CASE AUTH/2954/4/17

HEALTH PROFESSIONAL v ASTRAZENECA

Conduct of a representative

A health professional from a clinical commissioning group (CCG) complained about the conduct of a named representative (representative A) from AstraZeneca. AstraZeneca had sponsored a practice nurse forum meeting at which the complainant alleged that representative A had falsely stated that AstraZeneca had a special arrangement with the CCG and the CCG was in favour of Symbicort (formoterol plus budesonide).

The complainant noted that the CCG was part of the area prescribing committee and subscribed to, and promoted, the area's management guidelines for asthma and COPD (chronic obstructive pulmonary disease); neither Symbicort nor Turbohaler appeared in those guidelines. AstraZeneca knew this because at a meeting in 2016 to discuss the promotion of Symbicort locally various approaches were agreed including that:

- **for patients stabilised on Symbicort Turbohaler the CCG did not proactively encourage a review and a switch**
- **all new patients/prescriptions for inhaled budesonide and formoterol combination would be started on DuoResp Spiromax, in accordance with local guidelines;**
- **all inhalers should be prescribed by brand name, in accordance with best practice to avoid confusion at dispensing; and**
- **AstraZeneca representatives were not to promote Symbicort locally as it was not covered by the current guidelines.**

The detailed response from AstraZeneca is given below. AstraZeneca explained that representative A had attended the practice nurse forum in question. Representative B had been at the 2016 meeting during which the promotion of Symbicort locally was discussed along with his/her regional business manager (RBM).

The Panel noted AstraZeneca's submission that representative A promoted Symbicort for asthma and COPD at the practice nurse forum and although he/she did not discuss the CCG guidelines specifically, as the delegates had generally discussed costs he/she read out the following in-call statement in relation to the CCG's position on Symbicort:

'[The] CCG recommends a formoterol/budesonide combination as one of the options on the asthma/COPD formulary. The specific product choice is down to the prescribers' discretion, and should be decided upon after discussion and agreement with the patient/carer. The CCG does however recommend that all prescribing of inhaled corticosteroids/long-acting beta agonist combinations should be done by brand name, and due to a commercial agreement between the CCG and AstraZeneca, cost should not be a barrier to prescribing Symbicort. For further information contact [named individual].'

The Panel noted that this statement was first emailed by the RBM to, *inter alia*, representative B in early October 2016 with an instruction that it should be shared with customers in every call in the CCG. The email which advocated the statement's proactive use stated that its further use was subject to discussion at an account level. That same day, representative B emailed recipients of the RBM's email advising that the statement should not be used until a meeting with the CCG clarified matters. Representative B subsequently clarified the position by email following a meeting with the RBM and the CCG advising that the statement should only be used verbally and reactively if cost came up as a barrier to prescribing Symbicort and that it was 'specifically in relation to maintaining patients on Symbicort as opposed to new patients'. The email stated that the CCG supported continuing Symbicort in patients who were stable and well controlled (as opposed to new patients). The email then made it clear that the guidelines applied to new patients only, not existing, and a switch from existing therapies should only occur as part of a CCG driven review initiative. Whilst the email described when the in-call statement could be used it did not unambiguously reflect the company's overall local promotional strategy in relation to Symbicort. This was a significant omission given that, according to AstraZeneca, it had been discussed at the meeting with the CCG and representative B understood that Symbicort could only be promoted locally in certain patients. The Panel noted that the complainant's recollection of the meeting differed: he/she stated that it was agreed that, locally, Symbicort would not be promoted to health professionals. It was difficult in such circumstances to determine where the truth lay.

The Panel also noted the apparent confusion within the CCG about the status of the guidelines. Representative B's email stated that the guidelines had not yet been launched within the CCG and there was still confusion around the class and products that sat within it. The RBM's unsigned account of the investigation interview referred to the author of the guidelines who stated that 'the guidelines were just that and it was up to the prescriber what they prescribed'. The RBM did, however, state that it was AstraZeneca's strategy for the CCG to maintain patients on Symbicort rather than target new patients.

Representative A who ran the nurse forum meeting at issue did not receive the RBM's October 2016 email nor the emails from representative B. Representative A's signed account of the investigation interview referred to a document which contained in-call statements for a number

of CCGs which was emailed by the RBM to representatives in January 2017. The Panel noted that representative A recalled that when the in-call statement email was sent, he/she was also told that the statement in relation to the CCG at issue only applied to patients established on Symbicort rather than new patients. The Panel queried why this was not included in the email in question and the accompanying table of in-call statements. Whilst the covering email did state 'All of these statements are reactive' the table of in-call statements included a column headed 'Can I raise proactively or reactively?' and was marked as 'TBC' for the CCG statement in question. Further, 3 in-call statements in the table were listed for proactive use which directly contradicted the covering email. Whilst the company's local plan for the CCG referred to reactive use of the in-call statement, the Panel considered that the table of in-call statements should be capable of standing alone. The Panel considered that the email sent by the RBM in January 2017 regarding in-call statements when considered with the accompanying table was not clear about the CCG in-call statement's reactive or proactive use, nor was there any clarity about the company's local promotional strategy and therefore it advocated a course of action likely to be in breach of the Code. A breach of the Code was ruled.

The Panel noted that representative A knew that the in-call statement only related to patients established on Symbicort but did not make this clear at the nurse forum meeting in question. In the Panel's view this omission meant that the use of the in-call statement at the meeting was misleading. The Panel ruled a breach of the Code. The impression that it applied to all patients, including new patients, could not be substantiated and a further breach of the Code was ruled. In the Panel's view, to mislead the audience in this regard meant that the representative had not maintained a high standard of ethical conduct and a breach of the Code was ruled.

The Panel noted that the parties' understanding of the agreement reached in 2016 differed in relation to whether, and if so how, Symbicort would be promoted within the CCG. It was beholden upon the company to be clear in such circumstances about the agreement reached and in this regard it was of concern that the outcome had not been agreed in writing between the parties. It was of the utmost importance that such agreements were clearly and unambiguously communicated to the field force. The complainant's understanding was that AstraZeneca representatives were not to promote Symbicort to local health professionals as it was not covered by the current guidelines. The Panel accepted that the complainant must have felt strongly about this matter to be moved to complain. The Panel noted that the complainant did not comment on the in-call statement but noted that many patients were stabilised on Symbicort Turbohaler and the local CCG did not proactively encourage a review and a switch to another product. Representative A was sure he/she was told that the in-call statement only applied to established patients but did not refer to such patients being stable and well-controlled. The Panel noted AstraZeneca's submission that given the in-call statement was not clear about which patients within the CCG Symbicort could be used in, it advocated a course of action which was contrary to local arrangements and the Panel thus ruled a breach of the Code.

The Panel noted its comments and rulings above and considered that high standards had not been maintained. The Panel considered that the failure to give clear and unequivocal instructions to representative A was compounded by the fact that the company's stated local promotional strategy was not reflected in the local plan for the CCG and the failure to confirm the outcome of the 2016 meeting in writing. A breach of the Code was ruled.

A health professional from a clinical commissioning group (CCG), complained about the conduct of a named representative from AstraZeneca UK Limited. AstraZeneca had sponsored a local practice nurse forum meeting in April at which the complainant alleged that the representative had made false claims about the use of Symbicort Turbohaler (formoterol plus budesonide) within the local CCG. Symbicort was indicated for use in relevant patients with asthma or chronic obstructive pulmonary disease (COPD).

COMPLAINT

The complainant stated that the representative promoted Symbicort at the meeting in question and claimed that AstraZeneca had a special arrangement with the CCG and that the CCG was in favour of Symbicort.

The complainant noted that the CCG was part of an area prescribing committee and subscribed to, and promoted, the area's management guidelines for asthma and COPD; neither Symbicort nor Turbohaler appeared in those guidelines. AstraZeneca knew this because at a meeting in October 2016 to discuss the promotion of Symbicort locally, various approaches were agreed including that:

- many patients were stabilised on Symbicort Turbohaler, the CCG did not proactively encourage a review and a switch;
- all new patients/prescriptions for inhaled budesonide and formoterol combination would be started on DuoResp Spiromax, in accordance with local guidelines;
- all inhalers would be prescribed by brand name, in accordance with best practice to avoid confusion at dispensing; and
- AstraZeneca representatives were not to promote Symbicort to local health professionals as it was not covered by the current guidelines.

When writing to AstraZeneca, the Authority asked it to consider the requirements of Clauses 7.2, 7.4, 15.2, 15.4, 15.9 and 9.1 of the Code.

RESPONSE

AstraZeneca stated that it was extremely disappointed to receive the complaint. After conducting a thorough investigation, including

a review of call notes as well as speaking to the representatives involved, the company considered that the situation arose due to misunderstandings by a number of AstraZeneca representatives (due in part to inadequate briefing) as well as by the complainant.

AstraZeneca submitted that it had interviewed representative A who had attended the practice nurse forum in April 2017, representative B who had been at the meeting in 2016 and his/her line manager, the regional business manager (RBM), who was also present at that meeting. The meeting in 2016 was with the CCG's senior clinical commissioning pharmacist and was initiated by representative B. There were no other attendees. AstraZeneca provided notes from interviews with its two employees.

AstraZeneca submitted that there were a number of objectives for the 2016 meeting, including a discussion as to how it could assist in the roll-out of the CCG's recently issued guidelines about the prescription of respiratory medicines. A week before the meeting the RBM had emailed a statement to representative B and two other local, relevant field-based staff in relation to a commercial agreement that the local commercial account manager had negotiated with the CCG. The email stated:

> 'In light of a commercial agreement between [the CCG] and AstraZeneca, please ensure the below statement is shared with customers in every call in this CCG;
>
> *"The CCG recommends a formoterol/budesonide combination as one of the options on the asthma/COPD formulary. The specific product choice is down to the prescribers' discretion, and should be decided upon after discussion and agreement with the patient/carer. The CCG does however recommend that all prescribing of [inhaled corticosteroids/long active beta-agonist] ICS/LABA combinations should be done by brand name, and due to a commercial agreement between the CCG and AstraZeneca, cost should not be a barrier to prescribing Symbicort. For further information contact [the complainant]."'*

Representative B responded to all recipients of this email to state that he/she understood that the statement should only be used reactively and that he/she would clarify this with the local senior commissioning pharmacist.

AstraZeneca submitted that this statement was then subsequently discussed a week later at the 2016 meeting and it was clarified that it should only be used reactively if cost came up as a barrier to prescribing Symbicort in the CCG for patients already established on the medicine who were stable and well controlled (as opposed to new patients). It was also agreed that Symbicort should not be promoted in the CCG for new patients, given that it was not included in the CCG guidelines. Representative B's understanding of the impact of this on the promotion of Symbicort in the CCG was that Symbicort could still be promoted for patients established and well controlled on the medicine and that AstraZeneca would be transparent if health professionals asked if Symbicort was on the CCG guidelines for new patients and state that it was not. AstraZeneca submitted that contrary to the complainant's understanding, the agreement and the CCG guidelines did not mean that Symbicort could not be promoted in the CCG at all, rather that it could only be promoted for certain patients.

On the same day, immediately following the 2016 meeting, representative B summarised what was agreed with the CCG in an email to the RBM and to the local primary care representatives (copy provided).

The nurse forum in April 2017 was organised by a number of local practices and was attended by nurses from those practices. Representative A provided lunch and was given a 10-15 minute slot at the beginning of the meeting to present. AstraZeneca did not have an agenda for the meeting; the list of attendees was included in the meeting notes (copy provided).

Representative A stated that he/she did not discuss the CCG guidelines specifically but at the end of his/her presentation he/she read out the in-call statement noted above in relation to the CCG's position on Symbicort because there had been general discussion about cost amongst the delegates at the meeting.

The statement was provided to representative A by the RBM in January 2017 as part of a wider document that contained in-call statements for several CCGs (copies provided). The representative was 'pretty sure' that he/she was also told at the time that the in-call statement in relation to the CCG only applied to patients established on Symbicort rather than new patients. This did not appear to be covered in the RBM's email in January 2017 but the email did note that the statement was to be used reactively. At the nurse forum, representative A did not consider it necessary to clarify that the statement only referred to certain patients and did not recall anyone asking for clarification.

When interviewed as part of the investigation in to this complaint, the RBM stated that he/she received the in-call statement from the commercial account manager for the region at the time. The RBM did not know whether the statement had been certified; the commercial account manager would have agreed the statement with the CCG but as he/she was no longer with AstraZeneca this could not be confirmed.

When questioned about his/her understanding of the agreement with the CCG and whether the statement meant that Symbicort could only be promoted locally for patients established on the medicine, the RBM stated that that was not his/her understanding. However, it was the strategy that had been adopted by AstraZeneca in the CCG. This strategy was not stated in the RBM's email as the attachment contained in-call statements for a number of CCGs, but it was reflected in the account plan in place when the nurse forum took place. This account plan noted

that the objective for the CCG was to protect and maintain Symbicort by communicating the CCG in-call statement.

AstraZeneca submitted that given the above, it appeared that the statement provided to representatives A and B in relation to the position of Symbicort in the CCG was misleading; as a stand-alone item it did not clarify that Symbicort should not be promoted in the CCG for new patients, given that it was not included in the CCG guidelines. Thus, the statement that representative A read out at the nurse forum was misleading and could not be substantiated. AstraZeneca acknowledged a breach of Clauses 7.2 and 7.4.

Further, given that the in-call statement was not clear as to which patients within the CCG could be prescribed Symbicort, it advocated a course of action which was contrary to the current arrangements in place at the CCG and thus would be likely to lead to a breach of the Code. AstraZeneca acknowledged a breach of Clauses 15.4 and 15.9 in that regard.

AstraZeneca submitted that as representative B clarified the use of the in-call statement with the CCG and representative A was provided with an inadequate brief, the conduct of neither amounted to a failure to maintain high standards; the company thus refuted a breach of Clause 15.2 in that regard. However, the provision of such a briefing to the two representatives did amount to such a failure, and AstraZeneca acknowledged that the actions of the commercial account manager who provided the statement for circulation, were in breach of Clause 15.2.

Finally, it appeared that the in-call statement regarding the promotion of Symbicort in the CCG was not certified, in breach of Clause 15.9. AstraZeneca considered that this was a failure by the company to maintain high standards, in breach of Clause 9.1.

AstraZeneca apologised for the failures noted above and would act to address these as a matter of priority.

PANEL RULING

The Panel noted AstraZeneca's submission that representative A presented an overview of Symbicort and its use in asthma and COPD at a practice nurse forum in April 2017 and left a number of leavepieces behind at the end of the meeting. Representative A did not discuss the CCG guidelines specifically but at the end of his/her presentation read out the following in-call statement in relation to the CCG's position on Symbicort as there had been a general discussion about costs amongst the delegates:

> 'The CCG recommends a formoterol/budesonide combination as one of the options on the asthma/COPD formulary. The specific product choice is down to the prescribers' discretion, and should be decided upon after discussion and agreement with the patient/carer. The CCG does however recommend that all prescribing of ICS/LABA combinations should be done by brand name, and due to a commercial agreement between the CCG and AstraZeneca, cost should not be a barrier to prescribing Symbicort. For further information contact [named individual].'

The Panel noted that this statement was first emailed by the RBM to representative B and two other local, field-based staff in October 2016 with an instruction that the recipients should 'ensure that it was shared with customers in every call' in the CCG. The email which advocated the statement's proactive use stated that its further use was subject to discussion at account level. That same day, representative B emailed recipients of the RBM's email advising that the statement should not be used until a meeting with the CCG clarified matters. Representative B subsequently clarified the position by email a week later following a meeting earlier that day with the RBM and the CCG's clinical commissioning pharmacist advising that the statement should only be used verbally and reactively if cost came up as a barrier to prescribing Symbicort and that it was 'specifically in relation to maintaining patients on Symbicort as opposed to new patients'. The email stated that the clinical commissioning pharmacist supported continuing Symbicort in patients who were stable and well controlled (as opposed to new patients). The email then made it clear that the guidelines applied to new patients only, not existing, and a switch from existing therapies should only occur as part of a CCG driven review initiative. Whilst the email described when the in-call statement could be used it did not unambiguously reflect the company's overall local promotional strategy in relation to Symbicort. This was a significant omission given that, according to AstraZeneca, it had been discussed at the meeting with the CCG clinical commissioning pharmacist and representative B's understanding was that Symbicort could only be promoted locally in certain patients. The Panel noted that the complainant's recollection of the meeting differed: he/she stated that it was agreed that Symbicort would not be promoted to health professionals in the CCG. It was difficult in such circumstances to determine where the truth lay.

The Panel also noted the apparent confusion within the CCG about the status of the guidelines as evidenced in the material provided by AstraZeneca. Representative B's email a week after the meeting in October 2016 stated that the guidelines had not yet been launched effectively in the CCG and there was still confusion around the class and products that sat within it. The RBM's unsigned account of the investigation interview referred to the local formulary pharmacist who was the author of the guidelines who stated that 'the guidelines were just that and it was up to the prescriber what they prescribed'. The RBM did, however, state that it was AstraZeneca's strategy for the CCG to maintain patients on Symbicort rather than target new patients.

Representative A who ran the nurse forum meeting did not receive any of the 2016 emails from the RBM or representative B outlined above. Representative A's signed account of the investigation interview referred to a document which contained in-call statements for a number of CCGs which was emailed by the RBM to representatives in January 2017.

The Panel noted that representative A recalled that when the in-call statement email was sent, he/she was also told that the statement in relation to the CCG at issue only applied to patients established on Symbicort rather than new patients. The Panel queried why this was not included in the email in question and the accompanying table of in-call statements. Whilst the covering email did state 'All of these statements are reactive' the table of in-call statements included a column headed 'Can I raise proactively or reactively?' and was marked as 'TBC' for the CCG statement in question. Further, 3 in-call statements in the table were listed for proactive use which directly contradicted the covering email. Whilst the company's local plan for the CCG referred to reactive use of the in-call statement, the Panel considered that the table of in-call statements should be capable of standing alone. The Panel considered that the email sent by the RBM in January 2017 regarding in-call statements when considered with the accompanying table was not clear about the CCG in-call statement's reactive or proactive use, nor was there any clarity about the company's local promotional strategy and therefore it advocated a course of action likely to be in breach of the Code. A breach of Clause 15.9 was ruled.

The Panel noted that according to the signed account of the investigation interview, representative A knew that the in-call statement only related to patients established on Symbicort but he/she did not make this clear at the nurse forum meeting in April 2017. In the Panel's view this omission meant that the use of the in-call statement at the meeting was misleading. The Panel ruled a breach of Clause 7.2. The impression that it applied to all patients, including new patients, could not be substantiated and a breach of Clause 7.4 was ruled. In the Panel's view, to mislead the audience in this regard meant that the representative had not maintained a high standard of ethical conduct and a breach of Clause 15.2 was ruled.

The Panel noted that the parties had a different understanding of the agreement reached at the meeting in October in relation to whether and if so how Symbicort would be promoted within the CCG. It was beholden upon the company to be clear in such circumstances about the agreement reached and in this regard it was disappointing and of concern that the outcome had not been agreed in writing between the parties. It was also of the utmost importance that any such agreements were clearly and unambiguously communicated to the field force. The complainant's understanding was that AstraZeneca representatives were not to promote Symbicort to local health professionals as it was not covered by the current guidelines. The Panel accepted that the complainant must have felt strongly about this matter to be moved to complain. The Panel noted that the complainant did not comment on the in-call statement but noted that many patients were stabilised on Symbicort Turbohaler and the CCG did not proactively encourage a review and a switch to DuoResp Spiromax. Representative A was sure he/she was told that the in-call statement only applied to established patients but did not refer to such patients being stable and well-controlled. The Panel noted AstraZeneca's submission that given the in-call statement was not clear about which patients within the CCG Symbicort could be used in, it advocated a course of action which was contrary to the arrangements in place at the CCG and the Panel thus ruled a breach of Clause 15.4.

The Panel noted its comments and rulings above and considered that high standards had not been maintained. The Panel considered that the failure to give clear and unequivocal instructions to representative A was compounded by the fact that the company's stated local promotional strategy was not reflected in the local plan for the CCG and the failure to confirm the outcome of the meeting of October in writing. A breach of Clause 9.1 was ruled.

Complaint received **18 April 2017**

Case completed **12 July 2017**