CASE AUTH/2355/9/10

MEMBER OF THE PUBLIC v TAKEDA

Promotion of Mepact

The Authority received a complaint that visitors to Takeda's website were greeted by a news story that Mepact (mifamurtide) had not been approved by the National Institute for health and Clinical Excellence (NICE). The complainant alleged that the story, which did not sit behind a heath professional website, actively promoted Mepact in breach of the Code.

The detailed response from Takeda is given below.

Although the Panel considered that it was unclear whether the complaint was only about the statement on the home page of the website or if it also encompassed the press release to which it was linked, given that the two could not reasonably be separated both were considered together.

The Panel noted that the major portion of the home page of the Takeda UK website was comprised of a central section headed 'What's New'. Listed below the heading was a series of dates and below each was a brief description of a notable event or company achievement. Under 'August 2010' the following appeared:

> **'NICE says no to life saving treatment for childhood bone cancer.**
>
> **Takeda announces that in its draft appraisal [NICE] does not recommend the use of Mepact for the treatment of bone cancer (osteosarcoma) in children, adolescents and young adults'.**

By clicking onto the date the reader was taken to the full press release which was in the 'Media Centre' section of the website. Given the way in which it could be accessed however, the Panel queried whether the press release was in fact a public announcement.

The Panel considered that the announcement on the home page, which was the same as the title of the press release, 'NICE says no to life saving treatment for childhood bone cancer', was in effect a very strong claim for Mepact. The Panel queried whether such a claim was factual and presented in a balanced way. In addition the announcement on the home page raised unfounded hopes of successful treatment and would, on the balance of probabilities, encourage members of the public to read the whole of the press release. The press release began with some very positive bullet points for Mepact which referred, *inter alia*, to 'improve survival in childhood cancer', 'reduces the risk of death by almost one third' and 'save an additional eight lives each year'. It also stated that Takeda wanted to ensure that suitable young patients diagnosed with osteosarcoma were 'provided with a fighting chance …'. In the Panel's view the announcement on the home page and the press release itself would encourage members of the public to ask their health professional to prescribe Mepact, a prescription only medicine. A breach of the Code was ruled which was upheld on appeal by Takeda. The Panel further considered that as the short description of the press release on the homepage of the Takeda website and the press release itself both contained very strong claims that were contrary to the Code they were in effect advertisements for Mepact aimed at, *inter alia*, the public; a breach of the Code was ruled which was upheld on appeal by Takeda.

The Panel considered that to describe Mepact as a 'life saving treatment' meant that high standards had not been maintained. A breach of the Code was ruled which was upheld on appeal by Takeda.

The Panel also ruled a breach of Clause 2 of the Code because it considered that it was particularly important that information made available to the public about such a sensitive issue as survival in childhood cancer was fair and balanced and did not raise unfounded hopes of successful treatment.

Upon appeal by Takeda the Appeal Board noted that although it had upheld the Panel's other rulings it did not consider that the circumstances warranted a ruling of a breach of Clause 2 and no breach of Clause 2 was ruled.

The Authority received a complaint about the promotion of Mepact (mifamurtide) on Takeda UK Ltd's website.

COMPLAINT

The complainant noted that visitors to Takeda's website were greeted by a latest news story detailing Mepact's failure to win approval from the National Institute for health and Clinical Excellence (NICE). The story actively promoted Mepact and did not sit behind any health professional website. The complainant alleged a breach of the Code.

When writing to Takeda, the Authority asked it to respond in relation to Clauses 2, 9.1, 22.1 and 22.2 of the Code.

RESPONSE

Takeda refuted the allegation that the press release in question constituted promotion to the public. Like many pharmaceutical company websites, new material was highlighted on the home page. On the home page of the Takeda UK website, in a section entitled 'What's new?', there was a series of links to other areas of the website, including the media

section. One of these links was the factual statement 'NICE says no to life saving treatment for childhood bone cancer'. By clicking on this statement, the reader was directed to a press release in an area of the site clearly intended for the media, having the title 'Media Section'.

To address the specific allegation made by the complainant that the press release 'did not sit behind any health professional section', the supplementary information to Clause 22.2 permitted non-promotional information about prescription only medicines to be made available to the public in a number of ways, including via press announcements. Takeda believed that the press release in question fulfilled the requirements of Clause 22.2 and that it was non promotional.

The press release detailed a newsworthy topic ie the recent negative decision by NICE in relation to Mepact. The product was referred to in the introductory bullet points in order to put the subsequent information into context. The remainder and majority of the press release referred to osteosarcoma, for which the product was licensed, the process used by NICE to assess medicines and quotations from a number of stakeholders about the NICE opinion.

The few statements within the press release about Mepact were balanced and factual, and Takeda did not consider that they were promotional. Nor were they made to encourage members of the public to ask their health professional to prescribe a specific prescription only medicine.

Takeda also refuted any suggestion that the press release raised unfounded hopes of successful treatment, or that it was misleading with respect to the safety of the product. The press release did not state that Mepact was a 'cure', nor that it could be used in all osteosarcoma patients. The press release was clear that the product was for use in 'suitable young patients that are diagnosed with osteosarcoma' to provide them with a 'fighting chance'.

As press releases of this nature were permitted by the Code, Takeda strongly believed that it had maintained high standards in issuing this press release to the consumer media and placing it in the media area of its website, and was therefore not in breach of Clause 9.1. Takeda also refuted any allegation that it had brought discredit upon, or reduced confidence in the industry, contrary to the requirements of Clause 2.

PANEL RULING

The Panel considered that it was unclear whether the complaint was only about the statement on the home page of Takeda's website or if it also encompassed the press release. In the Panel's view, however, given the statement on the homepage was inextricably linked to the press release, the two could not reasonably be separated and in that regard both elements were considered together.

The Panel noted that the major portion of the home page of the Takeda UK website was comprised of a central section headed 'What's New'. Listed below the heading was a series of dates in reverse chronological order. Below each date was a brief description of a notable event or company achievement. Under 'August 2010' the following appeared:

> 'NICE says no to life saving treatment for childhood bone cancer.
>
> Takeda announces that in its draft appraisal [NICE] does not recommend the use of Mepact for the treatment of bone cancer (osteosarcoma) in children, adolescents and young adults'.

By clicking onto the date the reader was taken to the full press release which was in the 'Media Centre' section of the website. Given the way in which it could be accessed however, the Panel queried whether the press release was in fact a public announcement.

The Panel considered that the announcement on the home page, which was the same as the title of the press release, 'NICE says no to life saving treatment for childhood bone cancer', was in effect a very strong claim for Mepact. The Panel queried whether such a claim was factual and presented in a balanced way. In addition the announcement on the home page raised unfounded hopes of successful treatment and would, on the balance of probabilities, encourage members of the public to read the whole of the press release. The press release began with some very positive bullet points for Mepact which referred, *inter alia*, to 'improve survival in childhood cancer', 'reduces the risk of death by almost one third' and 'save an additional eight lives each year'. It also stated that Takeda wanted to ensure that suitable young patients diagnosed with osteosarcoma were 'provided with a fighting chance …'. In the Panel's view the announcement on the home page and the press release itself would encourage members of the public to ask their health professional to prescribe Mepact, a prescription only medicine. A breach of Clause 22.2 was ruled. The Panel further considered that as the short description of the press release on the homepage of the Takeda website and the press release itself both contained very strong claims that were contrary to Clause 22.2, they were in effect advertisements for Mepact aimed at, *inter alia*, the public; a breach of Clause 22.1 was ruled.

The Panel considered that to describe Mepact as a 'life saving treatment' meant that high standards had not been maintained. A breach of Clause 9.1 was ruled.

With regard to Clause 2, the Panel considered that it was particularly important that information made available to the public about such a sensitive issue as survival in childhood cancer was fair and balanced and did not raise unfounded hopes of successful treatment. Clause 2 was reserved as a sign of particular censure. The Panel considered

that the circumstances warranted such a ruling and a breach of Clause 2 was ruled.

APPEAL BY TAKEDA

Takeda submitted that the press release was issued to communicate the negative decision by NICE about the use of Mepact in the treatment of osteosarcoma. It was not a 'good news' story about the product. The intention also was to communicate Takeda's disappointment at this likely outcome. To put this into context, basic facts about the medicine's efficacy were included, all of which were factual and could be substantiated (Mepact summary of product characteristics (SPC), Meyers *et al* 2008, Picci 2007). As the main aim of Mepact treatment was to increase the overall survival of patients with osteosarcoma, it was impossible to refer to its efficacy without referring to the possibility of it saving lives.

Takeda addressed the points made in the Panel ruling.

'NICE says no to life saving treatment for childhood bone cancer'

In response to the Panel's query about whether the statement 'NICE says no to life saving treatment for childhood bone cancer' was factual and presented in a balanced way, Takeda noted that Section 5.1 of the Mepact SPC stated; 'MEPACT significantly increased the overall survival of patients with newly-diagnosed resectable high-grade osteosarcoma when used in conjunction with combination chemotherapy when compared to chemotherapy alone'.

Takeda noted that the Panel considered that the statement raised unfounded hopes of successful treatment. Mepact had been shown to significantly increase overall survival in osteosarcoma, therefore Takeda did not believe that stating that the product could save lives did raise unfounded hope. In addition, the announcement of a negative decision from NICE in relation to a medicine usually meant that it was unlikely to be available, therefore it reduced hope of access to treatment. The press release was aimed at journalists, but even if a patient found Takeda's website and went to this specific page, they were extremely unlikely to ask their physician for a medicine that they knew was unavailable on the NHS. Thus the press release could not be construed as encouraging members of the public to ask their health professional to prescribe a specific medicine. Takeda did not believe that the statement was contrary to the requirements of Clause 22.2.

'Given the way it could be accessed however, the Panel queried whether the press release was in fact a public announcement.'

Takeda submitted that this statement did not make clear what it was about 'the way it could be accessed' that changed this press release into a public announcement. This was an important issue, as factual press releases were specifically allowed under Clause 22.2, and this was the intent of this piece.

It could not be because it could be accessed without proof that the reader was a journalist, as this conflicted with previous case precedent where the Panel had ruled that it was acceptable to have press releases in a 'media section' of a company website (Cases AUTH/2160/8/08 and AUTH/2161/8/08). It was also not part of the original complaint, which asked why this press release was not behind a health practitioner barrier. As previously stated there was currently no such requirement for a press release.

Takeda submitted that if it was the fact that the press release could be accessed directly from the homepage, it was important to note that the fundamental function of a homepage was to be a central point from which everything on the website could be found. There were many other companies who had press releases on their websites and these were usually accessible via the homepage. Takeda provided examples of press releases of a similar nature to the one at issue, which were obtained from other corporate websites.

Takeda submitted that the term 'public announcement' implied that it was communicated to a large number of people, which was incorrect. Takeda was not such a well known company that people were likely to find its website by accident. Someone would have to specifically look for the Takeda UK website or for information on Mepact. 'Pageview' data taken from the website during the period immediately following the press release (from 13 August) showed that most visitors to the site did not access its media pages, and of those that did, only a very small number accessed this press release. If Takeda had attempted to make a 'public announcement' it would need a very different media outlet to reach patients.

Takeda noted that the small peak in usage of the Mepact press release coincided not with the actual announcement on 13 August, but with the date Takeda received the complaint ie the majority of people who viewed the page were the complainant and company personnel who needed to view it in order to respond to the complaint.

In summary Takeda did not believe that this item was a public announcement – it was intended to be a press release, and this was clear from its location on the website as well as its format, content and the reality of its actual use, which was by a very small number of people. It therefore did not constitute advertising to the public.

'The press release began with some very positive bullet points for Mepact'

Takeda submitted that all the statements included in the press release were factual and could be substantiated. They accurately reflected why Mepact had a licence, and the data that substantiated them was included in the SPC. As

noted above, these statements were included to put into context Takeda's disappointment, and the disappointment of a number of patient organisations, regarding the NICE announcement. The statements were not intended to raise unfounded hope of successful treatment or to encourage members of the public to ask their health professional to prescribe Mepact. As noted previously, the announcement of a negative decision from NICE in relation to a medicine meant that it was unlikely to be available, therefore it reduced hope of access to treatment.

For these reasons, Takeda did not believe that including the statements in the press release rendered it in breach of Clause 22.2.

'Takeda wanted to ensure that suitable young patients diagnosed with osteosarcoma were "provided with a fighting chance"'

Takeda submitted that the reference to a 'fighting chance' was in relation to the fact that Mepact significantly increased the overall survival of patients with newly-diagnosed resectable high-grade osteosarcoma when used in conjunction with combination chemotherapy when compared to chemotherapy alone. The SPC stated:

> 'Mepact significantly increased overall survival in patients with newly diagnosed resectable high grade osteosarcoma …'.
>
> 'In a randomised phase III study of 678 patients … the addition of Mepact to chemotherapy (either doxorubicin, cisplatin and methotrexate with or without ifosfamide resulted in a relative reduction of the risk of death of 28% (p = 0.0313, HR = 0.72 [95% confidence interval (CI): 0.53, 0.97])'.

This was based on the results of Meyers *et al*, the pivotal phase III study, in which the authors concluded 'The addition of MTP to chemotherapy resulted in improvement in 6-year overall survival from 70% to 78% (p = 0.03; relative risk = 0.71). This is an almost one third reduction in the risk of death'.

In simple terms, a patient has more chance of survival if they received Mepact and chemotherapy than if they received chemotherapy alone. The phrase 'fighting chance' also acknowledged that no medicine was 100% effective, including Mepact. Takeda thus did not believe that including this statement in the press release was in breach of Clause 22.2.

Takeda agreed that statements in the press release were 'strong', but they were factual, and balanced in the context of the medicine's purpose and the intention of the item. Takeda did not believe that they were in effect an advertisement for Mepact aimed at the public and therefore disagreed with the ruling of a breach of Clause 22.1. The item was clearly in the media section of the website, and to assert that press releases could not contain positive, factual statements about a medicine would mean that no newsworthy information about a prescription only medicine could ever be communicated via a media item. This would be unfair to both the industry and patients, as they would effectively be prohibited from balancing negative media stories coming from other sources, leading to poor quality information being communicated to the public.

Describing Mepact as 'life saving treatment'

Takeda submitted that as Mepact had been shown to significantly increase the overall survival of patients with newly-diagnosed resectable high-grade osteosarcoma when used in conjunction with combination chemotherapy when compared to chemotherapy alone, it was difficult to describe what it did without stating that it could preserve life. There was no other reason to use the Mepact other than to try and achieve this aim. Mepact was not for symptomatic relief, and this licence was not based on surrogate markers. The Mepact licence was based entirely on saving lives, and this was reflected in the SPC as described above. As such, it was difficult for Takeda to describe the effect of Mepact in anything but these terms.

The number of patients' lives that could be saved was based on a simple, conservative calculation of the number of osteosarcoma patients in the UK, their current survival rate, and what the effect would be if the number of deaths was reduced by 29% (Picci).

Takeda submitted that it was appropriate to state the licensed effect of Mepact in a press release. Every press release for a study or new licence included this information. As noted above, Takeda had found several currently available press releases on other corporate websites that made positive factual statements about the relevant medicine. The press release was factual and in the media section of the website which was in line with previous rulings. Takeda thus did not believe that describing Mepact in this way failed to maintain high standards in breach of Clause 9.1.

Takeda did not consider that issuing a factual (and in context, mostly negative) press release about one of its medicines and adding it to the media section of its website brought the industry into disrepute. Takeda believed that the Panel's ruling of a breach of Clause 2 for the placement of the press release on the company website was inappropriate and inconsistent with previous rulings.

Takeda noted that a ruling of a breach of Clause 2 was a sign of particular censure and reserved for such circumstances. Examples of activities that were likely to be in breach of Clause 2 included prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that fell short of competent care and multiple/cumulative breaches of a similar and

serious nature in the same therapeutic area within a short period of time. Takeda, therefore, did not believe that it had breached Clause 2. This was backed by case precedent, as in previous rulings on similar cases, even when the content of the press release was found to be in breach, no breach of Clause 2 was ruled (Cases AUTH/2147/7/08, AUTH/2160/8/08 and AUTH/2161/8/08).

Takeda took its responsibilities under the Code extremely seriously and pending the outcome of the case, it had removed the press release from its website. Takeda trusted that the details allayed concerns about the press release, its placement on Takeda's website, and demonstrated that the information contained therein was balanced within the context of the communication, factual and did not contravene the requirements of the Code.

COMMENTS FROM THE COMPLAINANT

The complainant considered that the appeal did not go far enough to explain why such an emotively worded press release was available to any site visitor as opposed to being made available solely for health professionals. In the complainant's view the Code (and spirit of the Code) rejected the notion that 'factual' claims could be worded in such a way that they replicated newspaper sub-headings – claims such as 'life saving' which, whilst arguable factually correct, were perceived differently by members of the public than they were by members of the pharmaceutical industry.

The complainant queried the company's claim that, as a relatively small company, it was not possible for people to stumble upon its corporate website. Whilst perhaps a realistic assessment of company size this was not a sound argument. If a 'strong statement' that could be considered to border on promotion reached one person it was the same as if it reached a thousand. The complainant considered that Takeda's argument that the website was not visited by a vast number of people was irrelevant. The company could not control who visited the website and therefore should assume that any number of people could see anything that it placed there.

APPEAL BOARD RULING

The Appeal Board noted that the press release entitled 'NICE says no to life saving treatment for childhood bone cancer' was written in response to the negative decision by NICE in relation to the use of Mepact in the treatment of osteosarcoma in children, adolescents and young adults. The Appeal Board noted Takeda's submission that the press release was issued to tell journalists about Takeda's disappointment about the decision by NICE. Takeda's representatives at the appeal noted that NICE was a public body and that its decision had effectively denied patients access to Mepact. The representatives further stated that Takeda had a corporate responsibility to ensure that patients had access to medicines.

The press release began with some very positive bullet points for Mepact which included '… the first treatment shown to improve survival in childhood bone cancer', '… reduces the risk of death by almost one third …' and '… potential to save an additional eight lives each year'. It also stated that Takeda wanted to ensure that suitable young patients diagnosed with osteosarcoma were 'provided with a fighting chance …'. The Appeal Board considered that the press release made strong claims for Mepact, the language was highly emotive and the press release lacked balance.

The Appeal Board considered that irrespective of whether members of the public read the press release, its emotive language and the fact that they could access it meant that it had the potential to encourage them to ask their health professional to prescribe Mepact, a prescription only medicine. The Appeal Board upheld the Panel's ruling of a breach of Clause 22.2. The Appeal Board further considered that as the short description of the press release on the homepage of the Takeda website and the press release itself both contained very strong claims that were contrary to Clause 22.2, they were in effect advertisements for Mepact aimed at, *inter alia*, the public. The Appeal Board upheld the Panel's ruling of a breach of Clause 22.1. The appeal on these points was unsuccessful.

The Appeal Board considered that the highly emotive and unbalanced language of the press release meant that high standards had not been maintained. The Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The appeal on this point was unsuccessful.

Although it noted its rulings above, the Appeal Board did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and thus it ruled no breach of that clause. The appeal on this point was successful.

Complaint received **7 September 2010**

Case completed **4 February 2011**