CASE AUTH/2265/9/09

CONSULTANT RESPIRATORY PHYSICIAN v ASTRAZENECA

Promotion of Symbicort

A consultant respiratory physician complained about the conduct of a former representative from AstraZeneca in relation to the promotion of Symbicort (formoterol and budesonide) for chronic obstructive pulmonary disease (COPD).

The complainant's name appeared on the front of a document entitled 'Effective treatment of Chronic Obstructive Pulmonary Disease The NHS Challenge' next to the AstraZeneca logo. The complainant alleged that this might give the impression that she had either written or endorsed the document. Unbeknown to the complainant the document had been forwarded electronically to the local formulary group and had also been discussed in various primary care committees. The complainant had not written the report or approved of its contents. AstraZeneca had not asked for permission to use her name in such a misleading way. The report was written by the representative for the complainant who had asked for evidence why she should change her prescribing practice for patients with COPD. There was no mention that the representative was the author nor that the report was produced for the complainant's information only.

The detailed response from AstraZeneca is given below.

The Panel noted that the complainant's name, job title and hospital appeared in the lower right hand corner whilst the AstraZeneca corporate logo appeared in the bottom left hand corner. Text along the bottom referred the reader to prescribing information on the final four pages of the document. The document discussed the regional prevalence and financial burden of COPD and the estimated cost savings if an alternative ICS/LABA (inhaled corticosteroid/long acting B2 agonist) combination prescribing strategy to that currently used was adopted.

The Panel noted from the complainant that she had met the representative when speaking at a local meeting and the representative had promoted a switch from Seretide to Symbicort for cost and efficacy reasons. The complainant had asked for supporting evidence. However as acknowledged by AstraZeneca and contrary to company policy, there was no evidence that the representative had explained the Symbicort Budget Impact Model (BIM) tool nor that the complainant had requested a hard copy report. Nonetheless the representative subsequently provided the complainant with a hard copy and stated that a copy was going to be provided to the respiratory health care facilitator in primary care. Professional commitments and absence prevented the complainant from looking at the hard copy or reading relevant email correspondence. The complainant accepted that she should have checked the document more carefully. AstraZeneca acknowledged that again, contrary to company policy, there was no evidence that the complainant consented to the subsequent dissemination of the document.

The Panel considered that the design and layout of the front page implied that the complainant had written or otherwise endorsed the document. This was certainly the impression given to the local respiratory lead who received a copy by email. This was unacceptable and misleading about the complainant's role; a breach of the Code was ruled as acknowledged by AstraZeneca. It implied endorsement which in the Panel's view was contrary to the conventions of the profession; a breach of the Code was ruled as acknowledged by AstraZeneca. The Panel noted that the document at issue was in the format approved for use by the company and there was nothing on the front cover to dispel the impression that the report was written or endorsed by the named individual. High standards had not been maintained in this regard. A breach of the Code was ruled.

The Panel was very concerned about the role of the representative. Company procedures had not been followed. High standards had not been maintained and a further breach of the Code was ruled in this regard.

The Panel noted that the document was not a reprint of a published document nor was the complainant quoted within. No breaches of the Code were thus ruled.

A consultant respiratory physician complained about the conduct of a former representative from AstraZeneca UK Limited in relation to the promotion of Symbicort (formoterol and budesonide) for chronic obstructive pulmonary disease (COPD).

COMPLAINT

The complainant stated that her name had appeared on the front of a document entitled 'Effective treatment of Chronic Obstructive Pulmonary Disease The NHS Challenge' next to the AstraZeneca logo which might give the impression that she had either written or had endorsed the document which was compiled by the former AstraZeneca representative. Unbeknown to the complainant the document had been forwarded electronically for discussion to the local formulary

group and had also been discussed in various primary care committees. The complainant had neither written the paper, nor approved of its contents and nor had AstraZeneca asked for her permission to use her name in such a misleading way. The report was written by the representative as the complainant had asked for evidence why she should change her prescribing practice for patients with COPD. The representative had suggested a switch from Seretide to Symbicort for cost and efficacy reasons but there was no mention on the title page or in the report that the representative was the author and the report was produced for the complainant's information only.

Without the complainant's knowledge or approval the document subsequently appeared to have been fairly widely distributed and from discussions with colleagues in primary and secondary care the complainant strongly suspected that the assumption of 'consultant approval' ultimately led to the document being forwarded for discussion to the local formulary group meeting. The complainant was very unhappy that her name had been abused in this way and thought that AstraZeneca had breached Clause 10 of the Code. From discussions with senior managers at AstraZeneca the complainant understood that the company acknowledged its mistake (and had apologised verbally for this) and would carry out its own investigation. AstraZeneca had offered to send the complainant a summary of its own investigation once it was completed. However the complainant would like to ensure that mechanisms were in place so that this did not happen again and that as much as possible the document was taken out of circulation.

The complainant subsequently provided further information.

The complainant stated that she very rarely saw medical representatives but did meet the representative in question before a local educational meeting about COPD for GPs and practice nurses sponsored by AstraZeneca in Spring 2009 to discuss the programme. During that meeting the representative tried to convince the complainant to change her prescribing practice for COPD patients (switch from Seretide to Symbicort for cost and efficacy reasons). The complainant was not convinced and asked the representative for supporting evidence. The complainant's subsequent talk at the meeting was about a few case studies of COPD patients and had nothing to do with any pharmacological treatment.

The complainant had no further contact with the representative until a chance meeting in the hospital some time in mid July. The representative handed the complainant a paper copy of the document at issue and mentioned that she was also going to give a copy to the respiratory health care facilitator in primary care. At that stage the complainant was not aware of any work regarding Symbicort/Seretide by the local community health and care partnership. This had not been discussed in the local respiratory partnership meeting – a quarterly meeting between primary and secondary care representatives to discuss respiratory issues. The complainant was in a rush and had no time to discuss the document. The complainant did not look at the document again until she was emailed by the local respiratory lead expressing his surprise that a document with her name and the AstraZeneca logo had been forwarded to the local formulary group for discussion.

The complainant was copied into the email from the respiratory health care facilitator in primary care forwarding the document to the lead GP and a community pharmacist which arrived after the complainant's three week summer break. The complainant unfortunately did not open the attachment and so remained unaware that the front cover of the document implied that she had written or endorsed it. However the complainant did not think that her failure to respond to this email with an enclosed document bearing her name only (unbeknown to her at that time) amounted to consent for its ongoing distribution and considered that this should have been discussed verbally with her beforehand. The complainant strongly suspected from discussions with pharmacy and medical colleagues that the assumption of 'consultant approval' ultimately led to the document being forwarded to the local formulary group and various primary care committees.

The complainant accepted that she should have checked the document more carefully in the first instance but she felt strongly that the front cover with the title of the document, her name, designation and place of work plus the AstraZeneca logo was very misleading. There was no mention in the document of its author and even if it was only supposed to have been for the complainant it should have clearly stated the author's name on the front cover and that it was provided to the complainant for information only with no possible implication that she was involved in the report.

The representative sent the electronic version out (which from discussion with AstraZeneca seemed to breach company policies) and this obviously opened the door to rapid dissemination. There was no mention in the representative's email that the report was to be treated confidentially and was not for further dissemination and, according to the respiratory health care facilitator in primary care, the representative knew that she was going to forward it to the lead GP and a community pharmacist. The representative also copied it to her successor and one other colleague (the complainant did not know what his position in the company was).

The complainant was obviously concerned that the electronic version had gone beyond the local region by now and there was probably little she

could do about it. AstraZeneca was carrying out an internal investigation and would send the complainant a copy within the next two weeks. It had acknowledged its mistake verbally and offered to self report to the Authority but the complainant had chosen to initiate a complaint herself.

The complainant would like to ensure that AstraZeneca would put procedures in place that similar documents were now clearly labelled regarding their authorship and she hoped that the document bearing her name was taken out of circulation as much as possible.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clauses 7.2, 9.1 and 9.3 of the Code in addition to Clauses 10.2, 10.3 and 10.4. The complainant had referred to Clause 10 in general.

RESPONSE

AstraZeneca stated that it took the complainant's concerns extremely seriously and had therefore undertaken a prompt and thorough investigation to establish the facts and take any necessary corrective action.

The issues that had been raised all related to the Symbicort Budget Impact Model (BIM). The BIM was a promotional tool in the form of a spreadsheet that was used by representatives to demonstrate a health-economic argument for the use of Symbicort in either asthma or COPD. The tool contained input fields for the entry of local demographic and product usage data from which the health-economic claims were automatically generated by a pre-programmed algorithm. It was created and certified by AstraZeneca for use by representatives promoting Symbicort.

Representatives were trained to use their laptop to explain and present the tool to a health professional and, if requested by the health professional, the representative could generate and print out a single written summary report (entitled 'Effective treatment of Chronic Obstructive Pulmonary Disease' if the therapy area being discussed was COPD) that they handed over directly to that health professional. The representative could personalise the report by putting the recipient's name and details on the front page of the report.

AstraZeneca believed that the overall complaint related to two aspects of the printed summary report generated by the BIM; firstly the appearance on the front page of the complainant's name and secondly the manner of the subsequent use and dissemination of the report by AstraZeneca.

AstraZeneca reviewed all the relevant approval and training documentation for the BIM, interviewed relevant existing employees involved in the creation, approval and training of the BIM tool and contacted and interviewed the representative in question who had left the company before this complaint arose.

AstraZeneca's investigation established the following:

1 With regard to the information that appeared on the front page of the written summary report:

- The complainant did not write the summary report, nor did she contribute to or endorse the content in any way. In fact, she was not aware that her name appeared on the front page of this report when it was first handed to her by the representative.
- The front page of the summary report prepared for the complainant had her name printed on it without a clarification that she was the recipient and nor was there a clarification that it had actually been prepared by AstraZeneca or its representative. This unintentional lack of clarification and the positioning of the complainant's name on the front sheet of the report could misleading imply that the complainant was the author of the report.
- The Symbicort BIM tool had no facility for entering any details on the front sheet of the summary report other than the recipient's name, and institutional details. The representative could personalise the summary report by entering in the recipient's details and then print a hardcopy, which was then handed to the recipient. The representatives were trained to only send an electronic version of the summary report with the recipients' prior permission and head office authorization. In this isolated case, approval to send the summary report electronically was granted by head office which did not first check that prior written permission had been granted by the recipient.
- The front page of the summary report prepared for any recipient might misleadingly appear to ascribe to that recipient the views contained in the report. Although this was unintentional (the intention was merely to personalise the report), sufficient care had not been taken to avoid such an impression. Furthermore, such an impression constituted a misleading claim regarding the authorship of the summary report. Therefore AstraZeneca accepted that the summary report breached Clauses 10.4 and 7.2.

2 With regard to the manner of the use and dissemination of the report:

- There was no evidence that the representative clearly explained the nature of the Symbicort BIM tool to the complainant, nor that the complainant specifically requested a hard-copy summary report from it.
- There was no evidence that the complainant requested, or gave consent to the representative to share a copy of the summary report with any other NHS colleagues either in hard copy or electronically. Although the complainant was aware of the representative's intention to share

a copy with the respiratory health care facilitator in primary care (an NHS colleague with whom the representative had separately discussed the BIM) she at that stage had not had a chance to view the hard copy.
- The representative obtained permission from head office for the electronic dissemination of the summary report. This permission was, however, granted without the proper internal approval process as stated above.
- AstraZeneca accepted that the unfortunate misleading impression regarding authorship created by the front page of the summary report and the manner in which it had been disseminated without the informed consent of the complainant was in breach of Clause 9.3.

This was a genuine unintentional mistake with a hard copy containing the error on its front page given to the health practitioner. AstraZeneca responded immediately it knew of the error and instigated a full investigation with a formal explanation and apology, independent of a complaint to the Authority. All the actions taken had been consistent with a company keen to maintain high standards when a genuine error had been made. This was an isolated set of events and immediate steps had been taken to ensure this was not replicated and AstraZeneca therefore denied a breach of Clause 9.1.

The summary report was not a quotation from the complainant; therefore, AstraZeneca did not believe Clause 10.2 was applicable nor that the summary report was in breach of Clause 10.2.

The summary report was not a quotation taken from a public broadcast, private occasion, medical conference or symposium. Therefore AstraZeneca did not believe Clause 10.3 was applicable nor that the summary report was in breach of Clause 10.3.

In response to the complainant's initial direct complaint to AstraZeneca (and before receiving the complaint via the Authority), AstraZeneca conducted an urgent investigation and took the following immediate actions:

- All relevant representatives were told to stop using the Symbicort BIM tool and delete it from their laptops, with immediate effect.
- BIM tools and all other similar types of documents for all brands were reviewed to ensure similar issues did not exist.

In addition, action was being taken with the individual who authorised the electronic dissemination of the complainant's report and all representatives would be reminded of the Code and AstraZeneca requirements relating to the use of BIM tools.

With regard to the retrieval of copies of the summary report prepared for the complainant, AstraZeneca was only aware of the dissemination of one hard-copy (the copy given to the complainant herself). It was not possible for AstraZeneca to retrieve the email versions that had now been distributed within the NHS.

In conclusion, AstraZeneca had addressed this matter with the seriousness it fully warranted and had offered the complainant a written apology.

AstraZeneca was determined to understand all the learnings from this case, share them widely within the company and ensure that such an error did not occur again.

PANEL RULING

The Panel noted that the 20 page document was headed 'Effective Treatment of Chronic Obstructive Pulmonary Disease. The NHS challenge'. The complainant's name, job title and hospital appeared in the lower right hand corner whilst the AstraZeneca corporate logo appeared in the bottom left hand corner. Text along the bottom referred the reader to prescribing information on the final four pages of the document. The document discussed the regional prevalence and financial burden of COPD and the estimated cost savings if an alternative ICS/LABA (inhaled corticosteroid/long acting B2 agonist) combination prescribing strategy to that currently used was adopted.

The Panel noted from the complainant that she had met the representative when speaking at a local meeting and the representative had promoted a switch from Seretide to Symbicort for cost and efficacy reasons. The complainant had asked the representative for supporting evidence. However as acknowledged by AstraZeneca and contrary to company policy, there was no evidence that the representative had explained the Symbicort BIM tool nor that the complainant had requested a hard copy report. Nonetheless the representative subsequently provided the complainant with a hard copy and stated that a copy was going to be provided to the respiratory health care facilitator in primary care. Professional commitments and absence prevented the complainant from looking at the hard copy or reading relevant email correspondence. The complainant accepted that she should have checked the document more carefully. AstraZeneca acknowledged that again, contrary to company policy, there was no evidence that the complainant consented to the subsequent dissemination of the document.

The Panel considered that the design and layout of the front page implied that the complainant had written or otherwise endorsed the document. This was certainly the impression given to the local respiratory lead who received a copy by email. This was unacceptable and misleading about the complainant's role; a breach of Clause 7.2 was ruled as acknowledged by AstraZeneca. It implied endorsement which in the Panel's view was contrary to the conventions of the profession a breach of Clause 9.3 was ruled as acknowledged by AstraZeneca. The Panel noted that the

document at issue was in the format approved for use by the company and there was nothing on the front cover to dispel the impression that the report was written or endorsed by the named individual. High standards had not been maintained in this regard. A breach of Clause 9.1 was ruled.

The Panel was very concerned about the role of the representative. Company procedures had not been followed on the creation and dissemination of the material. High standards had not been maintained and a further breach of Clause 9.1 was ruled in this regard.

The Panel noted that the complainant had cited Clause 10 of the Code which referred to the provision of reprints and the use of quotations. The Authority had referred to Clauses 10.2, 10.3 and 10.4. The document was not a reprint of a published document nor was the complainant quoted within. No breach of Clauses 10.2, 10.3 and 10.4 was thus ruled.

Complaint received **10 September 2009**

Case completed **17 November 2009**