CASE AUTH/2492/3/12

PRESCRIBING ADVISOR v MEDA

EpiPen booklet

A prescribing advisor complained about the tone and content of a booklet entitled 'The Case for EpiPen (Adrenaline) Auto-Injector' which he had received from Meda Pharmaceuticals. In the complainant's view the document was sensationalist, emotive and unsubstantiated. Overall, the complainant considered that the booklet was unprofessional and sought to create alarm rather than provide a rational, proportionate response to a competitor product.

The detailed response from Meda is given below.

The complainant objected to the claim 'Moving away from EpiPen Auto-Injector to an alternative auto injector brand should be carefully considered on a regional level...' as he considered it was reasonable, and in fact now being encouraged, to make decisions at a local level.

The Panel disagreed with Meda's submission that there was no difference between 'regional' and 'local' in this context. The Panel noted that the booklet appeared to use 'regional' and 'PCT' interchangeably, referring to the 'PCT region' and 'region or PCT'. The booklet was distributed to PCTs and in that regard the Panel considered that the target audience would understand 'regional' to cover a much larger geographical area than that covered by a PCT. This appeared to be the complainant's understanding. The Panel considered that the use of the term 'regional' in this context was misleading; a breach of the Code was ruled.

The complainant alleged that the claim 'Many patients are likely to be unhappy with the prospect of a change from EpiPen Auto-Injector to an alternative device' was unsubstantiated conjecture.

The Panel considered that although the claim stated 'Many patients are *likely* to be unhappy…' (emphasis added), this did not negate the impression that many patients *would* be unhappy to change from EpiPen to an alternative device; there was no data to substantiate such a claim. The Panel ruled a breach of the Code. The Panel considered that in the absence of substantiating data the claim was misleading. A breach of the Code was ruled.

The complainant objected to the claims 'There would need to be a regional decision …' 'This is a massive task…' as he considered that this did not have to be done on a regional basis.

The Panel noted its comments above in relation to the term regional. The Panel considered that its ruling above applied here and ruled a breach of the Code. The Panel considered that it was likely that switching a patient's adrenaline auto injector would inevitably require retraining of patients, physician's and others. The claim in question was followed by a detailed discussion of the tasks required and a flow chart setting out a PCT implementation plan. Meda had provided no data to quantify the amount of time this would require. In that regard the Panel considered that the claim 'This is a massive task' was misleading and could not be substantiated, and breaches of the Code were ruled.

The complainant noted the claim 'The time and costs required to move patients from EpiPen Auto-Injector to Jext is a questionable use of scarce health resources…' and was not persuaded that it was Meda's role to influence the priorities of PCTs in this way.

The Panel considered that it was not unacceptable for companies to put forward an economic case as to why patients should stay on their medicines and not be switched to others. Such activities, however, had to comply with the Code. The Panel considered that the claim at issue implied that anyone who decided to change patients from EpiPen to Jext would waste NHS resources. In the Panel's view this failed to recognize the professional standing of the audience to which the booklet was directed. A breach of the Code was ruled.

A prescribing advisor complained about the tone of a 15 page, A4 booklet entitled 'The Case for EpiPen (Adrenaline) Auto-Injector' (ref UK/EPI/11/0053d) which he had received from Meda Pharmaceuticals Limited. In the complainant's view the document was sensationalist, emotive and unsubstantiated. Overall, the complainant considered that the booklet was unprofessional and sought to create alarm rather than provide a rational, proportionate response to a competitor product in a competitive market.

When writing to Meda, the Authority asked it to respond in relation to Clauses 7.2, 7.4 and 9.2 of the Code.

1 Claim 'Moving away from EpiPen Auto-Injector to an alternative auto injector brand should be carefully considered on a regional level...'.

This claim appeared in the summary section on page 3 of the booklet.

COMPLAINT

The complainant considered it was perfectly reasonable, and in fact now being encouraged, to make decisions at a local level and was likely to be done on a clinical commissioning group (CCG) basis in future.

RESPONSE

Meda stated that the booklet in question was sent to primary care trusts (PCTs) to help them understand the financial considerations of the various adrenaline auto injector brands available in the UK. Meda considered the booklet was accurate, fair and balanced in its presentation of data and information on anaphylaxis, relevant clinical guidelines and the factors that PCTs should consider when deciding which brands to select.

Meda agreed with the complainant; regional decisions were currently taken at PCT level and were likely to be taken by CCGs in the future. However, there seemed to be a simple disagreement on the definition of 'regional'. In Meda's view, there was no difference between 'regional' and 'local' in this context. Therefore, Meda stood by the recommendation that changing auto injector brand was a decision that should be taken on a regional level. This was to ensure that appropriate and consistent training was delivered and the risk of confusion and mistakes during administration were minimised.

PANEL RULING

The Panel noted that Meda agreed with the complainant's statement that regional decisions were currently taken at a local level and were likely to be taken by clinical commissioning groups in the future. The Panel disagreed with Meda's submission that there was no difference between 'regional' and 'local' in this context.

The Panel noted that the booklet appeared to use 'regional' and 'PCT' interchangeably, referring to the 'PCT region' and 'region or PCT'. There was detailed discussion of changes required at a PCT level. The claim in question had to stand alone in relation to the requirements of the Code. Context was, however, important. A subsequent paragraph on the page in question explained that the booklet considered the cost implications for the NHS serving a typical population of 100,000 (PCT/health board). Nevertheless, the booklet was distributed to PCTs and in that regard the Panel considered that the target audience would understand 'regional' to cover a much larger geographical area than that covered by a PCT. This appeared to be the understanding of the complainant. The Panel considered that the use of the term 'regional' in this context was misleading and a breach of Clause 7.2 was ruled.

2 Claim 'Many patients are likely to be unhappy with the prospect of a change from EpiPen Auto-Injector to an alternative device'.

This claim appeared on page 9 of the booklet under the heading 'Is moving to another adrenaline auto injector worthwhile?'.

COMPLAINT

The complainant alleged that this claim was unsubstantiated conjecture on the part of Meda.

RESPONSE

Meda submitted that a change in medicine for any patient was a significant event, particularly when the medicine was one that a quarter of a million patients currently carried and relied on as a potentially life-saving treatment. It was not unreasonable to assume that many patients might be concerned if they were switched to a device which was significantly different in appearance, size, colour and method of administration. Meda had experience of this with its asthma inhaler products, whereby patients sought reassurance from its medical information service regarding different devices. Similarly, reassurance was often sought when a change was made to product packaging.

Meda submitted that despite this, the claim in question was not definitive and deliberately used the words 'many patients are likely to be unhappy' to ensure the reader understood that not all patients would feel this way. The text in this section of the piece highlighted the resource considerations that management bodies should take when considering a wholesale switch between products. The specific claims made were intended merely to highlight the need to ensure that patients who were given a new product were appropriately trained. This was a responsible position to take.

PANEL RULING

The Panel noted Meda's submission that it was a reasonable assumption on its part that many patients would be unhappy if they were changed from EpiPen to an alternative auto injector. Although the claim stated 'Many patients are *likely* to be unhappy…' (emphasis added), the Panel did not consider that this negated the impression that many patients *would* be unhappy to change from EpiPen to an alternative device. There was also no data to substantiate such a claim. The Panel ruled a breach of Clause 7.4. The Panel considered that in the absence of substantiating data the claim was misleading. A breach of Clause 7.2 was ruled.

3 Claims 'There would need to be a regional decision …', 'This is a massive task…'.

These claims appeared on page 9 of the booklet and followed that at issue in point 2 above.

COMPLAINT

As mentioned in point 1 above the complainant considered that this did not have to be done on a regional basis.

RESPONSE

Meda somewhat agreed that the language used ('a massive task') could have been better chosen, but stood by the view that retraining all patients, health professionals (including GPs, practice nurses, pharmacists etc) and associated stakeholders (including care-givers such as parents, friends, teachers, school nurses, youth groups etc) was a

significant, time consuming and potentially expensive undertaking. This was especially relevant in the context of anaphylaxis, where all adrenaline auto injectors had a different method of administration and correct use of the device was critical for the successful treatment of a life-threatening condition.

PANEL RULING

The Panel noted its comments above in relation to the term regional. The Panel considered that its ruling in point 1 above applied here and ruled a breach of Clause 7.2.

The Panel noted that the complainant had not explained why the phrase 'This is a massive task' was misleading. The Panel further noted Meda's submission that it somewhat agreed that the language used ('a massive task') could have been better chosen, but stood by its view that retraining all patients, health professionals and associated stakeholders was a significant, time consuming and potentially expensive undertaking. The Panel considered that it was likely that switching a patient's adrenaline auto injector would inevitably require retraining of patients, physician's and others involved in the care of the patient. The claim in question was followed by a detailed discussion of the tasks required and a flow chart setting out a PCT implementation plan. Meda had provided no data to quantify the amount of time this would require. In that regard the Panel considered that the claim 'This is a massive task' was misleading and could not be substantiated, in breach of Clauses 7.2 and 7.4.

4 Claim 'The time and costs required to move patients from EpiPen Auto-Injector to Jext is a questionable use of scarce health resources…'.

This claim appeared on page 14 of the booklet and was the final highlighted block of text.

COMPLAINT

The complainant was not persuaded that it was Meda's role to influence the priorities of PCTs in this way.

RESPONSE

Meda considered that it had an ethical responsibility to inform existing and future customers of EpiPen Auto Injectors of the circumstances surrounding adrenaline auto injector use and how their consideration of an alternative product was likely to impact on them. This was relevant to individual health professionals and to healthcare organisations such as PCTs. Meda was very surprised to receive this complaint as pharmaceutical companies commonly put forward an economic case to key decision makers, be it nationally or regionally.

Meda disagreed that this was an unprofessional document, or that it breached Clauses 7.2, 7.4 or 9.2 the Code. It was an attempt to communicate important information about the implications of switching adrenaline auto injector devices. Recent evidence of PCT/trust communications received by Meda highlighted that there was confusion over the correct use of auto injectors and the company considered that it was important to correct this situation. Meda provided examples of documents from two PCTs about a proposed switch from EpiPen to Jext which contained serious errors about the use of Jext (such as 'Jext is a similar device and can be used exactly like an EpiPen'). This was inconsistent with the product summary of product characteristics (SPC) and potentially harmful and this matter had previously been brought to the Authority's attention.

PANEL RULING

The Panel noted the complainant's allegation that it was not Meda's role to influence the resource priorities of PCTs. The Panel considered, however, that it was not unacceptable for companies to put forward an economic case as to why patients should stay on their medicines and not be switched to an alternative. Such activities, however, had to comply with the Code.

The Panel considered that the claim at issue implied that anyone who decided to change patients from EpiPen to Jext would waste NHS resources. In the Panel's view this failed to recognize the professional standing of the audience to which the booklet was directed. A breach of Clause 9.2 was ruled.

Complaint received **22 March 2012**

Case completed **30 May 2012**