PHARMACIST v ALK-ABELLÓ

Alleged conduct of a representative

A pharmacist complained about information given to him by a named ALK-Abelló representative about Jext and EpiPen, both of which were adrenaline auto injectors. Jext was marketed by ALK-Abelló and EpiPen was marketed by Meda Pharmaceuticals. Both products were indicated for the emergency treatment of anaphylaxis. According to the respective summaries of product characteristics (SPCs), Jext was activated by a 'place and push' technique and EpiPen by a 'swing and jab' motion.

The complainant alleged that the ALK-Abelló representative had told him that EpiPen, which had previously been on the formulary, had been discontinued, which was not so. Further that the route of administration of Jext was identical to that of EpiPen. The complainant reviewed the SPC for Jext and considered this claim was incorrect and could be the difference between life and death. Finally, the complainant was told that Jext had a 24 month shelf life once it reached the pharmacy, but this was incorrect; some Jext on his shelf only had a shelf life of 14 months.

The detailed response from ALK-Abelló is given below.

The Panel noted that the parties' accounts differed. The complainant stated that he and the ALK-Abelló representative met at his pharmacy on a specified date in mid-January. ALK-Abelló submitted very detailed evidence that neither the named representative nor any other representative had called on a pharmacist with the same initial and surname as the complainant on that date. Although the named representative had been at an evening meeting on that day, the complainant had stated that he was not at that meeting. The Panel had to make a ruling on the evidence before it. The complainant had the burden of proving his complaint on the balance of probabilities. ALK-Abelló's comprehensive review suggested that the complainant and the named representative had not met. The Panel considered that, on the balance of probabilities, the complainant had not proven there had been a meeting between him and the representative and thus the allegations that the representative had misled the complainant were ruled not to be in breach of the Code.

A pharmacist complained about information given to him about Jext and EpiPen, both of which were adrenaline auto injectors. Jext was marketed by ALK-Abelló Limited and EpiPen was marketed by Meda Pharmaceuticals. Both products were indicated for the emergency treatment of anaphylaxis. According to the respective summaries of product characteristics (SPCs), Jext was activated by a 'place and push' technique and EpiPen by a 'swing and jab' motion.

COMPLAINT

The complainant alleged that he had been told by an ALK-Abelló representative that EpiPen, which had previously been on the formulary, had been discontinued. On further investigation the complainant discovered that this was incorrect and the medicine was still available. The complainant further alleged that he was told not to worry about the route of administration of Jext as it was identical to that of EpiPen. The complainant reviewed the Jext SPC and considered this claim was incorrect and could be the difference between life and death. Finally, the complainant alleged that he was told that Jext had a 24 month shelf life once it reached the pharmacy, but he considered that this was incorrect; the complainant noted that he had Jext on his shelf with a 14 month shelf life.

The complainant had spoken to local colleagues and those in neighbouring primary care trusts (PCTs) and was concerned that this information could lead to a fatality. The complainant stated that his patients were extremely concerned and would rather have a medicine with which they were familiar.

The complainant could only provide the first name of the representative in question; he stated which county he worked in but not the address of his pharmacy.

When writing to ALK-Abelló, the Authority asked it to respond in relation to Clauses 2, 7.2, 7.3, 15.2 and 15.9 of the Code.

RESPONSE

ALK-Abelló stated that the only contact between an ALK-Abelló representative and any pharmacist with the same initial and surname as the complainant was at a meeting in late January 2012 organised by the Local Pharmaceutical Committee (LPC) to update local pharmacists on the support available to health professionals and patients following the PCT's decision to recommend Jext as the adrenaline auto injector of choice. There had never been any one-to-one dialogue or other contact between any ALK-Abelló representative and anyone with the same initial and surname as the complainant in the locality outside of this meeting.

ALK-Abelló submitted that in December 2011 the local PCT recommended that Jext was prescribed as the preferred adrenaline auto injector from February 2012. A detailed letter was sent from the PCT in December 2012 to all community pharmacy contractors to outline the process for this change (copy provided). That letter advised that stocks of EpiPen be reduced. Nowhere was it stated or implied that EpiPen had been discontinued. In

January 2012 the same letter was sent to all community pharmacists with a letter from ALK-Abelló, a pad of patient information leaflets, a Jext simulator and a Jext training DVD (copies were provided).

ALK-Abelló stated that the LPC hosted two identical evening training meetings in January 2012 which were attended by approximately 60 pharmacists. A delegate with the same initial and surname as the complainant attended the second meeting. The ALK-Abelló representative named by the complainant gave a brief presentation on anaphylaxis and Jext which included a video demonstration of the correct use of Jext (a copy was provided). The audience then practised the correct activation of Jext using simulators provided.

ALK-Abelló submitted that no ALK-Abelló representative had ever made any of the statements alleged by the complainant.

With regard to the injection method, ALK-Abelló submitted that the LPC had taken the switching of the preferred adrenaline auto injector to Jext as an opportunity to improve community pharmacists' knowledge of anaphylaxis and the use of adrenaline auto injectors. Pharmacists were ideally placed to ensure patients were able to correctly use an adrenaline auto injector as it was well documented that training of patients and health professionals needed to improve. The entire meeting, together with all of the supporting materials provided, demonstrated and reinforced the correct use of Jext.

ALK-Abelló noted that, whilst Jext was always promoted for use as per its SPC [place and push], it would activate correctly if used as per the EpiPen SPC [swing and jab].

In relation to shelf life, ALK-Abelló stated that the letter from the LPC, all of the materials provided by ALK-Abelló and the presentation given by the ALK-Abelló representative in question described shelf-life from date of manufacture.

ALK-Abelló submitted that the above had been confirmed by a representative of the LPC present at both of the January meetings (a copy of an email was provided).

ALK-Abelló therefore refuted the alleged breaches of Clauses 2, 7.2, 7.3, 15.2 and 15.9 of the Code.

FURTHER INFORMATION FROM THE COMPLAINANT

Following a request for further information on his recollection of the representative's comments in relation to the administration of Jext compared with EpiPen, the complainant stated that 'The event occurred at my pharmacy and not at the event. In fact it was before the event'. The complainant confirmed that he met the representative in question in mid-January and that he did not attend the LPC meeting in late January as he was out of the country.

FURTHER INFORMATION FROM ALK-ABELLÓ

Following a request for further information, ALK-Abelló submitted that the representative in question always specifically trained 'place and push', and discussed 'swing and jab' only when raised by the customer. Following a further request for more information, ALK-Abelló submitted that it only had one ALK-Abelló employee with the same first name as that provided by the complainant. The representative's local PCT had decided to switch from EpiPen to Jext as the adrenaline auto injector of choice and so the representative's name appeared on Jext information received by health professionals in the region. The representative had not visited any retail pharmacy in the area; the representative's only contact with retail pharmacists had been at two identical LPC meetings in January. The attendee list for the first meeting indicated that no one with the complainant's name had attended (copy provided).

ALK-Abelló submitted that in mid-January, on the date the complainant claimed to have met the named representative at his pharmacy, the representative had first had an afternoon meeting with a nurse specialist group and then the LPC evening meeting described above (approval forms and delegate lists were provided). The rest of the representative's day was spent travelling.

ALK-Abelló submitted information to indicate that none of its representatives visiting pharmacies in the region could have been confused with the representative in question (they either had a very different first name or were a different gender).

Records of every UK pharmacist with the same initial and surname as the complainant ever visited at their pharmacy by an ALK-Abelló representative were provided. None of those visits were on the date the complainant claimed to have met the representative in question.

Copies of the relevant training materials were provided.

PANEL RULING

The Panel noted that the parties' accounts differed. The complainant stated that he and a named ALK-Abelló representative met at his pharmacy in mid-January. ALK-Abelló had submitted very detailed evidence that neither the named representative nor any other of its representatives had called on a pharmacist with the same initial and surname as the complainant on that date. The complainant's name was not on the delegate list for the first evening meeting in January. Someone with the same initial and surname as the complainant had attended the second evening meeting organised by the named representative in late January but the complainant had stated that it was not him as he was out of the country. Despite repeated requests the complainant had not provided details of his address. ALK-Abelló submitted that the pharmacists in the relevant region

visited on the date in question were called upon by representatives of a different gender to the representative in question. The Panel had to make a ruling on the evidence before it. The complainant had the burden of proving his complaint on the balance of probabilities. ALK-Abelló's comprehensive review suggested that the complainant and the named representative had not met. The Panel considered that, on the balance of probabilities, the complainant had not proven there had been a meeting between him and the named representative and thus the allegations that the representative had misled the complainant were ruled not to be in breach of Clauses 7.2, 7.3, 15.2, 15.9 and 2.

Complaint received **26 March 2012**

Case completed **6 June 2012**