

## **ANONYMOUS EMPLOYEE v OTSUKA EUROPE**

### **Alleged promotional information on company website**

An anonymous employee who described him/herself as a concerned health professional, complained that Otsuka UK webpages promoted prescription only medicines to the public. The webpages were part of the Otsuka Europe website and the matter was taken up with Otsuka Europe.

The complainant stated that as the Otsuka UK website products page listed the brand names, non-proprietary names and indications of the medicines sold by Otsuka UK, it promoted them to the public and encouraged patients to ask their health professionals for these medicines. The webpages did not specify who the intended audience of the website was and contained links to the Japan website which promoted products not available in the UK as well as a link to the pipeline of products which should not be aimed at the general public or patients as it raised unfounded hopes of treatments and promoted those that were available in various countries in Europe including the UK.

The complainant was disappointed to see promotional information on the website, especially after the recent cases that had been published regarding company websites. When a case was published, the complainant hoped that other companies would review their own practice and learn from the mistakes of others. This appeared not to be the case.

The complainant provided screenshots of webpages which referred to Abilify (aripiprazole), Samsca (tolvaptan), Jinarc (tolvaptan) Sprycel (dasatinib) and Pletal (cilostazol).

The detailed response from Otsuka Europe is given below.

The Panel noted Otsuka's submission that the webpage in question formed part of the Otsuka Europe website and could be reached by one of two ways; directly by clicking on the 'Our Products in Europe' link at the bottom of the home page of the Otsuka UK section of the website or indirectly by clicking on 'What We Do For Patients' at the top of the same page. The latter took the reader to a webpage that listed the therapeutic areas for Otsuka medicines and scrolling down the page led to a section that displayed the brand and non-proprietary name (but not the indication) in separate squares for each of Otsuka's medicines licensed in the UK. If the readers clicked on any of the medicine names or the 'Read more' button which appeared to the right of the squares, he/she was taken directly to the webpage in question.

The Panel noted that it appeared that there was a third way of reaching the webpage in question: if a reader clicked on 'What We Do For Patients' there were five options to select from on the right hand side of the page including 'Therapeutic Areas' and below

this 'Our Products in Europe' which the Panel assumed also took the reader to the webpage in question.

The Panel noted that the 'Therapeutic Areas' section referred to above stated, *inter alia*, that in Europe, Otsuka was focused on central nervous system (CNS) disorders, endocrinology, nephrology and oncology before inviting readers to visit the global website for more information about Otsuka's global portfolio and the Otsuka Holdings website for information on pipeline products. This was followed by a section on CNS Disorders which began by stating that 'Otsuka's commitment to providing innovative solutions for central nervous system (CNS) disorders began more than 30 years ago, when our researchers took the first steps in the creation of a drug that would eventually provide a new treatment option for millions of sufferers of schizophrenia and bipolar disorder'. It also stated 'While creating new products we put emphasis on providing robust evidence to regulatory authorities showing that any new drugs offer an improvement on what has gone before and that they represent good value in terms of improving patient outcomes'.

The Panel noted Otsuka's submission that on reaching the webpage in question there was a statement at the top of the page that all Otsuka medicines were prescription-only medicines, and that the reader should refer to the summary of product characteristics (SPC) or patient information leaflet (PIL) if more information was required. The names, indication and link to the relevant SPC and PIL was then listed for all Otsuka medicines licensed in the UK. The Panel noted Otsuka's submission that for each medicine listed the link to the relevant SPC and PIL was provided immediately after the reference to the medicine. The reader would have to scroll down the list of medicines in order to see all the brand names, non-proprietary names and indications. According to Otsuka the link provided for each SPC and PIL was a direct, single click link to the relevant document on the Electronic Medicines Compendium. The Panel further noted Otsuka's submission that there were no claims made for any of the medicines, specifically or more generally and that the information provided constituted reference information as permitted by the Code.

The Panel considered that the information about each product on the webpage for the public was not unacceptable in relation to the requirements for reference information (as referred to in the supplementary information to the Code), the Panel noted that the webpage in question listed the product names and indications for all of Otsuka's prescription only medicines within one screen. As far as the Panel was aware, whether a reader clicked on a specific medicine or the 'Read more' button referred to above, he/she was taken to the top of the webpage in question and would then have to scroll down to find the medicine he/she wanted to find out more about. The Panel noted that Otsuka carried out compliance monitoring of digital activities including its websites in March 2019 and the report provided by Otsuka stated that an observation in relation to the Otsuka UK website was that the product pages included product name, generic name and indication and there was a risk that this could be seen as encouraging the public to ask for a specific medicine and promotion to the public. The recommendation given was to review and update the wording on the products section of the UK website. The Panel considered that given the information on the 'Therapeutic Areas' section of the UK website and the fact that members of the public looking for information on a particular product would see the name and indication for all of Otsuka's products, meant that the webpage advertised prescription only medicines to the public and, on balance, a breach

of the Code was ruled. The Panel considered that, on the balance of probabilities, the information might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine and, on balance, ruled a breach of the Code.

The Panel noted that supplementary information to the Code included that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them. The Panel noted its comments and ruling above. In the Panel's view, the webpage at issue promoted prescription only medicines and therefore access should have been restricted to health professionals and other relevant decision makers because information had not been provided for the public as required by the relevant supplementary information. The Panel noted that access to the webpage had not been so restricted and therefore a breach of the Code was ruled.

The Panel noted its comments and rulings above and considered that Otsuka had failed to maintain high standards and a breach of the Code was ruled.

The Panel noted the complainant's allegations that the website contained links to the Japanese website which promoted products not available in the UK as well as a link to the pipeline of products which should not be aimed at the general public or patients as it raised unfounded hopes of treatments. Otsuka made no submission with regard to the latter. In the Panel's view, it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate website, however language, context, location, layout, intended audience and overall impression were important factors when deciding whether such references were acceptable. Such references should not otherwise constitute promotion of an unlicensed medicine. The Panel did not have before it a copy of the webpages which referred to Otsuka's pipeline products. Whilst the Panel had concerns about the context in which the link was provided, it noted that based on the very narrow allegation, the complainant had not explained why he/she considered the page on pipeline products raised unfounded hopes of treatments for the general public or patients nor had he/she provided evidence in this regard. The Panel noted that pipeline products, were not classified as prescription only medicines and no breach of the Code was ruled.

The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that the link to the Japanese organisation's website was inappropriate as alleged. A pop-up box made it very clear that the reader was leaving a website under Otsuka Europe's control and going to a website, the content of which was not Otsuka Europe's responsibility. The link was to the home page rather than a product page or similar. The Panel ruled no breach of the Code.

The Panel did not consider that the particular circumstances in 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 the Code was ruled.

An anonymous employee who described him/herself as a concerned health professional, complained that Otsuka UK webpages promoted prescription only medicines to the public. The webpages were part of the Otsuka Europe website and the matter was taken up with Otsuka Europe.

## COMPLAINT

The complainant stated that as the Otsuka UK website products page (<https://www.otsuka-europe.com/uk/products>) listed the brand names, non-proprietary names and indications of the medicines sold by Otsuka UK, it promoted them to the public and encouraged patients to ask their health professionals for these medicines. The webpages did not specify who the intended audience of the website was and contained links to the Japan website which promoted products not available in the UK as well as a link to the pipeline of products which should not be aimed at the general public or patients as it raised unfounded hopes of treatments and promoted those that were available in various countries in Europe including the UK.

The complainant was disappointed to see promotional information on the website, especially after the recent cases that had been published regarding company websites. When a case was published, the complainant hoped that other companies would review their own practice and learn from the mistakes of others. This appeared not to be the case.

The complainant provided screenshots of webpages which referred to Abilify (aripiprazole), Samsca (tolvaptan), Jinarc (tolvaptan) Sprycel (dasatinib) and Pletal (cilostazol).

When writing to Otsuka Europe, the Authority asked it to consider the requirements of Clauses 2, 9.1, 26.1 and 26.2.

## RESPONSE

Otsuka Europe explained that the webpage in question formed part of the Otsuka Europe website, which consisted of, *inter alia*, separate sections for each European affiliate, and the pages highlighted by the complainant were from the Otsuka UK section. With this in mind, the response was sent jointly from both Otsuka Europe and Otsuka UK.

Otsuka noted that the complainant referred to 'recent cases that had been published regarding company websites' and the company was aware of the details of these cases. The Otsuka UK website had been reviewed and the company was confident that the information provided in relation to its medicines was non-promotional, appropriate for the intended public audience and met the requirements of reference information.

The webpage in question could be reached directly from the home page of the Otsuka UK section of the website by clicking on the link 'Our Products in Europe'.

It could also be reached indirectly by clicking on 'What We Do For Patients' which took the reader to a webpage that listed the therapeutic areas for Otsuka medicines.

Scrolling down that page brought the reader to a section that displayed the brand and non-proprietary name (but not the indication) for each of Otsuka's medicines licensed in the UK. If

the readers clicked on any of the medicine names or the 'Read more' button, he/she was taken directly to the webpage in question.

On reaching the webpage in question there was a statement at the top of the page that all Otsuka medicines were prescription-only medicines, and that the reader should refer to the summary of product characteristics (SPC) or patient information leaflet (PIL) if more information was required. The names, indication and link to the relevant SPC and PIL was then listed for all Otsuka medicines licensed in the UK. The link provided for each SPC and PIL was a direct, single click link to the relevant product document on the Electronic Medicines Compendium. There were no claims made for any of the medicines, specifically or more generally.

Otsuka noted in the recently published cases, eg Case AUTH/3107/10/18, the Panel was concerned that, because of the way that medicines were referred to on the relevant company's website, members of the public looking for information on one particular medicine would automatically be faced with the brand name, non-proprietary name and indication of all of the relevant company's medicines. This was not the case for the Otsuka UK section of the website; as noted above (and evidenced in the screen shots provided by the complainant), medicines were listed and for each medicine a link to the relevant SPC and PIL was provided immediately after reference to the medicine. The reader would have to scroll down the list of medicines in order to see all the brand names, non-proprietary names and indications.

Otsuka also noted in the recently published cases that the Panel appeared to be concerned that company websites referred to the brand name, non-proprietary name and indication for medicines and considered that this might render the website promotional. The brand name, non-proprietary name and indication were all referred to for each medicine listed on the Otsuka UK section of the website. However, given that reference information was intended to be 'a library resource for members of the public giving information relating to prescription only medicines which have marketing authorizations', Otsuka did not consider it unreasonable to provide the names by which the reader might know the medicine, and its indication. The alternative would be that members of the public would have to click on the link for each SPC or PIL in order to ascertain if this was in fact the information they were searching for, which would expose them to far more data on a medicine than they were trying to find.

Given the above, Otsuka did not consider that the information provided on the webpage in question constituted promotion of any prescription-only medicine to the public and it refuted a breach of Clause 26.1.

The information provided constituted reference information as permitted by Clause 26.2. It was factual, presented in a balanced way, did not raise unfounded hopes of successful treatment and was not misleading with respect to the safety of any medicine. No statements were made on the webpage that might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine. The information provided represented fairly the current body of evidence relating to each medicine and its benefit/risk profile. Otsuka refuted a breach of Clause 26.2.

Otsuka noted that the complainant also referred to links to the website of the Otsuka parent organisation in Japan. There were links to the Japanese organisation's website displayed at the bottom of each of the pages on the website, however, if the link was clicked a pop-up message made it very clear to the reader that he/she was leaving a website under Otsuka Europe's control and going to a website, the content of which was not Otsuka Europe's responsibility.

However, if the reader followed the link, he/she was taken to the home page of the Japanese parent organisation which Otsuka did not consider to be inappropriate.

With regard to Clause 28.1, in relation to access to the website, the supplementary information referred to the requirement to restrict access to promotional material on websites that contained information intended for both health professionals/other relevant decision makers as well as the public. As the entire website at issue was aimed at the public, Otsuka did not consider that this clause was relevant.

Otsuka further noted that the complainant had also stated that the Otsuka website did not specify the intended audience although the company had not been asked to address the clause relevant to this (Clause 28.5). The supplementary information to that clause stated that it was good practice for each page of a company website to include a statement identifying the intended audience; given that the audience for the entire website was the public, Otsuka did not consider that this was necessary.

Given the above, Otsuka did not consider that the webpage in question, or how it was accessed, constituted a failure to maintain high standards and it denied a breach of Clause 9.1. Otsuka did not consider that it had reduced confidence in, or brought disrepute upon, the pharmaceutical industry and therefore the company denied a breach of Clause 2.

## **PANEL RULING**

The Panel noted that Clause 26.1 prohibited the promotion of prescription only medicines to the public. Clause 26.2 permitted information about prescription only medicines to be supplied directly or indirectly to the public but such information must be factual, presented in a balanced way, must not raise unfounded hopes of successful treatment and must not encourage 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 set out the detailed requirements for reference information which was intended to provide a comprehensive library resource for members of the public giving information relating to prescription only medicines which had marketing authorizations. Reference information must represent fairly the current body of evidence relating to a medicine and its benefit/risk profile.

The Panel noted Otsuka's submission that the webpage in question formed part of the Otsuka Europe website and could be reached by one of two ways; directly by clicking on the 'Our Products in Europe' link at the bottom of the home page of the Otsuka UK section of the website or indirectly by clicking on 'What We Do For Patients' at the top of the same page. The latter took the reader to a webpage that listed the therapeutic areas for Otsuka medicines and scrolling down the page led to a section that displayed the brand and non-proprietary name (but not the indication) in separate squares for each of Otsuka's medicines licensed in the UK. If the readers clicked on any of the medicine names or the 'Read more' button which appeared to the right of the squares, he/she was taken directly to the webpage in question.

The Panel noted that it appeared that there was a third way of reaching the webpage in question: if a reader clicked on 'What We Do For Patients' there were five options to select from on the right hand side of the page including 'Therapeutic Areas' and below this 'Our Products in Europe' which the Panel assumed also took the reader to the webpage in question.

The Panel noted that the 'Therapeutic Areas' section referred to above stated, *inter alia*, that Otsuka people were passionate about developing and delivering products in areas with unmet medical needs. It stated that in Europe, Otsuka was focused on central nervous system (CNS) disorders, endocrinology, nephrology and oncology before inviting readers to visit the global website for more information about Otsuka's global portfolio and the Otsuka Holdings website for information on products that were currently in the pipeline. This was followed by a section on CNS Disorders which began by stating that 'Otsuka's commitment to providing innovative solutions for central nervous system (CNS) disorders began more than 30 years ago, when our researchers took the first steps in the creation of a drug that would eventually provide a new treatment option for millions of sufferers of schizophrenia and bipolar disorder'. It also stated 'While creating new products we put emphasis on providing robust evidence to regulatory authorities showing that any new drugs offer an improvement on what has gone before and that they represent good value in terms of improving patient outcomes'.

The Panel noted Otsuka's submission that on reaching the webpage in question there was a statement at the top of the page that all Otsuka medicines were prescription-only medicines, and that the reader should refer to the summary of product characteristics (SPC) or patient information leaflet (PIL) if more information was required. The names, indication and link to the relevant SPC and PIL was then listed for all Otsuka medicines licensed in the UK. The Panel noted Otsuka's submission that for each medicine listed the link to the relevant SPC and PIL was provided immediately after the reference to the medicine. The reader would have to scroll down the list of medicines in order to see all the brand names, non-proprietary names and indications. According to Otsuka the link provided for each SPC and PIL was a direct, single click link to the relevant document on the Electronic Medicines Compendium. The Panel further noted Otsuka's submission that there were no claims made for any of the medicines, specifically or more generally and that the information provided constituted reference information as permitted by Clause 26.2.

The Panel noted its comments about reference information above and whilst the Panel considered that the information about each product on the webpage for the public was not unacceptable in relation to the requirements for reference information (as referred to in the supplementary information to Clause 26.2), the Panel noted that the webpage in question listed the product names and indications for all of Otsuka's prescription only medicines within one screen. As far as the Panel was aware, whether a reader clicked on a specific medicine or the 'Read more' button referred to above, he/she was taken to the top of the webpage in question and would then have to scroll down to find the medicine he/she wanted to find out more about. The Panel noted that Otsuka carried out compliance monitoring of digital activities including its websites in March 2019 and the report provided by Otsuka stated that an observation in relation to the Otsuka UK website was that the product pages included product name, generic name and indication and there was a risk that this could be seen as encouraging the public to ask for a specific medicine and promotion to the public. The recommendation given was to review and update the wording on the products section of the UK website. The Panel considered that given the information on the 'Therapeutic Areas' section of the UK website and the fact that members of the public looking for information on a particular product would see the name and indication for all of Otsuka's products, meant that the webpage advertised prescription only medicines to the public and, on balance, a breach of Clause 26.1 was ruled. The Panel considered that, on the balance of probabilities, the information might encourage members of the public to ask their health professional to prescribe a specific prescription only medicine and, on balance, ruled a breach of Clause 26.2.

The Panel noted that Clause 28.1 required that promotional material about prescription only medicines directed to a UK audience which was provided on the internet must comply with all relevant requirements of the Code. The supplementary information stated that unless access to promotional material about prescription only medicines was limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified. This was to avoid the public needing to access material for health professionals unless they chose to. The MHRA Blue Guide stated that the public should not be encouraged to access material which was not intended for them. The Panel noted its comments and ruling above. The Panel noted Otsuka's submission that as the entire website at issue was aimed at the public, Clause 28.1 was not relevant. In the Panel's view, the webpage at issue promoted prescription only medicines and therefore access should have been restricted to health professionals and other relevant decision makers because information had not been provided for the public as required by the relevant supplementary information.

The Panel noted that access to the webpage had not been so restricted and therefore a breach of Clause 28.1 was ruled.

The Panel noted its comments and rulings above and considered that Otsuka had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted the complainant's allegations that the website contained links to the Japanese website which promoted products not available in the UK as well as a link to the pipeline of products which should not be aimed at the general public or patients as it raised unfounded hopes of treatments. Otsuka made no submission with regard to the latter. In the Panel's view, it was not necessarily unacceptable for a company to refer in general terms to its pipeline products on its corporate website, however language, context, location, layout, intended audience and overall impression were important factors when deciding whether such references were acceptable. Such references should not otherwise constitute promotion of an unlicensed medicine. The Panel noted its comments above with regards to the 'Therapeutic Areas' section of the UK website which included a link to the Otsuka Holdings website for information on products that were currently in the pipeline. The Panel did not have before it a copy of the webpages which referred to Otsuka's pipeline products. Whilst the Panel had concerns about the context in which the link was provided, it noted that based on the very narrow allegation, the complainant had not explained why he/she considered the page on pipeline products raised unfounded hopes of treatments for the general public or patients nor had he/she provided evidence in this regard. The Panel noted that pipeline products, were not classified as prescription only medicines and Clause 26.2 only applied to prescription only medicines. No breach of Clause 26.2 was ruled.

The Panel noted Otsuka's submission that there were links to the Japanese organisation's website displayed at the bottom of each page on the website, however, if the link was clicked a pop-up message made it very clear to the reader that he/she was leaving a website under Otsuka Europe's control and going to a website, the content of which was not Otsuka Europe's responsibility. However, if the reader followed the link, he/she was taken to the home page of the Japanese parent organisation, rather than a product page, which Otsuka did not consider to be inappropriate. The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that the link to the Japanese organisation's website was



inappropriate as alleged. Given the pop-up box and link to the home page rather than a product page or similar as described above, the Panel ruled no breach of Clause 9.1.

The Panel did not consider that the particular circumstances in 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**      **7 June 2019**

**Case completed**        **23 April 2020**