CASE AUTH/2949/3/17

HOSPITAL DOCTOR v A. MENARINI

Yellow Card Scheme details missing from company website

A hospital doctor complained after he had accessed the A. Menarini corporate website to find out more about, and report an adverse event to, one of the company's medicines. The complainant submitted that a number of links on the website did not work including one promising 'more information on medicines licensed in the UK'. There were no adverse event reporting forms or information to be found nor a link to the Yellow Card Scheme. The website stated:

- **Adverse events should be reported. Reporting forms and information can be found at. Adverse events should also be reported to A. MENARINI FARMACEUTICA INTERNAZIONALE S.R.L. Phone no. 0800 085 8678'**

The complainant could not see when this section of the website was last updated but considered that it was very low standards to have so many broken links, particularly when it came to adverse event reporting. The complainant queried whether the company took adverse event reporting seriously.

The detailed response from A. Menarini is given below.

The Panel noted A. Menarini's submission that the complaint concerned the webpage which could be reached by clicking on the 'Products' tab on the homepage of the corporate website.

The Panel noted that the webpage was examined and approved in 2011. The Panel disagreed with A. Menarini's submission that the homepage and the Products/Welcome webpage were corporate advertising and did not contain information that required certification. The Panel noted that the Code required that, *inter alia*, educational material for the public or patients issued by companies which related to diseases or medicines but was not intended as promotion for those medicines must be certified.

The Panel noted A. Menarini's submission that the Products/Welcome webpage did not contain promotional information and neither did it contain material about a medicine intended for patients taking that medicine.

The Panel considered that the complainant had not established that the website was promotional. No breach of that part of the Code which required an adverse event reporting statement, including reference to the Yellow Card Scheme, to be included on promotional material was ruled.

The Panel noted that access to the website was not limited to health professionals and other relevant decision makers, and it was therefore a source of information for the public including patients taking the company's medicines. The page in question was the introductory page to a section which provided information about the company's products. In the Panel's view given its likely readership included patients taking the company's medicines the section therefore should include the statement below or similar:

> **'Reporting of side effects**
> **If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet.**
> **You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.**
> **By reporting side effects you can help provide more information on the safety of this medicine'.**

The Panel noted that A. Menarini had originally decided that details about the Yellow Card Scheme ought to appear on the page in question but when it noticed the missing Yellow Card hyperlink it decided not to close the webpage since the company telephone number was included. The Panel considered that this was insufficient. The reference to the Yellow Card Scheme was missing. A breach of the Code was ruled.

The Panel was very concerned that despite discovering that the hyperlink to the Yellow Card Scheme had disappeared, and promptly notifying its parent company responsible for website maintenance, no action was apparently taken until three months later when A. Menarini was notified of the present complaint. This showed a disregard for patient safety issues. The Panel was similarly concerned about the disappearance of a hyperlink to the electronic medicines compendium. In the Panel's view high standards had not been maintained and a breach of the Code was ruled.

A hospital doctor complained about the adverse event reporting function on the A. Menarini UK website, (menarini.co.uk); he had wanted to find out more about, and report, an adverse event about Adenuric (febuxostat), marketed by A. Menarini.

COMPLAINT

The complainant explained that one of his patients who was being treated for gout had experienced an adverse reaction. As the complainant did not see many gout patients, he searched the manufacturer's website to get more information about Adenuric and was disappointed with its general quality and was surprised at the number of links that did not work. For instance, the 'Stamp out gout' link led nowhere and the link promising 'more information about licensed medicines in the UK' did not work either.

The complainant then tried to report the adverse event which appeared not to be possible on this website as the links did not work. There were no

reporting forms or information to be found nor a link to the Yellow Card Scheme. The website stated:

- **Adverse events** should be reported. Reporting forms and information can be found at. Adverse events should also be reported to A. MENARINI FARMACEUTICA INTERNAZIONALE S.R.L. Phone no. **0800 085 8678**'

The complainant could not see when this section of the website was last updated but considered that it was very low standards to have so many broken links, particularly when it came to adverse event reporting. The company should surely have this section working properly and check often to make sure it worked. The complainant stated that he could not believe this website was properly maintained with so many broken links. It did not look like the company took adverse event reporting seriously.

When writing to A. Menarini, the Authority asked it to consider the requirements of Clauses 4.9, 9.1 and 26.3 of the Code.

RESPONSE

A. Menarini noted that the complaint concerned the Products/Welcome webpage (www.menarini.co.uk/Products/Welcome) which could be reached by clicking on the tab 'Products' on the homepage of the corporate website (menarini.co.uk).

The corporate website went live on 20 July 2011. The Code in force then was the 2011 Code. The homepage (copy provided) and the Products/Welcome webpage (copy provided) were considered corporate advertising and as such did not contain information that required certification (as otherwise would have been required by Clauses 14.1, 14.2 or 14.3 of the Code). Hence, these webpages were examined to ensure that they did not contravene the Code or the relevant statutory requirements in line with the supplementary information to Clause 14.3 'Examination of Other Material'. The webpages were approved on 20 July 2011.

A. Menarini noted that Clause 4.9 required that 'All promotional material must include the prominent statement "Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to [relevant pharmaceutical company]'. Since the Products/Welcome webpage did not contain promotional information, Clause 4.9 did not apply and so A. Menarini denied a breach of that clause.

Clause 26.3 required that:

> 'Any material which relates to a medicine and which is intended for patients taking that medicine must include the statement below or a similar one:
>
> > "Reporting of side effects
> > If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine"'.

Since the Products/Welcome webpage did not contain material about a medicine intended for patients taking that medicine, Clause 26.3 did not apply and so the company also denied a breach of that clause.

Clause 9.1 required high standards to be maintained at all times.

A. Menarini submitted that despite the fact that a statement on adverse event reporting was not required by the Code, it decided, before the website went live, to add such a statement to the Products/Welcome webpage. The statement read:

> 'Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to A. MENARINI FARMACEUTICA INTERNAZIONALE S.R.L. Phone no. 0800 085 8678.'

However, as reported by the complainant, the hyperlink to the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card website was missing. The disappearance of that hyperlink was discovered by the local safety manager on 31 January 2017 and promptly communicated to A. Menarini's parent company, which provided technical support and maintenance of the site. The cause of this technical problem had not been identified and was under investigation. In the meantime, the company decided not to close the webpage since the statement included a company telephone number that could be called to report adverse events.

The 'Stamp out gout' website was under construction and the link did not lead to any further information or entity.

The sentence 'Information about licensed medicines in the UK may be found at (*)' previously read: 'Information about licensed medicines in the UK may be found at www.medicines.org.uk/emc (*)'. That the hyperlink to the electronic medicines compendium (eMC) was no longer there was also discovered on 31 January 2017 by the local safety manager, and was promptly communicated to the parent company. The technical causes for this were being investigated.

A. Menarini stated that it endeavoured to maintain the highest standards in all of its activities and communications, including its corporate website. Technical issues were difficult to avoid entirely, and it had undertaken to correct any issues following the internal discovery by the local safety manager.

A. Menarini stated that the website had been examined and would be corrected within one working week. That being said, and due to the time that had elapsed and the fact that at least one health professional had complained about the website, it

agreed that it should have acted more quickly and that a higher standard could have been achieved as required by Clause 9.1.

A. Menarini apologised for the confusion that might have been caused for the complainant and possibly for other website users. The company had implemented corrective actions and was committed to creating more robust systems to ensure that these technical problems did not resurface.

PANEL RULING

The Panel noted A. Menarini's submission that the complaint concerned the webpage which could be reached by clicking on the tab 'Products' on the homepage of the corporate www.menarini.co.uk website.

The Panel noted that the webpage was examined and approved, against the 2011 Code, on 20 July 2011 before going live the same day. The Panel disagreed with A. Menarini's submission that the homepage and the Products/Welcome webpage were considered corporate advertising and as such did not contain information that required certification. The Panel noted that Clause 14.3 required that, *inter alia*, educational material for the public or patients issued by companies which related to diseases or medicines but was not intended as promotion for those medicines must be certified in advance in a manner similar to that provided for by Clause 14.1.

The supplementary information to Clause 26.2 allowed for the provision of non-promotional information about prescription only medicines to the public by means of, *inter alia*, reference information made available by companies on their websites or otherwise as a resource for members of the public. Pharmaceutical companies were not obliged to provide reference information but it was considered good practice to provide, as a minimum, the regulatory information comprising the summary of product characteristics (SPC), the package leaflet (PIL) and the public assessment report (PAR) (UK or European) where such a document existed.

The Panel noted A. Menarini's submission that Clause 4.9 did not apply because the Products/ Welcome webpage did not contain promotional information and that Clause 26.3 did not apply either as the webpage did not contain material about a medicine and which was intended for patients taking that medicine.

The Panel noted that Clause 4.9 only required the adverse event reporting statement to be included on promotional material and considered that the complainant had not established that the website was promotional. No breach of Clause 4.9 was ruled.

The Panel noted that access to the website was not limited to health professionals and other relevant decision makers, and it was therefore a source of information for the public including patients taking the company's medicines. The page in question was the introductory page to a section which provided information about the company's products. In the Panel's view, given that its likely readership included patients taking the company's medicines the requirements of Clause 26.3 were triggered. The section therefore should include the statement below or similar:

> **'Reporting of side effects**
> If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine'.

The Panel noted that A. Menarini had originally decided that details about the Yellow Card Scheme ought to appear on the page in question. The Panel noted A. Menarini's submission that on noticing the missing Yellow Card hyperlink it decided not to close the webpage since the statement included a company telephone number that could be called to report adverse events. The Panel considered that this was insufficient. The reference to the Yellow Card Scheme was missing. A breach of Clause 26.3 was ruled.

The Panel was very concerned that despite discovering on 31 January 2017 that the hyperlink to the MHRA Yellow Card Scheme had disappeared, and promptly notifying its parent company responsible for website maintenance, no action was apparently taken until A. Menarini was notified of the present complaint on 27 March 2017. This showed a disregard for patient safety issues. The Panel was similarly concerned about the disappearance of the hyperlink to the electronic medicines compendium. In the Panel's view high standards had not been maintained and a breach of Clause 9.1 was ruled.

During its consideration of this case, the Panel was concerned to note A. Menarini's submission that the webpage in question had been examined in accordance with the supplementary information to Clause 14.3 of the 2011 Code. It appeared not to have been reviewed in accordance with the requirements of the Code since. The Panel noted that the complainant queried when the webpage was last updated. Clause 14.5 stated that material which was still in use must be recertified at intervals of no more than two years to ensure that it continued to conform with the relevant regulations relating to advertising and the Code. A. Menarini had not been asked to comment on Clause 14.3 or 14.5 and the Panel could therefore make no rulings in that regard. The Panel requested that A. Menarini be advised of its concerns.

Complaint received **24 March 2017**

Case completed **7 June 2017**