CASE AUTH/2171/10/08

VOLUNTARY ADMISSION BY ABBOTT

Synagis email

Abbott Laboratories voluntarily admitted that an email about Synagis (palivizumab), which one of its representatives had sent to a number of health professionals breached the Code. Synagis was indicated for the prevention of a serious lower respiratory tract disease requiring hospitalisation caused by respiratory syncytial virus (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 treated for bronchopulmonary dysplasia within the last 6 months, and children less than 2 years of age with haemodynamically significant congenital heart disease.

Abbott explained that the email was sent as a follow-up to a meeting when the health professionals concerned had expressed an interest in being sent a link to a page on the Joint Committee on Vaccination and Immunisation (JCVI) website, which contained guidelines for the use of Synagis.

To this email, the representative attached a letter from a medicines management committee to the specialised commissioning lead for the paediatric network. This letter asked whether the various regional paediatric networks had reached consensus about the use of palivizumab and advised them that, until a consensus was reached, they should continue to support the policy (issued by a named regional group) recommending the use of palivizumab in premature neonates with chronic lung disease or congenital heart disease. This letter had been forwarded to Abbott by the assistant commissioning director for two primary care trusts with permission to pass it on to local health professionals to whom the advice was likely to be relevant.

Unfortunately, as well as the link to JCVI guidelines, the representative copied and pasted some text from the website, outlining the recommendations regarding palivizumab. Abbott considered this email would be perceived as promotional. It did not, however, have prescribing information attached and had not been formally certified. Similarly, the attached letter, which would also be classified by the Code as promotional when distributed in this manner, had not been certified and did not include prescribing information. Furthermore, the section of the JCVI guidelines reproduced within included a recommendation that palivizumab could be prescribed in children with severe immuno-deficiency which was not within the terms of the particulars listed in the summary of product characteristics (SPC).

The representative had confirmed that she had been given permission to email these customers. She copied in the lead pharmacist for acute commissioning in the region, as a courtesy, because the letter had been forwarded to Abbott by her assistant. She had not obtained permission from her to copy her into the email but did not feel this was necessary as she would already have been aware of the content.

The representative had been briefed specifically about the use of email; the briefing very clearly laid out the potential Code issues regarding emailing customers, and stressed that it was completely inappropriate to mention company products in any email of this nature. The representative had also recently passed refresher training on the Code that stressed the importance of certifying all promotional material. In the context of these briefings, Abbott believed that the representative had not maintained high standards.

Abbott stated that as a result of this incident it would rebrief all of its sales representatives reminding them of their responsibilities regarding the Code when it came to emailing with customers and reinforcing the importance of compliance in this regard.

Abbott submitted that although it had striven to maintain high standards throughout, it was impossible to fully regulate against an individual's lapse of judgement. The representative would shortly be the subject of internal disciplinary proceedings.

The Panel noted that the representative had been asked by a group of health professionals to provide a link to a page on the JCVI website which contained guidelines for the use of Synagis. To an email containing this information, entitled 'Funding availability and DoH Guidelines for Palivizumab', the representative had attached a copy of a letter from the chairperson of a medicines management committee to a specialised commissioning lead for the paediatric network entitled 'Palivizumab – Indications for RSV in neonates'. The Panel noted that although the representative had fulfilled a request her first responsibility was to act in accordance with the Code, regardless of customers' wishes to the contrary and the representative's intention to be helpful.

The Panel considered that the email and attached letter, given they had been sent by a representative with a commercial interest in palivizumab, clearly promoted the use of Synagis as acknowledged by Abbott. The material did not include prescribing

information and nor had it been certified. Breaches of the Code were ruled as acknowledged by Abbott.

The Panel noted that the email referred to the use of palivizumab in 'Children under 2 years of age with severe congenital immuno-deficiency'. This was outwith the licensed indications for Synagis. A breach of the Code was ruled as acknowledged by Abbott.

The Panel noted that the email had been sent to a group of health professionals who, according to the representative, had given their prior permission to be so contacted. No documentation had been provided to substantiate the representative's position. In this regard the Panel considered that companies must be very sure that health professionals had given their express permission for promotional materials to be emailed to them. The Panel noted, however, that the lead pharmacist for acute commissioning had been sent the email without her permission; it was irrelevant that the recipient was already aware of the content. A breach was ruled.

The Panel considered that the representative had not maintained a high standard of ethical conduct. A breach was ruled.

The Panel noted that a ruling of a breach of Clause 2 was reserved as a sign of particular censure. The supplementary information to Clause 2 stated that activities likely to be in breach of that clause included, *inter alia*, promotion prior to the grant of a marketing authorization and conduct of company employees/agents that fell short of competent care. The Panel considered that Abbott had been badly let down by its representative. However, given that the email had gone to a small group of health professionals who had asked for further information about local and national guidelines, that the reference to the use of palivizumab in an unlicensed group of children had reported verbatim the findings of a national expert advisory committee and the matter related to the misguided actions of one individual, the Panel decided, on balance, not to rule a breach of Clause 2.

Abbott Laboratories Limited voluntarily admitted that an email about Synagis (palivizumab), which one of its representatives had sent to a number of health professionals, was in breach of the Code. Synagis was indicated for the prevention of a serious lower respiratory tract disease requiring hospitalisation caused by respiratory syncytial virus (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, and children less than 2 years of age with haemodynamically significant congenital heart disease.

COMPLAINT

Abbott explained that the email was sent as a follow-up to a meeting on 25 July when the health professionals concerned had expressed an interest in being sent a link to a page on the Joint Committee on Vaccination and Immunisation (JCVI) website, which contained guidelines for the use of Synagis.

To this email, the representative attached an electronic copy of a letter from a medicines management committee to a specialised commissioning lead for the paediatric network. This letter asked whether the various regional paediatric networks had reached consensus about the use of palivizumab and advised them that, until a consensus was reached, they should continue to support the policy (issued by a named regional group) recommending the use of palivizumab in premature neonates with chronic lung disease or congenital heart disease. This letter had been forwarded to Abbott by the assistant commissioning director for two primary care trusts (PCTs) with verbal permission to pass it on to local health professionals to whom the advice was likely to be relevant.

Unfortunately, as well as the link to JCVI guidelines, the representative copied and pasted some text from the website, outlining the recommendations regarding palivizumab. Abbott considered this email would be perceived as promotional. It did not, however, have prescribing information attached and had not been formally certified. Similarly, the attached letter, even though it was not generated by Abbott and it had been given permission to circulate it to PCT customers, would also be classified by the Code as promotional, when distributed in this manner; it had not been certified, nor did it include prescribing information. Furthermore, the section of the JCVI guidelines reproduced within, included a recommendation that palivizumab could be prescribed in an indication (children with severe immuno-deficiency) that was not within the terms of the particulars listed in the summary of product characteristics (SPC). This recommendation was not mentioned in any of Abbott's promotional materials and should not have been passed on to customers in this manner.

Abbott considered that this email was in breach of Clauses 3, 4.1 and 14.1 of the Code.

In relation to Clause 9.9 the representative had confirmed that she had been given permission to email these customers. She copied in the lead pharmacist for acute commissioning in the region, as a courtesy, because the letter had been forwarded to Abbott by her assistant. She had not obtained permission from her to copy her into the email but did not feel this was necessary as she would already have been aware of the content enclosed.

The representative had been briefed specifically

about the use of email, on 14 June last year; the briefing very clearly laid out the potential Code issues regarding emailing customers, and stressed that it was completely inappropriate to mention company products in any email of this nature. The representative had also recently passed a Code refresher online training module (14 July) that stressed the importance of certifying all promotional material. In the context of these briefings, Abbott believed that the representative had not maintained high standards in breach of Clause 15.2.

Abbott stated that as a result of this incident it would rebrief all of its sales representatives reminding them of their responsibilities regarding the Code when it came to emailing with customers and reinforcing the importance of compliance in this regard.

Abbott submitted that it had striven to maintain high standards throughout and that, even when thorough precautions were taken to ensure Code compliance, it was impossible to fully regulate against an individual's lapse of judgement. The representative would shortly be the subject of internal disciplinary proceedings.

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Paragraph 5.4 of the Constitution and Procedure provided that the Director should treat a voluntary admission as a complaint if it related to a potentially serious breach of the Code or if the company failed to take appropriate action to address the matter. Issuing uncertified material and promoting medicines outwith their marketing authorization were serious matters and the admission was accordingly treated as a complaint.

When writing to Abbott the Authority asked it to respond in relation to Clauses 2, 3.1, 4.1, 9.1, 9.9, 14.1 and 15.2.

RESPONSE

Abbott explained that at various recent meetings, local clinicians expressed an interest, to one of its representatives, in obtaining further information relating to local and national guidance on the use of palivizumab. They specifically requested a link to the website on which the JCVI had published its recommendations on the use of palivizumab in the prevention of RSV infection in young children. The representative was also asked for a copy of a letter from a medicines management committee (to a specialised commissioning lead for the paediatric network) which contained advice to regional paediatric networks on policy regarding the use of this treatment. This letter had been forwarded to Abbott by the assistant commissioning director for two PCTs with verbal permission to pass it on to those clinicians to whom the advice was likely to be relevant.

The letter advised the local networks that, until a consensus was reached, they should continue to support the policy (issued by a named regional group) recommending the use of palivizumab only in the treatment of premature neonates with chronic lung disease or congenital heart disease.

To put the advice contained within this letter in context, Abbott noted that these recommendations restricted the use of palivizumab to a cohort of patients that was significantly smaller than the licensed indications for the product – which allowed palivizumab to be used in all children under two years of age who had chronic lung disease or haemodynamically significant congenital heart disease, as well as all premature neonates, who were less than 6 months old at the start of the RSV season, whether or not they had heart or lung disease. As a result, the representative's proactive distribution of this letter facilitated the distribution of existing information to the clinicians involved but would not serve any other commercial purpose and could, if anything, restrict the use of palivizumab in the region. The representative now realised she should not have involved herself in the distribution of this information within this group of clinicians and left this role to someone within the NHS.

The JCVI recommendations were published in 2004 as a result of the formal review of the findings of a separate expert group meeting, held in 2002. The JCVI was an independent expert advisory committee set up by the Department of Health (DoH). The published recommendations, issued in 2004 and documents on the JCVI website – the web address of which had been requested from its representative – were as follows:

'The following children should be recommended for palivizumab prophylaxis

- Children under 2 years of age with chronic lung disease, on home oxygen or who have had prolonged use of oxygen
- Infants less than 6 months of age who have left to right shunt haemodynamically significant congenital heart disease and/or pulmonary hypertension
- Children under 2 years of age with severe congenital immuno-deficiency.'

Palivizumab was not licensed for the treatment of infants with congenital immuno-deficiency. For this reason, Abbott did not reproduce the third bullet point in promotional materials and it accepted that the inclusion of these recommendations, in full, would be construed as promoting outside of the terms of the marketing authorization. However, the intention behind giving clinicians these recommendations was to facilitate the provision of information to those who had expressed an interest in locating these independent guidelines.

When considering this complaint, Abbott asked the Authority to take into account the intention behind the email which was that of a genuine desire to provide these clinicians with independently produced materials, which had been generated

specifically for this audience and which had been verbally requested by everyone to whom the email was addressed.

The company, however, accepted that the text which was copied and pasted from the JCVI website constituted a breach of Clause 3, as discussed above, albeit regarding use of the product in line with national recommendations published on behalf of the DoH.

Abbott also accepted that the inclusion of its product name within the attached letter and the email, meant that the communication was promotional material in its own right. Prescribing information was not provided and the material had not been certified and, as such, was in breach of Clauses 14.1 and 4.1.

Abbott did not believe this email represented a breach of Clause 9.9 because the representative concerned had confirmed that she had been given permission to email these customers.

With regard to Clauses 9.1 and 15.2, the company noted that it strove to ensure that a culture of high standards and compliance were central to all of its activities. Every affiliate had been asked to focus on 'core values', which should underpin its behaviour in every aspect of the business. Abbott's mission statement included the following advice 'We strive to earn the trust of those we serve by committing to the highest standards of quality, excellence in personal relationships, and behaviour characterized by honesty, fairness and integrity'. Abbott provided details of its ongoing compliance programme.

Abbott stated that whilst the actions of this individual representative were unacceptable, it took the training of its representatives, with regard to Code compliance, extremely seriously. Details of the representative's training on the Code, and the successful completion of various modules, was provided.

All Abbott representatives were trained on the Code and received regular briefings to remind them of their responsibilities regarding the Code, as required. The representative briefing provided to its sales force, which was most relevant to this complaint, discussed the use of uncertified material (with specific reference to email) and discussion of off-licence indications.

This briefing contained the following guidance relating to email:

'Representatives may only initiate or engage in correspondence (by any means eg email, text message, fax etc) with health professionals and relevant administrative staff if all of the following are true:

- Prior permission is given by the recipient
- The content does not mention any pharmaceutical product by name (trade or generic)
- The content does not refer in any way to a pharmaceutical product (eg its use or its properties etc)…'

The same briefing provided the following guidance relating to uncertified materials:

'… therefore it is important understand that:

- Representatives may not initiate or engage in any correspondence concerning a pharmaceutical product (even if the product is not mentioned by name)
- Representatives may not initiate or engage in any correspondence with the purpose of promoting a product
- Under the ABPI Code of Practice no promotional material can be sent/used/issued/distributed by representatives until it has been certified by company signatories in accordance with Clause 14 of the Code…'

Finally the briefing provided the following guidance, regarding off-licence indications:

'… a sales representative's activities are perceived as promotional in nature. If there is any discussion relating to data on the use of any medicine in an indication for which it does not yet have a license it will be construed as promotion, and hence, a breach of the Code of Practice (Clause 3).

The briefing concluded with the following warning:

'Abbott as a company strives to live by its values – Pioneering, Achieving, Caring and Enduring – through the actions and behaviours of all of us. Setting high standards is a foundation on which we base our behaviours. Breaches of the ABPI Code of Practice are taken extremely seriously and are a disciplinary matter.'

In view of this complaint, additional 'face to face' training regarding the Code would be implemented across the entire sales force to further reinforce the messages that the company instilled in its sales representatives from their induction onwards. This would include where it might be more appropriate for a representative to decline to be the distributor of information that might have been requested by attendees of meetings.

In view of the ongoing compliance activities of the organisation, the extensive training this individual received and the specific guidance issued – relating to the issues that were central to this case – Abbott submitted that it had maintained high standards throughout and that every effort had been taken to ensure Code compliance. As soon as the company became aware of this matter, it conducted a full internal investigation and as a result of that investigation, it voluntarily reported this issue to the Authority, as well as completing formal disciplinary proceedings against the individual concerned.

Abbott therefore accepted the actions of this

individual representative were in breach of the Code, specifically Clauses 3, 9.9, 15.2, 14.1 and 4.1. Abbott, however, believed that it had maintained high standards throughout and it believed that its actions since had been entirely appropriate and were not likely to reduce confidence in the pharmaceutical industry, nor had the representative actions prejudiced patient safety or public health. Abbott therefore did not consider that a breach of Clause 9.1 or of Clause 2 was appropriate.

PANEL RULING

The Panel noted that the representative had been asked by a group of health professionals to provide a link to a page on the JCVI website which contained guidelines for the use of Synagis. To an email containing this information, entitled 'Funding availability and DoH Guidelines for Palivizumab', the representative had also attached a copy of a letter from the chairperson of a medicines management committee to a specialised commissioning lead for the paediatric network entitled 'Palivizumab – Indications for RSV in neonates'. The Panel noted that although the representative had fulfilled a request her first responsibility was to act in accordance with the Code, regardless of customers' wishes to the contrary and the representative's intention to be helpful.

The Panel considered that the email and attached letter, given they had been sent by a representative with a commercial interest in palivizumab, clearly promoted the use of Synagis as acknowledged by Abbott. The material did not include prescribing information and nor had it been certified. Breaches of Clauses 4.1 and 14.1 were ruled as acknowledged by Abbott.

The Panel noted that the email referred to the use of palivizumab in 'Children under 2 years of age with severe congenital immuno-deficiency'. This was outwith the licensed indications for Synagis. A breach of Clause 3.1 was ruled as acknowledged by Abbott.

The Panel noted that the email had been sent to a group of health professionals who, according to the representative, had given their prior permission to be so contacted. No documentation had been provided to substantiate the representative's position. In this regard the Panel considered that companies must be very sure that health professionals had given their express permission for promotional materials to be emailed to them. The Panel noted, however, that the lead pharmacist for acute commissioning had been sent the email without her permission; it was irrelevant that the recipient was already aware of the content. A breach of Clause 9.9 was ruled.

The Panel considered that the representative had not maintained a high standard of ethical conduct. Breaches of Clauses 9.1 and 15.2 were ruled.

The Panel noted that a ruling of a breach of Clause 2 was reserved as a sign of particular censure. The supplementary information to Clause 2 stated that activities likely to be in breach of that clause included, *inter alia*, promotion prior to the grant of a marketing authorization and conduct of company employees/agents that fell short of competent care. The Panel considered that Abbott had been badly let down by its representative. However, given that the email had gone to a small group of health professionals who had asked for further information about local and national guidelines, that the reference to the use of palivizumab in an unlicensed group of children had reported verbatim the findings of a national expert advisory committee and the matter related to the misguided actions of one individual, the Panel decided, on balance, not to rule a breach of Clause 2.

Proceedings commenced **6 October 2008**

Case completed **18 November 2008**