CASE AUTH/2387/2/11

PHARMACEUTICAL COMPANY EMPLOYEE v ALK-ABELLÓ

Promotion of Jext

A pharmacist, who worked as a consultant to Lincoln Medical, complained that ALK-Abelló had circulated two documents, a formulary pack and a formulary template for its yet to be launched product Jext (adrenaline auto-injector). Lincoln Medical marketed Anapen (adrenaline auto-injector).

The complainant considered that claims about 'better/longer' shelf life were identical to those for Anapen, ruled to be misleading in Case AUTH/2359/9/10. The complainant thus alleged that the claims for Jext were also misleading.

Further, the complainant alleged that a claim that with Jext 'there is less likelihood of needle stick injury' was unsubstantiated given that Jext was not yet available anywhere in the world and so there was no patient experience of its use. The complainant was advised that there had been no needle stick accident or event with Anapen in the 10 years that it had been licensed and approved in 19 countries.

The detailed response from ALK-Abelló is given below.

The Panel noted that Jext received a marketing authorization on 12 November 2010. The formulary pack and template were distributed for use on 18 and 30 November. The promotion of Jext was after receipt of its marketing authorization and thus no breach of the Code was ruled.

Both documents included details of the shelf life from manufacture (24 months) and this was longer than the other available adrenaline auto-injectors. EpiPen and EpiPen Junior each had a shelf life of 18 months and Anapen Junior of 21 months from the date of manufacture. The documents referred to a potential cost saving of 25% by using Jext instead of EpiPen.

The formulary pack stated that Anapen 300mcg had a shelf life of 24 months from the date of manufacture. Jext and EpiPen cost the same, £28.77. Anapen cost £30.67.

The summary in the formulary pack stated that Jext had a '33% longer shelf-life than EpiPen/EpiPen Jr and 14% longer than Anapen Junior, potentially reducing the number of auto-injectors that a patient has to replace in a lifetime' and referred to the 'longer maximum shelf-life' of Jext vs Epipen in relation to cost savings. Another section headed 'From a PCT perspective' referred to the longer maximum shelf-life'. Page 9 of the formulary pack also referred simply to 'longer maximum shelf-life'. This page included the statement 'It is also conservative to assume the patient has the device for the entire shelf-life from date of manufacture'. References to shelf life also appeared on pages 7 and 10. The Panel noted that it was not always clear, particularly in the summary, that the shelf life was from the date of manufacture.
The Panel did not consider that the claims for Jext were identical to those for Anapen in Case AUTH/2359/9/10 as alleged. In some instances in the present case, Case AUTH/2387/2/11, it was clear that the longer shelf life related to the maximum shelf life from date of manufacture. In the Panel's view 'shelf life' to a customer meant the amount of time they could keep a product before it went out of date. The supply chain was relevant. The Panel considered that the claim in the summary for '33% longer shelf-life …' was misleading. The impression was given that patients would receive Jext with a full 24 months of shelf life and this could not be guaranteed and thus the claim could not be substantiated. Breaches of the Code were ruled.

The Panel noted that neither the previous case, Case AUTH/2359/9/10, nor the material before it now, claimed a better shelf life and this aspect of the current complaint was not considered.

With regard to the claim in the formulary template that with Jext 'there is less likelihood of needle stick injury' the Panel noted the data provided by both parties. ALK-Abelló submitted that the risk of needle stick injury was minimised because after administration a protective shield engaged, locked and covered the needle and thus removed the risk of needle stick injury. Five cases of needle stick injury using EpiPen were reported in 2008-2010. The Panel considered that reducing the risk of needle stick injury would be of interest irrespective of the size of that risk. Given the design of the Jext auto-injector the Panel did not consider that the claim 'there is less likelihood of needle stick injury' was unsubstantiable as alleged. No breach of the Code was ruled.

The Panel noted its rulings outlined 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.

A pharmacist who worked as a consultant to Lincoln Medical complained that ALK-Abelló Ltd had circulated two documents, a formulary pack (ref 569AD) and a formulary template (ref 584AD) for its yet to be launched product, Jext (adrenaline tartrate). Copies of the documents were provided.

It had previously been decided that private complaints from pharmaceutical company employees had to be accepted. To avoid this becoming a means of circumventing the normal procedures for inter-company complaints, the employing company would be named in the report. The complainant was advised that this would happen and given the opportunity to withdraw the complaint but he did not do so and the complaint thus proceeded. Lincoln Medical was advised accordingly.

Lincoln Medical marketed Anapen (adrenalin auto-injector).

COMPLAINT

The complainant considered that claims about 'better/longer' shelf life were identical to those for Anapen ruled to be misleading in Case AUTH/2359/9/10. The complainant thus alleged that the claims for Jext were also misleading.

Further, the complainant noted that the Formulary Application Form Template – Jext, in the section headed 'Consequences of not using proposed drug' and repeated on page 4 in the section 'Patient Benefits', there was the claim that with Jext 'there is less likelihood of needle stick injury'. The complainant alleged that this claim was unsubstantiated given that Jext was not yet available anywhere in the world and so there was no patient experience of its use. The complainant had searched the literature and checked with Lincoln Medical and was advised that there had been no needle stick accident or event with Anapen in the 10 years that it had been licensed and approved in 19 countries.

When writing to ALK-Abelló, the Authority asked it to respond in relation to the requirements of Clauses 2, 3.1, 7.2 and 7.4 of the Code.

RESPONSE

ALK-Abelló submitted that Jext 150mcg and Jext 300 mcg received marketing authorizations on 12 November 2010. The two documents in question; Jext Formulary Pack and Jext Formulary Template were certified and approved for first use on 18 November and 29 November 2010 respectively. Both were distributed to the key account managers at ALK-Abelló on 18 and 30 November 2010 to provide pharmacists and senior clinicians in hospital and primary care organisations with the necessary information to facilitate formulary applications for Jext. Therefore ALK-Abelló denied the alleged breach of Clause 3.1 as Jext had been granted a marketing authorization before it started any promotional activity.

ALK-Abelló explained that adrenaline auto-injectors, as with all medicines, had a licensed shelf life from the date of manufacture as stated in the summary of product characteristics (SPC). Clause 3.2 stated '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 Jext Formulary Pack and Jext Formulary Template stated that Jext had a maximum shelf life of 24 months from date of manufacture, a claim that was consistent with the particulars listed in the SPC. Further, both documents also stated that EpiPen and EpiPen Junior (Dey Pharma) had a maximum shelf life of 18 months, Anapen 300/Anapen 500 a maximum shelf life of 24 months and Anapen Junior a maximum shelf life of 21 months. All comparisons were consistent with the individual products' SPCs.

The claims about shelf life in Case AUTH/2359/9/10 were ruled to be misleading and not capable of substantiation because they referred to the unequivocal claim 'Anapen auto-injectors have a longer shelf life than Epipen'. The document ruled in breach of Clauses 7.2 and 7.4 referred simply to shelf life and not maximum shelf life from date of manufacture or indeed licensed shelf life as noted by the Panel.

ALK-Abelló denied the alleged breaches of Clauses 7.2 and 7.4 as it was made very clear that the comparisons referred to the maximum shelf life from date of manufacture of the products as stated in their SPCs. It was further stated in the materials that it was conservative to assume that the patient had the device for the entire shelf life from date of manufacture.

A comparison using maximum shelf life from date of manufacture was appropriate as this was the most conservative measure of the benefit of the additional 6 months' maximum shelf life of Jext compared with EpiPen in a cost minimisation comparison.

Therefore, ALK-Abelló considered that all claims about shelf life in the Jext Formulary Pack and Jext Formulary Template were accurate, balanced and fair. The material was sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of Jext and all claims and comparisons were consistent with the products' SPCs and, as such, could be substantiated.

ALK-Abelló explained that needle stick injury was defined as 'an accidental puncture of the skin with an unsterilized instrument'.

ALK-Abelló noted that following administration of EpiPen and Anapen the used needle remained exposed. Exposed needles presented a risk of needle stick injury not only to the patient but also to health professionals and carers, such as paramedics, school staff and parents. Being able to effectively manage the risk of such injuries and their possible consequences was ideal, however small the risk, and

was recognised in a recent EU directive. Clause 6 of Council Directive 2010/32/EU stated workers' exposure must be eliminated by providing medical devices incorporating safety-engineered protection mechanisms. With Jext the risk of needle stick injury was minimised because after administration a protective shield engaged, locked and covered the needle and removed the risk of needle stick injury.

Needle stick injury with used adrenaline auto-injectors represented a small but definite risk. Five cases of needle stick injury using EpiPen in the UK were reported to the marketing authorization holder in the period 2008-2010. Review of the case narratives shows that all incidents would have been prevented by the built in locking needle shield of Jext. This represented approximately 10% of accidental injuries with EpiPen reported during this period which was consistent with the number of reported incidents disposing of a used adrenaline auto-injector in the Medwatch database in the US.

Part of the release specification of Jext was that the locking needle shield was able to resist more than 100N of applied force for more than ten seconds. Short of deliberately disassembling Jext, it was impossible to access the needle after injection.

ALK-Abelló therefore denied the alleged breach of Clause 7.4 as the claim 'there is less likelihood of needle stick injury' could be substantiated.

ALK-Abelló strongly denied the alleged breach of Clause 2 as it had always maintained high standards of ethical promotion of Jext. The company did not believe that at any stage any of its activities or materials had brought discredit upon the pharmaceutical industry.

PANEL RULING

The Panel noted that Jext received a marketing authorization on 12 November 2010. The formulary pack and template were distributed for use on 18 and 30 November. The promotion of Jext was after receipt of its marketing authorization and thus no breach of Clause 3.1 was ruled.

Both documents included details of the shelf life from manufacture (24 months) and this was longer than the other available adrenaline auto-injectors. EpiPen and EpiPen Junior each had a shelf life of 18 months and Anapen Junior of 21 months from the date of manufacture. The documents referred to a potential cost saving of 25% by using Jext instead of EpiPen.

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The Panel did not consider that the claims for Jext were identical to those for Anapen in Case AUTH/2359/9/10 as alleged. In some instances in the present case, Case AUTH/2387/2/11, it was clear that the longer shelf life related to the maximum shelf life from date of manufacture. In the Panel's view 'shelf life' to a customer meant the amount of time they could keep a product before it went out of date. The supply chain was relevant. The Panel considered that the claim in the summary for '33% longer shelf-life …' was misleading. The impression was given that patients would receive Jext with a full 24 months of shelf life and this could not be guaranteed and thus the claim could not be substantiated. A breach of Clause 7.2 and 7.4 was ruled.

The Panel noted that neither the previous case, Case AUTH/2359/9/10 nor the material before it now claimed a better shelf life and this aspect of the current complaint was not considered.

With regard to the claim in the formulary template that with Jext 'there is less likelihood of needle stick injury' the Panel noted the data provided by both parties. ALK-Abelló submitted that the risk of needle stick injury was minimised because after administration a protective shield engaged, locked and covered the needle and removed the risk of needle stick injury. Five cases of needle stick injury using EpiPen were reported in 2008-2010.

The Panel considered that reducing the risk of needle stick injury would be of interest irrespective of the size of that risk. Given the design of the Jext auto-injector the Panel did not consider that the claim 'there is less likelihood of needle stick injury' was unsubstantiable and unsupported due to lack of patient experience of its use as alleged. No breach of Clause 7.4 was ruled.

The Panel noted its 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.

Complaint received **15 February 2011**

Case completed **4 April 2011**