CASE AUTH/2037/8/07

PRIMARY CARE TRUST PHARMACEUTICAL ADVISER v TEVA

Promotion of Qvar

The pharmaceutical adviser to a primary care trust (PCT) complained about what had been said by the medical director of Teva at an educational meeting organised by the company. Teva marketed Qvar, a CFC-free beclometasone (BDP) inhaler.

The complainant noted that the discontinuation of Becotide (BDP inhaler) by GlaxoSmithKline and the planned phasing out of CFC-containing BDP inhalers had caused a number of problems in recent months. The launch of Clenil Modulite by Trinity-Chiesi the second CFC-free BDP inhaler on the market had further escalated this problem.

The complainant stated that the problems were currently; the lack of guidance and information of when CFC-BDP would cease to be available, there was no clear guidance of when to switch to CFC-free BDP inhalers; the potency difference between Qvar and Clenil Modulite. Qvar was approximately twice as potent as Clenil and thus CFC-free prescribing required prescribing by brand (it was potentially hazardous if patients received the wrong inhaler); the fact that Qvar was not licensed for use in children under 12 years of age.

The complainant was concerned that at the meeting Teva's medical director had emphasised the following: a requirement to switch to CFC-free BDP due to the phase out of Becotide/Becloforte (this was not currently a requirement) and that there was now no choice but to switch to Qvar or Clenil. This was inaccurate as generic CFC-BDP was still available.

However, the speaker had not referred to the continued availability of generic CFC-BDP, which was quite clearly still a treatment option for patients, or the fact that Qvar was not licensed for use in children. This was a concern when the company was encouraging a therapeutic switch.

The complainant alleged that it was inappropriate and potentially hazardous to patients for a company to encourage a switch to its product when the meeting was advertised as an educational meeting. It was also inappropriate and potentially hazardous to patients, for a company to encourage a switch to a product without highlighting the licensing limitations for children. In response to a question about the licensing, the medical director stated that the issue was with the Medicines and Healthcare products Regulatory Agency (MHRA) and would be licensed imminently. This was speculation and by no means guaranteed, and such information should not be shared in a meeting of health professionals; such a forum should be for factual information and not speculation.

The complainant stated that in response to a question about generic CFC-BDP, the medical director explained that he was unsure of the continued availability of CFC gases and that he did not believe that supplies would exceed 12 months. He also actively discouraged this course of action, which again was inappropriate for this forum. Teva currently marketed CFC-BDP inhalers and the medical director should be in a better position to provide all the information that was required of him, as opposed to providing information that was favourable for the promotion of Qvar. Any discontinuation of a product should require a minimum notice period.

The Panel noted that at the meeting at issue, 'How to Improve Asthma in General Practice', the title of the medical director's presentation was 'Implications of the CFC phase out and the introduction of Beclomethasone CFC Free Alternatives'. The Panel did not accept Teva's submission that the presentation was not promotional. In the Panel's view, although there was an educational content it nonetheless promoted Qvar.

The Panel noted Teva's submission regarding the continued availability of generic CFC-BDP which, although a theoretical possibility, did not appear to be a long-term practical solution to the discontinuation of Becotide/Becloforte. According to Teva no company had applied for a CFC gas allocation in 2008 and so CFC-BDP was expected to be exhausted sooner rather than later. In any event, Teva had submitted that it was unlikely that the current manufacturers of CFC-BDP would be able to fill the gap left by Becotide/Becloforte. Clinicians had no choice but to eventually switch to CFC-free BDP. There was no set date when CFC-BDP would no longer be available. The Panel considered that, in the context of a presentation about the implications of CFC phase out, it was not necessarily misleading to encourage health professionals to plan ahead for a time when CFC-BDP would no longer be available. No breach of the Code was ruled.

The Panel noted that the medical director did not state in his presentation that, unlike Becotide, Qvar was not licensed for use in children under 12. Although, according to Teva, less than 15% of asthmatics were under 12 years of age, this group would nonetheless present clinicians with important practical and clinical considerations as they planned to switch patients to CFC-free BDP. In that regard the Panel considered that, in the context of the presentation at issue, the omission of such information was misleading. A breach of the Code was ruled.

According to the complainant, he had asked the medical director about the use of Qvar in children and received the reply that the issue was with the MHRA and the product would be so licensed imminently. Teva submitted that the medical director had referred to the need to conduct a growth study and that results from that would not be due until the second half of 2008 and following this a paediatric licence would be expected in a short period of time. When asked for more information the medical director had stated that the timing of the regulatory process was not something that could be shared. The medical director had stated that Teva anticipated a successful application process with appropriate timings as Qvar was licensed for use in children in 10 European countries. Nonetheless, the Panel noted that its ruling above that it was misleading not to mention that Qvar was not licensed for children below the age of 12.

The Panel was concerned that the complainant appeared to have been left with the impression that the change in licence to allow paediatric use was imminent. Teva had submitted that it expected the licence to be granted shortly after the completion of the paediatric growth study which was due in the second half of 2008. There appeared to be a difference of opinion.

The answer given to the complainant was in response to an unsolicited enquiry. There was no evidence to show that on the balance of probabilities the answer was not factual and accurate, or that it was either misleading or promotional. The answer could thus take advantage of one of the exclusions to promotion. The Panel did not consider that in this regard Qvar had been promoted for use in children. No breach of the Code was ruled.

The pharmaceutical adviser to a primary care trust (PCT) complained about a meeting organised by Teva UK Limited. Teva marketed Qvar, a CFC-free beclometasone (BDP) inhaler.

COMPLAINT

The complainant noted that the discontinuation of Becotide (a CFC-containing BDP inhaler) by GlaxoSmithKline and the planned phasing out of CFC-containing BDP inhalers had caused a number of problems in recent months. The launch of Clenil Modulite by Trinity-Chiesi the second CFC-free BDP inhaler on the market had further escalated this problem.

The complainant stated that the problems were: currently: the lack of guidance and information of when CFC-BDP would cease to be available, there was no clear guidance of when to switch to CFC-free BDP inhalers; the fact that Qvar was approximately twice as potent as Clenil and thus CFC-free prescribing required prescribing by brand (it was potentially hazardous if patients received the wrong inhaler), and the fact that Qvar was not licensed for use in children under 12 years of age.

The complainant had been concerned about Teva's activities for some time and had tried to deal with the matter locally in the past, as to his knowledge Teva had not broken ABPI rules. In a previous post the complainant had spoken to the marketing manager at length over Teva's sponsorship of a local guidelines meeting.

The complainant had a number of concerns about an educational meeting he had attended in August 2007. The meeting had two speakers, a chest physician and the medical director of Teva.

The complainant was concerned that the latter had emphasised a requirement to switch to CFC-free BDP due to the phase out of Becotide/Becloforte (this was not currently a requirement) and stated that there was now no choice but to switch to Qvar or Clenil. This was inaccurate as generic CFC-BDP was still available.

However, the speaker had not referred to the continued availability of generic CFC-BDP, which was quite clearly still a treatment option for patients and the fact that Qvar was not licensed for use in children. This was a concern when the company was encouraging a therapeutic switch.

The complainant alleged that it was inappropriate and potentially hazardous to patients for a company to encourage a switch to its product when the meeting was advertised as an educational meeting. It was also inappropriate and potentially hazardous to patients, for a company to encourage a switch to a product without highlighting the licensing limitations for children. In response to a question about the licensing, the medical director stated that the issue was with the Medicines and Healthcare Products Regulatory Agency (MHRA) and would be licensed imminently. This was speculation and by no means guaranteed, and such information should not be shared in a meeting of health professionals; such a forum should be for factual information and not speculation.

The complainant stated that in response to a question about generic CFC-BDP, the medical director explained that he was unsure of the continued availability of CFC gases and that he did not believe that supplies would exceed 12 months. He also actively discouraged this course of action, which again was inappropriate for this forum. Teva currently marketed CFC-BDP inhalers and the medical director should be in a better position to provide all the information that was required of him, as opposed to providing information that was favourable for the promotion of Qvar. Any discontinuation of a product should require a minimum notice period.

When writing to Teva, the Authority asked it to respond in relation to Clauses 3.2, 7.2, 7.4, 9.5 and 2.

RESPONSE

Teva was disappointed that a complaint had been made to the Authority as it appeared that in this instance a company could make a verbal statement that was not acceptable to an individual health professional in response to a question in an open forum and

someone could complain without determining the factual position. This complaint related to the questions and statements made by the complainant and not the content of the presentation itself.

Teva was also very disappointed in the complainant's behaviour as it was clear from his questions to the medical director that he required a more detailed discussion, so the medical director offered to continue these discussions with him in private after the public session was concluded. Unfortunately this was not possible as the complainant left immediately after the question session. This was most regrettable as some of the misconceptions included in the complaint could have been answered there and then.

Teva submitted that following the launch of Clenil it had worked closely with the Department of Health (DoH) and the MHRA to try to ensure effective and consistent communication to health professionals to minimise any confusion between products and to ensure appropriate actions were taken. This was because generic prescriptions of CFC-free BDP could potentially result in patients receiving an incorrect dose of BDP as Qvar and Clenil had different relative potencies. Following this realisation Teva conducted market research amongst pharmacists and following submission of these data, the MHRA recommended, in August 2006, that both Clenil and Qvar should be prescribed by brand. Following this, and during Teva's medical director's meetings with health professionals during 2007 it had become increasingly clear that there was limited understanding of the phase out of products containing CFCs and the potential availability of product following the discontinuation of Becotide and Becloforte announced in October 2006.

Teva was very concerned by this low level of awareness and understanding of the situation in general and so it had worked very closely with the MHRA and DoH to determine the best way to communicate with health professionals particularly now that Becotide and Becloforte were no longer available. It was confirmed in a meeting between Teva, the MHRA and the DoH that no company had applied for a CFC allocation for 2008 with the clear implication that products containing CFCs would be exhausted in the early part of 2008. In addition Teva confirmed that some of the components for the inhalers were also in short supply as manufacturing had ceased some time ago.

At this meeting Teva predicted that its product Beclazone MDI would be exhausted in March 2008 and potentially sooner if there was increased demand. Teva estimated that Beclazone Easi-Breathe could be exhausted approximately 12 months later but once again this would be sooner if an increased demand for this product was seen after Becotide was discontinued. This data was contained in the slide presentation made in August which was provided together with the email confirming that it was presented and sent to the above agencies.

It was agreed by all attendees that Teva should increase its educational activities, which included speaker meetings to try to increase health professionals' understanding and awareness of this issue. This was supported by all agencies present. Teva agreed to meet again in September to assess the impact of the Becotide/Becloforte withdrawal during August.

Teva noted that the complainant stated that the planned phase out of CFC-BDP inhalers had caused a number of problems in recent months and that the launch of Clenil Modulite, the second CFC-free BDP on the market, had further escalated this problem. Teva was unaware of any problems in the market place, and as neither of the actions highlighted in this paragraph had been implemented by Teva it did not see that they were relevant to a complaint against it.

Teva noted the complainant's comments that the current problems were:

- Lack of guidance and information. – Teva agreed that this was currently lacking, but guidance could only be given by the MHRA, the DoH and NHS management. Teva had attempted to influence these organisations but it was not within its power to provide guidance to NHS managers in any capacity.

- The 2:1 potency differential between Qvar and Clenil although Teva could not agree that this was a problem as both were administered with the same puff pattern to patients. If the MHRA guidance was followed and the products were prescribed by brand there was no danger of patients receiving the wrong product and this was what the MHRA letter of August 2006 recommended.

- The fact that Qvar was not licensed for use in children younger than 12 years although again Teva did not agree that this was a problem as currently many products were available for use in these children, including Beclazone which was available as an MDI, Autohaler and Easi-Breathe device.

Teva noted that the complainant had been concerned about its activities for some time and had previously tried to deal with the matter locally although to his knowledge Teva had not broken ABPI rules. He also claimed to have spoken to Teva's marketing manager. Teva stated that it had not received any formal complaints from the complainant before this one, and if, as he stated that no ABPI rules were broken, then it submitted that his statement of concern was inappropriate.

In addition Teva confirmed that its marketing manager had not spoken to the complainant; the complainant had interacted with the sales manager in his previous post.

Teva noted the complaint relating to the presentation (provided) by its medical director. This presentation was in three sections:

- The market and costs associated with prescription

of asthma medicines and the provision of healthcare for asthma patients. These data were derived from reputable sources and were correct. These discussions were paramount for the understanding of the transition because if patients were transferred on to more expensive products such as combinations then there would be significant increases in cost to the NHS.

- A review of some of the long-term clinical data for Qvar to make the point that not all BDP formulations had the same effect in patients and this needed to be considered by health professionals when they prescribed products. No long-term clinical studies with Clenil were discussed as no studies had been conducted with end points of symptom free days and quality of life assessments. This had been confirmed in writing by Trinity-Chiesi and copies of these letters had been previously submitted to the committee. Additional copies could be supplied upon request.

- The requirements to prescribe CFC-BDP by brand as the history of these types of guidance had not been well understood by health professionals.

At the end of the presentation the Qvar prescribing information was displayed and summaries of product characteristics (SPCs) were available on request. There was no mention of special patient groups, use outside licence, or dosing etc, as this was not appropriate to the subject and therefore none of the matters contained in the complaint were included in the presentation.

Teva submitted that the subject and content was chosen as this was a subject that was currently under discussion locally and the chairman agreed that there needed to be a greater understanding of the situation so that patients could be managed appropriately in a potential move to CFC-free alternatives. The presentation was clearly structured and was educational in content as defined by addressing a subject of which the audience had little knowledge. Teva therefore submitted that this was not a promotional presentation and was appropriately delivered by its medical director.

Teva noted that the complainant had requested clarification stating that Qvar was not licensed in children under the age of 12 in contrast to Clenil which was so licensed. Teva's medical director agreed that Qvar was not licensed in children and also stated that the complainant's statement that Clenil was licensed in children under the age of 12 was misleading. The medical director answered each part of the question as follows:

Qvar paediatrics – At the meeting with the MHRA in August, Teva's medical director agreed to conduct a growth study as requested and a clinical research organisation had already been selected, a protocol had been written and Teva expected to enrol the first patients in early 2008 with results in the second half of 2008. After that Teva would expect a registration in the UK in a short period of time. Currently the Qvar MDI was approved for use in children in the US and in 10 European countries.

Teva's medical director however stated that Teva anticipated a successful application process with appropriate timings as Qvar was licensed for use in children in 10 European countries. When further pressed by the complainant for additional information, Teva's medical director had stated that this was not possible as the timing of the regulatory process was not something that could be shared.

To ensure a balanced answer Teva's medical director also corrected the complainant's statement that Clenil was licensed for use in children under 12 years of age. Teva's medical director had stated that Clenil was only licensed for use in children under the age of 15 years when using a Volumatic spacer, therefore he suggested that this should be communicated whenever the use of Clenil in children was discussed. Teva's medical director also stated that he had confirmed that this was correct with the MHRA at a recent meeting.

Teva's medical director completed the answer to be fair and balanced by stating that CFC products such as Beclazone MDI, Beclazone Easi-Breathe, Airomir and Aerobec Autohaler were also approved for use in children.

The complainant then asked when Teva would be phasing out Beclazone as this was not yet a requirement under the Montreal Protocol. Teva's medical director's response was the same as that provided to the MHRA and DoH ie at current market usage Beclazone MDI would cease to be available in March 2008 or sooner if there was an increase in demand following the withdrawal of Becotide. Teva was currently re-evaluating the situation and, as stated to the meeting, once this was defined it would communicate the revised information to the chairman for dissemination to the audience. At the meeting Teva's medical director stated that Teva hoped to be able to supply Beclazone Easi-Breathe for a further 12 months after the MDI but once again this depended on whether there was an increase in demand.

The complainant responded that generic products would take up the volume from Becotide and Beclazone. Teva's medical director stated that Beclazone and Becotide represented 80% of the BDP market and only three low volume suppliers were unaccounted for and it was very unlikely that they could supply such a large increase in volume due to their own supply constraints, and as no company had applied for a CFC allocation for 2008 there was no indication that any product of significant size was about to replace CFC-BDP demand and satisfy the current level of generic prescriptions. Therefore once Becotide and Becloforte were discontinued it was likely that they would accelerate the use of remaining stocks of other CFC-BDP products.

When the complainant asked Teva's medical director to be more specific he indicated that Teva would not be able to provide a better estimate until after 10 September and he offered to email or talk to him as soon as this was clear. The complainant did not take up this offer.

The complainant then thanked Teva's medical director for the reply which he took to mean that he agreed; the medical director expected to receive his email address after the meeting, and was therefore surprised to find that the complainant had left without any communication or contact.

Teva's response to some of the complainant's statements were:

A requirement to switch to CFC-free due to the phase out of Becotide/Becloforte (this was not currently a requirement)

Teva submitted that although CFC-BDP therapy had not been reclassified to non-essentiality and thus officially commence a phase out of CFC-BDP, there would be a need to evaluate patients as supplies would no longer satisfy market demand. In view of the time taken to review patients it seemed prudent for physicians and PCTs to develop their plans before product availability was decreased.

Teva concluded that although the statement was correct in the light of the Montreal Protocol it did not reflect the current UK situation as it failed to take into account product availability.

The speaker emphasised that there was now no choice but to switch to CFC-free and the options were Clenil or Qvar. This was inaccurate as generic CFC-BDP was still available

Teva submitted that until recently this statement would have been correct with approximately 50% of CFC-BDP prescriptions satisfied by the Becotide range of products and 30% by the Beclazone range. However, as had been outlined above once these products were exhausted there would not be sufficient replacement products as only three low volume suppliers would remain. Therefore when these products were exhausted patients would need to move to CFC-free alternatives. Clearly there were a number of these options available and were not limited to just Qvar and Clenil.

Teva submitted that generic CFC-BDP was therefore not a long-term option for significant prolongation as insufficient product would be available. Teva therefore regarded the complainant's comment as incorrect and as the answers given by Teva's medical director were factually correct it did not believe that it breached the Code in any way.

There was no mention of continued generic CFC-BDP

Teva submitted that this had been covered above

There was no mention of the fact that Qvar was not licensed in children

Teva submitted that the presentation was about the discontinuation of CFC-BDP and no discussions or claims were made relating to the use of any product in special patient groups. Once again Teva failed to see why the lack of a paediatric licence was a concern for the complainant as Qvar was appropriate therapy for patients aged ≥12 years ie more than 85% of asthmatics. Indeed if minority groups were to be assessed and discussed a totally different lecture would have been required.

Teva submitted that in addition as required by the Code, had any further information been required, the prescribing information was shown on the last slide and its medical director would have happily discussed this with any of the delegates on request, and he confirmed that the SPC was available at the meeting.

It was inappropriate to encourage a switch to the sponsor's product when the meeting was advertised as an educational meeting

Teva submitted that the purpose of an educational meeting was to impart knowledge to an audience of which they previously had little information. The presentation contained significant data regarding the phase out of CFCs and was well received by the audience and the chairman found the content most interesting. Teva's medical director did not advocate a switch to Qvar as this would have been clearly inappropriate, he did however indicate that, in the next six months or so, patients receiving CFC-BDP would need to have their therapy reviewed and changed to a CFC-free alternative. Teva's medical director did not advocate a switch to Qvar but he did contend that UK health professionals now needed to consider the therapeutic strategies as availability of CFC-BDP would decline rapidly.

Paediatric licence

Teva failed to understand the complainant's comment relating to the paediatric indication on several accounts. Firstly as stated before, Teva's medical director did not suggest that a licence would be granted imminently. Secondly, as the product was already licensed in children below 12 in ten European countries and also in the US it would be very unusual if Teva was unable to obtain approval in the UK – although no guarantee could be given. Teva would follow the process agreed with the MHRA and conduct the paediatric growth study, after which it had every confidence that a licence would be granted.

Teva submitted that as the reply was given in response to questions from the complainant it clearly was not a promotional message and as the statement was factually correct and reflected agreements with the MHRA it did not contravene the Code.

Paediatric therapies within the presentation

Teva submitted that this was a short presentation relating to the phase out of CFC-BDP and it was not appropriate to discuss special patient populations and unlicensed indications such as doses in children.

Teva submitted that if its medical director had included children he would have had to discuss not only Qvar but also the issues relating to Clenil having a licence in children less than 15 years (not the 12 years

for Qvar as was the usual age in the asthma therapeutic guideline in the UK and US) and that Clenil was only approved for use in this group when prescribed with a Volumatic spacer. To discuss these details and other important differences between the products would have required a totally different presentation and this was not the subject of the meeting.

Teva submitted that its medical director was, however, able to provide factual answers to the complainant's questions and therefore rejected that these answers were speculative as claimed.

They were based on sound agreements with the MHRA and clinical research organizations and the details of the clinical trial programme that were discussed with the audience were as agreed with the MHRA. Teva submitted that it was appropriate to respond to questions in this factual manner as it was an educational meeting and indeed if its medical director had failed to do so Teva expected the complainant would have called him evasive. Teva therefore submitted that the presentation could not be regarded as promotional and this and the answers to this question did not breach the Code.

Switch of patients to Qvar

Teva submitted that its medical director did not state that products would have to be switched but he did state that if there was no CFC-BDP product available then alternative strategies would need to be employed and owing to the large number of patients, and manufacturing lead times, it was now time to consider those options. Although the complainant would like to believe that generic CFC-BDP would remain a viable alternative it was simply not the case and owing to the large number of patients any remaining CFC-BDP supplies were likely to be exhausted sooner than expected.

Teva's medical director had agreed that it would communicate the position as soon as it could define it after 10 September when August data would be available. The position had not changed and Teva would be communicating with the chairman of the meeting as agreed.

Discontinuation of products in the UK

Teva agreed with the complainant's comments about a minimum period. The period of notification required was only 3 months and there was no specific requirement to notify the market any sooner. Teva therefore had no requirement at present to formally notify the heath professions until December 2007.

Meeting audience

Teva submitted that the meeting was attended by 96 local health professionals (56 general practitioners, 29 nurses, 4 hospital doctors and 7 PCT and managerial staff) which was an indication that the subject of the meeting was of great interest.

Review of the specific clauses of the Code

Teva submitted that the meeting was well balanced and the presentations were accurate and the questions were answered accurately and factually, it therefore denied a breach of Clause 2.

No unsolicited mention was made of any unauthorised indications in the educational presentation. When Teva's medical director was questioned about the paediatric licence the responses were accurate and reflected the company's agreement with the MHRA following its meeting in August. Teva therefore denied a breach of Clause 3.

All data already presented to the MHRA, DoH and the costs and market data in the presentation were derived from Teva's recent submission to the National Institute for Health and Clinical Excellence (NICE) health technology assessment. Teva therefore submitted that all data were validated and correct; none of the information provided at the meeting was in breach of Clause 7.2.

Teva submitted that the comparisons made were from data contained in the relevant SPCs for Qvar, Clenil and Becotide and were therefore correct. The comparison therefore did not breach Clause 7.4.

Teva submitted that the presentation was detailed, contained data that the audience had not seen before and provided up-to-date and accurate information about the CFC phase out and prescribe by brand recommendations from the MHRA for CFC-free products. All questions were answered factually with data that had already been agreed with the MHRA and DoH and no misleading or evasive statements were made. Teva therefore submitted that the meeting upheld high standards. The company thus denied a breach of Clause 9.1.

Conclusion

Teva was very disappointed that the complainant had complained in this manner without establishing whether his beliefs or claims were credible and correct. The company was also concerned that the complainant had based his complaint on answers given in response to his own questions. The responses accurately reflected validated data presented to two government agencies and were therefore correct.

Teva therefore concluded that:

- The presentation given by Teva's medical director was educational in content and was fair, balanced and appropriate for the audience that attended
- The audience was appropriate and consisted of health professionals
- The situation reflecting CFC phase out was accurately stated
- The process by which Teva expected to receive regulatory approval in the UK was accurately stated and the audience was not led to believe that it was imminent as it was stated that the study would end in the second half of 2008 and this was a necessary step before any licence could be granted.

Teva submitted that neither the meeting nor any of the answers to the complainant's questions breached any of the clauses of the Code including Clauses 2, 3.2, 7.2, 7.4 and 9.1.

PANEL RULING

The Panel noted that the meeting at issue, 'How to Improve Asthma in General Practice', which had been sponsored by Teva, featured two speakers one of whom was the medical director for Teva UK Ltd. The title of the medical director's presentation was 'Implications of the CFC phase out and the introduction of Beclomethasone CFC Free Alternatives'. A copy of the presentation, with notes, was provided.

The Panel noted Teva's comments that the complaint concerned questions and statements made by the complainant and not the content of the presentation. The Panel did not consider that it was necessarily unacceptable to make a complaint on this basis. The questions had arisen as a result of material included or not included in the presentation.

The Panel did not accept Teva's submission that the medical director's presentation was not promotional. In the Panel's view, although there was an educational content it did promote the prescription, supply, sale or administration of Qvar and thus met the definition of promotion (Clause 1.2 of the Code). The presentation concluded with a slide showing the Qvar prescribing information.

The Panel noted Teva's submission regarding the continued availability of generic CFC-BDP, which although a theoretical possibility, did not appear to be long-term practical solution to the discontinuation of Becotide/Becloforte. According to Teva no company had applied for a CFC gas allocation in 2008 and so CFC-BDP was expected to be exhausted sooner rather than later. In any event, Teva had submitted that it was unlikely that the current manufacturers of CFC-BDP would be able to fill the gap left by Becotide/Becloforte. Clinicians had no choice but to eventually switch to CFC-free BDP. There was no set date when CFC-BDP would no longer be available. According to Teva's presentation the company anticipated that over the next few years only CFC-free products and dry powder devices would be permitted. The Panel considered that, in the context of a presentation about the implications of CFC phase out, it was not necessarily misleading to encourage health professionals to plan ahead for a time when CFC-BDP would no longer be available. No breach of Clauses 7.2 and 7.4 was ruled.

The Panel noted that the medical director did not state in his presentation that, unlike Becotide, Qvar was not licensed for use in children under 12. Although, according to Teva, less than 15% of asthmatics were under 12 years of age, this group would nonetheless present clinicians with important practical and clinical considerations as they planned to switch patients to CFC-free BDP. In that regard the Panel considered that, in the context of the presentation at issue, the omission of such information was misleading. A breach of Clause 7.2 was ruled.

The Panel noted that, according to the complainant, he had asked the medical director about the use of Qvar in children and received the reply that the issue was with the MHRA and the product would be so licensed imminently. Teva submitted that the medical director had referred to the need to conduct a growth study and that results from that would not be due until the second half of 2008 and following this a paediatric licence would be expected in a short period of time. When asked for more information the medical director had stated that the timing of the regulatory process was not something that could be shared. The medical director had stated that Teva anticipated a successful application process with appropriate timings as Qvar was licensed for use in children in 10 European countries. Nonetheless, the Panel noted that its ruling above that it was misleading not to mention that Qvar was not licensed for children below the age of 12 and that the use of Qvar in children was discussed in response to an unsolicited enquiry.

The Panel was concerned that the complainant appeared to have been left with the impression that the change in licence to allow paediatric use was imminent. Teva had submitted that it expected the licence to be granted shortly after the completion of the paediatric growth study which was due in the second half of 2008. There appeared to be a difference of opinion.

The Panel considered that the answer given to the complainant was in response to an unsolicited enquiry. There was no evidence to show that on the balance of probabilities the answer was not factual and accurate, or that it was either misleading or promotional. The answer could thus take advantage of one of the exclusions to promotion given in Clause 1.2 of the Code. The Panel did not consider that in this regard Qvar had been promoted for use in children. No breach of Clause 3.2 was ruled.

The Panel noted its rulings above and did not consider that overall high standards had not been maintained. No breach of Clause 9.1 was ruled. The Panel did not consider that the matter warranted a ruling of a breach of Clause 2 of the Code which was a sign of particular censure and reserved for such use.

Complaint received 17 August 2007

Case completed 30 October 2007