

DIRECTOR OF RESEARCH v ASTRAZENECA

Tweet about the incidence of a disease

A director of research, based in the US, complained about the following tweet posted by AstraZeneca on 11 December 2014 from the San Antonio Breast Cancer Symposium: 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer'. The complainant explained that he was both a medical professional with a UK licence and the husband of a breast cancer survivor. He understood that survival rates were above 98% for early breast cancer.

The complainant queried the evidence upon which the tweeted statement was made, the target audience and whether AstraZeneca had considered the negative effect that the tweet could have on a woman recently diagnosed with early breast cancer. The complainant noted that AstraZeneca had cited O'Shaughnessy (2005) on a fact sheet in support of the statement however the figure of 30% was an unreferenced comment from the author and not based on any data. Despite contacting the company several times, the complainant noted that he had not received a formal reply and that the tweet was still posted on the company's twitter page on 9 January 2015.

The complainant asked that his complaint be considered with regard to the lack of evidence for the statement, the distress caused to those impacted by breast cancer and the company's lack of a formal response.

The detailed response from AstraZeneca is given below.

The Panel noted that the tweet was sent from AstraZeneca's global twitter account. The global headquarters was based in the UK thus the twitter account had to comply with the UK Code.

The Panel noted that the complainant was concerned that the tweeted statement 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer' could not be substantiated. It was referenced to O'Shaughnessy (2005); the statement in the paper was unreferenced and appeared in the introduction section. In 2009 an 'Advanced breast cancer: diagnosis and treatment' guideline from the National Institute for Health and Care Excellence (NICE) stated that data generated in the West Midlands in 2012 indicated that in addition to the 5% of patients with metastases when they were diagnosed with breast cancer, a further 35% of all those with a primary diagnoses went on to develop metastases in the 10 years after diagnosis with little data to quantify the number of cases of advanced breast cancer developing after 10 years. It was stated that in summary there was little information available regarding advanced breast cancer; up to

40% of those diagnosed with breast cancer would develop advanced disease within 10 years. The 2012 pilot report from the West Midlands noted that although the outcomes of breast cancer had improved greatly over the past 20 years, dealing with recurrent and metastatic disease remained a significant and challenging problem, particularly given the high prevalence of the disease. It was further noted that the data at issue was not a suitable basis for estimating the full extent and nature of recurrent and metastatic breast cancer nationally.

The Panel noted that the complainant referred to a survival rate of more than 98% for early breast cancer but considered that this referred to 5 year survival – Cancer Research UK had produced data to show that for stage 1 cancer at diagnosis, 5 year relative survival was 99.1% and for stage 2 breast cancer at diagnosis it was 87.6%. As stated above, however, a proportion of women with breast cancer would go on to develop metastatic disease within 10 years or longer.

The Panel considered that the situation was difficult. Precisely quantifying the percentage of women diagnosed with early breast cancer who would then go on, perhaps many years later, to develop metastatic breast cancer was extremely difficult and at any time point would encompass women who had been first diagnosed years apart and who thus might have received very different treatment regimens. Thus when figures for metastatic disease were calculated, they were retrospective in terms of the initial diagnosis and might not reflect what newly diagnosed patients could expect in the future given advances in treatment. Nonetheless it was important that health professionals and patients with early breast cancer knew of the possibility of metastatic disease developing even if the original diagnosis had been made some years ago; any figure so used must reflect the requirements of the Code and be capable of substantiation. The Panel noted the limitations of the data and that the complainant bore the burden of proof. AstraZeneca had some data to support its position. Whilst it might have been helpful to provide more information about the data, on balance the Panel considered that given the difficulty in determining a precise figure, the reference to 'approximately 30% of women' in the tweet was not unreasonable. No breach of the Code was ruled. The Panel considered, on balance, that the statement could be substantiated by O'Shaughnessy and data taken from the West Midlands. No breach of the Code was ruled.

The Panel noted that the complainant had asked that his complaint be considered with regard to the distress cause to those impacted by breast cancer.

The Panel sympathised with the complainant's position but nonetheless considered that this aspect of the complaint was not covered by any of the clauses raised and thus it made no ruling in that regard. The complainant had also asked that the complaint be considered on the basis of the lack of response from AstraZeneca. The Panel noted that AstraZeneca had responded, albeit not within the time frame specified by the complainant. The company, however, had not been asked to consider the relevant clause of the Code and so in that regard the Panel could not make a ruling.

A director of research based in the US, complained about a tweet posted by AstraZeneca. The tweet stated 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer'. The tweet carried the hashtags #breastcancer and #SABCS14 (San Antonio Breast Cancer Symposium 2014) and included a graphic to illustrate the statement.

COMPLAINT

The complainant stated he was both a medical professional with a UK licence and the husband of a cancer survivor – his wife had had the misfortune to be diagnosed with breast cancer on two separate occasions – both distinct tumours which required gruelling and unpleasant treatments but based on good evidence of long-term survival with therapies including surgery, chemotherapy, radiotherapy and hormonal therapies. The complainant understood that the survival rates were above 98% for early breast cancer.

On 11 December 2014, AstraZeneca posted a tweet and an image which stated that '30% of women with early breast cancer will develop advanced or metastatic breast cancer'.

The complainant responded to the company via twitter and email to query the evidence upon which the statement was made, the target audience and whether it had considered the negative effect that the tweet could have on a woman recently diagnosed with early breast cancer. The complainant noted that he had not had a formal written response from AstraZeneca so far and the tweet was still posted on the company's twitter page on 9 January 2015.

The complainant also emailed the American Cancer Society to ask if it was aware of the evidence behind this statement; it stated that it could not find the evidence to support the statement. Although AstraZeneca provided a reference (O'Shaughnessy 2005) on its fact sheet, the statistic was an unreferenced comment from the author and not based on any data.

The complainant asked that his complaint be considered based on the lack of evidence for the statement, the distress caused to him, his family and others impacted by breast cancer and the lack of a formal response from AstraZeneca. Obviously, if the statement was true for women with early breast cancer treated in 2014 then the complainant would apologise but he suspected that this was not so.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clauses 7.2 and 7.4 of the 2014 Code and to note the supplementary information to Clause 23.2 Information to the Public, and Clause 25.

RESPONSE

AstraZeneca noted that complaint was about a non-promotional tweet which was sent at 5.50pm (GMT) on 11 December 2014, by its global corporate affairs team who had attended the 2014 San Antonio Breast Cancer Symposium. The tweet was sent from the AstraZeneca global twitter account - @AstraZeneca. The global corporate affairs team was part of the global organisation and did not report into the UK marketing company, although its offices were based in the UK.

The tweet was produced and then peer-reviewed by corporate affairs. As the tweet was non-promotional it was not certified. The entire content of the tweet was taken from an infographic approved by AstraZeneca global nominated signatories according to their procedures. The infographic was created by global as a background information fact sheet for use with media communications during the San Antonio Breast Cancer Symposium and made available to other functions and affiliates to use subject to their own procedures.

The tweet would have been received by all followers of the AstraZeneca global twitter account and it contained the text 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer'. The tweet also contained a graphic which depicted 30 out of 100 symbols, representing the female body, emboldened and coloured differently, to represent the 30% described in the statement. This non-promotional tweet was sent to communicate the current unmet need in breast cancer despite the many advances made over the last few decades and to stimulate thought and debate during the San Antonio Breast Cancer Symposium. The target audience was anyone interested in, attending or following the San Antonio Breast Cancer Symposium, which was why the official hash tag of the symposium (#SABCS14) was included, as well as (#breastcancer). The audience could include health professionals, patients, non-government organisations and media etc. AstraZeneca understood that twitter was an open-source social network, accessible to the public, however the content of the tweet was suitable for that audience and in line with relevant provisions of the Code. The tweet did not receive any other complaints or replies besides those of the complainant; however, AstraZeneca regretted if even one person was upset by the tweet and it sincerely apologised to the complainant for not replying to his last email more promptly.

The complainant cited an early breast cancer survival statistic in relation to his concerns about the factual accuracy of the tweet. Early breast cancer was defined as that which had not spread beyond the breast or the lymph nodes in the armpit on the same side of the body and with a tumour diameter of less

than 5cm. According to the widely accepted staging classification of breast cancer, early breast cancer met the criteria of stages 0-3A. The complainant cited that survival rates were above 98% for early breast cancer. According to data published on the Cancer Research UK website, 5 year survival rates in the UK for the most commonly diagnosed stages of early breast cancer, ie stages 1 and 2, were 99% and 88% respectively. Whilst this was so, AstraZeneca submitted that the statement in relation to the risk of progression, which was different to survival, was substantiated by a number of referenced articles, papers and national and European guidelines. These referenced papers, articles and guidelines supported the statement that approximately 30% of women diagnosed with early breast cancer would develop advanced or metastatic breast cancer in their lifetime (despite the high 5 year survival rates). Furthermore, the time from original breast cancer diagnosis to recurrence could vary widely and this was demonstrated in the Recurrent and Metastatic Breast Cancer Data Collection Project Pilot report where 19% of the patients were originally diagnosed more than 10 years before recurrence.

AstraZeneca submitted that the statement in the tweet was clear and unambiguous and there was no intention to mislead. As the statement was accurate and could be substantiated it complied with Clauses 7.2 and 7.4. AstraZeneca also submitted that the statement, issued to the public, complied with the supplementary information to Clause 23.2 and was in accordance with the provisions of the PMCPA guidance on digital communications and Clause 25.

AstraZeneca had corresponded with the complainant and provided the O'Shaughnessy reference to substantiate the tweeted statement. This initial correspondence was via twitter, first publicly and then latterly privately. The complainant who was based in the US subsequently telephoned the local AstraZeneca US offices on 16 December and then also emailed the office. These were dealt with according to the US company's medical information procedures. On 18 December the complainant emailed the US company again and demanded a reply by 9 January. The US personnel knew that the complainant's email related to the tweet sent by corporate affairs so they forwarded it to two colleagues in corporate affairs on 23 December 2014. Unfortunately, corporate affairs did not respond to the email before the deadline set by the complainant. However, AstraZeneca had since replied to his email and, given the sensitivity of the matter and his circumstances, had given him the opportunity to discuss his concerns with its global medical affairs leader for oncology.

In summary, AstraZeneca submitted that it had thoroughly investigated this matter and that it treated all such complaints seriously and responsibly. Whilst it had not received any other complaints it sincerely regretted that the complainant had apparently been upset by the tweet and this was clearly unintended. AstraZeneca submitted that the tweet was non-promotional and did not contain any information about medicines, was accurate and capable of substantiation. The

tweet was not misleading and complied with the Code with regard to communication with the public and on the Internet. AstraZeneca also considered the PMCPA guidance on digital communications. AstraZeneca therefore believed it had fully met all the relevant requirements of the Code regarding the communication.

FURTHER INFORMATION FROM THE COMPLAINANT

Before the response was received from AstraZeneca, the complainant provided a copy of an email from AstraZeneca and his comments upon it. These were sent to AstraZeneca.

The email, dated 23 January 2015, provided links to O'Shaughnessy and to a meta analysis of long-term outcome for early breast cancer published in the Lancet, 2012.

The complainant stated that O'Shaughnessy contained an unreferenced statement from the author in what he suspected was not a particularly influential journal; he was surprised that AstraZeneca chose this as its primary reference. With regard to the article from the Lancet, the complainant noted that it contained data from old studies some of which had control arms which would not be appropriate today. The tweet did not contain any qualification about whether or not modern treatment would reduce the 30% risk which was what the complainant suspected patients with new onset early breast cancer would find the most alarming. The complainant still did not understand who the target audience was for the tweet. Twitter was not just read by those attending medical conferences. The complainant noted the delay in receiving a formal, written, response; in his view he had still not received one unless AstraZeneca counted its email. The complainant further noted that the American Cancer Society could not find evidence to support AstraZeneca's statement in its tweet.

The complainant noted that the tweet at issue had now been removed which suggested that, on reflection, AstraZeneca's confidence in the data was not 100%.

FURTHER RESPONSE FROM ASTRAZENECA

AstraZeneca stated that it had addressed the issue of substantiation of the statement in the tweet above and it had no further comments except to add that The Oncologist, the journal in which O'Shaughnessy was published, had been established for more than twenty years; it had an extensive editorial board and its articles were peer-reviewed.

AstraZeneca submitted that it had referred to the Lancet paper in the email to the complainant in the anticipation that it would have dialogue with him and that this paper, when placed in proper context, would be part of the discussion in highlighting recurrence rates in breast cancer.

AstraZeneca had acknowledged that regrettably the email from the complainant which requested a reply by the 9 January was not responded to by

this deadline. This was at least in part because AstraZeneca closed its offices from 24 December until 2 January. The local US office handled the original contact from the complainant according to its procedures and forwarded the email to corporate affairs on the 23 December. AstraZeneca had offered the complainant the opportunity to discuss this matter directly to no avail, with the exception of his email of 26 January which was copied to the PMCPA.

AstraZeneca could not comment on the private correspondence the complainant had had with the American Cancer Society.

With regard to the complainant's allegation that the tweet had been removed because AstraZeneca accepted that the information was incorrect, AstraZeneca stated that although it did not consider the statement was incorrect, the fact that it had upset someone was sufficient grounds for its removal to avoid any risk of repetition and further upset.

FURTHER INFORMATION FROM ASTRAZENECA

In response to a request from the Panel for more information such that it could understand the context in which the tweet at issue was sent, AstraZeneca provided copies of other tweets about the San Antonio Breast Cancer Symposium sent from the global corporate affairs twitter account. The company noted that this included retweets of tweets originally sent from the US AstraZeneca twitter account '@AstraZenecaUS'. AstraZeneca reiterated that the tweet at issue had already been deleted and so was not included in the material now provided.

AstraZeneca noted that the tweet at issue was part of a much larger narrative about breast cancer. The strapline on the tweet, 'View more photos and videos' was a standard hyperlink on any tweet image or video posted on twitter; it linked to a tab on the twitter page that contained all of that user's photographs and videos. In the case of AstraZeneca, it linked to content on twitter (the relevant web address was given). Copies of the four photographs and video tweet features sent during and related to the breast cancer symposium were provided. AstraZeneca also provided a hard copy of relevant web pages and a link to a YouTube video from the San Antonio Breast Cancer Symposium 2013.

PANEL RULING

The Panel noted that the tweet was sent from AstraZeneca's global twitter account. The global headquarters was based in the UK thus the twitter account had to comply with the UK Code.

The Panel noted that the complainant was concerned that the tweeted statement 'Approximately 30% of women with early breast cancer will develop advanced or metastatic breast cancer' could not be substantiated. It was referenced to a 2005 paper by O'Shaughnessy; the statement in the paper was unreferenced and appeared in the introduction section. In 2009 an 'Advanced breast cancer: diagnosis and treatment' guideline from the National Institute for Health and Care Excellence (NICE) stated

that data taken from the West Midlands Cancer Intelligence Unit indicated that in addition to the 5% of patients with metastases at the time of diagnosis of breast cancer, a further 35% of all those with a primary diagnoses went on to develop metastases in the 10 years following diagnosis with little data to quantify the number of cases of advanced breast cancer developing after the 10-year time period. The guideline stated that in summary there was little information available regarding advanced breast cancer; up to 40% of those diagnosed with breast cancer would develop advanced disease within 10 years. The report from the West Midlands Cancer Intelligence Unit (2012) noted that although the outcomes of breast cancer had improved greatly over the past 20 years, dealing with recurrent and metastatic disease remained a significant and challenging medical problem, particularly in view of the high prevalence of the disease. It was further noted that data from the pilot was not a suitable basis for estimating the full extent and nature of recurrent and metastatic breast cancer nationally.

The Panel noted that the complainant referred to a survival rate of more than 98% for early breast cancer but considered that this referred to 5 year survival – Cancer Research UK had produced data to show that for stage 1 cancer at diagnosis, 5 year relative survival was 99.1% and for stage 2 breast cancer at diagnosis it was 87.6%. As stated above, however, a proportion of women with breast cancer would go on to develop metastatic disease within 10 years or longer.

The Panel considered that the situation was difficult. Precisely quantifying the percentage of women diagnosed with early breast cancer who would then go on, perhaps many years later, to develop metastatic breast cancer was extremely difficult and at any time point would encompass women who had been first diagnosed years apart and who thus might have received very different treatment regimens. In that sense when any figures for metastatic disease were calculated, they were by definition retrospective in terms of the initial diagnosis and might not reflect what newly diagnosed patients could expect in the future given advances in treatment. Nonetheless it was important that health professionals and patients with early breast cancer were aware of the possibility of metastatic disease developing even if the original diagnosis had been made some years ago and any figure so used must reflect the requirements of the Code and be capable of substantiation. The Panel noted the limitations of the data and that the complainant bore the burden of proof. AstraZeneca had some data to support its position. Whilst it might have been helpful to provide more information about the data, on balance the Panel considered that given the difficulty in determining a precise figure, the reference to 'approximately 30% of women' in AstraZeneca's tweet was not unreasonable. No breach of Clause 7.2 was ruled. The Panel considered on balance that the statement could be substantiated by O'Shaughnessy and data taken from the West Midlands indicating that 35% of patients would go on to develop metastatic breast cancer within 10 years. No breach of Clause 7.4 was ruled.

The Panel noted that the complainant had asked that his complaint be considered based on the distress cause to him, his family and others impacted by breast cancer. The Panel sympathised with the complainant's position but nonetheless considered that this aspect of the complaint was not covered by any of the clauses raised and thus it made no ruling in that regard. The Panel queried whether the complainant's concerns in this regard were covered by the Code. The company had been asked to note but not respond to Clause 25 and the supplementary information to Clause 23.2 and so the Panel did not make a ruling under either clause but it noted its comments above that the tweet came within the scope and the Code and based on the data available, the tweet was not unreasonable. The complainant had also asked that the complaint be considered on the basis of the lack of response from AstraZeneca. The Panel noted that AstraZeneca had responded to the complainant, albeit not within the time frame specified by the complainant – some of the delay

was due to intervening Christmas holidays. The company, however, had not been asked to consider Clause 7.5 and so in that regard the Panel could not make any ruling with regard to the requirements of that clause.

During its consideration of this case, the Panel noted that the tweet at issue had not been certified. The Panel queried whether in that regard the requirement of Clause 14.3 had been met. Clause 14.3 stated that educational material for the public or patients which related to diseases or medicines had to be certified in advance. The Panel requested that AstraZeneca be advised of its concerns in this regard.

Complaint received **12 January 2015**

Case completed **27 March 2015**