

DIRECTOR/SHIRE v NORGINE

Promotion of Movicol

Shire complained about an advertisement and a leavepiece for Movicol Paediatric Plain (polyethylene glycol (macrogol) 3350 plus electrolytes) issued by Norgine. That part of the complaint which involved an alleged breach of undertaking was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

Shire noted the prominent 'stamp' image on the advertisement which stated 'NICE [National Institute for health and Clinical Excellence] recommends MOVICOL Paediatric Plain FIRST-LINE' and submitted that Norgine had used this endorsement without the written permission of NICE.

The detailed responses from Norgine are given below.

The Panel did not consider that a statement that NICE had recommended a particular treatment meant that an official document had been reproduced as meant by the Code. No breach of the Code was ruled.

Shire noted that no reference was given to the NICE guidance referred to in the advertisement. The document referred to was CG99 'Constipation in children and young people: Diagnosis and management of idiopathic childhood constipation in primary and secondary care'.

The Panel noted that the Code required a reference to be given when promotional material referred to published studies. The claim at issue was not from a published study and it did not refer to a published study. No breaches of the Code were ruled.

Shire noted the stamp 'NICE recommends MOVICOL Paediatric Plain FIRST-LINE*'. The asterisk referred to the footnote 'NICE recommends MOVICOL Paediatric Plain first line for the treatment of constipation and faecal impaction in children'. Shire alleged that the advertisement did not clearly define the licensed indication for Movicol Paediatric Plain; the indication for a medicine, especially in children where there were important age restrictions, should be clear and unambiguous.

The advertisement did not state that NICE guidance recommended Movicol Paediatric for children younger than those it was licensed to treat. The NICE guidance in question cited doses of the paediatric formulation for use in children of under 1 year, 1-5 years and 5-12 years but stated in

a footnote that '...Movicol Paediatric Plain... does not have UK marketing authorisation 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...'

Shire noted that Movicol Paediatric Plain was indicated for the treatment of chronic constipation in children 2 to 11 years of age and for the treatment of faecal impaction in children from the age of five. Section 4.2 of the Movicol Paediatric Plain summary of product characteristics (SPC) stated 'Movicol Paediatric Plain is not recommended for children below five years of age for the treatment of faecal impaction, or in children below two years of age for the treatment of chronic constipation. For patients of 12 years and older it is recommended to use Movicol'

Shire alleged that claims that linked Movicol Paediatric Plain with the recommendation from NICE as '... first line for the treatment of constipation and faecal impaction in children' promoted treatment of those two conditions in children as young as 1 year old with this product. Shire noted that this was raised as a concern by the Panel in Case AUTH/2348/8/10. Shire had not seen the mailer at issue in that case, but understood from the case report that it included the footnote from the NICE guidance as noted above regarding the age of children for whom Movicol Paediatric Plain was licenced. The Panel, nonetheless, considered that the mailer potentially recommended the use of Movicol Paediatric Plain outside of its licensed indication. No such warning was included in the advertisement now at issue.

In summary, therefore, Shire alleged that the advertisement now at issue promoted use of Movicol Paediatric Plain outside of the terms of the marketing authorization. Shire further alleged that the claims were misleading, did not represent the NICE recommendation accurately or fairly, and did not encourage rational use of the medicine.

The Panel noted the comments from both parties regarding Case AUTH/2348/8/10. It noted that each case was considered on its own merits.

The Panel examined the advertisement now at issue. The copy included the claim and its asterisked footnote. The brand name Movicol Paediatric Plain and generic name were also included. The rest of the advertisement included a visual of a child holding a number 4 around which the words 'Bulk Soften Stimulate Lubricate' were

printed. The rest of the advertisement consisted of the prescribing information and the statement regarding reporting adverse events.

The only information about the patient population was given in the prescribing information which stated, in line with the SPC that Movicol Paediatric Plain was 'For the treatment of chronic constipation in children 2-11 years of age. For the treatment of faecal impaction in children from the age of 5 years'.

The Panel noted that the NICE guideline recommend the use of Movicol Paediatric Plain within the SPC indication. The NICE guideline also recommended use of the product outside the SPC. No mention of this was made in the advertisement. The advertisement might encourage health professionals to look at the NICE guideline. The Panel noted that the NICE guideline was clear regarding the licensed and unlicensed use of Movicol Paediatric Plain. This was a difficult situation. The NICE guideline recommended the use of Norgine's product and Norgine should be able to refer to this in its advertising whilst not advertising outside the licensed indication. The use of the product was given in the advertisement. If Norgine had mentioned the unlicensed NICE guideline recommendation in the advertisement then it could be argued that it was promoting outside the marketing authorization. Taking all the circumstances into account the Panel considered that the advertisement was not inconsistent with the Movicol Paediatric Plain SPC. The product had not been promoted outside its marketing authorization as alleged. No breach of the Code was ruled.

The Panel noted its comments above and did not consider that the claim was misleading as alleged; the NICE guideline had recommended Movicol Paediatric Plain for first line treatment. The advertisement was not such that it would not encourage rational use. No breaches of the Code were ruled.

Shire alleged that the promotion of a medicine outside of its marketing authorization, particularly for very young children, posed potentially serious patient safety concerns and was a failure to maintain high standards and brought the industry into disrepute.

The Panel did not consider that the advertisement promoted Movicol outside its marketing authorization. It thus did not consider that Norgine had failed to maintain a high standard. Nor had the company brought discredit to or reduced confidence in the pharmaceutical industry. No breaches of the Code including Clause 2 were ruled.

Shire had not seen the mailer at issue in Case AUTH/2348/8/10 and was not party to the undertaking given by Norgine in that case. As set out above it appeared from the case report that the claims at issue and ruling might also be relevant to the advertisement.

The Panel considered that the material at issue in Case AUTH/2348/8/10 was different to that now at issue. In the previous case the matters ruled upon were that the NICE guideline recommended the use of Movicol Paediatric Plain for children under 12 but had not referred to the adult formulation of Movicol. The Panel had queried whether Movicol Paediatric Plain had been promoted beyond the scope of its marketing authorization but there had been no complaint in that regard so the Panel had not made a ruling. There could be no breach of the undertaking given in Case AUTH/2348/8/10 and thus the Panel ruled no breach of the Code.

Shire noted that the leavepiece promoted Movicol for use in adults and children. One page included a similar stamp to that used in the advertisement at issue above. In the leavepiece the claim 'NICE Guideline recommends Movicol Paediatric Plain FIRST-LINE*' appeared as a stamp. The asterisk referred the reader to a second claim immediately below 'NICE Guideline CG99 recommends Movicol Paediatric Plain as the first-line treatment for constipation in children.'

Shire stated that its serious concerns about the advertisement were brought to Norgine's attention in late November 2010. In its response, Norgine agreed to suspend use of the advertisement pending conclusion of inter-company dialogue via a meeting. Shire understood this to include suspension of other promotional activities using this imagery, statements and claims. Shire and Norgine met in March 2011 to discuss issues raised by the advertisement. The leavepiece was offered at a UK gastroenterology annual meeting in March 2011 and used the same imagery and claims; it was prepared in January 2011 ie a month *after* Norgine agreed to suspend use of the advertisement pending inter-company dialogue. Due to the serious nature of the concerns raised over this campaign, Shire believed continued use of this campaign, including preparation of new items using the same claims and messages, constituted a failure to maintain high standards and brought the industry into disrepute.

The leavepiece lacked any warnings of the age restrictions for Movicol Paediatric Plain in comparison to the broader NICE guidance, and therefore also promoted this product outside of its marketing authorization. This marketing campaign for Movicol Paediatric Plain, in the form of the advertisement and the leavepiece had been used for at least nine months.

During this time prescribers could be left with a lasting impression that Movicol Paediatric Plain should be used first-line in children from one year old, as endorsed by NICE. Nowhere in the campaign did Norgine clearly advise prescribers of the lower age restrictions of this product (2 years for chronic constipation and 5 years for faecal impaction). Neither did the materials note the recommendation to obtain informed consent (as set out by NICE) when prescribing this agent to

children younger than in whom it was licensed. Shire considered that Norgine should issue a corrective and statement in the form of a 'Dear Doctor' letter to make these restrictions clear.

The Panel noted the accounts of inter-company dialogue in relation to the advertisement. Norgine had stopped using the advertisement until that matter had been settled. The Panel understood Shire's frustration about the use of the leavepiece which had been prepared after Norgine had suspended use of the advertisement. However the Constitution and Procedure did not require Norgine to suspend use of the advertisement at issue, nor the leavepiece in question. Failure to do so did not amount to a breach of the Code. Thus the Panel ruled no breaches of the Code including Clause 2.

Shire Pharmaceuticals Limited complained about the promotion of Movicol Paediatric Plain (polyethylene glycol (macrogol) 3350 plus electrolytes) by Norgine Pharmaceuticals Limited. At issue were an advertisement (ref MO/10/2014) which had appeared in Paediatric Nursing, November 2010 and a leavepiece (ref MO/2277/JAN/11).

That part of the complaint which involved an alleged breach of undertaking was taken up by the Director as the Authority was responsible for ensuring compliance with undertakings.

A Advertisement

1 Stamp 'NICE recommends MOVICOL Paediatric Plain FIRST-LINE*'

COMPLAINT

Shire noted the prominent 'stamp' image on the advertisement which stated 'NICE [National Institute for Health and Clinical Excellence] recommends MOVICOL Paediatric Plain FIRST-LINE' and submitted that Norgine had confirmed that it had used this endorsement without the written permission of NICE. Shire alleged a breach of Clause 9.6.

RESPONSE

Norgine confirmed that it had not sought permission from NICE to refer to its guidance in promotion as it did not consider that such permission was needed.

Clause 9.6 prohibited the reproduction of official documents in promotional material unless written permission had been given by the appropriate body. Reference to the NICE guideline in the advertisement did not constitute the reproduction of an official document and so Norgine did not believe that failure to seek permission to use was in breach of Clause 9.6.

PANEL RULING

The Panel did not consider that the use of a statement in promotional material that NICE had recommended a particular treatment meant that an official document had been reproduced as prohibited by Clause 9.6. The clause prohibited, for example, the reproduction of a prescription form without permission. The Panel did not consider that the claim at issue constituted reproduction of an official document as meant by Clause 9.6. The Panel ruled no breach of Clause 9.6.

2 Stamp 'NICE recommends MOVICOL Paediatric Plain FIRST-LINE*'

COMPLAINT

Shire stated that the specifics of which NICE guidance was referred to in the advertisement was not clear since it was not referenced anywhere. Norgine had confirmed that the document referred to was CG99 'Constipation in children and young people: Diagnosis and management of idiopathic childhood constipation in primary and secondary care'.

A breach of Clauses 7.6 and 7.8 was alleged.

RESPONSE

Norgine stated that Clause 7.6 stated that when promotional material referred to published studies, references must be given. NICE guidance was not a published study, it was a guideline issued by an official body which was easily accessible to all without the need for an exact reference. Norgine therefore submitted that just referring to a national guideline did not come under the scope of 'published studies' and hence there was no breach of Clause 7.6. It was possible, of course, to substantiate the statements by consulting the NICE guidance itself.

Clause 7.8 was quite specific in its scope, which was limited to the reproduction of artwork. No reproduction of artwork was involved in the advertisement; therefore there could be no breach of Clause 7.8.

PANEL RULING

The Panel noted that Clause 7.6 required a reference to be given when promotional material referred to published studies. The claim at issue did not refer to a published study. It would have been helpful to include a reference for the NICE guideline but failure to do so did not amount to a breach of Clause 7.6. Thus the Panel ruled no breach of that clause. The Panel noted that Clause 7.8 was similar but related to artwork, illustrations and graphs. The claim at issue was not from a published study and thus no breach of Clause 7.8 was ruled.

3 Stamp 'NICE recommends MOVICOL Paediatric Plain FIRST-LINE*'

The asterisk referred to the footnote 'NICE recommends MOVICOL Paediatric Plain first line for the treatment of constipation and faecal impaction in children'

COMPLAINT

Shire alleged that the advertisement did not clearly define the licensed indication for Movicol Paediatric Plain. Shire considered that the indication for a medicine, especially in children where there were important age restrictions, should be made clear and unambiguous.

The advertisement did not state that NICE guidance recommended Movicol Paediatric for children younger than those it was licensed to treat.

The NICE guidance in question (CG99) gave the doses of the paediatric formulation for use in disimpaction, and ongoing maintenance (chronic constipation, prevention of faecal impaction) for children of under 1 year, 1-5 years and 5-12 years but stated in a footnote:

'At the time of publication (May 2010) Movicol Paediatric Plain is the only macrogol licensed for children under 12 years that includes electrolytes. **It does not have UK marketing authorisation 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.** Movicol Paediatric Plain is the only macrogol licensed for children under 12 years that is also unflavoured.' (emphasis added).

Shire stated that Movicol Paediatric Plain was indicated:

'For the treatment of **chronic constipation** in children **2 to 11 years of age**. For the treatment of **faecal impaction** in children from the **age of five years**, defined as refractory constipation with faecal loading of the rectum and/or colon' (emphasis added).

Section 4.2 of the Movicol Paediatric Plain summary of product characteristics (SPC) also stated:

'MOVICOL Paediatric Plain **is not recommended for children below five years of age for the treatment of faecal impaction, or in children below two years of age for the treatment of chronic constipation.** For patients of 12 years and older it is recommended to use MOVICOL' (emphasis added).

Shire alleged that claims that plainly and directly linked Movicol Paediatric Plain with the recommendation from NICE as '... first line for the treatment of constipation and faecal impaction in children' promoted treatment of those two conditions in children as young as 1 year old with this product.

Shire noted that this point had been raised as a concern by the Panel in Case AUTH/2348/8/10. Shire had not seen the mailer (MO/10/1995) at issue in that case, but understood from the case report that it included a footnote that stated:

'[MOVICOL Paediatric Plain] does not have a UK marketing authorisation for use in faecal impaction in children under 5 years and for chronic constipation in children under 2 years. Informed consent should be obtained and documented.'

The Panel, nonetheless, considered that the mailer potentially recommended the use of Movicol Paediatric Plain outside of its licensed indication. No such warning was included in the advertisement now at issue.

In summary, therefore, Shire alleged that the advertisement promoted use of Movicol Paediatric Plain outside of the terms of the marketing authorization in breach of Clause 3.2.

Shire further alleged that the claims were misleading, did not fairly or accurately represent the NICE recommendation and did not encourage rational use of the medicine, in breach of Clauses 7.2 and 7.10.

RESPONSE

Norgine denied that the advertisement recommended off-licence use. There was no specific content in the body of the advertisement which promoted use outside licence. The focus of the advertisement was to notify prescribers that Movicol Paediatric Plain was now recommended for first line use.

The advertisement contained prescribing information which was quite clear as to the licensed uses for the product. As with all prescribing information, prescribers were further directed to refer to the SPC before prescribing. The Movicol Paediatric Plain SPC made clear the ages of children for whom it was licensed. Therefore there was sufficient information in the advertisement to make it clear what the licensed age groups were for this product.

All NICE guidance documents stated the following on their first page: 'This guidance represents the view of NICE, which was arrived at after careful consideration of the evidence available. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. **However, the guidance does *not* override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer, and informed by the summary of product characteristics of any drugs they are considering'** (emphasis added).

Therefore it was clear that NICE guidelines did not have primacy when it came to a health professional prescribing a medicine for a patient. NICE guidance did not override the responsibility of health professionals to make prescribing decisions informed by the relevant SPC.

Norgine asserted that both the journal advertisement and the leavepiece (point B below) appropriately and sufficiently drew prescribers' attention to the fact that the guideline on treating constipation in children recommended Movicol Paediatric Plain as first-line treatment. Norgine submitted that it was reasonable to draw prescribers' attention to this fact, but it was up to them to make a prescribing decision only after referring to the SPC.

Norgine believed this was analogous to and consistent with the presentation of data that was derived from a clinical study containing off-licence data in promotional material. So long as the presentation of data within the context of the promotional item was within the product licence, it was acceptable to present the data which was within licence. Norgine therefore denied a breach of Clause 3.2.

Regarding the alleged breach of Clause 7.2, Shire had stated that the claims did not accurately reflect the NICE guidance and were thus misleading. However, Norgine was unable to identify exactly what Shire believed was misleading as it had not stated this clearly. The only interpretation Norgine could infer was that Shire believed it was misleading for Norgine not to have stated the age range considered by NICE, which according to the Panel's ruling in Case AUTH/2348/8/10 would be inappropriate. Regardless, Norgine did not believe it was misleading to refer only to a subset of the guidance, so long as the subset was representative of the overall guidance. There was no doubt, as the Panel had confirmed in Case AUTH/2348/8/10, that the guidance recommended Movicol Paediatric Plain for an age range that included that stated in the advertisement.

Shire had further alleged a breach of Clause 7.10 but had not indicated the basis for that allegation. The advertisement was clearly within the scope of the licence and the context of the NICE guidance. Therefore Norgine could not see what aspect was in breach of Clause 7.10.

PANEL RULING

The Panel noted the comments from both parties regarding Case AUTH/2348/8/10. It noted that each case was considered on its own particular merits.

The Panel examined the advertisement now at issue. The copy included the claim and its asterisked footnote. The brand name Movicol Paediatric Plain and generic name were also included. The rest of the advertisement included a visual of a child holding a number 4 around which

the words 'Bulk Soften Stimulate Lubricate' were printed. The rest of the advertisement consisted of the prescribing information and the statement regarding reporting adverse events.

The only information about the patient population was given in the prescribing information which stated under the subheading 'uses' that Movicol Paediatric Plain was 'For the treatment of chronic constipation in children 2-11 years of age. For the treatment of faecal impaction in children from the age of 5 years'. This was in line with the SPC.

The Panel noted that the NICE guideline recommend the use of Movicol Paediatric Plain within the SPC indication. The NICE guideline also recommended use of the product outside the SPC. No mention of this was made in the advertisement at issue. The advertisement might encourage health professionals to look at the NICE guideline. The Panel noted that the NICE guideline was clear regarding the licensed and unlicensed use of Movicol Paediatric Plain. The Panel considered that this was a difficult situation. The NICE guideline recommended the use of Norgine's product and Norgine should be able to refer to this in its advertising whilst not advertising outside the licensed indication. The use of the product was given in the advertisement. If Norgine had mentioned the unlicensed NICE guideline recommendation in the advertisement then it could be argued that it was promoting outside the marketing authorization. Taking all the circumstances into account the Panel considered that the advertisement was not inconsistent with the Movicol Paediatric Plain SPC. The product had not been promoted outside its marketing authorization as alleged. No breach of Clause 3.2 was ruled.

The Panel noted its comments above and did not consider that the claim was misleading as alleged; the NICE guideline had recommended Movicol Paediatric Plain for first line treatment. The advertisement was not such that it would not encourage rational use. No breach of Clauses 7.2 and 7.10 were ruled.

4 Alleged breaches of Clauses 2 and 9.1

COMPLAINT

Shire alleged that there were potential serious patient safety concerns associated with the promotion of a medicine outside of its marketing authorization, particularly for very young children. Shire believed this constituted a failure to maintain high standards and brought the industry into disrepute.

RESPONSE

As stated above, Norgine did not consider the material was in breach of Clause 3.2 and so it could not see any grounds for concern in respect of

patient safety and therefore denied breaches of Clauses 2 and 9.1.

Given that NICE would never recommend an action that would place patient safety at risk and that the licensed indication for the product was clearly stated and that the presentation of the data in the advertisement had been constructed in response to the Panel's comments in Case AUTH/2348/8/10, it was difficult to see where high standards had not been maintained or safety placed at risk. Norgine therefore strongly denied any breach of Clause 9.1.

Whilst Norgine did not consider that the data was presented in such a way as to be considered promotional in children under the age of 2, Norgine's ongoing safety surveillance had not raised concerns which would cause it to challenge the position of NICE or the British National Formulary for Children.

Given that breaches of Clause 2 were reserved as a particularly serious censure, Norgine further denied the alleged breach of Clause 2.

Norgine made additional comments on the alleged breach of Clauses 2 and 9.1 at point B below.

PANEL RULING

The Panel noted its rulings in point A3. It agreed with the complainant that promoting a medicine outside its marketing authorization was a serious matter that could potentially have patient safety concerns. However the Panel did not consider that the advertisement promoted Movicol outside its marketing authorization. It thus did not consider that Norgine had failed to maintain a high standard. Nor had the company brought discredit or reduced confidence in the pharmaceutical industry. No breach of Clauses 9.1 and 2 was ruled.

5 Alleged breach of undertaking

COMPLAINT

Shire had not seen the mailer (ref MO/10/1995) at issue in Case AUTH/2348/8/10 and was not party to the undertaking given by Norgine in that case. As set out in point A3 above it appeared from the case report that the claims at issue and ruling might also be relevant to the advertisement. Shire requested, therefore, that the Panel consider a breach of Clause 25.

RESPONSE

Norgine denied that it had breached its undertaking since that undertaking referred specifically and solely to the promotion of Movicol (the adult formulation) in the over 12s, not Movicol Paediatric Plain. Norgine therefore did not consider that this was a valid allegation, no undertaking in respect of promotion of Movicol Paediatric Plain was made and therefore no breach should be ruled.

PANEL RULING

The Panel considered that the material at issue in Case AUTH/2348/8/10 was different to that now at issue. In the previous case the matters ruled upon were that the NICE guideline recommended the use of Movicol Paediatric Plain for children under 12 but had not referred to the adult formulation of Movicol. The Panel had queried whether Movicol Paediatric Plain had been promoted beyond the scope of its marketing authorization but there had been no complaint in that regard so the Panel had not made a ruling. There could be no breach of the undertaking given in Case AUTH/2348/8/10 and thus the Panel ruled no breach of Clause 25.

B Leavepiece

The leavepiece promoted Movicol for use in adults and children. One page included a similar stamp to that used in the advertisement at issue above. In the leavepiece the claim 'NICE Guideline recommends Movicol Paediatric Plain FIRST-LINE*' appeared as a stamp. The asterisk referred to a second claim immediately below 'NICE Guideline CG99 recommends Movicol Paediatric Plain as the first-line treatment for constipation in children.'

COMPLAINT

Shire stated that its serious concerns about the advertisement were brought to Norgine's attention on 26 November 2010. In its response of 9 December 2010, Norgine agreed to suspend use of the advertisement pending conclusion of inter-company dialogue via a meeting. Shire understood this to include suspension of other promotional activities using this imagery, statements and claims. Shire and Norgine met on 18 March 2011 to discuss the issues raised by Shire about the advertisement.

The leavepiece was offered at the British Society of Gastroenterology's (BSG) annual meeting on 15 March 2011. It used the same imagery and claims. The date of preparation, January 2011, was one month *after* Norgine agreed to suspend use of the advertisement pending inter-company dialogue.

Due to the serious nature of the concerns raised over this campaign, Shire believed its continued use, including preparation of new items using the same claims and messages, constituted a failure to maintain high standards and brought the industry into disrepute. A breach of Clauses 2 and 9.1 was alleged.

The leavepiece lacked any warnings of the age restrictions for Movicol Paediatric Plain in comparison to the broader NICE guidance, and therefore also promoted the product outside of its marketing authorization, in breach of Clause 3.2. Shire stated that for at least nine months during which this marketing campaign, in the form of the advertisement and the leavepiece, had been used, prescribers could be left with a lasting impression

that Movicol Paediatric Plain should be used to treat chronic constipation or faecal impaction first-line in children from one year old, as endorsed by NICE. Nowhere in the campaign were prescribers advised of the lower age restrictions of this product (2 years for chronic constipation and 5 years for faecal impaction). Neither was the recommendation to obtain informed consent (as set out in the NICE guidance itself) when prescribing this agent to children younger than in whom it was licensed, mentioned.

Shire believed that the responsible course of action was for Norgine to issue a corrective and explanatory statement in the form of a 'Dear Doctor' letter to make these restrictions clear.

RESPONSE

Norgine was unclear as to Shire's specific concerns in respect of a breach of Clause 3.2 and assumed that the allegation had arisen because Norgine did not specify the difference between the licensed indication for Movicol Paediatric Plain and the age range stated in the NICE guideline. Since the leavepiece was in line with the licence and the undertaking in Case AUTH/2348/8/10, Norgine denied a breach of Clause 3.2.

Shire appeared to allege the breaches of Clause 2 and 9.1 on its assertion that Norgine ignored commitments made during inter-company dialogue. Norgine submitted that its letter of 9 December clearly demonstrated that this was not so.

The inter-company dialogue was protracted for various reasons however, in the spirit of the initial concerns raised by Shire, Norgine voluntarily offered to suspend the use of the journal advertisement whilst inter-company dialogue was on-going. This was a gesture of goodwill to enable the discussions to progress in a constructive manner and despite the protracted timeline in meeting, the advertisement remained suspended.

Neither in Shire's response to Norgine's letter of 9 December or at any other point prior to the meeting in March, did Shire request that Norgine suspend anything other than the advertisement.

Shire alleged that the continued use of the material constituted a failure to maintain high standards. There was no requirement in the Authority's Constitution and Procedure for a company to cease use of material in response to competitor concerns until such time as inter-company agreement had been reached.

Norgine took a responsible approach to reviewing material alleged to be in breach by competitors, and if it considered allegations to be founded, it took immediate action. However, Norgine did not consider other materials to be in breach of the Code on this occasion; hence the need for dialogue to better understand Shire's position. Norgine therefore denied the allegation of a breach of

Clause 9.1. Norgine also denied the allegation of a breach of Clause 2, which was a particular censure reserved for the most serious matters.

Shire did not allege any specific breach relating to the length of time taken to hold the inter-company meeting. However, Norgine believed that there was an implied criticism but it strongly repudiated any suggestion that it was responsible for the delay. Norgine had hoped to have the inter-company meeting in early January ie as soon as possible after its proposal for such a meeting was agreed by Shire on 22 December. However, for various reasons the earliest mutually agreeable date for a meeting was 18 March. Norgine was very disappointed with the time it took to arrange this meeting, as it genuinely wanted to meet Shire as early as possible to explore its concerns about the material and see if a course of action could be agreed which might avoid any further complaints.

In relation to both the leavepiece and advertisement, Norgine stated that if the Panel ruled no breaches of some or all of the allegations Clauses 3.2, 7.2, 7.6, 7.8, 7.10, 9.6 and 25 there might be no case for a breach of Clause 9.1.

As Norgine did not consider the material to be in breach of Clause 3.2 it could not see any grounds for concern in respect of patient safety and it therefore denied breaches of Clause 9.1.

Given that NICE would never recommend an action that would place patient safety at risk and that the licensed indication for the product was clearly stated and that the presentation of the data in the advertisement had been constructed in response to the Panel's comments in Case AUTH/2348/8/10, it was difficult to see where high standards had not been maintained. Norgine therefore denied the allegation of a breach of Clause 9.1.

In relation to the alleged breach of Clause 2 on the leavepiece and advertisement, if the Panel ruled no breaches of some or all of the allegations, Clauses 3.2, 7.2, 7.6, 7.8, 7.10, 9.1, 9.6 and 25, there might be no case for a breach of Clause 2.

Norgine noted that Clause 2 was a sign of particular censure and should be reserved for such circumstances. Such circumstances would include, *inter alia*, prejudicing patient safety. Shire alleged that there were serious safety concerns associated with the promotion of Movicol Paediatric Plain outside of its marketing authorization.

The Panel needed to consider whether serious safety concerns existed in this specific case if it ruled a breach of Clause 3.2. Norgine contended that there were no serious safety concerns in respect of this product and that even if the Panel considered that the medicine had been promoted outside of its marketing authorization (an allegation which Norgine strongly refuted), then it was not the case that simply because the promotion was said to have been to very young children, that this made

any safety concerns raised automatically serious. Indeed, not only NICE but also the British National Formulary for Children recommended the use of Movicol Paediatric Plain in children under 2 years of age. Neither of these highly respected organisations would ever recommend anything that was even remotely likely to prejudice patient safety.

Norgine did not believe Shire had raised any other allegations in respect of the promotion of Movicol Paediatric Plain which might lead the Panel to consider that there had been a breach of Clause 2. Shire had, nonetheless, contended that Norgine's alleged breach of undertaking should give rise to a ruling of a breach of Clause 2. As stated in point A5 above, Norgine contended that there was no breach of undertaking. There was therefore no case to answer in this regard.

PANEL RULING

The Panel noted the accounts of inter-company dialogue in relation to the advertisement. Norgine had ceased use of the advertisement until that matter had been settled. The Panel understood Shire's frustration about the use of the leavepiece which had been prepared after Norgine had suspended use of the advertisement at issue in point A above.

However the Constitution and Procedure did not require Norgine to suspend use of the advertisement at issue, nor the leavepiece in question. Failure to do so did not amount to a breach of the Code. Thus the Panel ruled no breach of Clauses 9.1 and 2 of the Code.

Complaint received **11 April 2011**

Case completed **1 July 2011**
