CASE AUTH/3248/9/19

VOLUNTARY ADMISSION BY ASTRAZENECA

Product-related re-tweets

AstraZeneca UK Limited voluntary admitted that one of its employees had used his/her personal Twitter account to re-tweet nine tweets about Forxiga (dapagliflozin) and one tweet about Lynparza (olaparib). Forxiga was indicated for use in adults with insufficiently controlled type 2 diabetes. Lynparza was indicated for maintenance and treatment of certain cancers.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with AstraZeneca.

AstraZeneca explained that the original tweets about dapagliflozin were posted by health professionals following a presentation of clinical trial data (DAPA-HF study) at the European Society of Cardiology (ESC) in Paris. The data from that presentation was not currently within the licensed indications for Forxiga. The original tweets were re-tweeted on a personal Twitter account by a UK-based employee of AstraZeneca's global organisation. The re-tweets had subsequently been deleted.

It was further discovered that the employee's Twitter account contained a tweet about Lynparza which was subsequently deleted.

AstraZeneca stated that it had reminded employees globally and reinforced that product-related content (including study results) were not allowed on employees' personal social media channels. AstraZeneca submitted that it had a clear policy on the use of personal social media with respect to company related content.

The detailed response from AstraZeneca is given below.

The Panel noted that the original nine tweets about Forxiga posted by health professionals concerned the use of the medicine in heart failure. The posts were re-tweeted by a UK-based AstraZeneca global employee using his/her personal account. In the Panel's view, the re-tweets had to comply with the Code.

The Panel noted that all of the re-tweets were positive about the results for dapagliflozin in heart failure in patients with or without diabetes.

The Panel noted that the employee's Twitter followers included both health professionals and members of the public.

The Panel considered that the re-tweets promoted Forxiga for an unlicensed indication and advertised a prescription only medicine to the public. Thus the Panel ruled breaches of the Code as acknowledged by AstraZeneca.

The Panel considered that the re-tweets should have been certified prior to use. AstraZeneca acknowledged that the re-tweets had not been certified and a breach of the Code was ruled.

With regard to the tweet about Lynparza, 'AstraZeneca's Lynparza gets EU nod as first-line ovarian cancer maintenance treatment', also re-tweeted by the same AstraZeneca employee, the Panel considered that it also advertised a prescription only medicine to the public and had not been certified prior to use. Breaches of the Code were ruled. The Panel noted that the indications for Lynparza in ovarian cancer appeared to be second line ie in patients who were in response to platinum-based chemotherapy. The Panel considered that the re-tweet promoted an unlicensed indication and a breach of the Code was ruled.

The Panel was mindful of the complex issues that had to be addressed by companies when advising staff about social media use. The increasing use of social media, both in the personal and business capacity, presented compliance challenges. It was therefore critical that companies provided clear and tailored guidance for employees which was regularly reviewed.

The Panel noted that the employee in question was trained on the Global Standard: Social Medica Personal Use in January 2018, however updated versions of this standard (February 2018 and August 2019) had not been 'read and signed' by the employee. AstraZeneca explained that technical issues relating to the use of a new template resulted in the employee not receiving an automated version update in his/her training account. The Panel noted, however, that the employee was alerted to the availability of the updated guidance via a number of other channels.

The Panel noted that in a series of company announcements in August 2019 to coincide with the release of the latest version of the Global Standard it appeared that AstraZeneca employees were positively encouraged to post certain work-related content on their personal social media accounts. This was reinforced by the use of phrases 'Empowering you to bring our unique culture to life on social media', 'When can I post work-related content on social media' followed by four questions to consider to ensure compliance with the Global Standard and finally 'Good to go! Can't wait to see your posts'. The items listed as appropriate to post included, *inter alia,* 'Is it about scientific advancements?.' The Panel considered that following this company announcement it was possible that the employee had decided that the tweets related to scientific advancements and therefore re-tweeting was encouraged. It appeared to the Panel that although the announcement related to the same Global Standard issued in August 2019, the content had been presented very differently in the announcement.

The Panel noted that following notification of the dapagliflozin related re-tweets AstraZeneca posted a reminder to employees about its social media policy including a link to the document via its internal social media platform. A second reminder to employees in September, following identification of another product-related re-tweet by the same AstraZeneca employee, set out three things to watch out for when posting content on personal social media. Firstly, was the material product-related or about disease education/awareness, secondly was it confidential and thirdly did it contain personal data about others that you did not have consent for. If the answer was yes then staff were told not to post it.

The Panel considered that it might be difficult for some employees to balance the positive endorsement from AstraZeneca to post certain work-related content and the need for employees to make a judgement about what they may post.

The Panel noted its comments and rulings above and considered that high standards had not been maintained by AstraZeneca; a breach of the Code was ruled.

AstraZeneca UK Limited voluntarily admitted that one of its employees had used his/her personal Twitter account to re-tweet product-related tweets. The products concerned were Forxiga (dapagliflozin) and Lynparza (olaparib).

Forxiga was indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise as monotherapy when metformin was considered inappropriate due to intolerance and in addition to other medicinal products for the treatment of type 2 diabetes.

Lynparza (150mg and 100mg) was indicated, *inter alia*, as monotherapy for the: maintenance treatment of adult patients with advanced (FIGO stages III and IV) *BRCA1/2*-mutated (germline and/or somatic) high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer who were in response (complete or partial) following completion of first-line platinum-based chemotherapy; and maintenance treatment of adult patients with platinum-sensitive relapsed high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who were in response (complete or partial) to platinum-based chemotherapy.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat the voluntary admission as a complaint, the matter was taken up with AstraZeneca.

VOLUNTARY ADMISSION

AstraZeneca asked the Panel to consider a breach of Clauses 3.2 and given that re-tweets which were issued by AstraZeneca would normally be certified, it also asked that Clauses 14.3 and 26.1 be considered if applicable.

AstraZeneca explained that re-tweets of posts made on Twitter about clinical trial data for dapagliflozin from the 'DAPA-HF' study. The original posts were made by health professionals following a presentation at the European Society of Cardiology (ESC) in Paris (31 August – 4 September 2019). These were re-tweeted on a personal twitter account by a UK-based employee of AstraZeneca's Global organisation. AstraZeneca was alerted to the situation by another named UK pharmaceutical company on 6 September 2019.

AstraZeneca explained that top line results from the DAPA-HF (Dapagliflozin And Prevention of Adverse-outcomes in Heart Failure) study were presented in a 'Hot Line Session' (Late-Breaking Science) in the scientific programme at the ESC on 1 September. The data from that presentation was not currently within the licensed indications for Forxiga. Forxiga was indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise: as monotherapy when metformin was considered inappropriate due to intolerance; in addition to other medicines for the treatment of type 2 diabetes. Forxiga 5mg was also indicated in adults for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥ 27 kg/m^2, when insulin alone did not provide adequate glycaemic control despite optimal insulin therapy.

On the day that it first knew about the re-tweets, AstraZeneca reminded employees about the company's social media policy and provided a link to the document via its internal social media platform.

On investigation, it was discovered that the named employee had used his/her personal Twitter account to make nine re-tweets of data from DAPA-HF. The employee was asked to delete all of these re-tweets and he/she confirmed that this had been completed in early September.

The employee was trained on the Global Standard: Social Media Personal Use (December 2014, Version 3) in January 2018. Subsequently, there had been two further updates, February 2018 and August 2019. The updates were in a new template and thus versioned as 1 and 2 vs 4 and 5 had the original template been used. The result of this was that the employee did not receive an automated version update in his/her training account, and thus, had not 'read and signed' the two latest versions. All of the versions of this standard made it clear that product-related tweets were prohibited.

The latest version of the Global Standard, (August 2019, Version 2) was made available to all employees in the AstraZeneca documents repository, and its publication was communicated to the business at the time (August 2019) on the AstraZeneca Global intranet site. It was also posted on the company announcements page at the same time. The latest version of the guidance had been specifically sent to the employee to read and sign, to ensure the avoidance of any doubt.

On 12 September, AstraZeneca informed the company that had alerted it that the DAPA-HF related tweets from the employee's Twitter account had been deleted.

AstraZeneca was subsequently alerted by the same company that the employee's Twitter account contained one further tweet (dated July 26) concerning another AstraZeneca product, Lynparza (olapari). Following further investigation this tweet was deleted from the employee's Twitter account later that day.

AstraZeneca stated that on 13 September it further reminded employees globally, and reinforced that product-related content (including study results) were not allowed on employees' personal social media channels.

AstraZeneca submitted that it took its responsibilities to ensure appropriate usage of social media by its employees very seriously, as shown by its Global Standard, by its prompt investigation of this matter and by the remedial actions that it had put in place. As part of the company's commitment to continuous improvement it would analyse this case and draw appropriate lessons in order to further its commitment to ensuring that it complied comply with the Code.

When writing to AstraZeneca, attention was drawn to Clauses 9.1 in addition to Clauses 3.2, 14.3 and 26.1 cited by the company.

RESPONSE

AstraZeneca submitted that it had no further comments on the requirements of Clauses 3.2, 9.1, 14.3 or 26.1.

With regards to the employee in question, AstraZeneca gave details of his/her 59 followers on Twitter, which included, 3 cardiac surgeons (who were his/her friends), and family and friends.

AstraZeneca submitted that it had a clear policy on the use of personal social media with respect to company related content. It widely socialised the updated policy when published in August. Furthermore, the company had created new training materials to help reinforce the key principles. Within any company, and especially in AstraZeneca with 8,300 employees in the UK, personal social media was difficult to actively monitor due to data privacy. Thus, it was possible that this voluntary admission was not an isolated case; the company continued to investigate any potential breaches of its social media policy and took corrective action where that was necessary to ensure best adherence to its policies and the Code.

PANEL RULING

The Panel noted the use of social media, including Twitter, to provide information to the public was a legitimate activity if the material complied with the Code. Each case needed to be considered on its own particular merits.

The Panel noted that the original nine tweets which were posted by health professionals following a presentation of the top-line results from the DAPA-HF (Dapagliflozin And Prevention of Adverse-outcomes in Heart Failure) at the ESC Congress in September 2019 concerned clinical data for dapagliflozin and its use in heart failure. Details of the nine posts were provided by AstraZeneca. The posts were re-tweeted by a UK-based AstraZeneca global employee using his/her personal account. In the Panel's view, the re-tweets had to comply with the Code.

The Panel noted that the first tweet which was re-tweeted by the AstraZeneca employee stated 'DAPA-HF truly impressive … it did all the things we hoped for #heartfailure improved symptoms, reduced hospital admissions and increased survival. Dapagliflozin was as effective in heart failure patients without #diabetes as in those with #T2D'. The remaining tweets appeared to include slides of the clinical trial presented including the DAPA-HF trial design, baseline characteristics and treatment and the primary composite outcome and all were positive about the results for dapagliflozin in heart failure in patients with or without diabetes.

The Panel noted that the employee's Twitter followers included both health professionals and members of the public.

The Panel considered that the re-tweets about the DAPA-HF clinical trial results promoted dapagliflozin (Forxiga) for an unlicensed indication and advertised a prescription only medicine to the public. Thus the Panel ruled breaches of Clause 3.2 and 26.1 as acknowledged by AstraZeneca.

The Panel considered that the re-tweets should have been certified prior to use. The Panel further noted that the nature of Twitter was such that tweets could be broadly and quickly disseminated in the public domain. When material was available to the public it needed to comply with the relevant requirements of the Code. Certification of material for the public was covered by Clause 14.3. AstraZeneca acknowledged that the re-tweets had not been certified and a breach of Clause 14.3 was ruled.

With regard to the tweet about Lynparza, 'AstraZeneca's Lynparza gets EU nod as first-line ovarian cancer maintenance treatment', also re-tweeted by the same AstraZeneca employee,

the Panel considered that it also advertised a prescription only medicine to the public and had not been certified prior to use. Breaches of Clauses 26.1 and 14.3 were ruled. The Panel noted that the indications for Lynparza in ovarian cancer appeared to be second line ie in patients who were in response to platinum-based chemotherapy. The Panel considered that the re-tweet promoted an unlicensed indication and ruled a breach of Clause 3.2 of the Code.

The Panel was mindful of the complex issues that had to be addressed by companies when advising staff about social media use. The increasing use of social media, both in the personal and business capacity, presented compliance challenges. In the Panel's view, employees might feel inclined to endorse posts which related to their company and depending on the content such activity might or might not fall within the scope of the Code. It was therefore critical that companies provided clear and tailored guidance for employees which was regularly reviewed.

The Panel noted AstraZeneca's submission that it took its responsibilities to ensure appropriate use of social media by employees very seriously.

The Panel noted that the employee in question was trained on the Global Standard: Social Medica Personal Use (December 14 Version 3) in January 2018. The Panel noted AstraZeneca's submission that updated versions of this standard (February 2018 and August 2019) had not been 'read and signed' by the employee. According to AstraZeneca this was due to the updates being in a new template and thus being versioned as 1 and 2 (vs 4 and 5 had the original template been used) resulting in the employee not receiving an automated version update in his/her training account. The Panel noted AstraZeneca's submission that all three versions made it clear that product-related tweets were prohibited. The version the employee had been trained on stated 'You must take care to ensure that contributions or posts intended to represent your personal views are not worded in such a way as to suggest that the content is endorsed by AstraZeneca or is considered to speak on behalf of the Company. In particular, references to AstraZeneca, its operations, personnel, products or affiliations should be avoided when engaging in social media for personal use'. The Panel did not have Version 1 (February 2018) before it but noted that the updated version (2 August 2019) was clearer that employees were not permitted to post original content that was product-related or engage with (liking, sharing, commenting on) content that was product-related or was about disease education/awareness topics from third party sources. It was stated that there were no exceptions. The Panel noted that according to AstraZeneca this latest version of the Global Standard was made available to all employees in the AstraZeneca documents repository, and its publication was communicated to the business on the AstraZeneca Global intranet site and posted on the company's announcement page at the time. The Panel noted that whilst the employee in question did not receive an automated version update in his/her training account, he/she was alerted to the availability of the updated guidance via a number of other channels.

The Panel noted that in a series of company announcements in August 2019 to coincide with the release of the latest version of the Global Standard it appeared that AstraZeneca employees were positively encouraged to post certain work-related content on their personal social media accounts. This was reinforced by the use of phrases 'Empowering you to bring our unique culture to life on social media', 'When can I post work-related content on social media' followed by four questions to consider to ensure compliance with the Global Standard' and finally 'Good to go! Can't wait to see your posts'. The items listed as appropriate to post were 'Is it a job posting…', 'is it about our company culture, recognition of people or awards?', 'Is it about scientific advancements or non-product related scientific publications?' and 'Is it appropriate, compliant and clear any opinions are my own?'. The Panel considered that following this

company announcement it was possible that the employee had decided that the tweets related to scientific advancements and therefore re-tweeting was encouraged. It appeared to the Panel that although the announcement related to the same Global Standard issued in August 2019, the content had been presented very differently in the announcement.

The Panel noted that following notification of the dapagliflozin related re-tweets AstraZeneca posted a reminder to employees about its social media policy including a link to the document via its internal social media platform. A second reminder to employees in September, following identification of another product-related re-tweet by the same AstraZeneca employee, set out three things to watch out for when posting content on personal social media. Firstly, was the material product-related or about disease education/awareness, secondly was it confidential and thirdly did it contain personal data about others that you did not have consent for? If the answer was yes then staff were told not to post it. The Panel noted that the content of the Global Standard again had been presented differently in this second reminder.

The Panel considered that it might be difficult for some employees to balance the positive endorsement from AstraZeneca to post certain work-related content and the need for employees to make a judgement about what they may post.

The Panel noted its comments and rulings above and considered that high standards had not been maintained by AstraZeneca; a breach of Clause 9.1 was ruled.

Complaint received **30 September 2019**

Case completed **7 February 2020**