CASE AUTH/2348/8/10

GENERAL PRACTITIONER v NORGINE

Movicol mailing

A GP complained that a Movicol (polyethylene glycol (macrogol) 3350 plus electrolytes) mailing, sent by Norgine, seriously misrepresented a recent clinical guideline from the National Institute for Health and Clinical Excellence (NICE) detailing the diagnosis and management of idiopathic constipation in children and young people.

The complainant noted that the first page of the gate-folded mailing was 'stamped', 'Breaking news from NICE' followed by 'New recommendations for constipation in children and young people'. The following page was headed 'NICE news for constipated children' below which was the claim 'Movicol Paediatric Plain/Movicol is now recommended as first-line treatment of faecal impaction and chronic constipation in children and young people.

The detailed submission from Norgine is given below.

The Panel noted that the mailing was about the treatment of constipation and faecal impaction in children and young people ie children aged 2-11 years for whom Movicol Paediatric Plain was indicated (for the treatment of faecal impaction, children had to be at least 5 years old) and young people aged 12 years and above for whom Movicol was indicated. The mailing referred to both products and featured the prescribing information for both.

The Panel considered that anyone reading the mailing would assume that NICE had specifically recommended Movicol Paediatric Plain or Movicol as first line treatment of chronic constipation and faecal impaction in children and young people ie both the under and over 12s. This was not so. The relevant NICE quick reference guide included a clinical management section which stated that for disimpaction and for maintenance therapy, polyethylene glycol 3350 plus electrolytes should be offered as first line treatment. A footnote to both recommendations read 'At the time of publication (May 2010), Movicol Paediatric Plain is the only macrogol licensed for children under 12 years that includes electrolytes … Movicol Paediatric Plain is the only macrogol licensed for children under 12 years that is also unflavoured'. Table 4 of the quick reference guide detailed the recommended doses of the paediatric and adult formulations of polyethylene glycol 3350 plus electrolytes and referred to both as unflavoured. The footnote referred to above, that had appeared in the clinical management section, also appeared at the bottom of table 4. The Panel considered that NICE had, in effect, specifically recommended Movicol Paediatric Plain for the under 12s only. It had not specifically recommended any brand of polyethylene glycol 3350 plus electrolytes for the 12s and over ie 'young people' as also referred to in the mailing. The Panel noted that Movicol as referred to in the mailing was lemon/lime flavoured; Movicol Plain was unflavoured. Neither adult formulation of Movicol had been specifically referred to in the NICE quick reference guide. The Panel thus considered that with regard to the treatment of children aged 12 years and over, the mailing was misleading as to the NICE guidance. A breach of the Code was ruled.

A general practitioner complained about a Movicol (polyethylene glycol (macrogol) 3350 plus electrolytes) mailing (ref MO/10/1995) sent by Norgine Pharmaceuticals Limited. The mailing informed health professionals about a recent clinical guideline from the National Institute for Health and Clinical Excellence (NICE) detailing the diagnosis and management of idiopathic constipation in children and young people.

COMPLAINT

The complainant noted that the first page of the gate-folded mailing was 'stamped', 'Breaking news from NICE' followed by 'New recommendations for constipation in children and young people'. The following page was headed 'NICE news for constipated children' below which was the claim 'Movicol Paediatric Plain/Movicol is now recommended as first-line treatment of faecal impaction and chronic constipation in children and young people.

The complainant alleged that the mailing seriously misrepresented the NICE guidance which referred to polyethylene glycol 3350 plus electrolytes.

When writing to Norgine the Authority asked it to respond in relation to Clause 7.2 of the Code.

RESPONSE

Norgine agreed that the wording in the NICE guidance was as the complainant stated. However, Norgine considered the mailing was a promotional item which notified health professionals of the endorsement by NICE of polyethylene glycol 3350 and electrolytes as first line treatment for constipation in children and young people, of which Movicol Paediatric Plain and Movicol were Norgine's brands. As such, Norgine believed this item complied with the Code.

Moreover, NICE qualified the generic polyethylene

glycol 3350 plus electrolytes recommendation with a footer which stated 'At the time of publication (May 2010), Movicol Paediatric Plain is the only macrogol licensed for children under 12 years that includes electrolytes'. This was similarly qualified in the mailing.

Consequently, Norgine believed that the mailing, used in a promotional context, did not breach Clause 7.2 as it provided accurate information reflecting the NICE guidance for the management of constipation in children and young people.

PANEL RULING

The Panel noted that the mailing was about the treatment of constipation and faecal impaction in children and young people. In the Panel's view this patient population included those children aged between 2 years and 11 years for whom Movicol Paediatric Plain was indicated (for the treatment of faecal impaction, children had to be at least 5 years old) and young people aged 12 years and above for whom Movicol was indicated. The mailing referred to both products and featured the prescribing information for both.

The Panel considered that anyone reading the mailing would assume that NICE had specifically recommended Movicol Paediatric Plain or Movicol as first line treatment of chronic constipation and faecal impaction in children and young people ie both the under and over 12s. This was not so. The NICE quick reference guide 'Constipation in children and young people', provided by Norgine, included a clinical management section which stated that for disimpaction and for maintenance therapy, polyethylene glycol 3350 plus electrolytes should be offered as first line treatment. A footnote to both recommendations read 'At the time of publication (May 2010), Movicol Paediatric Plain is the only macrogol licensed for children under 12 years that includes electrolytes … Movicol Paediatric Plain is the only macrogol licensed for children under 12 years that is also unflavoured'. Table 4 of the quick reference guide detailed the recommended doses of the paediatric and adult formulations of polyethylene glycol 3350 plus electrolytes and referred to both as unflavoured. The footnote referred to above, that had appeared in the clinical management section, also appeared at the bottom of table 4. The Panel considered that, given the footnote, NICE had, in effect, specifically recommended Movicol Paediatric Plain for the under 12s only. It had not specifically recommended any brand of polyethylene glycol 3350 plus electrolytes for the 12s and over ie 'young people' as also referred to in the mailing. The Panel noted that Movicol as referred to in the mailing was lemon/lime flavoured; Movicol Plain was unflavoured. Neither adult formulation of Movicol had been specifically referred to in the NICE quick reference guide. The Panel thus considered that with regard to the treatment of children aged 12 years and over, the mailing was misleading as to the NICE guidance. A breach of Clause 7.2 was ruled.

During its consideration of this case the Panel noted that Movicol Paediatric Plain was indicated for the treatment of chronic constipation in children 2 to 11 years of age. It could be used for the treatment of faecal impaction in children from the age of 5. The NICE quick reference guide, however, recommended its use in children aged less than one year old and up to 12 years old. The Panel noted that the NICE quick reference guide stated as a footnote that '[Movicol Paediatric Plain] does not have a UK marketing authorization for use in faecal impaction in children under 5 years or for chronic constipation in children under 2 years. Informed consent should be obtained and documented'. The mailing featured the same footnote. The Panel queried whether, by referring to the NICE guidance, which it knew recommended the use of Movicol Paediatric Plain in patients for whom it was not licensed, and including the footnote, Norgine had in effect promoted Movicol Paediatric Plain beyond the scope of its marketing authorization.

The Panel further noted that with regard to the adult formulation of polyethylene glycol 3350 plus electrolytes (unflavoured) the NICE quick reference guide stated that for disimpaction in a child/young person 12-18 years of age the dose should be 4 sachets on the first day, then increased in steps of 2 sachets daily to a maximum of 8 sachets daily. The Movicol summary of product characteristics (SPC), however, stated that the dose was simply 8 sachets daily.

The Panel requested that Norgine be advised of its concerns.

Complaint received **16 August 2010**

Case completed **23 September 2010**