CASE AUTH/2488/3/12

LEAD PHARMACIST v MEDA

Email promotion of EpiPen

A lead pharmacist complained about an uninvited email from Meda, entitled 'Re. Adrenaline Autoinjectors & Patient Safety' which referred to confusion regarding the different administration techniques for the various auto-injectors. According to the email local GPs had suggested Meda contact the complainant to discuss the matter and that local clinicians had been led to believe that there was no difference in the administration method. The email referred specifically to the 'swing & jab' method of using EpiPen (marketed by Meda) and stated that there was no data to show what the clinical outcome would be if a 'place and push' auto-injector [ie Jext, marketed by ALK-Abelló] was administered in the manner of EpiPen. Meda was gravely concerned that inaccurate information about other auto-injectors having the same method of administration [as EpiPen] would cause confusion and put lives at risk.

The email seemed to imply that there were safety concerns with alternative products but the complainant knew of no evidence to substantiate this. The complainant stated that his local primary care trust (PCT) had not received any reports of concerns from GPs. The complainant alleged that the email constituted disguised promotion.

The detailed response from Meda is given below.

The Panel noted that the email referred to adrenaline auto-injectors and to EpiPen by name. It referred to adrenaline delivery at the point of a life threatening allergic emergency and the indication of anaphylaxis. It further stated that as EpiPen had been the auto-injector of choice for over 15 years, health professionals, carers and patients were familiar with its unique swing and jab method of administration. The Panel considered that the email was promotional.

The Panel considered that the title of the email, 'Re. Adrenaline Autoinjectors & Patient Safety', implied that it contained safety information rather than promotional messages. Email recipients would look at the title of an email before deciding when and whether to open it. The Panel noted that as the email was promotional its title rendered it disguised in that regard. A breach of the Code was ruled. This ruling was not appealed.

The Panel did not consider that the email implied that there were safety concerns *per se* with other adrenaline auto-injectors, but rather that there was confusion as to whether they could be administered in exactly the same way as EpiPen and that local GPs had suggested Meda contact the pharmacist. According to the email the confusion would put lives at risk. Given its view that the email did not imply there were safety concerns with the other adrenaline auto-injectors as alleged, the Panel considered that Meda did not need to substantiate this narrow point and thus ruled no breach of the Code. This ruling was not appealed.

The Panel noted that Meda had not provided any details of the 'local GPs' who had suggested it contact the complainant. Meda submitted that one health professional in the area recommended that it write to the pharmacist.

The Panel noted the documents issued by various PCTs, and provided by Meda to support its submission that there was confusion, were about each PCT's decision to change its auto-injector of choice from EpiPen to Jext. One document stated, *et al*, that Jext could be used 'exactly like an EpiPen' and documents from the other PCTs appeared to be very similar in that regard.

The Panel considered that it was extremely important that adrenaline auto-injectors were used correctly. It noted that although health professionals in some PCTs had been given information about the similarity of the administration of EpiPen and Jext none of the PCT documents were from the complainant's PCT. The identity of the complainant had not been disclosed to Meda. The company would know which PCTs had been sent the email in question. The Panel did not know what information the complainant's PCT had distributed regarding the change to Jext. The complaint was about the email from Meda and in that regard the Panel noted that it stated 'that there were no data to show what might happen if a "place and push…design of [adrenaline auto-injector] is administered in the manner of an EpiPen…'.

It appeared from Meda's own submission that one local GP had been concerned. This was inconsistent with the email which stated 'Local GPs have suggested for us to contact you to discuss this'. There was no evidence before the Panel to indicate that there were many local clinicians who had been led to believe that there was no difference in the administration method as stated in the email or that there was local confusion. The Panel considered that the email was misleading in this regard and the statement had not been substantiated and thus the Panel ruled breaches of the Code. These rulings were appealed by Meda.

The Panel noted that the Code required that, *et al*, email must not be used for promotional purposes, except with the prior permission of the recipient. No such permission had been granted by the complainant who referred to the email as 'uninvited' and a breach of the Code was ruled as

acknowledged by Meda. This ruling was not appealed.

The Appeal Board considered that Meda's submissions had been confusing and inconsistent but it noted that at the appeal further and better particulars had been produced to show that many GPs did not clearly understand the difference in the way that the various auto-injectors (notably EpiPen and Jext) should be administered. The Meda representatives stated that over forty GPs and pharmacists had expressed concern in this regard and between twelve and fifteen had asked Meda to write to PCTs about the matter. Taking all the circumstances into account the Appeal Board did not consider that the email was misleading on this point. No breach of the Code was ruled. In the Appeal Board's view the claim had been substantiated. No breach of the Code was ruled. The appeal on both points was successful.

A lead pharmacist complained about an uninvited email from Meda Pharmaceuticals Limited. The email was entitled 'Re. Adrenaline Autoinjectors & Patient Safety' and referred to confusion regarding the way of administering different auto-injectors. According to the email local GPs had suggested Meda contact the complainant to discuss the matter. The email stated that each adrenaline auto-injector had been designed with a substantially different administration technique. Meda believed that local clinicians had been led to believe that there was no difference in the administration method. The email referred specifically to the 'swing & jab' method of using EpiPen (an adrenaline auto-injector marketed by Meda) and as this had been the adrenaline auto-injector of choice for over 15 years, health professionals, patients and carers were very familiar with its use. The email stated that there was no data to show what would happen if a 'place and push' auto-injector [ie Jext, marketed by ALK-Abelló] was administered in the manner of the EpiPen and the subsequent impact on successful adrenaline delivery at the point of life threatening allergic emergency. Meda was gravely concerned that inaccurate information about other auto-injectors having the same method of administration [as EpiPen] would cause confusion and put lives at risk.

The email explained that Meda had written to the complainant about this matter at the suggestion of local GPs.

COMPLAINT

The complainant stated that he was instrumental in the recent local approval to use Jext. The email seemed to imply that there were safety concerns with alternative products but the complainant was not aware of any evidence to substantiate this. The complainant stated that he worked at the local primary care trust (PCT) and he knew that the PCT had not received any reports of concerns from GPs. The complainant alleged that the email constituted disguised promotion.

When writing to Meda the Authority asked it to respond in relation to Clauses 7.2, 7.4, 9.9 and 12.1 of the Code.

RESPONSE

Meda stated that the author of the email was recommended to write to the pharmacist concerned by a local health professional. This was stated in the email at issue although the health professional concerned was not named. Meda stated that it was surprised that the complainant had not received reports of concerns from local GPs as Meda had received such concerns from numerous GPs and other health professionals in various regions of the UK.

Meda submitted that the email attempted to make clear that adrenaline auto-injectors had different methods of administration and to point out that there had been repeated instances of confusion, whereby some prescribers believed they could be used in the same way. Evidence of this was provided in a letter from a PCT, which stated that 'Jext can be used exactly like an EpiPen'. In addition, another document from the same PCT, entitled 'Introducing Jext', stated that 'Jext and EpiPen share the same simple 2 step method of activation'. Meda submitted that this document had been used by three NHS organisations in a near identical format and the company had repeatedly raised this issue with the PMCPA to no avail (Cases AUTH/2462/12/11 and AUTH/2405/5/11, plus recent correspondence relating to the inaccurate promotion of Jext). The information in these PCT documents was incorrect and might be a serious risk to patient safety. Meda stated that it had also raised this matter with the PCT. Meda had attempted to highlight the differences between all three adrenaline auto-injectors in the UK market for the benefit of patient safety.

Meda submitted that the email's author took a responsible decision, at the suggestion of a health professional, to inform a senior pharmacist of these findings, who could convey this important information to local health professionals. The content of the email was factually correct and did not breach Clauses 7.2 or 7.4. The email was not intended to be promotional; it was written as factual information in support of the lead pharmacist's organisation and patient safety and was therefore not certified. If however the Panel considered that the email was promotional, then Meda apologised and acknowledged that as it was sent uninvited it would be in breach of Clause 9.9.

Meda did not believe that the email was disguised promotion. It was clear from which company the email had been sent, the product at issue and it presented factual information in an accurate and balanced manner. No attempt was made to claim an advantage for EpiPen over any competing device, nor were any features of EpiPen discussed except for the method of administration, which was the point of the email.

In Meda's view this situation would have been avoided if the PMCPA had taken a more serious view of ALK-Abelló's failure to accurately promote the method of administration of Jext. In the interest of patient safety, Meda wanted to ensure that EpiPen was administered with a swing and jab technique, Jext with a place and push technique and Anapen with a place and click technique, consistent with their marketing authorizations. An article published in The Pharmaceutical Journal helped to explain the importance of this matter (Holloway and Sharma 2012); in addition, a response to the article from a senior UK pharmacist supported the view that it was vital that pharmacists and patients were trained in the different methods of administration of the various auto-injectors (Jerman 2012). Meda urged the Authority to consider this information and the implications of failed administration of adrenaline in an anaphylactic emergency.

Following a request for further information, Meda submitted that it was made clear to the email's author during day to day contact with health professionals that they had significant concerns about the way Jext had been promoted in their region, which left many of them with the impression that Jext could be used in the same way as EpiPen. The evidence to support this was the PCT documents and others. The email's author was advised to contact the medicines management committee of the PCT to correct this false impression. The recipients of the email were identified through previous contact with them. The author of the email had routine contact with members of medicines management committees of various PCTs and so was known to the recipients before the email was sent. There were seven recipients, of whom five requested a meeting to discuss the points raised and appreciated the contact.

PANEL RULING

The Panel noted that the email at issue referred to adrenaline auto-injectors and to EpiPen by name. It referred to adrenaline delivery at the point of a life threatening allergic emergency and the indication of anaphylaxis. It further stated that 'EpiPen Auto-Injector has been the AAI [adrenaline auto-injector] of choice for over 15 years and as a result GPs, pharmacists, hospital doctors, nurses, caregivers and patients are all very familiar with its unique swing and jab method of administration'. Given the content of the email the Panel considered that it was promotional and found it difficult to understand how it could be viewed as anything other.

The Panel considered that the title of the email 'Re. Adrenaline Autoinjectors & Patient Safety', implied that it would contain safety information rather than promotional messages. Email recipients would look at the title of an email before deciding when and indeed whether or not to open such an email. The Panel noted its decision that the email was promotional and considered that the title of the email meant that it was disguised in that regard. A breach of Clause 12.1 was ruled. This ruling was not appealed.

The Panel did not consider that the email at issue implied as alleged that there were safety concerns *per se* with other adrenaline auto-injectors, but rather that there was confusion as to whether other such injectors could be administered in exactly the same way as EpiPen and that local GPs had suggested Meda contact the pharmacist. According to the email the confusion would put lives at risk. Given its view that the email did not imply there were safety concerns with the other adrenaline auto-injectors as alleged there was no need for Meda to provide evidence to substantiate this narrow point and thus the Panel ruled no breach of Clause 7.4. This ruling was not appealed.

The Panel noted that Meda had not provided any details of the 'local GPs' who suggested Meda contact the medicines management pharmacist. Meda submitted that one health professional in the area recommended that Meda write to the pharmacist.

The Panel noted the documents issued by various PCTs and provided by Meda in support of its submission that there was confusion. All communicated the decision of the relevant PCT to change its auto-injector of choice from EpiPen to Jext. One document issued by a PCT stated, *et al*, that Jext could be used 'exactly like an EpiPen'. This document also provided details of actions taken by the PCT, including training by the manufacturer to support the change from EpiPen. The documents from the other organisations appeared to be very similar. All were entitled 'Introducing Jext' and contained an image of the Jext 150mcg and 300mcg injection devices. In two of these documents the text on the injection devices which described the injection technique was visible. In a section 'Important point to remember' was the statement 'Jext and EpiPen share the same simple 2 step administration'. In addition the documents provided reasons for the change.

The Panel considered that it was extremely important that adrenaline auto-injectors were used in accordance with the instructions in the relevant summary of product characteristics (SPC). It noted that although some evidence had been supplied regarding information given to health professionals in various PCTs about the similarity of the administration of EpiPen and Jext no evidence had been supplied of any local confusion. The Panel, however, noted Meda's submission that it had received concerns from numerous GPs and other health professionals and that there were repeated instances of confusion whereby some prescribers believed EpiPen and Jext could be used in the same way. None of the various PCT documents were from the complainant's PCT. The identity of the complainant had not been disclosed to Meda. The company would know which PCTs had been sent the email in question. The Panel did not know what information the complainant's PCT had distributed regarding the change to Jext. The complaint was about the email from Meda and in that regard the Panel noted that it stated 'that there were no data to show what might happen if a "place and push…

design of [adrenaline auto-injector] is administered in the manner of an EpiPen…'.

It appeared from Meda's own submission that one local GP had been concerned. This was inconsistent with the email which stated 'Local GPs have suggested for us to contact you to discuss this'. There was no evidence before the Panel to indicate that there were many local clinicians who had been led to believe that there was no difference in the administration method as stated in the email or that there was local confusion. The Panel considered that the email was misleading in this regard and the statement had not been substantiated thus the Panel ruled breaches of Clauses 7.2 and 7.4. This ruling was appealed by Meda.

The Panel noted that the Code required that, *et al*, email must not be used for promotional purposes, except with the prior permission of the recipient. No such permission had been granted by the complainant who referred to the email as 'uninvited' and a breach of Clause 9.9 was ruled as acknowledged by Meda. This ruling was not appealed.

During the consideration of this case the Panel noted Meda's comment about previous cases Case AUTH/2405/5/11 and AUTH/2462/12/11. Both cases had been ruled not to be in breach of the Code and neither had been appealed by Meda (the complainant in both cases). A further letter setting out Meda's concerns had not been processed as the requirements of the Constitution and Procedure had not been met and it had not been submitted as a complaint.

The Panel was also concerned that a promotional email had been sent which had not been certified nor was prescribing information provided. It requested that Meda be advised of its concerns.

APPEAL BY MEDA

Meda remained extremely concerned that the Panel appeared not to have grasped the essential point of its message, which was to share the concerns of health professionals with their local/regional colleagues whose role was to advise on prescribing. The latter group had the influence and position to ensure clear and accurate information was provided to prescribers (and those involved in procurement) that adrenaline auto-injectors were not alike and must be used according to their licensed instructions. Meda remained concerned that this had not happened, possibly due to incorrect information from other companies.

In support of this view, Meda had already shown how a PCT and other NHS organisations had sent prescribers factually incorrect information. This had unknown consequences and it was this that Meda was attempting to address. Subsequent communication with the NHS organisations concerned had resulted in them understanding their mistakes and issuing corrected information to prescribers. However, Meda was sure the Appeal Board would agree it was preferable for this situation to be avoided.

Meda submitted that it had previously complained that ALK-Abelló's promotional and education material had inaccurately described how to administer Jext but the Panel twice ruled no breach of the Code (Cases AUTH/2462/12/11 and AUTH/2405/5/11). Meda did not appeal these rulings as it considered that it was unable to present this information any more clearly. If the Panel did not agree that correct instructions for use were vital to prescribers and users, then Meda was forced to accept this. However, Meda would not accept the perpetuation of this false information. For example, a prescriber had recently told Meda that a patient experienced bounce back from their thigh after they administered a different device in the manner of an EpiPen auto-injector, resulting in a failure to inject adrenaline. Meda submitted this was further evidence of a failure to provide prescribers with the correct information. Meda was actively following this up with the prescriber.

Meda hoped the PMCPA now appreciated the importance of this matter and that Meda was supported in future for taking a responsible approach to correcting such factual errors, whether published by the NHS or any other organisation. If such efforts were discouraged by the PMCPA, it would be extremely concerning for the pharmaceutical industry. Meda was encouraged that it took the correct action by the fact that five of the seven recipients of the email requested a meeting to discuss the points raised, whereas only one recipient had complained.

Meda submitted that the Panel appeared at first to appreciate the points raised in the message, stating that it considered it extremely important that adrenaline auto-injectors were used according to the instructions in the SPC. Although the Panel also appeared to appreciate the significance of the factually incorrect information issued by a number of NHS organisations it concluded that no such incorrect written information was issued by the complainant's PCT and therefore Meda's concerns and those of the GPs involved were not valid. This was confusing. The lack of written guidance from the complainant's PCT did not invalidate the concern, nor prove its absence in the relevant area. Meda's provision of material from various NHS organisations was intended to illustrate the point to the Panel, rather than prove its validity in a specific geographical area. Similarly, the number of GPs expressing concerns appeared to have influenced the ruling, whereas Meda submitted that even a single GP with concerns should be listened to and supported. Concerns were raised in the territories of all recipients of the email. Meda therefore strongly disputed that the email was misleading or unsubstantiated and therefore denied a breach of Clauses 7.2 and 7.4.

Meda was also keen to understand who was culpable if a patient was harmed because they failed to receive treatment due to receipt of inaccurate

information. Meda was committed to ensuring this did not happen and would continue to support its customers accordingly.

RESPONSE FROM THE COMPLAINANT

The complainant stated that he agreed with the Panel's rulings.

APPEAL BOARD RULING

The Appeal Board considered it was extremely important that adrenaline auto-injectors were used in accordance with their SPCs. It was also important that activities and materials complied with the Code.

The email at issue stated that 'Local GPs have suggested [that Meda] contact you to discuss [confusion regarding the mechanism of administration for different adrenaline auto-injectors]'. The complainant submitted that his local PCT had not received any reports of concerns from GPs. In its response Meda submitted that the email was sent to the complainant on the recommendation of a local health professional. The Panel had thus considered that the reference in the email to 'Local GPs' was misleading and could not be substantiated. Breaches of Clauses 7.2 and 7.4 were ruled.

The Appeal Board considered that Meda's submissions had been confusing and inconsistent but it noted that at the appeal further and better particulars had been produced. In that regard the Appeal Board noted that it had found it particularly helpful that the author of the email attended the appeal. The identity of the complainant had not been disclosed to Meda nor had the name of the relevant PCT. The Appeal Board considered that Meda had produced in its written and oral submissions, evidence to show that many GPs did not clearly understand the difference in the way that the various auto-injectors (notably EpiPen and Jext) should be administered. The Meda representatives stated that over forty GPs and pharmacists had expressed concern in this regard and between twelve and fifteen had asked the author of the email to write to PCTs about the matter. Taking all the circumstances into account the Appeal Board did not consider that the email was misleading on this point. No breach of Clause 7.2 was ruled. In the Appeal Board's view the claim had been substantiated. No breach of Clause 7.4 was ruled. The appeal on both points was successful

Complaint received **9 March 2012**

Case completed **28 June 2012**