

# HOSPITAL DOCTOR v A MENARINI

## Certification of company website

When the complainant in Case AUTH/2949/3/17 (a complaint about A Menarini's corporate website) was advised of the outcome in that case he submitted a number of comments related to the certification and approval of that website. The complainant noted the company's submission in the previous case that the web page at issue had been created and approved in 2011. The complainant stated that surely the website had been updated since then and even if not, the Code required materials to be recertified every two years. The complainant noted that the original screenshot he had saved referred to a campaign launched in 2014; the website had thus been updated since 2011 and so should have a more recent approval date.

The complainant stated that the company's submission in Case AUTH/2949/3/17 implied a very relaxed approach to patient safety and process. In particular, the complainant noted that despite knowing that a link to the Medicines and Healthcare products Regulatory Agency (MHRA) Yellow Card Scheme was missing from its website, the company did nothing until it received a complaint about it two months later.

The detailed response from A Menarini is given below.

The Panel noted A Menarini's submission that the webpage at issue was examined and approved against the 2011 Code. The website provided information about the company's products and access to it was not limited to health professionals and other relevant decision makers; it was a source of information for the public including patients taking the company's medicines. The Panel noted that A Menarini added a link to educational material for the public in January 2014 and its submission that it failed to review its website and certify the content at that time.

The Panel noted that the Code required that, *inter alia*, promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified.

The Panel noted A Menarini's submission that neither the content of the website, nor the link to the educational material for the public added in 2014 were promotional. The Panel considered that the complainant had not established that the website was promotional and no breach of the Code was ruled.

The Panel further noted, however, that the Code required, *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 to be certified.

The Panel noted that A Menarini had failed to certify the website when it was first created in July 2011 as required by the 2011 Code and a breach of that Code was ruled.

The Panel noted A Menarini's submission that the website had not been reviewed since July 2011. The Panel noted that the current Code required, *inter alia*, that material which was still in use 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. The Panel noted that A Menarini had not reviewed the website since July 2011 and as such it had not been re-certified in line with the Code and a breach was ruled.

The Code required companies to preserve certificates for material for not less than three years after the final use of the material. The Panel noted that as the website had never been certified, there was no certificate. A further breach of the Code was ruled.

The Panel noted its rulings above and considered that the failure to certify and re-certify its website meant that A Menarini had failed to maintain high standards. A robust certification procedure underpinned self-regulation. The Panel considered that A Menarini's lack of such a process and its failure to review and certify material aimed at the public or patients meant that it had brought the industry into disrepute. Breaches of the Code were ruled including of Clause 2.

The Panel noted its concern in Case AUTH/2949/3/17 in that despite discovering that the hyperlink to the MHRA Yellow Card Scheme had disappeared on 31 January 2017 and promptly notifying its parent company responsible for website maintenance, no action was apparently taken until A Menarini was notified of that complaint on 27 March 2017. This showed a disregard for patient safety issues. The Panel had ruled a breach of the Code in that case in relation to failing to maintain high standards. Noting the complainant's allegations in Case AUTH/2949/3/17 the Panel considered that patient safety was of the utmost importance and A Menarini's failures in this regard brought discredit upon and reduced confidence in the pharmaceutical industry. A further breach of Clause 2 was ruled.

A hospital doctor complained about the adverse event function on A Menarini's website which was taken up as Case AUTH/2949/3/17. When advised of the outcome of that case, whilst the complainant did not appeal the Panel's rulings of no breach of the Code, he submitted a number of comments which generally raised matters related to certification and approval of the website. In addition the complainant also referred to a patient safety matter dealt with in

Case AUTH/2949/3/17 but which had not been subject to an alleged breach of Clause 2. The new matter raised by the complainant and the alleged breach of Clause 2 were thus taken up as a new complaint under the Code.

## COMPLAINT

The complainant noted A Menarini's submission in Case AUTH/2949/3/17 that the webpage at issue ([www.menarini.co.uk/products/welcome](http://www.menarini.co.uk/products/welcome)) was created in 2011 and thus an older version of the Code applied. Initially he only registered this as an insight into the workings of an industry he did not know that well but thinking it over he was puzzled by the company's statement that this website was approved on 20 July 2011.

The complainant queried whether A Menarini really created this website in 2011 and never updated it in the past six years and considered that that could not be right; surely it must have been updated since then with new information. Even in the unlikely event that the company did not update the website, the complainant considered that it had a responsibility to keep its materials up-to-date. In that regard the complainant noted that Clause 14.5 required materials to be certified in their final form and recertified at intervals of two years. In that regard the web page must have been recertified nearly 3 times since it was originally approved in 2011. If changes had been made since 2011, there must have been a more recent approval or certification than 2011.

The complainant stated that he had noted from the original screenshot that he had saved, two links in the top right corner which A Menarini had since removed – 'Stamp out Gout' and 'Firing too quickly'. A google search showed 'Firing too quickly' was a premature ejaculation campaign launched in 2014. The complainant thus concluded that the website had been updated since 2011 to add that banner, contrary to A Menarini's submission. The complainant queried why the company referred to 2011 and not a more recent approval.

The complainant raised the following questions:

- Did A Menarini really not update its website since 2011 when it claimed it went live and was approved? Evidence suggested otherwise. If A Menarini's submission was true, it was in breach of Clause 14.5. It should review and approve all materials every two years and based on its submission in Case AUTH/2949/3/17, it admitted it did not. Where was the most [recent?] certificate which was issued for this website within the past 2 years?
- Had A Menarini updated its website after the launch and approval in 2011 without proper review process? At least one banner was added after 2011 – 'Firing too Quickly'; a campaign which was launched in January 2014. Also A Menarini admitted the adverse event statement disappeared since 2011. This kind of thing did not happen by itself. Someone gave instructions for changes to be made and did not check the outcome. In the

complainant's view it appeared that A Menarini had very poor control over who put what on its website. In that regard the complainant referred to Clauses 14.5 and 14.3.

- Why did A Menarini not act immediately when it found out its website had a problem? In Case AUTH/2949/3/17 the company submitted that it knew at the end of January 2017 that its website did not have all the required information, yet it only acted when it received a complaint two months later. This was poor form.

The complainant stated that the company's submission implied a very relaxed approach to patient safety and process. The company claimed the webpage was created and approved in 2011 and implied that it had been untouched since then. Clearly this was not the truth. The complainant suspected that the company had lied and that it had a very poor grip on its materials and processes. Clearly the website had been changed since 2011 without due process and review. In that regard the complainant cited Clauses 14.1, 14.5 and 14.6.

The complainant added that, even worse, the company was warned that it was non-compliant in January and for two months it did nothing until it received a complaint. The complainant alleged that this was very poor and irresponsible. The complainant expected higher standards from a pharmaceutical company when it came to patient safety and in that regard alleged breaches of Clauses 2 and 9.1.

When writing to A Menarini, the Authority asked it to respond in relation to the requirements of Clauses 2, 9.1, 14.1, 14.3, 14.5 and 14.6. In relation to the allegation that the matter at issue in Case AUTH/2949/3/17 was not dealt with promptly, the company was asked to respond in relation to the requirements of Clause 2 only (the alleged breach of Clause 9.1 had already been addressed).

## RESPONSE

A Menarini explained that, under the 2011 Code its website [www.menarini.co.uk](http://www.menarini.co.uk) was considered a corporate advertising website and as such did not contain information that required certification. However, when the link to the 'Firing too quickly' website, which contained educational material for the public, was added in January 2014 the company failed to review the website and certify the content appropriately.

A Menarini submitted that since it joined the ABPI it used a paper based approval system for materials which was ineffective and challenging to administer. From January 2016, the company implemented an electronic approval system which had helped in improving the approval process and the management of materials life cycle.

### Clauses 14.1 and 14.3

A Menarini noted that it was a requirement of Clause 14.1 of the 2014 Code that:

'Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by two persons on behalf of the company in the manner provided for by this clause. One of the two persons must be a registered medical practitioner or a pharmacist registered in the UK or, in the case of a product for dental use only, a registered medical practitioner or a pharmacist registered in the UK or a UK registered dentist. The second person certifying on behalf of the company must be an appropriately qualified person or senior official of the company or an appropriately qualified person whose services are retained for that purpose.'

It was a requirement of Clause 14.3 of the 2014 Code that:

'The following must be certified in advance in a manner similar to that provided for by Clause 14.1: educational material for the public or patients issued by companies which relates to diseases or medicines but is not intended as promotion for those medicines ...'

The menarini.co.uk website was considered a corporate advertising website under the 2011 Code and as such did not contain information that required certification. However, in January 2014 when the link to the 'Firing too quickly' website which contained educational material for the public was created, the company failed to review its website and certify the content appropriately. However, neither the content of the website nor the link to the educational material for the public website, were deemed to be promotional. A Menarini thus considered that it was in breach of Clause 14.3 but not in breach of Clause 14.1.

#### **Clause 14.5**

A Menarini noted that it was a requirement of Clause 14.5 of the 2016 Code that:

'The certificate for promotional material must certify that the signatory has examined the final form of the material to ensure that in his/her belief it is in accordance with the requirements of the relevant regulations relating to advertising and this Code, is not inconsistent with the marketing authorization and the summary of product characteristics and is a fair and truthful presentation of the facts about the medicine. The certificate for material covered by Clause 14.3 above must certify that the signatory has looked at the final form of the material to ensure that in his/her belief it complies with the Code. Material which is still in use must be recertified at intervals of no more than two years to ensure that it continues to conform with the relevant regulations relating to advertising and the Code.'

A Menarini submitted that it failed to review the website and certify the content appropriately in January 2014. Subsequently, the website should have been recertified no later than January 2016 as it was still in use. As the company had failed to

recertify the website appropriately, it accepted a breach of Clause 14.5.

#### **Clause 14.6**

A Menarini noted that it was a requirement of Clause 14.6 of the 2016 Code that:

'Companies shall preserve all certificates. In relation to certificates for promotional material, the material in the form certified and information indicating the persons to whom it was addressed, the method of dissemination and the date of first dissemination must also be preserved. In relation to certificates for meetings involving travel outside the UK, details of the programme, the venue, the reasons for using the venue, the audience, the anticipated and actual costs and the nature of the hospitality and the like must also be preserved. Companies shall preserve certificates and the relevant accompanying information for not less than three years after the final use of the promotional material or the date of the meeting and produce them on request from the Medicines and Healthcare products Regulatory Agency or the Prescription Medicines Code of Practice Authority. The certificates for material covered by Clause 14.3 above shall be preserved for not less than three years after the final use of the material and companies shall produce them on request from the Medicines and Healthcare products Regulatory Agency or the Prescription Medicines Code of Practice Authority.'

A Menarini noted that it failed to review and certify the website appropriately in January 2014 or recertified no later than January 2016 as it was still in use. No certificates had been preserved in relation to the website and in that regard A Menarini accepted a breach of Clause 14.6.

#### **Clauses 2 and 9.1**

In relation to the certification clauses above, A Menarini accepted that it had not maintained high standards at all times, in breach of Clause 9.1. The company also accepted a breach of Clause 2 in that its 'Activities or materials associated with promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry.'

In relation to Case AUTH/2949/3/17 under the allegation that the matter was not dealt with promptly, A Menarini denied a breach of Clause 2.

#### **PANEL RULING**

The Panel noted A Menarini's submission that the webpage at issue was examined and approved, against the 2011 Code, on 20 July 2011 before going live on the same day. The Panel noted that in Case AUTH/2949/3/17 it had disagreed with A Menarini's submission that under the 2011 Code its website www.menarini.co.uk was considered a corporate advertising website and as such did not contain information that required certification. The Panel noted that the website provided information about the company's products. The

Panel noted that access to the website was not limited to health professionals and other relevant decision makers, and it was therefore also a source of information for the public including patients taking its medicines.

The Panel noted that A Menarini added a link to the 'Firing too quickly' website, which it acknowledged contained educational material for the public in January 2014. The Panel noted A Menarini's submission that it failed to review its website and certify the content at that time.

Turning to Case AUTH/2960/6/17, the Panel noted that Clause 14.1 of the 2011 Code required that, *inter alia*, promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by two persons on behalf of the company in the manner provided for by this clause.

The Panel noted A Menarini's submission that neither the content of the website, nor the link to the educational material for the public added in January 2014 were promotional. The Panel considered that the complainant had not established that the website was promotional and the Panel therefore ruled no breach of Clause 14.1.

The Panel noted that Clause 14.3 of the 2011 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 in advance in a manner similar to that provided for by Clause 14.1.

The Panel noted that A Menarini had failed to certify the website when it was first created in July 2011 as required by the 2011 Code and a breach of Clause 14.3 was ruled as acknowledged by the company.

The Panel noted A Menarini's submission that the website had not been reviewed since July 2011. The Panel noted that Clause 14.5 of the current Code required, *inter alia*, that material which was still in use 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. The Panel noted that A Menarini had not reviewed the website since July 2011 and as

such it had not been re-certified in line with Clause 14.5 and a breach of the current Code was ruled as acknowledged by the company.

Clause 14.6 of the current Code stated, *inter alia*, that companies shall preserve all certificates and that the certificates for material covered by Clause 14.3 shall be preserved for not less than three years after the final use of the material and companies shall produce them on request from the Medicines and Healthcare products Regulatory Agency or the Prescription Medicines Code of Practice Authority. The Panel noted that as the website had never been certified, there was no certificate. The Panel therefore ruled a breach of Clause 14.6 as acknowledged by the company.

The Panel noted its rulings above and considered that the failure to certify and re-certify its website meant that A Menarini had failed to maintain high standards. A breach of Clause 9.1 of the current Code was ruled. The Panel noted that a robust certification procedure underpinned self-regulation. The Panel considered that A Menarini's lack of such a process and its failure to review and certify material aimed at the public or patients meant that it had brought the industry into disrepute. A breach of Clause 2 was ruled. These breaches were acknowledged by the company.

The Panel noted its ruling in Case AUTH/2949/3/17 in that it was very concerned that despite discovering that the hyperlink to the MHRA Yellow Card Scheme had disappeared on 31 January 2017 and promptly notifying its parent company responsible for website maintenance no action was apparently taken until A Menarini was notified of that complaint on 27 March 2017. This showed a disregard for patient safety issues. The Panel had ruled a breach of Clause 9.1 in that case. Noting the complainant's allegations in Case AUTH/2949/3/17 the Panel considered that patient safety was of the utmost importance and A Menarini's failures in this regard brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled.

**Complaint received**            **6 June 2017**

**Case completed**                **9 August 2017**