CASE AUTH/2972/8/17

ANONYMOUS, NON-CONTACTABLE HEALTHCARE JOURNALIST v UCB

UCB website

An anonymous, non-contactable complainant who stated that he/she was a healthcare journalist submitted a complaint about the UCB Pharma website. The complainant provided annotated screenshots. There were four allegations.

Firstly, the complainant alleged that the section labelled 'UCB's product list' stated that this information was 'specific to the UK'. However, it mentioned several products that were not part of UCB UK's portfolio.

The complainant alleged that inaccurate, misleading information about prescription only medicines was provided to the public (ie by placing on a website freely available to the public) and high standards had not been maintained.

The detailed response from UCB is given below.

The Panel noted UCB's submission that the available product list on its website was published as proactive reference information directed to a public audience. The Panel considered that the list in question was neither factual nor accurate and was thereby misleading. Breaches of the Code were ruled.

The Panel noted that the website listed 19 products that were no longer marketed by UCB but were, according to UCB, still available in the UK from other manufacturers. The Panel considered that, as acknowledged by UCB, its poor governance of the website meant that high standards had not been maintained and a breach was ruled.

Secondly, the complainant alleged that ten items were not recertified after two years, as required by the Code. High standards had not been maintained.

The Panel noted UCB's submission that in relation to the materials listed by the complainant posted in the 'Therapy area' section of its website, none had been re-certified after two years. The Panel ruled a breach of the Code in relation to each of the 10 items.

The Panel noted that a robust certification procedure underpinned self-regulation. The Panel considered that UCB's failure to review and re-certify material aimed at the public or patients meant that it had failed to maintain high standards. A breach of the Code was ruled.

The Panel noted that the educational materials listed had all been certified in advance between August and October 2012 and the Panel ruled no breach of the Code in this regard.

Thirdly, the complainant referred to three separate press releases on Briviact (brivaracetam) January 2016; July 2016, October 2016 and alleged that each had a 'black triangle' which was a requirement for promotional materials only (as required by Clause 4.10 of the Code). Press releases by definition should be non-promotional and hence would not require black triangles. The complainant pointed out that when one clicked on the links to read the press releases, the triangles actually appeared 'orange coloured!' The complainant alleged that high standards had not been maintained.

The Panel noted UCB's submission that the press releases were non-promotional and informed the intended audience of medical, trade and consumer journalists about the availability of Briviact (brivaracetam) in the NHS.

The Panel noted that material which related to a medicine and which was intended for patients taking a medicine which was subject to additional monitoring, an inverted black equilateral triangle must be included on it together with a statement about additional monitoring and reporting of side-effects. The Panel noted that contrary to the complainant's view, it was not only promotional material that required the inclusion of a black triangle. The Panel ruled no breach of the Code as it considered that the press releases were not specifically intended for patients taking the medicine.

The Panel considered that although there was no requirement to include the black triangle within press releases, its inclusion and accompanying explanatory text was, nonetheless, a prudent approach given the intended audience of medical, trade and consumer journalists and that it was likely that the journalists would ultimately disseminate the information to health professionals and members of the public.

The Panel noted that the inclusion of the inverted black triangle on press releases was not a Code requirement. In the Panel's view, it was a well-known and established symbol. Its appropriate use was an important part of medicines regulation. Thus, in the Panel's view, irrespective of the fact that its presence was not a Code requirement, the failure to publish the triangle in the correct colour across three press releases was, at the very least, inappropriate and might potentially cause confusion. The Panel also noted the complainant's comment that the company had not been meticulous or thorough enough to check whether the triangles were the required colour. High standards had not been maintained. A breach of the Code was ruled.

Finally, the complainant queried whether anyone at UCB checked and kept an eye on its website.

The Panel noted its rulings and comments above. The Panel noted the number of materials intended for patients which had not been correctly re-certified and the number of products that were incorrectly listed on its website. In the Panel's view, a robust certification procedure underpinned self-regulation. It was of concern that UCB only became aware of such matters on notification of the complaint rather than as a result of its own compliance oversight. The company's compliance failure in relation to these matters was compounded by the fact that they appeared to be longstanding; the earliest educational item was dated August 2012 and therefore ought to have been the subject of re-certification on two occasions. This was unacceptable, particularly in relation to materials directed at the general public including patients. No adequate explanation for the errors had been provided. The Panel considered that UCB's failure to review and re-certify materials aimed at the public or patients and the poor governance of its website which appeared to be longstanding meant that it had brought the industry into disrepute. A breach of Clause 2 was ruled.

An anonymous, non-contactable complainant who stated that he/she was a healthcare journalist submitted a complaint about the UCB Pharma Ltd website. The complainant provided annotated screenshots.

1 Product list

COMPLAINT

The complainant alleged that the section labelled 'UCB's product list' stated that this information was 'specific to the UK'. However, it mentioned several products that were NOT part of UCB UK's portfolio.

The complainant alleged that this was in breach of Clause 7.2 as information about medicines was inaccurate and misleading, Clause 26.2 as misleading information about prescription only medicines was provided to the public (ie by placing on a website freely available to the public) and Clause 9.1 as high standards had not been maintained.

The complainant provided the product list printed from UCB's website on 1 August 2017.

RESPONSE

UCB acknowledged that the product list available on the UCB UK website (www.ucbpharma.co.uk) was not up-to-date. From the list published on the website, products currently available from UCB in the UK were: Cimzia (Certolizumab pegol), Coracten (SR and XL) (Nifedipine), Dioctyl (Docusate sodium), Ethinyloestradiol (Ethinyloestradiol), Keppra (Levetiracetam), Neupro (Rotigotine), Nootropil (Piracetam), Moexipril hydrochloride, Tylex (Codeine phosphate hemihydrate), Vimpat (Lacosamide), Viridal (Alprostadil), Xyrem (Oxybate sodium), Xyzal (Levocetirizine dihydrochloride) and Zirtek (Cetirizine hydrochloride).

The products no longer marketed by UCB but available in the UK from other manufacturers were: Deponit (Glyceryl trinitrate), Olsalazine sodium, Elantan LA (Isosorbide mononitrate), Isosorbide Mononitrate Tablets (Isosorbide mononitrate), Isoket (Isosorbide dinitrate), Isoket Retard (Isosorbide dinitrate), and Minijets portfolio: Amiodarone Injection Minijet (Amiodarone hydrochloride), Atropine Injection BP Minijet (Atropine Sulphate), Calcium Chloride Injection Minijet (Calcium Chloride dehydrate), Epinephrine (Adrenaline) Injection Minijet (Adrenaline (Epinephrine hydrochloride), Furosemide Injection BP Minijet (Furosemide), Glucose Injection BP Minijet (Glucose), Lidocaine Hydrochloride Injection BP Minijet (Lidocaine), Magnesium Sulphate BP Minijet (Magnesium Sulphate), Morphine Sulphate Injection BP Minijet (Morphine Sulphate), Naloxone Hydrochloride Injection, Minijet (Naloxone), Sodium Bicarbonate Injection BP Minijet (Sodium Bicarbonate), Nitrocine (Glyceryl trinitrate) and Hydroxyzine hydrochloride.

UCB acknowledged that this inaccuracy was an oversight and confirmed that the page had been removed from the website for further review. However, the only information available for each product was the brand name (if available), generic name and main indication, with a clickable link to the electronic medicines compendium (eMC) website. UCB recognised that in some instances the link was not working (resulting in no results returned from the eMC website), however, this did not constitute misleading information with respect to the safety of the product or success of the treatment (Clause 26.2). UCB had no intent to raise public interest in a medicine which would be available at a later stage or conversely medicines no longer available in the UK from UCB. UCB therefore refuted a breach of Clause 26.2. UCB also disagreed with the complainant that Clause 7.2 applied to the available product list on this website as the list was published as proactive reference information directed to a public audience, therefore covered under the requirement of Clause 26.2.

Nevertheless, considering that better oversight could have been maintained, UCB accepted a breach of Clause 9.1.

PANEL RULING

The Panel noted that Clause 26.2 stated that information about prescription only medicines which was made available to the public either directly or indirectly must be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel noted that the supplementary information to Clause 26.2 allowed companies to make available reference information to provide a comprehensive

up-to-date resource on their websites or by way of a link from their website or by some other means. The primary purpose of reference information was to be a library resource for members of the public giving information relating to prescription only medicines which have marketing authorizations.

The Panel noted that as stated in the supplementary information to Clause 26.2 the requirements of Clause 7 relating to information (including Clause 7.2) also applied to information to the public. Clause 7.2 stated that Information, claims and comparisons must be, *inter alia*, accurate, balanced, fair and objective. They must not mislead either directly or by implication.

The Panel noted UCB's submission that the available product list on its website was published as proactive reference information directed to a public audience. The Panel considered that the list in question was neither factual as required by Clause 26.2, nor accurate as required by Clause 7.2 and the list in question was thereby misleading. Breaches of Clauses 7.2 and 26.2 were ruled accordingly.

The Panel noted that the website listed 19 products that were no longer marketed by UCB but were, according to UCB, still available in the UK from other manufacturers. The Panel considered that, as acknowledged by UCB, its poor governance of the website meant that high standards had not been maintained and a breach of Clause 9.1 was ruled.

During its consideration of this matter the Panel was concerned to note that in some instances the clickable links from the product list to the electronic medicines compendium (eMC) website were not working resulting in no results being returned from the eMC website. The Panel considered that if links were provided they should work and considered that this might be seen as another example of poor governance. The complainant had not directly raised this point. Nonetheless, the Panel requested that UCB be advised of its concerns.

2 Educational materials

COMPLAINT

The complainant alleged that materials on the website did not meet the certification requirements in the Code. The materials were:

1 Parkinson's disease factsheet – UK/12NE0077, September 2012
2 Parkinson's disease fast facts – UK/12NE0077a, August 2012
3 Epilepsy factsheet – UK/12VPE0061, October 2012
4 Epilepsy fast facts – UK/12VPE0061a, October 2012
5 Lupus factsheet – UK/12CI0090, October 2012
6 Lupus fast facts – UK/12CI0090, October 2012
7 Restless legs syndrome factsheet – UK/12NE0079, October 2012
8 Restless legs syndrome fast facts – UK/12NE0079a, October 2012
9 Rheumatoid Arthritis factsheet – UK/12CI00787, October 2012
10 Rheumatoid Arthritis fast facts – UK/12CI00787a, October 2012.

Clause 14.5 of the Code clearly 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.

As such, all ten items were alleged to be in breach of Clause 14.5 as none had been recertified after two years, as required by the Code. Ten separate breaches of Clause 14.5 were alleged. Also, by failing to certify after 2014, the complainant alleged that UCB had failed to maintain high standards in breach of Clause 9.1.

In addition, the case preparation manager had cited Clause 14.3 of the Code.

RESPONSE

UCB submitted that in relation to the materials listed by the complainant posted in the 'Therapy area' section of the UCB website, it accepted a breach of Clause 14.5 as the material had not been re-certified after two years. UCB also accepted a breach of Clause 9.1, as the company had failed to maintain high standards. All the materials were immediately withdrawn from the website.

PANEL RULING

The Panel noted that Clause 14.5 required, *inter alia*, 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. The Panel noted UCB's submission that in relation to the materials listed by the complainant posted in the 'Therapy area' section of its website, none had been re-certified after two years. The Panel ruled a breach of Clause 14.5 in relation to each of the 10 items listed by the complainant.

The Panel noted that a robust certification procedure underpinned self-regulation. The Panel considered that UCB's failure to review and re-certify material aimed at the public or patients meant that it had failed to maintain high standards. A breach of Clause 9.1 was ruled.

The Panel noted that Clause 14.3 required that certain items be certified in advance in a manner similar to that provided for by Clause 14.1. This included materials for the public or patients issued by companies which related to diseases or medicines but was not intended as promotion for those medicines. The Panel noted that the educational materials listed above had all been originally certified in advance between August and October 2012 and the Panel ruled no breach of Clause 14.3. That the original certification was lapsed was covered by the Panel's ruling of a breach of Clause 14.5 above.

3 Press releases

COMPLAINT

The complainant referred to three separate press releases on Briviact (brivaracetam) January 2016 – UK/15BRV0015b(1); July 2016 – UK/15BRV0015q,

October 2016 – UK/15BRV0015r and alleged that each had a 'black triangle' which was a requirement for promotional materials only (as required by Clause 4.10 of the Code). Press releases by definition should be non-promotional and hence would not require black triangles. The complainant pointed out that interestingly, when one clicked on the press release links to read the press releases, the triangles actually appeared 'orange coloured!' The complainant stated that this further confirmed his/her belief that UCB was either not well versed in the Code requirements or just not meticulous or thorough enough to check if the triangles were of the required colour. The complainant alleged that high standards had not been maintained.

When writing to UCB the Authority asked it to bear in mind the requirements of Clauses 14.3 and 26.3 of the Code in addition to Clause 9.1 which applied to the complainant's allegation that high standards had not been maintained.

RESPONSE

UCB submitted that the press releases were examined as per Clause 14.3 in a word format that was then subsequently used as PR material. In the examined version, in which the content was the same but the final layout different from that published on the website, the black triangle was the correct colour and adjacent to the first mention of the product. When the press release was published on the UCB UK website, the colour of the black triangle in the title changed to orange. UCB recognised that this inconsistency should have been detected and appropriate actions taken to remedy it. Following receipt of this complaint, the root cause of this technical issue had been identified and immediate remedial steps were underway to prevent this from happening in the future.

The complainant was also contesting the use of the black triangle in non-promotional material such as press releases, as it was not specifically mandated in Clause 4.10 of the Code. UCB submitted that the brivaracetam non-promotional press releases were directed to inform the intended audience of medical, trade and consumer journalists on the availability of Briviact (brivaracetam) in the NHS. As the intended audience were journalists familiar with the meaning of the black triangle, UCB considered it appropriate to include this with the following note:

> 'Note: ▼ The black triangle symbol applies to all new medicines and means that it is subject to additional monitoring by the European Medicines Agency. This allows for quick identification of new safety information. http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/document_listing/document_listing_000365.jsp.'

In addition, the use of the black triangle was noted by the MHRA when UCB submitted the initial version of job bag UK/15BRV00015b(1) as part of the national press release for vetting and this was not commented on as being inappropriate. Moreover, the press release was not intended for patients taking the medicine, therefore UCB did not accept that Clause 26.3 applied.

PANEL RULING

The Panel noted that the case preparation manager had raised Clause 14.3 and UCB had responded to this Clause in relation to the press releases. Noting the layout of the complaint, the Panel did not consider that the complainant's comment 'I wonder whether there is anyone in UCB who checked and kept an eye on its UK website' was a discrete allegation about the press releases. All of the allegations about specific materials were in indented paragraphs. The statement in question was a separate full paragraph which the Panel considered applied to the governance of the website generally rather than approval of the press releases. The Panel considered the complainant's comment under point 4 below in relation to Clause 2.

The Panel noted UCB's submission that the press releases were non-promotional and informed the intended audience of medical, trade and consumer journalists about the availability of Briviact (brivaracetam) in the NHS.

The Panel noted that Clause 26.3 covered material which related to a medicine and which was intended for patients taking that medicine and required, *inter alia*, that when the material related to a medicine which was subject to additional monitoring, an inverted black equilateral triangle must be included on it together with a statement about additional monitoring and reporting of side-effects. The Panel noted that contrary to the complainant's view, it was not only promotional material that required the inclusion of a black triangle.

The Panel considered that as the press releases were not specifically intended for patients taking the medicine Clause 26.3 did not apply and the Panel ruled no breach of that clause.

The Panel considered that although there was no requirement to include the black triangle within press releases, its inclusion and accompanying explanatory text was, nonetheless, a prudent approach given the intended audience of medical, trade and consumer journalists and that it was likely that the journalists would ultimately disseminate the information to health professionals and members of the public.

The Panel noted UCB's explanatory text:

> '▼ The black triangle symbol applies to all new medicines and means that it is subject to additional monitoring by the European Medicines Agency. This allows for quick identification of new safety information.'

The Panel noted UCB's submission that the black triangle was black when the press releases were examined but when published on the UCB UK website, the colour of the black triangle in the title changed to orange. The Panel also noted that, albeit somewhat belatedly and apparently on receipt of the complaint, UCB had identified the root cause of this technical issue.

The Panel noted that the inclusion of the inverted black triangle on press releases was not a Code requirement. Its use in promotional material reflected an agreement between the ABPI and the then Committee on Safety Medicines. In the Panel's view, it was a well-known and established symbol. Its appropriate use was an important part of medicines regulation. Thus, in the Panel's view, irrespective of the fact that its presence was not a Code requirement, the failure to publish the triangle in the correct colour across three press releases was, at the very least, inappropriate and might potentially cause confusion. The Panel also noted the complainant's comment that the company had not been meticulous or thorough enough to check whether the triangles were the required colour. High standards had not been maintained. A breach of Clause 9.1 was ruled.

During its consideration of this case the Panel noted that the final layout of the beginning of the version published on the website as provided by the complainant was different to that in the examined version. The published version had therefore never been examined in relation to the requirements of the Code. The Panel asked that UCB be advised of its concerns.

4 Summary

COMPLAINT

The complainant queried whether anyone at UCB checked and kept an eye on its website.

UCB was asked to respond to Clause 2.

RESPONSE

UCB recognised that the company should have maintained better oversight of the content of the website and therefore accepted a breach of Clause 9.1, as high standards had not been maintained.

UCB submitted that it took these findings very seriously and was committed to immediately rectifying the situation and had already:

- removed all the materials referenced in the complaint from the live website
- reviewing the full website and would correct any further inconsistency if identified
- UCB had identified potential root causes that led to this breach and was reviewing internal procedures.

In summary, UCB, while fully accepting this situation, submitted that it did not consider a breach of Clause 2 should be ruled, as the issues identified were not such to bring discredit upon, or reduce confidence, in the entire pharmaceutical industry and in no circumstances, was patient safety compromised. While the product list was inaccurate, those products no longer marketed by UCB were available through different manufacturers and UCB would have directed any enquiries to the appropriate source if contacted on the availability of such a product.

PANEL RULING

The Panel noted its rulings and comments above. The Panel noted the number of materials intended for patients which had not been correctly re-certified and the number of products that were incorrectly listed on its website. In the Panel's view, a robust certification procedure underpinned self-regulation. It was of concern that UCB only became aware of such matters on notification of the complaint rather than as a result of its own compliance oversight. The company's compliance failure in relation to these matters was compounded by the fact that they appeared to be longstanding; the earliest educational item was dated August 2012 and therefore ought to have been the subject of re-certification on two occasions. This was unacceptable, particularly in relation to materials directed at the general public including patients. No adequate explanation for the errors had been provided. The Panel considered that UCB's failure to review and re-certify materials aimed at the public or patients and the poor governance of its website which appeared to be longstanding meant that it had brought the industry into disrepute. A breach of Clause 2 was ruled.

Complaint received **21 August 2017**

Case completed **19 December 2017**