

# ANONYMOUS CONTACTABLE HEALTH PROFESSIONAL V A MENARINI

## Promotion of Migard

An anonymous contactable complainant who described themselves as a 'concerned UK health professional' complained about an advertisement for Migard (frovatriptan) on the BMJ website.

The complainant noted that instead of prescribing information, there was a link to an out-of-date summary of product characteristics (SPC).

The detailed response from A Menarini is given below.

The Panel noted A Menarini's submission that the material at issue was placed on the BMJ website by global colleagues without any knowledge, review or approval from the UK.

The Panel noted that it was an established principle under the Code that UK companies were responsible for acts and omissions of their overseas affiliates that came within the scope of the Code. The Panel considered that the Migard advertisement published in the BMJ came within the scope of the Code and A Menarini UK was thus responsible for it.

The Panel noted that prescribing information was required to be included in promotional material. The summary of product characteristics might be provided in certain situations providing that the legal classification and cost of the medicine were also provided. Although the SPC had been provided, the legal classification and cost of the medicine had not been. The Panel ruled a breach of the Code. As the material did not include the prescribing information or the link to it as required a further breach was ruled.

The Panel noted that the SPC that was linked to the advertisement appeared to be for frovatriptan 2.5mg and was dated November 2014. The current Migard SPC was dated April 2017. The Panel noted its comments and rulings above and considered that it appeared that A Menarini had been badly let down by its global affiliate. An old version of the SPC had been used in the advertisement. High standards had not been maintained and a breach of the Code was ruled.

The Panel noted that there did not appear to be any major differences between the two SPCs. Neither the complainant nor A Menarini had made any comments in this regard. The Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

An anonymous complainant who described themselves as a 'concerned UK health professional'

complained about an advertisement for Migard (frovatriptan) which appeared on the BMJ website. Migard was marketed by A Menarini and indicated for the acute treatment of the headache phase of migraine in adults.

## COMPLAINT

The complainant noted that instead of prescribing information, there was only a link from the website to an out-of-date summary of product characteristics (SPC).

When writing to A Menarini, the Authority asked it to consider the requirements of Clauses 2, 4.1, 4.2, 4.4 and 9.1 of the Code.

## RESPONSE

A Menarini explained that the Migard material at issue was generated, approved and placed on the BMJ website by global colleagues around January 2016, without any knowledge, review or approval from the UK. A Menarini believed that the material was intended for health professionals and because of the BMJ placement, this was likely to include UK health professionals.

A Menarini was aware of its responsibilities under the Code in relation to the review and approval of materials created by global when materials might be accessed by UK health professionals, patients or members of the public. However, on this occasion, the UK had no knowledge of the material and it was not included in the review and approval process.

A Menarini believed that the Migard material was accessible to UK health professionals. Migard was available in the UK at the time, although not actively promoted. During the review process, one member of the global team commented that 'Since the Brand Migard is also available in UK, please see my comments into the material related to the UK compliance', however, this direction was not followed.

A Menarini noted the difference between the SPC provided with the material at issue and the current UK SPC; copies of both were provided. A Menarini was not aware of the circumstances that seem to have led to the Migard material SPC being out-of-date, as alleged.

A Menarini had informed its global colleagues about the matter who were looking into it and making the necessary arrangements to remove the Migard material from the BMJ website.

A Menarini noted that it might not be appropriate for it to provide responses on behalf of global whilst its review on this matter was still ongoing. However, it provided the available information and comments in relation to the clauses from the UK perspective.

A Menarini explained that as the material at issue was intended for health professionals, global considered it appropriate to add the Migard SPC, sourced from the corporate regulatory department, instead of the prescribing information as required by the Code. The SPC was linked to all the webpages of the material by a single click link highlighted as a 'SmPC' box. However, A Menarini submitted that the material fell within the scope of the Code and should have met all of its relevant requirements. Therefore, A Menarini acknowledged that it had breached Clauses 4.1, 4.2 and 4.4.

A Menarini considered that its global colleagues should have included the UK in the review and approval process. The material fell within the scope of the Code and should have met all of its relevant requirements. A Menarini accepted a breach of Clauses 2 and 9.1.

## PANEL RULING

The Panel noted A Menarini's submission that the material at issue was generated, approved and placed on the BMJ website by global colleagues without any knowledge, review or approval from the UK. A Menarini believed that the material was intended for health professionals and because of the BMJ placement, was likely to include UK health professionals.

The Panel noted that it was an established principle under the Code that UK companies were responsible for acts and omissions of their overseas affiliates that came within the scope of the Code. The Panel considered that the Migard advertisement published in the BMJ came within the scope of the Code and A Menarini UK was thus responsible for it.

The Panel noted that material published on the BMJ included a picture of a woman with her hands on her head, the brand name (Migard) and generic name (frovatriptan) appeared on one side of the picture and the A Menarini group logo on the other. The footer stated that migraine was a chronic disorder occurring in both genders, although large surveys showed higher prevalence of this condition in women and went on to give the ratio of men to women and some information on the factors that might play a role in the pathogenesis of migraine. Below this was the statement 'Discover how a single treatment can prove useful for the many kinds of migraine patients' followed by 4 different photographs of patients titled Migraine, migraine with aura, menstrual migraine and weekend migraine with buttons on each to click for more information. At the bottom of the page was a link to the SPC and an adverse event reporting statement.

In the Panel's view it was clearly an advertisement for Migard.

The Panel noted that Clause 4.1 required prescribing information to be included in promotional material. Clause 4.2 listed the elements of the prescribing information and stated that the summary of product characteristics might be provided instead of information listed under sections i-viii of Clause 4.2 providing that the legal classification and cost of the medicine were also provided. Although the SPC had been provided in this case, the legal classification and cost of the medicine had not been. The Panel noted that Clause 4.2 listed the content of prescribing information which was required by Clause 4.1 to be provided with all promotional material. Failure to satisfy Clause 4.2 was therefore a breach of Clause 4.1. The Panel noted that the advertisement for Migard did not include the prescribing information as listed in Clause 4.2 and a breach of Clause 4.1 was ruled.

Clause 4.4 required that in the case of digital material such as advertisements in electronic journals, emails, electronic detail aids and suchlike, the prescribing information as required by Clause 4.1 might be provided either by inclusion in the digital material itself, or by way of a clear and prominent direct single click link. Although the advertisement included a link to the SPC, the material did not include the prescribing information or the link to it as required by Clause 4.1 and a breach of Clause 4.4 was ruled.

The Panel noted that the SPC linked to the advertisement in question as provided by A Menarini appeared to be for frovatriptan 2.5mg and was dated November 2014. The current Migard SPC provided by A Menarini was dated April 2017. Both SPCs listed Menarini International Operations Luxembourg S.A as the marketing authorisation holder and PL16239/0017 as the marketing authorisation number. The Panel noted its comments and rulings above and considered that it appeared that A Menarini had been badly let down by its global affiliate. Irrespective of the failure to comply with Clause 4.1 an old version of the SPC had been used in the advertisement. High standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted that there did not appear to be any major differences between the two SPCs. Neither the complainant nor A Menarini had made any comments in this regard. The Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

**Complaint received**                      **8 June 2018**

**Case completed**                              **3 September 2018**