ALK-ABELLÓ v MEDA

Promotion of EpiPen

ALK-Abelló complained about a booklet entitled 'The Case for Epipen (Adrenaline) Auto-Injector'. The booklet was sent by Meda Pharmaceuticals to pharmacy leads working at senior levels within primary care organisations (PCOs) as a response to several PCOs recommending a switch to Jext adrenaline auto injector from EpiPen. Both EpiPen and Jext were adrenaline auto injectors for treatment of allergic emergencies.

ALK-Abelló alleged that, with regard to Section 7 entitled 'The risks of changing from EpiPen Auto-Injector', Meda deliberately implied that there were life-threatening risks caused by changing from EpiPen to another adrenaline auto injector. Readers were likely to infer that the risk was associated with Jext as the majority of the booklet compared EpiPen to Jext. Meda was unable to substantiate the heading which was alleged to be misleading, not capable of substantiation and disparaging.

The detailed response from Meda is given below.

The Panel considered that it was not unreasonable to assume that there were risks involved in switching a patient's treatment from one on which they were already established and with which they were familiar. The risks would vary depending on the differences in treatment and the nature of the condition being treated. It noted that anaphylactic shock was a rare event but could have serious consequences.

The Panel considered that the reference to the implications for patients of not knowing how to use their auto injector in an emergency being 'life-threatening' would apply to all devices. There was no implication that the decision to switch from EpiPen was 'life-threatening', nor was any other specific auto injector mentioned in that regard. In the Panel's view it was not unreasonable to stress the need to ensure that appropriate training was given when anaphylactic patients were changed to a different auto injector.

The Panel did not consider that the reader would infer that the risks in Section 7 were associated with Jext as, in ALK-Abelló's view, the majority of the booklet compared EpiPen to Jext. This was not so. Sections 1-7 either discussed auto injectors in very general terms or identified all three available auto injectors without attaching disproportionate weight to any one, including Jext.

Overall, the Panel considered that there was no implication that switching patients to Jext put them at risk as alleged. On this narrow point the section was not misleading and nor was Jext disparaged. The Panel ruled no breach of the Code.

ALK-Abelló Limited complained about a booklet entitled 'The Case for Epipen (Adrenaline) Auto-Injector' (ref UK/EPI/11/0053d). The booklet was sent by Meda Pharmaceuticals to pharmacy leads working at senior levels within primary care organisations (PCOs) as a response to several PCOs recommending a switch to Jext adrenaline auto injector from EpiPen.

Meda marketed EpiPen and ALK-Abelló marketed Jext. Both products were adrenaline auto injectors for treatment of allergic emergencies.

Meda stated that it was grateful to ALK-Abelló for highlighting aspects where the booklet at issue could be improved, however the overall booklet was not unbalanced.

The booklet was mailed to pharmacy leads in primary care trusts (PCTs). Meda stated that it was clear that the booklet was not intended to be a simple two-page 'flyer', but a comprehensive document that presented a meaningful comparison between alternative adrenaline auto injectors. The primary objective was to draw attention to the differences between the products so that purchasing leads had relevant information on which to make purchasing decisions.

Products like EpiPen, Anapen and Jext were used when a patient experienced an anaphylactic reaction. In such emergency situations the patient might have only minutes to correctly administer treatment before their reaction to the allergen became life threatening. EpiPen had been the standard treatment for over 15 years, whereas Anapen and Jext had more recently entered the market.

Meda submitted that previous issues raised with the Authority related to the difference in administration technique between Jext and EpiPen, for example Cases AUTH/2405/5/11 and AUTH/2462/12/11. While the Panel did not uphold Meda's complaints that ALK-Abelló had failed to completely explain the administration technique for Jext, Meda strongly believed that the differences in administration technique between the two products were an important consideration for patients. At no point had Meda indicated that any product was better or worse than another with respect to efficacy or safety and had focused the comparison on the need to ensure that patients were taught the new administration technique, which Meda considered was the responsible position to take.

Meda understood that competitors and customers might take a different position regarding the need or otherwise for patient training in a new product, however, it considered it was important for those making purchasing decisions, who might be otherwise of the belief that the products were fully

interchangeable, had appropriate information to make an informed decision.

The booklet at issue contained seven main sections, in addition to a summary, prescribing information and references. Section 2 gave a brief overview of anaphylaxis and listed all three products without making any attempt to differentiate in any way. Section 3 highlighted the national guidelines. Section 4 highlighted the need for training in device use. Section 5 highlighted the support package provided by Meda specifically for EpiPen auto injector while section 6 highlighted the management considerations that needed to be made when switching in products is envisaged.

1 'The risks of changing from EpiPen Auto-Injector'.

This statement was the title for Section 7 of the booklet.

COMPLAINT

ALK-Abelló alleged that Meda deliberately implied that there were life-threatening risks caused by changing from EpiPen to another adrenaline auto injector. The reader was likely to infer that the risk was associated with Jext as the majority of the document compared EpiPen to Jext. Meda had previously made similar unfounded allegations about Jext to the PMCPA in Case AUTH/2462/12/11. Meda was unable to substantiate the allegations in Case AUTH/2462/12/11 and in inter-company dialogue for the case now at issue was again unable to substantiate the allegation in the booklet at issue, claiming that 'headings' could not be misleading and did not require substantiation.

ALK-Abelló alleged that this section was in breach of Clauses 7.2, 7.4 and 8.1.

RESPONSE

Meda submitted there was a significant difference between an 'exaggeration' and claiming a product caused 'life threatening risks'. There was also a difference between identifying a risk and claiming that risk was life threatening when considering the allegation with respect to Clause 8.1.

Meda submitted that, contrary to ALK-Abelló's comment, Meda did recognise that headings could be regarded as claims and that headings indicated the context of the following text. During the inter-company dialogue Meda noted that this heading was not a claim per se, but a statement indicating the content of the following paragraphs.

Meda noted ALK-Abelló's allegation that in this section Meda deliberately implied that there were 'life threatening risks' caused by changing from EpiPen to another adrenaline auto injector and that a reader was likely to infer that the risk was associated with Jext, as the majority of the document compared EpiPen to Jext.

Meda did not consider that the allegations were specific and did not correlate with the content of the section. There was nothing in Section 7 (or any part of the document) that indicated any comment on the safety of Jext. In fact the word Jext did not appear in the section at all. The full text was:

'Patients with anaphylaxis ensure that they avoid the allergy triggers and as such anaphylactic shock is a rare event for most patients. Patients need to be prepared, ensuring that they carry two adrenaline auto injector pens at all times and making sure that they and their relatives/carers know how to administer it in an emergency.

Moving anaphylactic patients away from the auto injector device with which they are familiar needs to be well planned; ensuring adequate training is in place for patients and the many groups that need to be able to use an adrenaline auto injector in an emergency.

Using an auto injector correctly is vitally important and any strategy of a PCT to move away from EpiPen Auto-Injector should not underestimate the size of the task to be undertaken in training individuals in adrenaline auto injector use. Indeed the implications for patients of not knowing how to use their adrenaline auto injector in an emergency are life threatening.'

Meda submitted that it failed to see how the need to ensure patients were trained in correct injection technique was in any way disparaging or misleading. It would be irresponsible not to train on administration technique.

Since it did not make the alleged claim (that there were 'life threatening risks' caused by changing from EpiPen to another adrenaline auto injector), Meda denied any breach of Clause 7.2. It could not therefore be in breach for not substantiating a claim that it did not make. Meda also denied that the section disparaged Jext; the booklet did not indicate Jext needed additional training or that it was inferior to EpiPen auto injector, only that all auto injectors required training in administration technique. Meda therefore denied any breach of Clause 8.1.

PANEL RULING

The Panel noted that Section 7 'The risk of changing from EpiPen Auto-Injector' discussed patient preparedness and training in relation to anaphylactic shock generally and included one sentence about the need for training if a patient was moved from a device with which they were familiar. The final paragraph noted the importance of using the auto injector correctly and advised that PCTs moving away from EpiPen should not underestimate the size of the training task. The final sentence read 'Indeed the implications for patients of not knowing how to use their auto-injector in an emergency are life-threatening'.

The Panel considered that it was not unreasonable to assume that there were risks involved in switching a patient's treatment from one on which they were already established and with which they were familiar. The risks would vary depending on the differences in treatment and the nature of the condition being treated. It noted that anaphylactic shock was a rare event but could have serious consequences.

The Panel considered that the reference to the implications for patients of not knowing how to use their auto injector in an emergency being 'life-threatening' would apply to all devices. There was no implication that the decision to switch from EpiPen was 'life-threatening', nor was any other specific auto injector mentioned in that regard. In the Panel's view it was not unreasonable to stress the need to ensure that appropriate training was given when anaphylactic patients were changed to a different auto injector.

The Panel did not consider that the reader would infer that the risks in Section 7 were associated with Jext as, in ALK-Abelló's view, the majority of the booklet compared EpiPen to Jext. This was not so. Sections 1-7 either discussed auto injectors in very general terms or identified all three available auto injectors without attaching disproportionate weight to any one, including Jext. The Panel noted that whilst the subsequent double page spread at Sections 8.1 and 8.2 compared EpiPen and Jext it did not consider that the reader would view the preceding section (Section 7.2) in light of such subsequent comparisons. Overall, the Panel considered that there was no implication that switching patients to Jext put them at risk as alleged. On this narrow point the section was not misleading and nor was Jext disparaged. The Panel ruled no breach of Clauses 7.2 and 8.1. As no claim was made in relation to Jext the Panel thus ruled no breach of Clause 7.4.

Complaint received **27 April 2012**

Case completed **4 July 2012**