ANONYMOUS, NON-CONTACTABLE HEALTH PROFESSIONAL v ABBVIE

Promotion of Synagis

An anonymous, non-contactable complainant complained about a meeting held by AbbVie in May 2018. The day-long meeting was a BPD (bronchopulmonary dysplasia) Masterclass which, *inter alia*, discussed the use of Synagis (palivizumab) marketed by AbbVie. Synagis was indicated for the prevention of serious lower respiratory tract disease requiring hospitalization caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease.

The complainant had decided to go after careful consideration of the detailed agenda sent to him/her by the AbbVie representative. The complainant stated that one of the sessions, however, was cut considerably short and the named representative used the time to forcefully interrogate the audience about their prescribing habits and their views on immunising infants outside of both the Joint Committee on Vaccination and Immunisation (JCVI) guidance and the product licence, namely twins. The complainant stated that the representative's conduct made him/herself and other members of the audience feel uncomfortable and had left him/her feeling that this was completely inappropriate and questioning the intent of the meeting. It was inappropriate for a representative to initiate group discussions about the off-licence prescribing habits of clinicians and he/she left the meeting perplexed about the possibility of any hidden agenda.

The detailed response from Abbvie is given below.

The Panel noted AbbVie's submission that there was some correlation between the events described in the complaint and what occurred at the meeting. AbbVie suspected that the presentation in question was 'The Real Impact of RSV – Think About What You Can't See', which addressed the factors that put children at risk of RSV, in particular BPD and prematurity, and included a discussion of the JCVI Guidelines.

The Panel noted that according to AbbVie the health professional completed the presentation in around 35 minutes, rather than the hour allocated; the presentation was not deliberately cut short by AbbVie. The remaining 25 minutes were questions from the audience, many of which related to AbbVie-specific information and were answered by the AbbVie representative. The Panel noted AbbVie's submission that its representative facilitated further discussion on topics related to the presentation including the use of Synagis in premature twins and multiples.

The Panel considered that according to the SPC each child that was part of a twin or other multiple birth might potentially meet the licensed criteria for Synagis. The Panel noted AbbVie's submission that that the preceding presentation listed multiple births as a risk factor for RSV and the discussion was limited to premature twins and using Synagis within the scope of its licence.

In the Panel view the complainant's allegation regarding out of license discussion 'namely twins' was not specific. The Panel considered that the complainant had not provided evidence to show that Synagis had been promoted outside of its licensed indication as alleged and thus no breach of the Code was ruled.

An anonymous, non-contactable complainant complained about a meeting held by AbbVie Ltd at a hotel in London in May 2018. The day-long meeting was a BPD (bronchopulmonary dysplasia) Masterclass which, *inter alia*, discussed the use of Synagis (palivizumab) marketed by AbbVie. Synagis was indicated for the prevention of serious lower respiratory tract disease requiring hospitalization caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. One group of children who would be indicated for Synagis treatment were those born at 35 weeks gestation or less and less than 6 months of age at the onset of the RSV season.

COMPLAINT

The complainant submitted that he/she had attended the meeting at issue, which had been organised by the local named AbbVie representative, to gain additional insight and knowledge on BPD. The complainant had decided to go after careful consideration of the detailed agenda sent to him/her by the representative. The complainant stated that one of the sessions, however, was cut considerably short and the named representative seized the opportunity to use the time to forcefully interrogate the audience about their prescribing habits and their views on immunising infants outside of both the Joint Committee on Vaccination and Immunisation (JCVI) guidance and the product licence, namely twins. The complainant stated that the representative's conduct made him/herself and other members of the audience feel uncomfortable and had left him/her feeling that this was completely inappropriate and questioning the intent of the meeting and whether he/she would consider any future meetings facilitated by AbbVie.

The complainant considered that it was inappropriate for a representative to initiate group discussions about the off-licence prescribing habits of clinicians and he/she left the meeting perplexed about the possibility of any hidden agenda.

When writing to AbbVie, the Authority asked it to consider the requirements of Clauses 3.1 and 3.2 of the Code.

RESPONSE

AbbVie submitted that the vague nature of the complaint gave it reason to believe that it was not genuine. The substance of the complaint was contained in a single sentence in which it was alleged that one of the meeting sessions was cut short and the AbbVie representative 'seized the opportunity to use the time to forcefully interrogate the audience regarding their prescribing habits and their views on immunising infants outside of both JCVI guidance and product licence namely twins'.

Other than the passing reference to twins, the complainant provided no details as to the alleged breach of the Code. If this were a genuine complaint, AbbVie would have expected the complainant to specify the practices allegedly discussed by the representative and how/why they fell outside of both JCVI guidance and product licence. Furthermore, the complainant waited for nearly two months after the meeting to submit the complaint. If the complainant was genuinely concerned about the meeting, AbbVie would have expected him/her to act more quickly.

AbbVie submitted that there was some correlation between the events described in the complaint and what occurred at the meeting. However, the lack of detail in the complaint, the delay in making it and the discrepancies between the events described in the complaint and reality suggested that the complainant was not present at the meeting.

AbbVie had discussed the matter with the representative in question and his/her line manager, who were the only AbbVie personnel at the meeting in question. AbbVie had also reviewed the related documents.

BPD Masterclass

AbbVie explained that Synagis was a monoclonal antibody which provided passive immunity to respiratory syncytial virus (RSV) in infants. The Synagis summary of product characteristics (SPC) listed three therapeutic indications for Synagis, covering three categories of children who were deemed to be at a high risk of contracting RSV:

i) premature babies who were less than six months old at the onset of RSV season (October);
ii) children who were less than two years old with bronchopulmonary dysplasia (BPD); and
iii) children who were less than two years old with haemodynamically significant congenital heart disease (CHD).

The BPD Masterclass was a promotional meeting organised and funded by AbbVie. The purpose was to bring paediatric and neonatal communities together to share and discuss hot topics in the current management of BPD and ensure continued optimal patient care. As explained above, children with BPD were one of the three populations included in the licensed indications for Synagis.
The Masterclass consisted of a mixture of talks and panels/Q&A sessions on topics related to BPD, led by various expert health professionals engaged by AbbVie. The attendees were paediatric and neonatal nurses and consultants. The representative and line manager both confirmed that the meeting appeared to be well-received on the day. This was confirmed by the attendees' feedback scores. The attendees were asked to score each session between 1 and 5 for 'Quality of Content', 'Relevance to You', and 'Improvement of Knowledge', and virtually every session averaged at least 4 out of 5 in each category. No complaints or concerns were raised by any attendee on the day and nor were any concerns recorded in the feedback documents (copies provided).

The alleged comments made by the representative

Although the complainant did not state which session of the Masterclass had been cut short, AbbVie suspected that it was the one entitled 'The Real Impact of RSV – Think About What You Can't See'. The slides for this session were provided. The presentation addressed the factors that put children at risk of RSV, in particular BPD and prematurity, and included a discussion of the JCVI Guidelines and what categories of patients fell within their scope.

The health professional completed the presentation in around 35 minutes, rather than the hour allocated, however if the complainant was alleging that AbbVie deliberately cut the presentation short, this was not so. The remaining 25 minutes of the session were filled by questions from the audience. Many of the questions related to AbbVie-specific information (eg the pricing of Synagis) and were not able to be answered by the presenter. The AbbVie representative responded appropriately to these questions and facilitated further discussion within the group on topics related to the presentation. There was no evidence that the representative 'forcefully interrogated the audience' and this was disputed by AbbVie.

Among the topics raised for discussion by the representative was that of the use of Synagis in twins and multiples. It was made clear that this was for premature twins and multiples. As stated in the response to Case AUTH/2997/12/17, the Code did not prohibit the promotion of medicines within their marketing authorisation but that were not funded by NHS England (to which the JCVI Guidelines related).

Since premature twins or multiples could fall within the indications listed in the Synagis SPC, discussion of this topic initially raised by the representative did not inherently constitute a breach of Clauses 3.1 or 3.2 of the Code. The discussion was limited

to premature twins and to using Synagis within the scope of its licence. AbbVie noted that the preceding presentation listed multiple births as a risk factor for RSV and so it would therefore have been a reasonable topic for discussion in the context of the meeting.

AbbVie noted the complainant's comments that he/she and other members of the audience felt uncomfortable with the representative's conduct. However, as noted above, none of the attendees complained at the time and they appeared happy to discuss this topic. The feedback for this particular session was positive, as was the feedback for the other sessions.

Conclusion

For the reasons set out above, AbbVie seriously doubted whether the complaint was genuine. Furthermore, it was strongly of the view that the complainant had not and could not discharge the burden of proof due to the vague nature of the complaint. As such, the case should not proceed. Despite this primary position, AbbVie stated that it took its obligations to comply with the Code very seriously and had thus responded in detail as set out above.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. Like all complaints, anonymous complaints were judged on the evidence provided. The complainant bore the burden of proving his/her complaint on the balance of probabilities.

The Panel noted AbbVie's submission that there was some correlation between the events described in the complaint and what occurred at the meeting. Whilst the complainant had not identified the presentation AbbVie suspected that the presentation in question was 'The Real Impact of RSV – Think About What You Can't See', which addressed the factors that put children at risk of RSV, in particular BPD and prematurity, and included a discussion of the JCVI Guidelines and what categories of patients fell within their scope.

The Panel noted that according to AbbVie the health professional completed the presentation in around 35 minutes, rather than the hour allocated; the presentation was not deliberately cut short by AbbVie. The remaining 25 minutes of the session were filled by questions from the audience, many of which related to AbbVie-specific information and were therefore answered by the AbbVie representative. The Panel noted AbbVie's submission that its representative facilitated further discussion within the group on topics related to the presentation including the use of Synagis in premature twins and multiples.

The Panel noted that the promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its summary of product characteristics. The Panel noted that the Code did not state that a medicine must be promoted in a manner that was consistent with JCVI guidance as implied by the complainant. It did however, require that all information, claims and comparisons must be accurate and must not be misleading either directly or by implication, by distortion, exaggeration or undue emphasis.

The Panel noted that according to its SPC, Synagis was indicated for the prevention of serious lower respiratory tract disease requiring hospitalisation caused by RSV in children at high risk for RSV disease:

- children born at 35 weeks of gestation or less and less than 6 months of age at the onset of the RSV season
- children less than 2 years of age and requiring treatment for bronchopulmonary dysplasia within the last 6 months
- children less than 2 years of age and with haemodynamically significant congenital heart disease

The Panel considered that each child that was part of a twin or other multiple birth might potentially meet the licensed criteria for Synagis. The Panel noted AbbVie's submission that that the preceding presentation listed multiple births as a risk factor for RSV and the discussion was limited to premature twins and using Synagis within the scope of its licence.

The Panel noted the complainant's allegation that the discussion was both out of licence and outside of the JCVI guidance. The Panel noted its comments above in this regard. The complainant referred to twins but otherwise gave little detail about his/her concerns. The Panel considered that the complainant had not provided evidence to show that Synagis had been promoted outside of its licensed indication as alleged and thus no breach of Clauses 3.1 and 3.2 was ruled.

Complaint received **29 June 2018**

Case completed **14 November 2018**