'A new way out of chronic constipation in women' in breach of Clause 7.10. The claim was all embracing as it implied that Resolor was licensed and could be used for all cases of chronic constipation and that was not so.

Norgine accepted (letter dated 14 May, 2010) Movetis' proposal that it would stop using the advertisement and any analogous items and its undertaking '... to ensure that all future promotional items clearly stated "in whom laxatives fail to provide adequate relief"'. Norgine informed Movetis that it considered that inter-company dialogue had been successful, but that if it were to see any future unqualified use of the indication it would proceed directly to a complaint to the Authority.

On 29 June, two of Norgine's representatives attended a Movetis satellite symposium at the Association of Coloproctology of Great Britain and Ireland meeting in Bournemouth, a folder (ref UK/RES/10/00013 June 2010); leavepiece (ref UK/RES/10/0005 June 2010) and a drop card (ref UK/RES/10/0004 June 2010) were picked up. All of the items contained the claim 'At last! A new way out of chronic constipation in women'. Norgine was very disappointed that despite the specific undertaking made to it as part of inter-company dialogue, the same claim was made in material that was produced after the undertaking was given. Norgine alleged that the material was in breach of Clauses 3.2, 7.2 and 7.10.

RESPONSE

Movetis stated that it understood that inter-company dialogue had successfully resolved the matter and it was, therefore, disappointed to receive this complaint sent directly to the Authority. Movetis firmly believed that it acted properly and in accordance with the Code and its undertaking to Norgine. All past and current items in the Resolor marketing campaign complied with the marketing authorization for the product.

An example of promotional material submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) for pre-vetting (ref RES-0027), was provided, accompanied by the MHRA approval letter dated 6 November 2009. The tagline approved by the MHRA read: 'The new way out of chronic constipation'.

When Resolor was launched in the UK, 22 March 2010, the tagline had evolved to: 'At last! A new way out of chronic constipation in women'. This tagline was used in the BMJ advertisement (ref RES0140-UKv1) over which Norgine and Movetis had corresponded and formed the basis for Movetis' subsequent undertaking.

Movetis did not agree with Norgine that the claim 'A new way out of chronic constipation in women' was not adequately qualified but in the spirit of resolving issues through inter-company dialogue, it confirmed (letter dated 24 May) that: 'all other current and future UK promotional items will comply with our undertaking to include the full licensed indication'.

Movetis submitted that the correspondence with Norgine demonstrated that both parties acknowledged that they had reached a successful resolution of the matter (copies provided).

Movetis' interpretation of this undertaking was clear – that in addition to the claims on the advertisement (and all future promotional items) it would clearly provide the full indication. Movetis did not undertake to change, remove or amend any of the existing claims in the advertisement.

All of Movetis' current and subsequent materials, including the leavepiece, folder and drop card at issue in this case, bore the full licensed indication for Resolor clearly, prominently, in large font with no distracting copy or imagery surrounding the statement. In this regard Movetis was confident that it had fully complied with its undertaking.

In conclusion, and to reiterate, Movetis firmly believed that it acted properly and in accordance with the Code and its undertaking to Norgine.

PANEL RULING

The folder, leavepiece and drop card at issue all included the claim 'At last! A new way out of chronic constipation in women' beneath the most prominent mention of the brand name. This was immediately followed by a picture of a woman's stomach beneath which was the claim 'Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief'.

The Panel considered that any qualification necessary to ensure compliance with the Code should be part of the claim itself or appear prominently within the same visual field. The Panel considered each item separately as the context of claims could be a relevant factor.

With regard to the A4 folder, the Panel considered that the qualification that Resolor was to be used when laxatives had not provided adequate relief should have appeared as part of the claim itself or immediately beneath it. The size of the folder was relevant. The visual separation of the claim from its qualification by the illustration of the woman's stomach meant that the claim at issue was inconsistent with the SPC. A breach of Clause 3.2 was ruled. The claim was also misleading about Resolor's licensed indication and did not promote its rational use; the claim could not stand alone without reference to another statement. Breaches of Clauses 7.2 and 7.10 were ruled.

With regard to the A5 leavepiece, the Panel noted that the layout was similar to the front of the folder. The qualification on page 1 was physically nearer to the claim at issue due to the smaller size of the item but again the claim and its qualifications were separated by the illustration. The physical separation was compounded by the fact that the qualification was in a smaller font size and less prominent font colour and background contrast than the claim at issue above. Further, page 3 of the leavepiece included the claim, omitting the phrase 'At last...' without any mention that the product could only be used when laxatives had failed to provide adequate relief. The Panel considered that the claim on both pages 1 and 3 was inconsistent with the SPC. A breach of Clause 3.2 was ruled. Breaches of Clauses 7.2 and 7.10 were also ruled for the same reasons as with the folder.

The drop card consisted of two sides and was the size of a large bookmark. The claim at issue was again separated from its qualification by the illustration of the woman's stomach. In addition the qualification appeared as the first of a series of claims on the front of the drop card which were of identical font size and colour and thus as a group were clearly differentiated from the prominent claim at issue above. The claim at issue was thus inconsistent with the SPC. Breaches of Clauses 3.2, 7.2 and 7.10 were ruled for the same reasons as with the folder.

APPEAL FROM MOVETIS

Movetis submitted that it had acted properly and in accordance with its marketing authorization and with the Code for all past and current items in the Resolor marketing campaign. Similar items from its campaign were subject to MHRA pre-vetting and were considered acceptable. The items at issue were well within the boundaries of current standard industry practice and the practice of Movetis' peers, including those in the same therapeutic area.

The Code did not stipulate how or where images should be positioned within an item. The Panel referred to 'visual field' and 'visual separation', neither of which were defined or covered in the Code; these were subjective terms and open to interpretation without further guidance.

The items at issue bore the full licensed indication for Resolor, not asterisked as a small text footnote, but clearly, prominently, in large font, with no distracting copy or imagery surrounding the statement.

RESPONSE FROM NORGINE

Norgine concurred with the Panel's view that any qualification of a claim necessary to ensure compliance with the Code should be part of the claim itself or appear prominently within the same visual field. In this case the qualification of the claim necessary to comply with the indications for the

product was neither part of the claim itself nor did it appear prominently within the same visual field due to the considerable physical separation of the claim and its qualification in the materials in question; it was difficult to see how the claim and the qualification could have been separated more than they were.

The marketing authorization application initially proposed that Resolor should be indicated for the treatment of chronic constipation in adults in whom laxatives failed to provide adequate relief. After review of the dossier, the indication was revised and endorsed by the CHMP to the symptomatic treatment of chronic constipation in women in whom laxatives failed to provide adequate relief (ref Resolor, European Public Assessment Report, page 4).

Norgine alleged that it was clear that from the start of the marketing authorization process, the manufacturers considered that the more important qualification was the restriction in use of the product to patients in whom laxatives failed to provide adequate relief. The restriction to women only emerged during the licensing process.

Norgine therefore submitted that claims for this product would only comply with the Code if the full qualifications of the indication were part of the claims.

APPEAL BOARD RULING

The Appeal Board noted that each item at issue was headed 'Resolor prucalopride. At last! A new way out of chronic constipation in women'. This claim was above a picture of a woman's stomach partially covered by the woman's hands which were angled downwards. Below the photograph was the second claim 'Resolor is indicated for symptomatic treatment of chronic constipation in women in whom laxatives fail to provide adequate relief'.

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licensed indication for Resolor and in its view the A4 folder promoted the rational use of the medicine. No breach of Clauses 3.2, 7.2 and 7.10 were ruled. The appeal was thus successful.

The Appeal Board noted that the front cover of the A5 leavepiece was closely similar to that of the A4 folder. The Appeal Board considered that its comments about the folder also applied to the front cover of the leavepiece. No breach of Clauses 3.2, 7.2 and 7.10 were ruled. The appeal on this point was thus successful.

The Appeal Board noted that when the leavepiece was opened out, the double page spread of pages 2 and 3 featured the product name and strapline 'A new way out of chronic constipation in women' at the bottom of page 3. To the right of that claim was the photograph of the woman's stomach and hands and to the right of that was that tagline 'Rx prucalopride 1-2mg od'. The Appeal Board noted that the claim 'A new way out of chronic constipation in women' was not qualified in any way and was followed by a very simple prescribing instruction. The Appeal Board was concerned that this was not sufficiently clear with regard to Resolor's indication that it was only for those women in whom laxatives had failed to provide adequate relief. The claim 'A new way out of chronic constipation' on page 3 was inconsistent with the SPC, misleading and did not promote rational use. The Appeal Board upheld the Panel's rulings of breaches of Clauses 3.2, 7.2 and 7.10. The appeal on this point was unsuccessful.

With regard to the drop card, the Appeal Board noted that the top half featured the heading, photograph and second claim as previously described. Although the bottom half of the card featured a number of claims for Resolor the heading and the second claim were only separated by the photograph; there was no intervening text. The Appeal Board noted its comments and rulings above with regard to the A4 folder and considered that they also applied to the drop card. The Appeal Board ruled no breach of Clauses 3.2, 7.2 and 7.10 of the Code. The appeal on this point was thus successful.

Complaint received **20 July 2010**

Case completed **2 November 2010**
