CASE AUTH/2359/9/10

# PHARMACIST v LINCOLN MEDICAL

## Promotion of Anapen

**A pharmacist complained about a letter and a detail aid issued by Lincoln Medical which promoted Anapen (adrenaline auto-injector).**

**The complainant noted that the letter claimed a cost saving, compared with a competitor product, on the basis that Anapen, although more expensive, had a longer shelf-life. As the detail aid specifically referred to a shelf-life of 24 months for Anapen 500mcg auto-injectors, the complainant ordered two. The Anapen that the complainant received from the wholesaler had less than a year's shelf life left; it was part of a batch that left the company with 19 months' shelf life left.**

**The complainant alleged that the claims made for Anapen with regard to its shelf-life were not accurate and could not be substantiated.**

**The detailed response from Lincoln Medical is given below.**

**The Panel noted that one page of the detail aid was headed 'Anapen – Economical for long-term protection'. Above a table of data comparing *inter alia*, shelf life of Anapen with that of Epipen was the unequivocal claim 'Anapen auto-injectors have a longer shelf life than Epipen'. The table of data stated that the shelf life for each presentation of Epipen was 18 months whereas the shelf life for Anapen was 21 or 24 months depending on the presentation. At the bottom of the page was the claim 'With the longer shelf life of Anapen, patients also gain the advantage of lower prescription charges since they may need only one prescription every two years'.**

**The Panel noted Lincoln Medical's submission that the licensed or approved shelf life left on Anapen started to shorten as soon as the adrenaline solution was put into the syringe, thus a customer would not receive Anapen with the full 21 or 24 months' licensed shelf life still intact. However, depending on delays or otherwise in the supply chain and rate of product turnover the Panel considered that, in theory, a pharmacist could order Anapen and Epipen at the same time from a wholesaler and receive products which had the same amount of shelf life left. In the Panel's view 'shelf life' to a customer meant the amount of time they could keep a product before it went out of date.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 impression that a pharmacist might receive Anapen with a full 24 months of shelf life was strengthened by the claim in the detail aid that patients might only need one prescription every 2 years.**

**The Panel considered that the detail aid was misleading as alleged. The impression that customers would receive Anapen with a 2 year shelf life could not be substantiated. Breaches of the Code were ruled.**

**Under a sub-heading of 'Anapen has the potential to reduce prescribing costs …' the letter stated 'Anapen has a longer shelf life when compared to Epipen, which means fewer repeat prescriptions per patient …'. The Panel noted its comments above and considered that they also applied here. Breaches of the Code were ruled.**

A pharmacist complained about the promotion of Anapen (adrenaline auto-injector) by Lincoln Medical Ltd. The material at issue was a 6 page, gate-folded detail aid (ref ANA/10-013) and a letter.

### COMPLAINT

The complainant noted that the letter claimed a cost saving compared with a rival make of adrenaline auto-injector, on the basis that Anapen, although more expensive, had a longer shelf life.

The complainant noted that the letter was accompanied by the detail aid which specifically stated that Anapen 500mcg had a shelf life of 24 months. On this basis, the complainant ordered two Anapen 500mcg auto-injectors for use in the private vaccination clinic at his pharmacy. The order was placed with a wholesaler on 3/09/2010 and delivered the same day. However, the Anapen that the complainant received expired 26/08/2011 ie less than 12 months from the date supplied.

The complainant stated that he contacted Lincoln Medical to explain the situation. The company stated that the batch in question was released with an expiry date of just 19 months. The complainant noted therefore, even if it had been sent to him directly from the manufacturers, there was no way that it would have had the 24 months shelf life as claimed in the detail aid.

The complainant submitted that he made it clear to the company that he had ordered its product on the basis of a claimed 24 month shelf life, and yet it did not seem to be concerned that this claim was at variance to the actual properties of its product. The complainant alleged that the claim did not comply with Clause 7.2 that 'Information…must be accurate', or Clause 7.4 'Any information … must be capable of substantiation'.

### RESPONSE

Lincoln Medical was surprised by the complaint

since it was well known that the shelf life for all injectables, as approved by the regulators throughout the world, began from the moment of compounding of the active substance into solution and vial or syringe filling. Shelf life was determined by the regulators from this start point and was then finalised and approved based on stability studies for that substance. Shelf life then was approved as 'X' or as 'Y' and was part of the product licence and indeed the summary of product characteristics (SPC). The Anapen 500 SPC clearly showed this was 2 years ie 24 months.

Lincoln Medical submitted that the complainant was confusing shelf life with labelled life which was of course indicated by labelling for every batch of product produced and released to market. The difference between shelf life and labelled shelf should be known by all pharmacists.

Lincoln Medical noted that the detail aid stated the licensed shelf life for both Anapen and Epipen. These were correct. Anapen had always had a longer licensed shelf life than Epipen due to a longer stability of the solution. This had never been questioned or challenged in any of the 23 countries where both brands were approved and licensed.

Lincoln Medical explained that once the adrenaline powder was compounded, the Anapen syringes were filled and they were then tested to set parameters and criteria and released for build out into the final device. Once built out they were once again tested for functionality and other parameters and batch released to various markets. All of these activities took time and the shelf life clock was running. The same applied to Epipen and all injectables which followed this manufacturing process. Lincoln Medical was proud to provide adrenaline auto-injectors globally with the best possible labelled shelf for all end-users. The company strove to provide best medico-economic value for payers, which in the UK was the NHS. It was able to do this because it started with a longer approved shelf life than that of Epipen which only had 18 months for all of its presentations. Since Epipen had to go through the same or similar release and build out testing it lost approved shelf too, leaving an even shorter labelled shelf.

In summary, Lincoln Medical did not accept that this was a valid complaint and was surprised that the complainant, as a pharmacist, did not know or was seemingly unable to understand the difference between approved shelf life for a compounded solution and labelled shelf which was the reality of what came to the market. Lincoln Medical further noted that the normal UK distribution chain of product going from manufacturer to pharmaceutical wholesaler who then shipped to a pharmacy, whether in a hospital or a high street, made it impossible to absolutely guarantee that full approved shelf life product could be supplied as these products frequently sat on shelves awaiting demand and the labelled shelf got shorter by the day.

Lincoln Medical considered that the complaint was somewhat disingenuous.

In response to a request for further information regarding a letter sent with the mailing, Lincoln Medical stated that the letter was, in fact, not sent to a GP nor was it sent to the complainant but was sent to a very small number of selected chief executive officers of a small number of primary care trusts. Lincoln Medical was thus unsure as to how it came into the complainant's possession.

Lincoln stated that it could not constructively add anything to its earlier comments in this matter and continued to be surprised that the complainant did not know, or seem to know, the difference between shelf life, as approved by regulators and shown in the SPC, and labelled shelf life as shown on a packaged product. It was somewhat disingenuous to expect a compounded solution to be commercially available on the same day as it was compounded, but the shelf life was so allocated by the regulators in the full knowledge that following compounding and filling etc it took time for the solution to be released with labelled shelf life reflecting its remaining life. Comparing shelf life as approved by the regulators for two different compounded solutions was therefore legitimate.

Lincoln Medical submitted that at no time had it compared anything different.

## PANEL RULING

The Panel noted that one page of the detail aid was headed 'Anapen – Economical for long-term protection'. Above a table of data comparing the presentation, unit cost and shelf life of Anapen with that of Epipen was the unequivocal claim 'Anapen auto-injectors have a longer shelf life than Epipen'. The table of data stated that the shelf life (not the 'licensed shelf life' as submitted by Lincoln Medical) for each presentation of Epipen was 18 months whereas the shelf life for Anapen was either 21 or 24 months depending on the presentation at issue. At the bottom of the page, beneath another table of data, was the claim 'With the longer shelf life of Anapen, patients also gain the advantage of lower prescription charges since they may need only one prescription every two years'.

The Panel noted Lincoln Medical's submission that the licensed or approved shelf life left on Anapen started to shorten as soon as the adrenaline solution was put into the syringe. It was understandable that a customer would not receive Anapen with the full 21 or 24 months' licensed shelf life still intact. The Panel noted that Epipen only had a licensed shelf life of 18 months. However, depending on delays or otherwise in the supply chain and rate of product turnover the Panel considered that, in theory, a pharmacist could order Anapen and Epipen at the same time from a wholesaler and receive products which had the same amount of shelf life left. 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 impression that a pharmacist might receive Anapen with a full 24 months of shelf life was strengthened by the claim that patients might only need one prescription every 2 years.

The Panel considered that the detail aid was misleading as alleged. A breach of Clause 7.2 was ruled. The impression that customers would receive Anapen with a full 24 months of shelf life could not be substantiated. A breach of Clause 7.4 was ruled.

The Panel noted that the letter, under a sub-heading of 'Anapen has the potential to reduce prescribing costs and deliver savings to the NHS' stated 'Anapen has a longer shelf life when compared to Epipen, which means fewer repeat prescriptions per patient …'. The Panel noted its comments above and considered that they also applied here. The letter implied unequivocally that the reader would always receive Anapen with a longer shelf life left on it than Epipen. Given the supply chain, this might not always be the case.

The Panel considered that the letter was misleading as alleged. A breach of Clause 7.2 was ruled. The impression that customers would always receive Anapen with a longer shelf life than Epipen could not be substantiated. A breach of Clause 7.4 was ruled.

**Complaint received** **24 September 2010**

**Case completed** **4 November 2010**