MEDA v ALK-ABELLÓ

Jext website

Meda Pharmaceuticals complained about ALK-Abelló's website (www.jext.co.uk) which provided health professionals and patients with information about anaphylaxis and its medicine, Jext (adrenaline tartrate auto-injector). Jext was indicated for the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings, foods, medicines and other allergens as well as idiopathic or exercise induced anaphylaxis. Meda also supplied an adrenaline auto-injector (EpiPen) for allergic emergencies.

Meda alleged that ALK-Abelló had not provided complete and accurate instructions for use of the device in breach of the Code; it had not accurately reflected the marketing authorization. Meda submitted that this was critically important as patients might have less than ten minutes to administer adrenaline in the event of an anaphylactic reaction. In addition, adrenaline auto-injectors were single use devices and if administered incorrectly, there was no second chance. Therefore the user must be trained and confident in the correct use.

Specifically, the Jext website had the method of administration presented as a series of images on both the patient and health professional sections. These images were reproduced from the summary of product characteristics (SPC) and the patient information leaflet (PIL). Image number 3 from Section 6.5 of the SPC and its accompanying text 'Place the black injector tip against your outer thigh, holding the injector at a right angle (approx. 90°) to the thigh' was absent from the instructions on both sections of the website.

The detailed response from ALK-Abelló is given below.

The Panel noted that Jext was indicated for use in the emergency treatment of severe, acute allergic reactions (anaphylaxis). It was critically important that patients knew exactly how to use the Jext auto-injector correctly. It was a single-use device and once activated could not be used again.

The website at issue included a page headed 'How does Jext work?' which illustrated, in a number of diagrams, how to use the device. The first four of these diagrams were the same as diagrams 1, 2, 4 and 5 of the SPC. The third diagram included in the SPC, but omitted from the website, depicted the Jext device held against the thigh with the 90° angle labeled. The third diagram on the website, however, clearly showed the device being held against the thigh at the correct angle. In the Panel's view the 90° angle was clearly illustrated albeit not labeled. In addition to the static diagrams on the website, patients could access a video via the same page of the website which demonstrated how to use Jext. In the Panel's view, the instructions for use on the website were not inconsistent with the particulars listed in the Jext SPC. No breach of the Code was ruled.

Meda Pharmaceuticals Limited complained about ALK-Abelló Ltd's website (www.jext.co.uk ref 552AD) which provided health professionals and patients with information about anaphylaxis and its medicine Jext (adrenaline tartrate auto-injector). Jext was indicated for the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings, foods, medicines and other allergens as well as idiopathic or exercise induced anaphylaxis. Meda also supplied an adrenaline auto-injector (EpiPen) for allergic emergencies.

COMPLAINT

Meda stated that Jext was launched in the UK in September 2011. The website at issue was a resource for patients and health professionals to receive information on the correct use of Jext. Meda alleged that ALK-Abelló had not provided complete and accurate instructions for use of the device in breach of Clause 3.2; it had not accurately reflected the marketing authorization.

Meda submitted that this was critically important due to the nature of the condition being treated. Evidence showed that patients might have less than ten minutes to administer adrenaline in the event of an anaphylactic reaction, depending on the allergen. In addition, adrenaline auto-injectors were single use devices, meaning that if they were administered incorrectly, there was no second chance. Therefore the user must be trained and confident in the correct use. This was especially relevant for a user who has been previously trained on a different auto-injector. Meda considered that ALK-Abelló had attempted to present Jext as identical to the current standard of care by deliberately omitting a step in the instructions for use.

Specifically, the Jext website had the method of administration presented as a series of images on both the patient and health professional sections. These images were reproduced from the summary of product characteristics (SPC) and the patient information leaflet (PIL). Image number 3 from Section 6.5 of the SPC and its accompanying text 'Place the black injector tip against your outer thigh, holding the injector at a right angle (approx. 90°) to the thigh' was absent from the instructions on both sections of the website.

Jext was administered differently from other adrenaline auto-injectors on the UK market. Meda considered that as a newly launched product with which patients and prescribers were unfamiliar, it

was even more important that they were presented with accurate and consistent information. Meda stated that the EpiPen auto-injector was the current standard of care and had been on the UK market for over 15 years. It was administered by a so called 'swing and jab' technique, where the device was held away from the outer thigh and positively jabbed against the leg to trigger the injection mechanism. In contrast, Jext used a 'place and press' method, whereby the device must be placed onto the leg and when in place, pressure applied to trigger the injection. Meda alleged that by excluding the description of the 'place' step in the instructions for use, ALK-Abelló might have placed users at risk of incorrect administration of the device. Worse, users might believe that they could administer Jext in the same way as they would an EpiPen auto-injector and that the devices were interchangeable.

Meda submitted that EpiPen auto-injectors were well established in the UK with a market share of over 95%. Therefore patients, prescribers, pharmacists and other stakeholders were versed in the method of administration. Meda further submitted that if a patient used the 'swing and jab' technique with Jext, the device might malfunction. Such errors in use could be catastrophic for a patient suffering from anaphylaxis. Meda therefore considered that it was vital that the complete instructions were displayed in educational and promotional materials. The website in question was both educational and promotional.

Since first contacting ALK-Abelló about this matter in September 2011, Meda had observed that other materials issued by ALK-Abelló contained the same set of incomplete instructions, for example a pad of instruction sheets for pharmacists to pass to patients (ref 593bAD). From a patient's perspective, it could be confusing to find that the instructions in the pack differed from those on the website and the leaflet provided by the pharmacist, which further highlighted the problem. Further examples were the quotations 'It's similar to your EpiPen, so you don't need any re-training' and 'if you're moving from your EpiPen, you use it in the same way.' Meda noted that although these statements were on an international Jext website (in English) and not part of this complaint, they helped to illustrate the company's concern.

Meda submitted that unfortunately inter-company dialogue had failed to resolve this matter. Meda had previously alleged that a Jext leavepiece was in breach of Clause 3.2 (Case AUTH/2405/5/11) and other clauses. In that case the PMCPA ruled there was no breach and part of the justification for the incomplete instructions for use was that the leavepiece was not part of the patient training support programme for Jext. In the present case, the instructions for use presented on the Jext website were explicitly for the support of patients and health professionals, in addition to being promotional. Meda therefore repeated its allegation that the website was in breach of Clause 3.2 and represented a potential risk to patient safety. The complete instructions for use of Jext should be consistently displayed on this and all other materials issued by ALK-Abelló.

RESPONSE

ALK-Abelló stated that Jext was an adrenaline auto-injector indicated for emergency self-administration of adrenaline to treat anaphylaxis. The Jext website was designed to be a resource for patients prescribed Jext with a separate section for health professionals treating patients with severe allergy. The website contained both graphic and audio-visual elements designed to instruct patients in the correct use of Jext in a potentially life threatening situation. These instructions for use were developed in conjunction with senior health professionals in the field of allergy and also with a patient organisation which represented patients living with severe allergy. The instructions for use were designed to be informative, concise and easily understood by the widest range of patients possible.

The instructions for use of Jext as shown on the website featured diagrams based on those in the SPC which had been simplified by removing one redundant diagram which specified that the device must be held at a 90° angle. The location of injection and 90° angle were clearly demonstrated in the subsequent diagram. The instructions on the website were further enhanced by an additional two diagrams advising the patient to call 999 and when to administer a second injection if required. ALK-Abelló believed the instructions for use of Jext as shown on the website were consistent with those in the SPC and the PIL. In Case AUTH/2405/5/11 the Panel ruled that the requirement to place the black tip of the Jext against the outer thigh at a 90° angle was clear in diagram number four in the SPC.

ALK-Abelló refuted the allegation that omitting diagram three was an attempt to present Jext as identical to EpiPen which required swinging from a distance of 10cm away from the thigh to activate the injection.

Directly below the instructions for use, in the same window on the website, was a direct link to a patient video which clearly demonstrated the correct administration technique with the recommendation 'To ensure that you, your family, friend and colleagues know how to administer your Jext, watch the comprehensive demonstration video.' A copy of this video was provided.

ALK-Abelló was concerned that Meda had complained directly to the PMCPA without inter-company dialogue or supporting data. Meda's statement about the possible malfunction of the Jext device was completely unfounded. ALK-Abelló submitted that Meda had deliberately abused the PMCPA system in an attempt to have published unfounded allegations denigrating Jext which could not be used in promotional literature without breaching the Code. ALK-Abelló therefore respectfully requested that Meda provide to both the PMCPA and ALK-Abelló robust data to substantiate these allegations or withdraw them unreservedly.

ALK-Abelló had provided Meda with details of the international website as part of a separate inter-

company dialogue on 26 September. Meda had acknowledged that this website was outside the scope of the Code. ALK-Abelló had received no further correspondence on this matter. ALK-Abelló believed therefore it was inappropriate for Meda to refer to this non-UK website in this complaint.

Both ALK-Abelló and Meda acknowledged that it was acceptable within the Code to be consistent with the particulars as listed in the SPC without reproducing verbatim those particulars, thus adhering to Clause 3.2.

Meda had requested that the Panel make a ruling that the complete instructions for use of Jext be consistently displayed on the website and all other materials issued by ALK-Abelló. Patient support and educational materials needed to be appropriate for the intended audience and might take different forms. Due to the range of patients prescribed adrenaline auto-injectors a one-size-fits-all approach was not appropriate, as such ALK-Abelló produced bespoke patient support and educational materials specific to different groups and based on recommendations of patient support groups and national allergy specialists. ALK-Abelló suggested that it was inappropriate to mandate how instructions for use were displayed, rather they should comply with Clause 3.2 in the most appropriate form for the intended audience.

ALK-Abelló took very seriously its commitment to abide by the Code and believed that the Jext instructions for use were fully consistent with the SPC and not in breach Clause 3.2.

PANEL RULING

The Panel noted that although ALK-Abelló had submitted that there had been a lack of inter-company dialogue, correspondence provided by Meda showed that the two companies had discussed, to some extent, the matter at issue. It appeared, however, that the complaint to the Authority raised some aspects of patient safety which had not previously been discussed with ALK-Abelló. Meda had, however, only alleged a breach of Clause 3.2 of the Code and so the Panel only considered this aspect of the complaint.

The Panel noted that Jext was indicated for use in the emergency treatment of severe, acute allergic reactions (anaphylaxis). It was critically important that patients knew exactly how to use the Jext auto-injector correctly. It was a single-use device and once activated could not be used again.

The website at issue included a page headed 'How does Jext work?' which illustrated, in a number of diagrams, how to use the device. The first four of these diagrams were the same as diagrams 1, 2, 4 and 5 of the SPC. The third diagram included in the SPC, but omitted from the website, depicted the Jext device held against the thigh with the 90° angle labeled. The third diagram on the website, however, clearly showed the device being held against the thigh at the correct angle. In the Panel's view the 90° angle was clearly illustrated albeit not labeled. In addition to the static diagrams on the website, patients could access a video via the same page of the website which demonstrated how to use Jext. In the Panel's view, the instructions for use on the website were not inconsistent with the particulars listed in the Jext SPC. No breach of Clause 3.2 was ruled.

Complaint received **6 December 2011**

Case completed **5 January 2012**