CASE AUTH/2997/12/17

ANONYMOUS HEALTH PROFESSIONAL v ABBVIE

Promotion of Synagis

A contactable, anonymous complainant who described him/herself as a 'very concerned' health professional complained about the presentation of Synagis (palivizumab) clinical data by an AbbVie representative at a meeting. Synagis was indicated for the prevention of serious lower respiratory tract disease requiring hospitalisation caused by respiratory syncytial virus (RSV) in children at high risk for RSV disease.

The complainant explained that at the meeting a number of health professionals gave presentations and an AbbVie representative talked about congenital heart disease (CHD) and presented specific case studies of patients who had various CHD complications together with reasons why they should be put forward for prophylaxis with Synagis. The case study slides appeared to be added into the presentation outside the medical approval process. A request for a copy of the case studies was refused. In the complainant's view, AbbVie was trying to influence the audience to prescribe Synagis to all CHD patients outside the NHS England (NHSE) Guidelines. The claims on the slides did not refer to any published data or local audits.

The complainant stated that having a representative presenting medical case studies and subsequent outcomes, completely reduced his/her confidence in the pharmaceutical industry and discredited the content of the whole educational event.

The detailed response from AbbVie appears below.

The Panel noted that the representative had delivered a promotional presentation on CHD which was certified as such and included a single case study at the end.

The Panel noted AbbVie's submission that a 'Pathways' document, a set of three scenarios, was used in the meeting. The scenarios were printed and left on tables during the session for discussion and were not formally presented as inferred by the complainant. Each scenario described a patient and then asked five questions about RSV immuno-prophylaxis and the use of Synagis.

The Panel noted that it was not unacceptable for a representative to discuss and present case studies as alleged, provided that the manner in which it was done complied with the Code. The Panel considered that there was no evidence that by allowing the representative to present and/or facilitate a discussion on the three scenarios within the Pathways document the representative or the company had failed to maintain high standards. No breach of the Code was ruled.

The Panel was concerned to note that the meeting organisers did not consider the Pathways document was promotional thus requiring certification. As the document had

not been certified, a breach of the Code was ruled as acknowledged by AbbVie. A robust certification procedure underpinned self-regulation and the failure to recognise the promotional nature of the document and therefore that it required certification, meant that AbbVie had failed to maintain high standards and a breach of the Code was ruled.

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 (SPC). The Panel noted the allegation that in the complainant's view, AbbVie was trying to influence the audience to prescribe Synagis to all CHD patients outside NHSE Guidelines. The Panel noted, however, that the Code did not state that a medicine must only be promoted in a manner that was consistent with NHSE Guidelines although it did 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 AbbVie's submission about the most recently published NHS commissioning arrangements for Synagis and the Joint Committee on Vaccinations and Immunisation (JCVI) recommendations on RSV and Synagis. The Panel noted that an undated, unsigned NHSE commissioning arrangements letter listed children over 2 years old as being not acceptable under the guidance for treatment due to little or no evidence for RSV prophylaxis. The JCVI document on RSV only referred to the use of Synagis in infants under 2 years of age. This was reflected in the presentation in question which referred to NHSE Guidance of November 2016 in relation to co-morbidities associated with CHD. The Panel noted that within a preceeding section 'Burden of RSV in CHD' one slide stated that 'Of 1806 US children aged under 5 years who died with bronchiolitis between 1979 and 1997, 9.9% had CHD'. The Panel was concerned about this statement in a promotional presentation noting Synagis' licensed indication. The Panel noted that other slides made it clear that data related to those aged less than 2 years, babies or small neonates. The Panel noted that the three scenarios in the Pathways document clearly referred to infants born in 2017. The Panel, whilst noting its concern above, did not consider that a general statement about the prevalence of CHD in patients under 5 years with bronchiolitis, within an introductory section about risk factors for CHD, was misleading or otherwise qualified the subsequent reference to NHSE Guidelines within section 'JCVI Guidelines for CHD'. The Panel noted the narrow allegation and did not consider that the complainant had established that AbbVie was trying to misleadingly influence the audience to prescribe Synagis to all CHD patients outside the NHSE Guidelines as alleged. No breach was ruled.

The Panel noted the complainant's general allegation that the claims on the slides did not refer to published data or local audits conducted including the outcomes of prophylaxis with the said patient cohort. The complainant had not provided any material to support his/her allegations in this regard and it was not clear which claims he/she considered required references to published data or local audits as alleged. It was not for the Panel to make out a complainant's allegation. The Panel thus ruled no breach of the Code.

The Panel noted its comments and rulings above and did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

A contactable, anonymous complainant, who described him/herself as a 'very concerned' health professional, complained about the presentation of clinical data about the use of Synagis (palivizumab) by an AbbVie representative at a meeting held on 15 September 2017 at a named hospital. Synagis was indicated for the prevention of serious lower respiratory tract disease requiring hospitalisation caused by respiratory syncytial virus (RSV) in children at high risk for RSV disease. The title of the meeting was 'Mini Embrace 2017, Empower, Educate & Engage'.

COMPLAINT

The complainant explained that at the hospital meeting, a number of health professionals gave presentations on various topics. Additionally, an AbbVie representative, who the complainant recalled was accompanied by his/her manager, delivered a talk on congenital heart disease (CHD). The complainant stated that the agenda for the meeting (ref AXSYN170496c) was prepared in April 2017.

In addition to the above, the complainant noted that the representative presented slides of specific case studies of patients who had various CHD complications together with reasons why they should be put forward for prophylaxis with Synagis. The complainant stated that he/she was appalled that AbbVie had put forward a representative to discuss and present clinical case studies. The case study slides did not appear to have any preparation codes displayed on them and appeared to be added into the presentation outside the medical approval process.

During the presentation, the complainant requested a copy of the case studies but was told they could not be shared. The complainant stated that in his/her view, AbbVie was trying to influence the audience to prescribe Synagis to all CHD patients outside the NHS England (NHSE) Guidelines. The claims on the slides did not refer to any published data or local audits conducted including the outcomes of prophylaxis with the said patient cohort.

The complainant stated that a representative presenting medical case studies and subsequent outcomes completely reduced his/her confidence in the pharmaceutical industry and discredited the content of the whole educational event; he/she would not be attending such meetings in the future.

In writing to AbbVie the Authority asked it to consider the requirements of Clauses 2, 7.2, 7.4, 9.1, 14.1 and 15.2 of the Code.

RESPONSE

AbbVie strongly refuted any suggestion that its alleged actions constituted a breach of Clause 2 (or indeed other clauses referred to by the Authority) and noted that it took its compliance and ethics obligations under the Code very seriously. AbbVie stated that in its view, the conduct of the meeting and the materials were appropriate; there was insufficient evidence to enable the complainant to discharge the burden of proof on the balance of probabilities.

AbbVie stated that the precise focus of the complaint and the specific case studies referred to by the complainant were unclear. Given this uncertainty, it had been hard to respond to the complaint but the company had addressed the pieces that it believed it could relate to below.

AbbVie noted that the complaint was submitted over 3 months after the meeting in question; in its view, a 'very concerned' health professional would have complained shortly after the meeting if he/she had genuine compliance concerns.

AbbVie stated that as part of its investigation, it had extensively interviewed the representative concerned and his/her line manager who also attended the meeting in question. The company did not accept the conduct and behaviours as alleged.

AbbVie provided a copy of the final agenda for the meeting along with the signed attendance sheet. The objective was to hold an educational meeting for health professionals to encourage discussion and best practice sharing before the RSV season started, which was usually between October and March. AbbVie's representatives' briefing material was provided which outlined the role of the representative during these meetings and the importance of compliance with the Code.

Based on its investigation, AbbVie did not consider that the complainant could prove, on the balance of probabilities, that he/she was at the meeting in question. Furthermore, it was AbbVie's view that nothing in the meeting discredited the industry. If the complainant was not at the meeting, then there was no basis for him/her to complain about the representative's conduct, nor to suggest that the meeting could be in breach of Clause 2.

AbbVie stated that there were a number of inaccuracies within the complaint to support its view that the complainant had not been at the meeting:

- The complaint stated the meeting ran from 9:30am-2:45pm. The final agenda, and save-the-date invitation (copies provided), showed that the meeting actually took place between 10am and 3:30pm on 15 September 2017. The draft agenda, which was not circulated to attendees, showed that the meeting was initially due to run between 9:30am and 2:45pm (copy provided).

- The preparation code (AXSYN170496c) cited by the complainant was that of the draft agenda not of the final document (ref AXSYN171184), the 'published agenda' had a preparation code. However, the final agenda had a different reference code. The draft agenda was not circulated to attendees.

- The complainant focussed on a number of presentations and specifically referred to a 'talk on CHD' and some 'specific case studies of patients who had various CHD complications'. These were referred to by the complainant as 'clinical case studies'. AbbVie provided copies of what it believed were the presentations at issue; 'CHD – What is a significant comorbidity?' and a Pathways document. The company submitted that it was most likely that the scenarios in the latter document were the focus of the complaint. This document was not a set of clinical case studies but hypothetical scenarios that were printed out and put on the tables to prompt discussion during the AbbVie facilitated workshop. The complainant's lack of precision about the materials supported the contention that he/she was not at the meeting.

- AbbVie stated that the complainant's statement that he/she requested a copy of the clinical case studies did not accord with its investigation which confirmed that no-one

at the meeting requested copies of either 'CHD – What is a significant comorbidity?' or of the Pathways document.

AbbVie referred to Clause 15.2 that, 'Representatives must at all times maintain a high standard of ethical conduct in the discharge of their duties and must comply with all the relevant requirements of the Code'. The points above undermined the credibility of the alleged breach of this clause. If the complainant was not at the meeting, then he/she could not make this allegation and the meeting could not have 'completely reduced' his/her confidence in the pharmaceutical industry and 'discredited the content' of the event.

AbbVie submitted that if the complaint was focussed on the presentation 'CHD – What is a significant comorbidity?', then this was given at the meeting by the representative and there was one case study included at the end of it.

The primary intention of the meeting was to clarify the profiles of babies that fell within the Department of Health's (DoH's) Joint Committee for Vaccination and Immunisation (JCVI) recommendations for infants who would benefit from prophylaxis with Synagis. The case study reinforced a patient profile of a baby falling within the JCVI recommendations rather than making claims about the product. In this case study the baby, who received Synagis, had no RSV illness during the RSV season. As part of the introductory slide to the case study, it quite clearly stated that 'this case study is representative only and individual patient response may vary'. As the case study was for illustrative purposes only, and there were no claims, there was no need for references.

Although the presentation in question was originally planned to be delivered by an external speaker, the final agenda sent to attendees made it known that the representative would present the session on CHD. It was not inappropriate, as alleged, for a representative to present the session. The representative who gave the presentation and facilitated the case study was suitably qualified to do so.

AbbVie stated that the meeting was promotional and the presentation was certified as such. AbbVie provided a copy of the approval certificate, details of the certifier's experience and qualifications and a list of supporting references.

AbbVie stated that, in its view, there had been no breach of the Code as the presentation was balanced, fair, substantiated and certified for use at a promotional meeting. The company referred to its comments above about Clause 15.2.

AbbVie noted that the Pathways document was a set of scenarios used within the patient centred communication element of the meeting which was an AbbVie-facilitated workshop.

These slides were not clinical case studies but on-label scenarios used in a workshop to address the challenges faced in ensuring babies, identified for RSV prophylaxis with Synagis, and who fell under the care of more than one unit during their early care, were appropriately followed-up and brought forward for Synagis injections at the start of the next year's RSV season. This could be challenging as Synagis injections might not be initiated for some months after the baby was discharged from the care of the physician who had identified the need for RSV prophylaxis. AbbVie stated that no claims were made in the text of the three scenarios or subsequent questions and there was no need to refer to published data as the complaint suggested.

AbbVie explained that during the session, attendees were divided by tables, every table had to discuss the scenarios, ask questions and then each health professional would provide feedback. The scenarios were printed and left on tables during the session for discussion and were not formally presented by a speaker. AbbVie submitted that there was no evidence to support the complainant's allegation that the scenarios were used to promote 'Synagis to CHD patients outside the NHSE Guidelines'; AbbVie noted that the Code did not prohibit the promotion of medicines that were not funded by the NHSE. Notwithstanding this, in the case of each of the three scenarios in the workshop, the decision as to whether Synagis use would be appropriate was left to workshop participants.

The JCVI recommendations on RSV identified three distinct groups of patients for which Synagis was recommended. The JCVI recommendations also allowed Synagis to be considered in a fourth group of babies 'where clinical judgement of other individual patient circumstances strongly suggest that prophylaxis would prevent serious RSV infection in infants who are at particular risk of complications from RSV'. The health professionals attending the workshop would have been fully aware of the content of the JCVI recommendations which were covered in the preceding session.

AbbVie stated that the most recently published NHS Commissioning arrangements for Synagis stated upfront that 'the policy to support the commissioning of palivizumab to reduce the risk of RSV in High Risk Infants for the 2017 vaccination season remains under the remit of Public Health England and the policy guidance is contained in the Green Book (Immunisation against Infectious Diseases) Chapter 27a'. Chapter 27a of the Green Book constituted the JCVI recommendations for RSV which, as stated above, allowed for clinical judgement on whether RSV prophylaxis with Synagis was appropriate. Against this background, it was relevant and appropriate to have the health professionals attend the workshop to discuss and agree whether, in their clinical judgement, prophylaxis with Synagis was appropriate for each clinical scenario. Given that the discussion was led by the health professionals and that no conclusion was drawn by AbbVie employees who facilitated the session, there was no evidence to support the complainant's statement that the scenarios were used to promote 'Synagis to CHD patients outside the NHSE Guidelines'.

AbbVie stated that, in its view, there had been no breach of the Code as the scenarios were for discussion only; no claims or comparisons were made.

AbbVie did, however, recognise that the document was not certified. As explained above, the intention of the document was not to promote Synagis, although it was used in the context of a promotional meeting and so this was a potential breach of Clause 14.1. It appeared that the document was not certified as the AbbVie meeting organisers considered it to be non-promotional. The relevant team members were being re-trained on this aspect of the Code.

In conclusion, AbbVie had serious concerns about the intention behind this complaint. Without prejudice to this, it did not believe there was sufficient evidence to discharge the burden of proof on the balance of probabilities.

PANEL RULING

The Panel noted that AbbVie accepted that the employee in question, who presented at the meeting, an account specialist, was a representative as defined by the Code and that the

meeting was promotional in nature. The representative had delivered a presentation entitled 'CHD – What is a significant comorbidity?' (ref AXSYN170496i) which was promotional and was certified as such and included a single case study at the end. The Panel noted the complainant's allegation that beyond this presentation, the representative also presented slides of specific case studies of patients who had various CHD complications and why he/she would put these patients forward for prophylaxis with Synagis.

The Panel noted AbbVie's submission that a Pathways document, a set of three scenarios, was used within the patient centred communication element of the meeting which was an AbbVie facilitated workshop. The Panel noted that according to AbbVie, the scenarios were printed and left on tables during the session for discussion and were not formally presented as inferred by the complainant. Each scenario described a patient and then asked five questions including: Should this baby receive RSV immuno-prophylaxis?; at each stage discuss and document the possible obstacles in identifying this baby for Synagis; who are the key individuals in this patient's care that can identify this baby for the Synagis programme – where do you think the responsibility lies? and explore strategies that ensures this patient is identified for Synagis throughout the patient journey.

The Panel noted that it was not necessarily unacceptable in principle under the Code for a representative to discuss and present case studies as alleged, provided that the manner in which it was done complied with the Code. The Panel noted that the complainant bore the burden of proof and considered that there was no evidence that, by allowing the representative to present and/or facilitate a discussion on the three scenarios within the Pathways document that he/she or the company had failed to maintain high standards on this narrow point. No breach of Clauses 9.1 and 15.2 were ruled.

The Panel noted that the Pathways document was not certified. The Panel noted that the Synagis meetings alignment toolkit for account specialists for the mini embrace meetings referred to pre-approved materials for all sessions other than the patient centred communication session. The Panel noted the content of the Pathways document which, according to AbbVie, was to be used during the patient centred communication session and was concerned that the meeting organisers did not consider the document was promotional thus requiring certification. The Pathways document had not been certified and the Panel therefore ruled a breach of Clause 14.1 as acknowledged by AbbVie. In the Panel's view, a robust certification procedure underpinned self-regulation and the failure to recognise the promotional nature of the Pathways document, and therefore that it required certification, meant that AbbVie had failed to maintain high standards and a breach of Clause 9.1 was ruled.

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 (SPC). 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 less than 2 years of age at high risk of RSV disease. The Panel noted the allegation that in the complainant's view, AbbVie was trying to influence the audience to prescribe Synagis to all CHD patients outside NHSE Guidelines. The Panel noted that the Code did not state that a medicine must only be promoted in a manner that was consistent with NHSE Guidance as implied by the complainant. The Code, however, did 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 AbbVie's submission about the most recently published NHS commissioning arrangements for Synagis and the JCVI recommendations on RSV and Synagis. The Panel noted that an undated, unsigned copy of an NHSE commissioning arrangements letter included children over 2 years old in a list of co-morbidities that were not acceptable under the guidance due to little or no evidence for RSV prophylaxis. The DoH's JCVI document on RSV only referred to the use of Synagis in infants under 2 years of age. This was reflected in the presentation in question which referred to NHSE Guidance of November 2016 in relation to co-morbidities associated with CHD. The Panel noted that within a preceeding section 'Burden of RSV in CHD' a slide entitled 'Evidence for risk factors in hsCHD' stated that 'Of 1806 US children aged under 5 years who died with bronchiolitis between 1979 and 1997, 9.9% had CHD'. The Panel was concerned about this statement in a promotional presentation noting Synagis' licensed indication. The Panel noted that other slides made it clear that data related to those aged less than 2 years or babies or small neonates. The Panel noted that the three scenarios in the Pathways document clearly referred to infants born in 2017. The Panel, whilst noting its concern above, did not consider that a general statement about the prevalence of CHD in patients under 5 years with bronchiolitis, within an introductory section about risk factors for CHD, was misleading or otherwise qualified the subsequent reference to NHSE Guidelines within the section 'JCVI Guidelines for CHD'. The Panel noted the narrow allegation and did not consider that the complainant had established that AbbVie was trying to misleadingly influence the audience to prescribe Synagis to all CHD patients outside the NHSE Guidelines as alleged. No breach of Clause 7.2 was ruled.

The Panel noted that the complainant had made a general allegation that the claims on the slides did not refer to any published data or local audits conducted including the outcomes of prophylaxis with the said patient cohort. The complainant, who had the burden of proving his/her complaint on the balance of probabilities, had not provided any material to support his/her allegations in this regard and it was not clear which claims he/she considered required references to published data or local audits as alleged. It was not for the Panel to make out a complainant's allegation. The Panel thus ruled no breach of Clause 7.4.

The Panel noted its comments and rulings above and did not consider that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use. No breach of Clause 2 was ruled.

Complaint received **18 December 2017**

Case completed **17 July 2018**