

# PRIMARY CARE TRUST PHARMACEUTICAL ADVISER v ASTRAZENECA

## Report presented at a meeting

A primary care trust pharmaceutical adviser complained about a report presented at a meeting of local practice managers sponsored by AstraZeneca. The report, 'Budget Impact Model for Asthma & COPD [chronic obstructive pulmonary disease]', related to Symbicort (budesonide/formoterol).

The complainant stated that the local practice managers were concerned that the information presented was contrary to local prescribing guidelines. The complainant alleged that the report appeared to be inappropriate for a group of practice managers who had no responsibility for prescribing budgets.

The Authority told AstraZeneca that it need not comment on the statement that the information was of a clinical nature contrary to local prescribing guidelines as this was not a matter for the Code.

The Panel noted that it was not necessarily unacceptable to provide practice managers with promotional information about medicines so long as the material was appropriate and tailored towards their role.

The presentation highlighted the current prescribing split between the two available combination inhalers, Symbicort and Seretide, using local prescribing data and illustrated the budgetary impact of adopting new treatment strategies for asthma and COPD versus the current strategies. Background information on the local patient population was provided as was the local annual cost saving as a result of a change in prescribing strategies. The report did not discuss clinical data for either product. References to the products were within a budgetary context.

The meeting organisers, the local primary care managers team, had invited an AstraZeneca representative to present the Symbicort budget impact model to twelve local general practice managers. The Panel was concerned that the presentation was not referred to on the agenda – it had been dealt with under matters arising; there was however no complaint on this point. Whilst the chairman had indicated that the model was suitable material for the audience, the Panel noted that it was for AstraZeneca to satisfy itself that the arrangements and material met the requirements of the Code. The Panel considered that the practice managers were appropriate administrative staff for the purposes of the presentation and that the material was tailored towards their needs. No breach of the Code was ruled.

The Panel considered that overall the meeting was an appropriate one to sponsor. The meeting lasted four hours and covered topics relevant to practice management. The costs incurred were reasonable. No breach of the Code was ruled.

The pharmaceutical adviser at a primary care trust complained about a report (ref SYMB 06 P10639) presented in a meeting of local practice managers by a representative from AstraZeneca UK Limited. The report related to Symbicort (budesonide/formoterol) and was titled 'Budget Impact Model for Asthma & COPD [chronic obstructive pulmonary disease]'.

## COMPLAINT

The complainant stated that local practice managers, having attended a meeting sponsored by AstraZeneca, were concerned that the information presented by the representative was of a clinical nature contrary to local prescribing guidelines. The complainant alleged that the report at issue appeared to be inappropriate for a group of practice managers who had no responsibility for prescribing budgets.

The complainant noted that Clause 19.1 discussed the provision of hospitality for appropriate administrative staff and required that meetings should be 'scientific, promotional and other such meetings'. The complainant could not see how the information in the report was appropriate to non-clinical managers.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clause 12.1 of the Code in addition to Clause 19.1 cited by the complainant. The company was informed that it need not comment on the statement that the information was of a clinical nature contrary to local prescribing guidelines as this was not a matter for the Code.

## RESPONSE

AstraZeneca explained that the meeting in question was organised and run by the local primary care managers team; a meeting agenda and list of attendees were provided. The meeting was held at a hospice and the organisers asked a local representative to provide a short presentation on the Symbicort budget impact model to a group of twelve local general practice managers. Prior to the meeting, the chairman had verbally agreed that AstraZeneca could sponsor the meeting and that the Symbicort budget impact model would be suitable to demonstrate to the attendees. AstraZeneca's sponsorship was clearly stated at the top

of the front page of the minutes arising from this meeting. This form of recognition of the sponsor was standard practice for this independent professional group rather than including it on the meeting agenda.

AstraZeneca paid £100 towards the meeting for a standard buffet sandwich lunch, tea and coffee ie £8.33 per head. There were no other costs associated with the meeting. Only appropriate administrative staff were invited to the meeting which had a clear educational content for the local practice managers attending as indicated by the agenda. The venue was appropriate and conducive to the purpose of the event. Subsistence was extended only to appropriate staff and the level of subsistence offered was in proportion to the size of the event and within industry standards. AstraZeneca denied a breach of Clause 19.1.

The chairman of the meeting asked the representative to present for 10 minutes on the Symbicort budget impact model at the beginning of the meeting as indicated in the agenda under matters arising from the minutes of the previous meeting. Symbicort was a combination inhaler therapy licensed for use in asthma and COPD. The Symbicort budget impact model had been developed to engage with appropriate NHS staff on the issue of local affordability. NHS budget holders were under increasing pressure to ensure that scarce resources were allocated efficiently and that spending stayed within their local constrained budgets. It was therefore important for pharmaceutical companies to demonstrate that their products were not only clinically effective but also delivered value for money. The model had been designed to estimate the potential financial impact of adopting Symbicort at a local population level. The model was populated with a default dataset drawn from published studies, national estimates of the prevalence of disease, national sales data and treatment patterns and NHS costs. The model allowed the user to vary a wide number of inputs to examine their effect on the model outputs.

In this particular case the Symbicort budget impact model illustrated the budgetary impact of adopting a particular treatment strategy for asthma and COPD using combination inhaler therapy. The presentation illustrated the current prescribing split between the two available combination inhaler products, Symbicort and Seretide using local prescribing data that provided detail on the volume dispensed of the different formulations of these products. A proposed strategy in terms of adjusting the split between these two combination products for treating asthma and COPD in this prescribing region was then presented. The budgetary impact was then compared of employing this new treatment strategy versus the status quo. The budget impact model was intended solely for an audience that had accountability for administering local prescribing budgets. The representative handed out printed copies of the presentation to attendees so that they could discuss the findings with prescribing colleagues in their respective practices.

The practice managers at the meeting were accountable for their practice budgets. AstraZeneca representatives presented clinical and promotional items to actual

prescribers in these GP surgeries. By presenting the economic argument to the practice managers this involved all key stakeholders in any decision making process, of which the practice manager was part. It was appropriate to discuss financial matters relating to budget impact models to practice managers who were accountable for their practice budgets. One of the many roles undertaken by practice managers was management of practice prescribing budgets through the creation of the practice formulary. They would ensure that all prescriptions were sent to the Prescription Pricing Authority (PPA) on a monthly basis to guarantee that the reimbursement process ran smoothly. Managers could monitor the prescribing habits of the practice and each individual prescriber via Prescribing Analysis and Cost Tabulation (PACT) data provided by the PPA on a quarterly basis. In general, practice managers should be familiar with all aspects of prescribing and the different mechanisms for primary care in the UK. It was therefore appropriate and relevant to present budgetary material to practice managers who had a local responsibility for their own prescribing budgets in their practices. This was also relevant given that Symbicort was listed on the local joint formulary in this particular primary care trust and hence the audience could be assumed to take an interest in this particular information.

AstraZeneca therefore denied a breach of Clause 12.1 of the Code in relation to the presentation and handout of this budgetary material to the practice managers at this meeting.

## PANEL RULING

The Code applied to the promotion of medicines to members of the United Kingdom health professions and to appropriate administrative staff (Clause 1.1). Clause 12.1 and its supplementary information stated that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in the particular information could reasonably be assumed. Promotional material should be tailored to the audience. The Panel noted that it was thus not necessarily unacceptable to provide practice managers with promotional information about medicines so long as the material was appropriate and tailored towards their role.

The Panel noted that the presentation highlighted the current prescribing split between the two available combination inhalers, Symbicort and Seretide, using local prescribing data and illustrated the budgetary impact of adopting new treatment strategies for asthma and COPD versus the current strategies. Background information on the local patient population was provided. The local annual cost saving as a result of a change in prescribing strategies was given as £363,980. The Panel noted that the report did not discuss clinical data for either product. References to the products were within a budgetary context.

The Panel noted that the meeting organisers, the local primary care managers team, had invited the representative to present the Symbicort budget impact

model to twelve local general practice managers. The Panel was concerned that the presentation was not referred to on the agenda – it had been dealt with under matters arising; there was however no complaint on this point. Whilst the chairman had indicated that the model was suitable material for the audience, the Panel noted that it was for AstraZeneca to satisfy itself that the arrangements and material met the requirements of the Code. Nonetheless it was unlikely that a chairman would have asked a representative to talk about irrelevant issues. The Panel noted AstraZeneca's submission about the role and responsibilities of practice managers and considered that they were appropriate administrative staff for the purposes of the presentation and that the material was tailored towards their needs. No breach of Clause 12.1 was ruled.

The Panel considered that overall the meeting was an appropriate one to sponsor in relation to the requirements of Clause 19.1. The agenda indicated that the meeting lasted from 9am to 1pm and covered topics relevant to practice management. The costs incurred of £8.33 per head were reasonable. No breach

of Clause 19.1 was ruled.

During its consideration of this case the Panel noted AstraZeneca's submission that recognition of its sponsorship appeared at the top of the front page of the meeting's minutes rather than on the agenda as this was standard practice for this independent professional group. This did not meet the requirements of Clause 19.3 of the Code and its supplementary information which required that such sponsorship must be disclosed in all papers relating to the meeting and in any published proceeding. The declaration should thus have appeared on the invitation and the agenda. Declaring sponsorship retrospectively in the minutes of the meeting was wholly inadequate; customers' wishes could not override the requirements of the Code. There was, however, no allegation on this point. The Panel thus asked that the company be advised of its views in this regard.

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| <b>Complaint received</b> | <b>19 February 2007</b> |
| <b>Case completed</b>     | <b>3 May 2007</b>       |