MEDA v ALK-ABELLÓ

Promotion of Jext

Meda complained about a leavepiece issued by ALK-Abelló for its adrenaline auto-injector Jext which was indicated for the emergency treatment of severe acute allergic reactions as well as idiopathic or exercise induced anaphylaxis.

Meda alleged that two diagrams, entitled 'Jext is designed to be easy to use', failed to accurately reflect the instructions for use in the marketing authorization of the product and exaggerated the simplicity of use of the device. The diagrams were derived from the product labelling but were not accompanied by explanatory text. Meda submitted that this was an incomplete depiction of the use of the product.

Meda considered that adrenaline auto-injectors were a technical and emotive treatment and their correct use depended on accurate information and comprehensive training. The Jext device was used differently from the current market leader and ALK-Abelló was obliged to present the instructions for use clearly and explicitly.

Whilst Meda did not dispute the claim that Jext was 'designed to be easy to use' it questioned whether the administration of adrenaline in an anaphylactic emergency was ever simple and submitted that it was untrue that Jext was simpler than other adrenaline auto-injector devices.

The detailed response from ALK-Abelló is given below.

The Panel compared the steps illustrated in the leavepiece with those included in Section 6.6 of the Jext summary of product characteristics (SPC). There were five illustrated steps in the SPC and two in the leavepiece. The two diagrams in the leavepiece were identical to the two diagrams on the barrel of the auto-injector itself. The only patient instruction included in the SPC which was not illustrated on the leavepiece was the final step to massage the injection area for 10 seconds and seek urgent medical help. The explanatory text next to the diagrams in the SPC noted that the black tip of auto-injector must be placed against the outer thigh and the auto-injector held at a 90º angle to the thigh. The Panel considered that these two requirements were clear in the two diagrams that appeared in the leavepiece.

The Panel considered that although only two of the five SPC diagrams had been reproduced in the leavepiece, the leavepiece did not exaggerate the simplicity of using Jext as alleged. The Panel further considered that Jext had been promoted in accordance with the terms of its marketing authorization; it did not consider that the claim 'Jext is designed to be easy to use' implied that administration of adrenaline was simple or that Jext was simpler to administer than other auto-injector devices as alleged. No breach of the Code was ruled on all the three points.

Meda Pharmaceuticals Limited complained about a leavepiece (ref 600AD) issued by ALK-Abelló Limited for its adrenaline auto-injector Jext. Jext was indicated for the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis. Meda also supplied an adrenaline auto-injector (EpiPen) for allergic emergencies.

COMPLAINT

Meda alleged that two small diagrams on the inside front flap of the leavepiece, entitled 'Jext is designed to be easy to use', failed to accurately reflect the instructions for use in the marketing authorization of the product, in breach of Clause 3.2 of the Code, and exaggerated the simplicity of use of the device, in breach of Clause 7.2.

The two diagrams were derived from the product labelling but were not accompanied by explanatory text. Meda submitted that this was an incomplete depiction of the use of the product. To put this into context, Meda noted that the summary of product characteristics (SPC) for Jext listed five steps for administration.

Meda noted that on the facing page of the leavepiece, the Jext device was shown unboxed, which, during inter-company dialogue, ALK-Abelló had stated was an adequate representation to the reader for complete instruction. Meda disagreed and submitted that even if the device was pictured on the same page, the reader would not be given a clear indication of the full instructions for use.

Adrenaline auto-injectors were a technical and emotive treatment and their correct use depended on accurate information and comprehensive training. The Jext device was used differently from the current market leader and ALK-Abelló was obliged to present the instructions for use clearly and explicitly.

Whilst Meda did not dispute the claim that Jext was 'designed to be easy to use' it questioned whether the administration of adrenaline in an anaphylactic emergency was ever simple and submitted that it

was untrue that Jext was simpler than other adrenaline auto-injector devices.

RESPONSE

ALK-Abelló stated that the promotional leavepiece was designed to be used with health professionals who were experienced prescribers of adrenaline auto-injectors. The leavepiece was not part of the patient training support programme for Jext; separate materials were available for this purpose.

ALK-Abelló submitted that the two diagrams on the inside front flap reproduced in full the illustrations used on the Jext auto-injector integral instructions for use, as approved by the Medicines and Healthcare products Regulatory Agency (MHRA) and 14 other European agencies. The leavepiece was designed so that at all times the recipient could clearly view two actual size photographs of Jext 300mcg and Jext 150mcg showing the instructions for use as displayed on the approved labelling.

ALK-Abelló stated that the illustrated, integral instructions for use were one of the enhanced safety features designed into Jext based on 15 years of feedback about adrenaline auto-injectors from health professionals, patients and carers. The leavepiece was designed to highlight these features to experienced adrenaline auto-injector prescribers as they would know that many patients failed to use their device correctly in the event of a potentially life-threatening anaphylactic reaction.

ALK-Abelló submitted that it was a commonly held belief that cartridge based adrenaline auto-injectors (such as Jext and EpiPen) had a two step activation process and that syringe based adrenaline auto-injectors (such as Anapen) had an extra operational step. Diagrams showing the two main steps of the activation process for cartridge based devices were included on both the US and UK EpiPen websites, included in Meda's EpiPen leavepiece and EpiPen instructions for use, and approved by the MHRA for inclusion on the device label for Jext, as illustrated in the leavepiece at issue.

ALK-Abelló submitted that the two actual size photographs of the approved, built-in instructions for use included on the leavepiece enabled the recipient to form their own opinion as to the simplicity or otherwise of Jext. The leavepiece was sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine, and all information provided was in accordance with the terms of the Jext marketing authorization and consistent with the Jext SPC.

ALK-Abelló denied breaches of Clauses 3.2 and 7.2 of the Code.

PANEL RULING

The Panel noted that the therapeutic indication for Jext listed in the SPC for the product was the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis.

The Panel noted ALK-Abelló's submission that the leavepiece was for use with health professionals who were experienced prescribers of adrenaline auto-injectors. The leavepiece was not for use with patients. ALK-Abelló had submitted that separate patient training materials were available.

The Panel compared the steps illustrated in the leavepiece with those included in Section 6.6 of the Jext SPC. There were five illustrated steps in the SPC and two in the leavepiece. The two diagrams in the leavepiece were identical to the two diagrams on the barrel of the auto-injector itself. The only patient instruction included in the SPC which was not illustrated on the leavepiece was the final step to massage the injection area for 10 seconds and seek urgent medical help. The explanatory text next to the diagrams in the SPC noted that the black tip of auto-injector must be placed against the outer thigh and the auto-injector held at a 90° angle to the thigh. The Panel considered that these two requirements were clear in the two diagrams that appeared in the leavepiece.

The Panel considered that although only two of the five SPC diagrams had been reproduced in the leavepiece, the leavepiece did not exaggerate the simplicity of using Jext as alleged. No breach of Clause 7.2 was ruled. The Panel further considered that Jext had been promoted in accordance with the terms of its marketing authorization. No breach of Clause 3.2 was ruled.

The Panel did not consider that the claim 'Jext is designed to be easy to use' implied that administration of adrenaline was simple or that Jext was simpler to administer than other auto-injector devices as alleged. No breach of Clause 7.2 was ruled.

Complaint received **27 May 2011**

Case completed **5 July 2011**